IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)
	)
Plaintiff,	)
	)
vs.	)
	)
ELI LILLY AND COMPANY,	)
	)
Defendant.	)
	)

Case No. 3AN-06-05630 CI

VOLUME 7

TRANSCRIPT OF PROCEEDINGS

March 11, 2008 - Pages 1 through 206

BEFORE THE HONORABLE MARK RINDNER
Superior Court Judge

A-P-P-E-A-R-A-N-C-E-S

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PROCEEDINGS

THE COURT: Please be seated. We are on the record in State of Alaska versus Eli Lilly and Company, 3AN-06-5630 Civil. Counsel are present. We are outside the presence of the jury.

I have provided to counsel my rulings on the designation -- designations and objections to the trial deposition and the exhibit depositions as to the Joey Eski deposition. I've also revisited and sustained a ruling on the Toleffson deposition and provided that to counsel as well. Counsel will note that with the Eski deposition I have a whole bunch of need to discusses there. These relate almost entirely to the testimony about what I'm going to use shorthand to describe as Lilly's lobbying efforts, and in an effort to, I guess -- the correct way to describe it as exempt drugs from the formulary requirements? Is that --

MR. ALLEN: Well, the way I describe it -- I'm sure they wouldn't agree with me -- is they were trying to carve out Zyprexa and all -- and I'll use their phrase and all mental health drugs from a review by the pharmacy

and therapeutics committee.

THE COURT: Okay. That's -- I'll use that for the time being to generally describe the topic. Whether that was it, I just wanted a shorthand way to describe it for the purpose of this --

MR. ALLEN: Open access.

THE COURT: Okay. Open access. Thank you. I think that's the term that I think the deposition used. The reason that I have need to discuss, is while I previously had ruled that I did not believe that the Noerr-Pennington doctrine which I believe bars claims and not necessarily evidence that relates to claims that aren't barred under that doctrine, I suggested that I had questions about the relevance of that topic to warnings that -- to the claims that are in this lawsuit that was not readily apparent, and the reason I have not discussed is, while I perhaps see a glimmer of something there, I usually can understand at least where one side or the other might be coming from in this case, and I really don't understand how that relates to the warnings claims in this case.

And so I'm going to give the

Plaintiffs an opportunity to try to educate me on the theory. We'll take that up in some order of things, but that's -- that's why I say I need to discuss. It's -- I just don't understand the theory under which that specific testimony is coming in and how it relates to the warning claim.

MR. ALLEN: Succinctly, Your Honor, it does not relate to the warning claim. I'm just going to tell you. It relates to their claim, Defense, that the State has done nothing to restrict the access. And I have to go through this transcript. I'm prepared to argue the other issue you're going to discuss today, but it does not go to warning claims; it rebuts their defense.

THE COURT: Okay. Given that we haven't heard their evidence of their defense, that probably makes my ruling a little bit easier because it's kind of -- let me hear what the defense is going to be and see what the evidence is, and if that goes beyond argument, we'll -- maybe -- but their -- go on, Mr. Allen.

MR. ALLEN: Well, first of all, and again, I will find the transcript references, but

when they say something to a jury concerning the fact -- and this is -- I think this is their words, that the State of Alaska hadn't done one thing; people come into this courtroom every day and order the medication to be prescribed; no one knew anything about this lawsuit; Mr. Campana, who is on the P & T -- he's involved in the P & T process didn't know anything about this lawsuit.

The door has been flung wide open. You cannot have people just make open statements to a jury and not be allowed to rebut those statements. That's the very essence of opening the door, and under Rule 104, I believe it's (b) of the Alaska Rules of Evidence, as in every state, you can have conditional relevance. Evidence can be admitted conditioned on facts that are expected, otherwise the orderly presentation of evidence would never be able to be conducted. You would have to have all witnesses in the hallway at all times. So evidence can be admitted prior to the introduction of other evidence when it is tied together.

THE COURT: Yeah, but you propose to tie it together by their testifying and I

can't really --

MR. ALLEN: No, sir.

THE COURT: -- put the burden on you to do that or on them to have to produce that evidence that will tie it together for you.

MR. ALLEN: But once -- Your Honor, once you make a statement to the jury -- it wasn't an inadvertent statement, it was an entire, using the Court's words, opening argument that the State -- and I'll find it for you.

THE COURT: I remember the argument. The question in my mind is it's argument. And whether I'm going to say the door was open because of argument in opening statements that I already told the jury isn't evidence or again --

MR. ALLEN: And we want to prove as part of our case -- we want to prove as part of our case that the State of Alaska, regardless of the claims of deceit, fraud, failure to warn, misrepresentation, the only action we can take is the action we're taking now. The State of Alaska cannot prevent the sale of Zyprexa; it cannot do so. The only thing it can do, the only thing it

can do is bring this action and seek penalties as part of the UTPA or it can also, if it's permitted, ask for a P & T review.

So it is relevant not only on their defense, but on our claim. And we're entitled to move forward with our claim. And, Your Honor, I've given 24 hours notice now that I have subpoenaed Dr. Duane Hopson who will be here tomorrow to testify, who they mentioned as part of their -- in their opening was one of the -- this is their words, the head doctor of Alaska, that will tell you how great this drug is -- and I'm paraphrasing now -- how great this drug is and this drug should not be restricted.

And I'm going to play Joey Eski in the morning before I put on Dr. Hopson, so I'm going to have conditional relevance proved up back to back. I'm going to put on Joey Eski's deposition concerning what they did, and I'm going to put Dr. Hopson on, and I surely should be entitled to do that as part of my claim and as part of my rebuttal of their defense.

This case has to be tried on the facts. They want to try the case based upon what they say is true. They're entitled to say what

they want to say, but we're entitled to say what we say.

THE COURT: But the question is if I'm going to allow it and, if so, when. And it's the when -- not restricting this if I think it's appropriate as rebuttal, and that's what you keep on saying, we want to play this as rebuttal, we want to play this to rebut their case, and --

MR. ALLEN: Your Honor, as I took a note from counsel, I am not the only counsel in the case. It is not just part of rebuttal. That's what I'm saying.

Tomorrow I want to put Ms. Eski's deposition testimony on, then I want to put on the head doctor -- this is their words -- the head doctor of Alaska who will talk about this issue concerning the open access and inability to restrict, which is part of our case which is to prove that this -- this is -- we think it's misleading; we think it's fraudulent; we think it's deceptive. And we're entitled to our view of the case. They're entitled to their view; but I'm entitled to put on evidence of our view of the case.

THE COURT: Well, again, without

hearing the testimony and seeing objections, it's a little hard to rule. But I am not necessarily restricting you from putting on a witness that would say, we can't prevent Zyprexa from being sold or to say, we have this committee that reviews these drugs, and then if they want to pursue this -- but Eski goes beyond that. It's not -- if you say that there are ways we do restrict, if that's what you're trying to rebut, Eski doesn't really do that. What she is is a way to avoid that way, and --

MR. ALLEN: I see Mr. Brenner agrees with you.

THE COURT: If you want to put on evidence that there are things that the State is doing to limit Zyprexa, including bringing this lawsuit and what the State couldn't do, which is to ban Zyprexa, and that the State has a committee that does, in fact, review these things and does look at safety and stuff, if you want to do that, but right now --

MR. ALLEN: But it's tomorrow, Your Honor. The State does have a committee. But tomorrow I will explain through Dr. Hopson and Nurse Eski together -- Nurse Eski, I

apologize, executive -- I think it is Executive Sales Representative Eski -- I will explain that the State's ability has been affected in part. It's called circumstantial evidence. When you walk to the window and you haven't seen it snow, but you know it snowed because snow is on the ground.

I'm going to prove through circumstantial evidence that one of the difficulties the State of Alaska has had in restricting the use of this drug is because the Defendants engaged in conduct in lobbying efforts, public relations firms, Alaska State Action Committees and truth squads to prevent a restriction on their drug.

So it is improper -- so the restrictions have been prevented by their conduct. So I wasn't there when the P & T committee did not conduct a review, but I know that the P & T committee did not conduct a review because more likely than not or a relevant reason is they lobbied the legislature and the P & T and the Medicaid department to prevent such a review. So -- and so you say it's not time. Not today, but tomorrow is the time --

THE COURT: Tomorrow is the time for you, but it's not -- I don't believe it's the time in the -- I mean, you want to quote 104, I think that's --

MR. ALLEN: 104(b).

THE COURT: -- 104(b). And I'm going to quote 611, which is, The Court shall exercise reasonable control of the mode and order of interrogating witnesses and presenting evidence, so as to make the interrogation and presenting effective for the ascertainment of the truth. And I think that this is rebuttal evidence and there needs to be other things. I'm not precluding you from introducing evidence as to what the State can do, and the kinds of committees the State and whether the State has been able to meet or those kinds of things from this doctor. But the Eski questions that are being asked in my mind don't -- it's not the time yet.

MR. ALLEN: Your Honor, could I ask this? Is the Court, upon the close of the evidence -- if they don't come forward with what they said they're going to come forward with, because if they bring up this issue of

restricting, I'm clearly, as the Court said, I'm entitled to rebut it. Are you going to instruct the jury prior to the close of the evidence that what they said on opening has to be disregarded?

THE COURT: If you -- I'm not going to make rulings about what I'm going to do on the close of the evidence until I've heard the evidence and we'll deal with jury instructions and those things. Everyone, when the cases are over, I'm sure on both sides, I'm going to have a bunch of applications, and I'll take them up then.

MR. ALLEN: Okay.

THE COURT: But at least for now that's -- as to Eski, my -- I think -- where I've got the -- I'm not going to preclude you from raising it down the road depending on how the evidence comes up. And if you want to put on Dr. Hopson to ascertain what the State can or can't do or did or didn't do and the fact that this lawsuit has been brought, you're able to do that in showing why the State needed to -- needs to bring a lawsuit and that part of bringing this lawsuit is the State's effort to restrict things.

MR. ALLEN: I take it -- I got the

Court's ruling. Can we, Your Honor, move forward with the issue at hand today, and that's the issue of the admissibility of the risk/benefit and other uses and the admissibility of evidence --

THE COURT: Let me just hear. Mr. Lehner wants to be heard on this subject.

MR. LEHNER: Your Honor, just very briefly. First time we're hearing today that the Plaintiffs intend to subpoena Dr. Hopson. Dr. Hopson was not on their witness list. Dr. Hopson was on our witness list. We heard earlier on about trial by ambush --

THE COURT: Well, he was on your witness list. You said you were going to call him. I'd be really surprised if they didn't have on their witness list all witnesses listed by the Defendants.

MR. ALLEN: We did. We did.

THE COURT: What's -- I don't know. Maybe they didn't --

MR. ALLEN: We did.

THE COURT: But we'll -- I mean --

MR. ALLEN: We did have that, Your Honor, and we subpoenaed this witness.

THE COURT: The -- just so that the record is clear, we're on the Eski deposition I say need to discuss. I suppose the proper decision now is not now, but you can renew your request later.

MR. ALLEN: Your Honor, I accept your ruling at this time.

THE COURT: All right. There were two issues raised in sort of the letter stuff that what was going on. One was a portion of somebody's testimony -- I'm not recalling exactly who -- where there was about a page and a half of questioning about all the lawyers that this witness consulted with on the defense side, and my understanding, just so that I make sure what I've got it right is -- this was a person who may have been a former Lilly employee but was no longer a Lilly employee at the time that the deposition took place, so at this point we're not talking about attorney/client; is that correct?

MR. ALLEN: That's correct. There's actually three witnesses; Torres, Bandick and Jordan. Three ex-employees. They were not current employees, they're ex-employees, and -- and you're right.

THE COURT: But I do recall that in one particular witness I sustained a bunch of objections to about a page-and-a-half worth of spending time meeting with lawyers for Lilly before the deposition.

MR. ALLEN: Jordan.

THE COURT: And my understanding is that the Plaintiffs believe that it goes to bias because they met with the lawyers. And the parties can make arguments. I think I understand -- understood the issue when I made my ruling.

I just think it's 403 material. I don't want to have to explain to a jury. I think it's confusing. I think that people are entitled to talk to whatever lawyers they want to and not talk to whatever lawyers they want to. Some people are entitled absolutely to talk to lawyers and I don't -- I think in the jury's -- jurors' mind it's confusing and I think the relevance is marginal.

MR. ALLEN: Well, Your Honor has made a ruling. I do have a different point of view.

THE COURT: You're entitled to make

your record.
MR. ALLEN: Let me make my record, Your Honor. It's three employees, Ms. Denise Torres, Global Marketing Director on Zyprexa, Mr. Michael Bandick. His title is either Brand Manager or Marketplace Manager. He's primarily responsible for the PCP launch and campaign. And Mr. Jack Jordan who was U.S. Marketing Director for Zyprexa, all ex-employees of Eli Lilly. Of course, if a witness comes -- a witness walks through this door and gets on the stand and gives testimony that is adverse to me and has no connection with either of the parties, that can be more damning than a witness who walks through the door, has a relationship with the parties, has been paid money by the parties and has met with the lawyers prior to the time the witness testified.
It goes directly to the issue of both credibility, which the jury's asked to weigh, is the credibility of a witness and the interest or bias or prejudice of a witness. If a witness is on the stand and testifies that I met with this lawyer, and this lawyer and this lawyer and this lawyer and this lawyer and these lawyers back here and

lawyers back at the Cook Hotel, and I didn't just meet with them on one occasion, I met with them on numerous occasions over many months, and then I'm trying to get this witness to testify and the witness testifies adversely to me, a reasonable inference can be drawn that the reason that the witness was more difficult and the testimony was more damaging is because he's met with all these people. It makes it more likely than not that the witness's testimony had been affected by his or her relationship with the parties.
And I -- the Court -- I accept the Court's rulings, but I will just say -- I have to say, for 24 years, that's just the way I've done it. And maybe I've -- I've been wrong, but I don't know.
MR. LEHNER: Your Honor, I just would point to Rule 613, which I think Mr. Allen cited. The requirement to do this requires that a foundation be laid and that the deponent be given an opportunity while testifying to explain or deny any prior statement or admit, deny or explain any bias or interest. I didn't see that in the record. But that's just to complete the record.

Can I go back, Your Honor? I didn't raise this issue about Dr. Hopson because I didn't have the piece of paper in front of me. We do have the Plaintiff's final witness statement. There is no savings clause in here, but more importantly, we would not have made the statement in our opening argument that we intend to bring him in their case and they did not intend to bring him had he been on their list, or had there been a savings clause on here. It was very much a part of our argument. I think it's extraordinarily prejudicial now if you allow them to go by ambush literally to come and say they are going to bring Dr. Hopson out when we relied upon what was indeed their final witness statement.
THE COURT: Again, I don't consider this to be surprise. I don't know about the final witness statement but Dr. Hopson has been known -- was going to be a witness in this case for quite some time. It's really talking about the order of presentation.
MR. LEHNER: We, in fact, deposed him. They took no opportunity to ask any questions at the deposition.

MR. ALLEN: That's our choice, and now we've subpoenaed him based upon the evidence that's coming in. We're entitled to subpoena witnesses within witness range and they deposed him, I think, two months ago.
MR. LEHNER: Entitled to subpoena witnesses who would be on the witness list.
THE COURT: I don't think there's surprise here. It's a witness who was going to testify and has been known as a witness regardless of who called him and I don't think you own a witness when you list him as your own, someone you want to use.
MR. LEHNER: I would not argue that it's surprise, Your Honor. Obviously we've used his name. I would argue that it's really prejudice to bring a witness who is not on the witness list, upon a representation upon which we relied that he was not going to be one of their witnesses.
THE COURT: Again, I'm going to allow Dr. Hopson to testify if they want to have him in their case in chief.
MR. ALLEN: Thank you, Your Honor. For the record I'm going to ask --

THE COURT: My ruling stands as to questions regarding talking to lawyers before the deposition.

I think that leads us now to a last question, which is what I'll call the testimony and documents on the off-label issue as it relates to -- which is out of the case as it relates to the other issues that should be in this case. I've generally taken the approach that I don't find the relevance of that issue, at least immediately to the warnings claim. It may be relevant for rebuttal purposes. On the other hand, I'm particularly looking at specific questions, which I realize everyone did these depositions while the off-label issue was still in this case, and those questions seemed very probing of that issue and not probing to me, at least, of the issues that remain in this case.

The documents, when I read them, have both elements in it. I do find this is sort of particularly -- it's been a difficult way of trying to parse it based on trying to just look at questions and maybe you can explain it some more to me. I particularly found it hard, I'll tell you, with the Jordan deposition which has

elements towards the end of some clearly warning claims, but most of it all seemed to be to the off-label claims.

MR. ALLEN: Can I make an attempt to do so, sir?

THE COURT: Sure.

MR. ALLEN: All right.

Your Honor, first thing I want to say for the record, I am not asking for the reinstitution of a cause of action on off-label promotion. That is not what I'm asking for at all.

THE COURT: That, I understand.

MR. ALLEN: Okay. I am not also asking to go into off-the-label matters. I am asking to be able to prove my claims under Alaska's Unfair Trade Practices Act, which includes a misrepresentation of the product's characteristics and a failure to warn.

Now, the question is: To whom -- I don't know -- I may have been wrong on the grammar. To whom do we claim Alaska's -- that the Defendants violated the UTPA and failed to warn? Is it to some doctors? Just a few doctor segment? The answer to that is, no, Your Honor.

We claim that Alaska's UTPA was violated and the Defendants failed to warn to all doctors --

THE COURT: I understand that, too.

MR. ALLEN: All right.

Now, in evaluating the use of a Zyprexa, it's a two-sided equation. It is both the risk of the product and the benefit of the product for all doctors who prescribe the drug under all circumstances. Evidence should be admissible for either side of this equation, and I think with due respect to the Court that the Defendants have done a good job of convincing you that I'm trying to get into off-label matters --

THE COURT: I don't think they've done that. It's how I'm looking at the questions. I mean, again, we -- I do understand this, too, and I see that as kind of a critical issue in trying to figure this out, but I'm looking at particular questions and we'll get to that in a second, I'm sure.

MR. ALLEN: I guess the Court would obviously hold that we're entitled to put in evidence concerning the risk for all doctors and the benefit for all doctors. I would think that would be something that evidence is clearly

relevant on both the risk side and the benefits side.

Now, in order -- when we -- and by the way, evidence can be admissible not only on both sides, it can be admissible on the risk side of the equation or the benefits side of equation or both sides of the equation. Now, Ms. Gussack has told you and Mr. -- Mr. Brenner -- anyhow, that when looking at the risk side of the equation, I'm going to show you in a minute, that you have to look at all the information, all the information that came from Eli Lilly to the prescribers, all the information. And we're also looking at not only the failure to warn, but the UTPA claim, and it's for all prescribers.

The benefit side of the equation, evidence on the benefit, it will be different depending on the reason for the prescription. Benefit is not a static concept. In other words --

THE COURT: I'm with you --

MR. ALLEN: Let me --

THE COURT: I'm with you. So I understand this too.

MR. ALLEN: Let me go on. And I

just want the Court to understand where we're coming from. If you would -- if I could finish, I could wrap it up, maybe we can get a conclusion here.

Primary-care doctors prescribe Zyprexa; that's just a fact. And, in fact, they have testified -- I'm going to show you in a second, we're going to get right to the evidence -- Ms. Gussack told this Court and this jury that primary care doctors, the reason they prescribe the drug is for on-label purposes. I am making no off-label claims here. I will show you in a minute, she said primary care doctors prescribe for on-label purposes.

So, therefore, if I am trying to produce evidence concerning the PCP campaign by definition and admission of the Defendants, it is for on-label purposes. I think maybe where we've gotten confused is that we've assumed that PCP means off-label. It does not mean off-label in this case by their own admission.

By the way, the testimony in the case is 40 percent of prescriptions are for uses other than schizophrenia and bipolar mania and 38 percent of the use in Alaska is for other than

schizophrenia and bipolar mania, so we have a significant amount of use of this product not for schizophrenia, and not for bipolar mania, so the benefit would have to be different.

Here's what I say. PCP is on-label. Here's what Ms. Gussack said to the jury, quoted exactly on opening. That is why when Lilly received approval from FDA in 2000 for Zyprexa to be used in bipolar disorder, that's why it started to move into calling upon primary-care doctors.

She's told this jury -- I accept her argument. For purposes of the introduction of the evidence concerning the other uses, I accept Ms. Gussack's own statement. We accept it. That the reason they went into PCP marketing is because for on-label purposes.

So it's not off-label. So then I'm entitled -- if you accept Ms. Gussack's statement, then I'm entitled to show -- to present evidence concerning what Lilly did, what Lilly said, what Lilly did or did not say, not to just to a select group of psychiatrists, but to all doctors. I'm entitled to see what they said about the risk and the benefits to all doctors,

including PCP doctors, because it was an on-label launch.

Here's the risk: Weight gain, hyperglycemia, diabetes, hyperlipidemia, tardive dyskinesia, extrapyramidal side effects and blood monitoring. Here are the benefits -- here's a literal equation. Schizophrenia, bipolar, bipolar maintenance and that would include by definition, mood, thought and behavior disorders. Mood, thought and behavior disorders is not off-label. It's not off-label because the PCP campaign, pursuant to their argument, was an on-label campaign.

Here's other uses, which you can look at.

How do we solve this issue? How do we solve this issue?

I suggest that you look over at this side of the room and ask them this question: Is mood, thought, and behavior disorder within the label for Zyprexa? If they say yes, if they say yes, it's within the label, then anything we introduce concerning that effort is within the label.

They will have to tell you yes.

They will have to tell you yes.

Now, here's what they said on opening statement, Your Honor. They said, but let's get something straight. It's prescription, so what it is -- let me get some water, please. I apologize to the Court. I have to get my glasses on. I can read better from here.

Our physicians make that hard choice every day, and this is their statement and we're going to talk a lot about that, and this case is going to involve a lot of information about how doctors make those decisions. They went on to tell this jury that the doctors engage in this risk/benefit analysis every time, every time they prescribe it to a patient. And it says a lot of patients -- now here's where we're talking about mood, thought and behavior disorders. Ms. Gussack says a lot of patients with schizophrenia don't see psychiatrists and that can be for a lot of reasons, not the least of which is large portions of this country there is not a psychiatrist on every corner.

In fact, a lot of our mental illness is treated by primary-care physicians or nurse practitioners, and we are lucky because

every time a physician who is trained and educated to identify these patients, that is why, she says here, right here, that is why when Lilly received approval from the FDA in 2000 for Zyprexa to be used in bipolar disorder, that's why it started to move into calling upon primary-care physicians.

So what she's told this Court and what she's told this jury and what we will accept for purposes of this trial is that what they did with PCP doctors and their campaign to PCP doctors is not off-label use. It is on-label use. That's what she says right here. So we're entitled to see what they said about both the risk side of the equation and the benefits side of the equation to PCP doctors.

She even went so far as to say, Your Honor, that we know that doctors aren't taking out their magnifying glass to look at each section of the label. Rather, she says, why are we so sure that doctors haven't been misled? Because the label and all of the information -- not just some of it, Your Honor, all of the information that Lilly shares with physicians -- and noted she didn't just say psychiatrists,

tells them about the side effects and risks associated with Zyprexa. Then she goes on to say that FDA is a cop on the beat. They're not dumb and stupid. And does Lilly have an obligation to tell about weight gain? No, doctors have gone to medical school.

And she concludes and says, concerning what we should look at concerning warning, concerning warning. But Lilly was sharing its information with doctors about weight gain and sharing its information with FDA and it wasn't -- look what she says, it wasn't just relying on the label. She says: Lilly trained its sales representatives who called on physicians to answer questions about weight gain and diabetes. And then she says: And what kind of information were the sales reps sharing with physicians when they made those calls? What were they sharing when they made the calls?

Now, in the PCP, and this is what Jack Jordan on the questions you asked about, he testifies -- remember, again, this is an on-label campaign. This is my questions to him at the time, and this is something they're asking you to reconsider now. I asked him: Anyhow, the

position -- and, Your Honor, the position is a term of art, it's a term of art -- tell the jury again if you haven't already, can you explain to the jury what a position is with regard to a medical product such as Zyprexa?

He says: A position is ultimately how we want your customers to think about your product.

And I said: And the position listed in this document -- which the Court will see in a minute, which they're trying to get out of Jordan's deposition -- is the safe -- safe, proven solution for mood, thought and behavioral disorders.

He said: That's correct. The very next sentence says: We will emphasize safety to address the barriers to adoption. And then he says: In the positioning of the product, we will emphasize to the doctors it's safe, and he agrees the document says that.

So, Your Honor, when we're looking at the PCP, when we're weighing the risk versus benefit equation, we're weighing this equation, we have to look at what this company knew and what conduct they engaged in to effect that

equation. This is the PCP strategy overview.

Remember, position. Now they recognize that PCPs may not prescribe antipsychotics. They say it's a challenge, that there's a barrier to the prescription and it's a doctor's aversion --

THE COURT: Let me just ask you a question. The portion of the Jordan deposition that you've just reviewed, my current ruling on that is that it's in.

MR. ALLEN: That current ruling is it's in. They asked -- of course --

THE COURT: I saw it came in -- I think it came in this morning.

MR. ALLEN: Right. And they're now trying to strike that and anything else. Yes, sir, you're right, it's currently in and I think it should stay in. The reason -- let me go on, Your Honor. Remember, when you see PCP, I don't want you to think off-label. I want you to think on-label. They have said it's on-label. It's not off-label.

They said, the reason it's a barrier to adoption of PCP is aversion to risk. It's aversion to risk. So, what are they going

to do? They are going to position -- remember, that means how we want doctors to think -- it's the safe, proven solution in mood, thought and behavioral disorders. We will emphasize safety to address the barrier to adoption, the barrier being doctors' aversion to risk.

And then remembering Mrs. Gussack's opening statement that says, you have to look at all of the information, you have to look at all of the information, how we trained our sales reps -- that's her words, not mine -- and what we trained them to do.

This is the Viva Zyprexa campaign which is an on-label document. It is a primary care document, and here's what they say and here's the documents I want to utilize and they're trying to restrict.

Their strategy in this document is to establish the position, again, that's what we want doctors to think of safe, proven solution for mood, thought and behavioral disturbances. And I think when the Court sees, I'm concerned that when the Court sees the words mood, thought and behavior, he's thinking off-label. But they have told this Court and they have told this jury

that that is an on-label bipolar disorder of statement.

So anytime we see the term mood, thought and behavior, we shouldn't be thinking off-label, we should be thinking on-label, because they said this entire launch was predicated on the approval for bipolar disorder. So, this should not be a key to think off-label. It should be a key to think on-label, on-label.

Now, what is the message they're going to deliver? Remembering Ms. Gussack told the jury that you have to look at how we train our sales representatives, you're going to see all the ways, beyond the label -- that's -- beyond the label, she said it's not -- you just don't look at the label. I want to show that and emphasize it to the Court.

THE COURT: I remember it.

MR. ALLEN: It's right there. We don't -- but Lilly was sharing its information and it wasn't just relying on the label, it wasn't just relying on the label.

So, here's what they say. Emphasize safety, ease of use, safety is the -- and this is the findings concerning their

message: Safety is the most important aspect of the information presented. They go on to say there is -- and this is in their key message elements, this is their words, how they want doctors to think. Low risk of medical complications. No blood monitoring is required --

THE COURT: All of this stuff you're showing me is in, right?

MR. ALLEN: The evidence is in, but you struck the testimony in both Mr. Jordan's deposition and Ms. Torres' deposition and Dr. Lechleiter's.

Let me give you one example. I'm sorry. I got up at 5:00 a.m. to do this, Your Honor but I have a very good recall on a lot of these depos since I took them.

Mr. Bandick testified to me under oath that they marketed this drug for -- for people as a mood stabilizer, and for people with mood, thought and behavior disorders.

You struck that testimony. You struck it when I tried to introduce it. I guess you struck it under the theory it was off-label. But it's not off-label; it's not. And these

people know what they've done. They have taken what used to be an off-label claim and they have told this jury because they have to, Your Honor, they have to.

If you ask them this question: Is mood, thought and behavior disorders on-label or is it off-label? If they tell you it's off-label, the federal government authorities, the criminal prosecutors will get them. But -- they'll get them, that's what they're looking into. But their position has always been that mood, thought and behavior is in-label. We accept that position for this trial. Mood, thought and behavior is within the label.

THE COURT: Let me ask that question. If it's within the label, why isn't all this testimony coming in yet? If all of these documents and testimony goes into establishing that Lilly did all this stuff within the label, then why isn't what Lilly told doctors about these things -- I mean, Mr. Allen is probably correct.

I struck this because I saw this as being efforts to establish that Lilly was doing things off-label, but if all of this stuff is

on-label and it was perfectly proper for Lilly to be doing this stuff, why doesn't it come in.

MR. BRENNER: Your Honor, it is on-label, but we've had a complete reversal of position here. Throughout all the depositions, they took the position it's off-label, and I don't understand how it's an element of the State's case to prove that we were on-label.

Let's be clear about what's going on here. They're not trying to prove it's on-label. They're trying to back-door what Your Honor's ruled out. And that's what's going on. Yes, our position consistently has been that's on-label. If the State wants to stipulate to that, we can take it out of the case. That's not why they are putting in these proofs, Judge.

MR. ALLEN: I'll stipulate to it.

MR. BRENNER: Then you can't argue from it that that really means off-label. Then we have no proof, if we stipulate to it, Judge, all of that can come our for both sides.

MR. ALLEN: I will stipulate for purposes of this case that the documents for mood, thought and behavior disorder are on-label. I will not contend it's off-label but I'm

entitled to produce the evidence of what they told physicians about mood thought and behavior.

THE COURT: A lot of what I struck was about whether treating for Alzheimer's is on-label, whether or not treating with kids is on-label, whether treating common depression is on-label. There's a lot of that testimony is what I struck. And --

MR. BRENNER: And that is the State's off-label case that's no longer germane to our proceedings here today.

MR. ALLEN: Your Honor, can I answer these false charges? Let's go back to what -- what we're talking about here, Your Honor, and let me finish and then we'll conclude. I think we now have an agreement from the Defendants that any document dealing with mood, thought and behavior disorder, because they have to say it, is within label. So, all questions surrounding mood, thought and behavior should come in. Here's one of the documents that they have --

THE COURT: Again, I'm hearing -- I'm seeing Mr. Brenner shake his head, and I don't think you have -- I'm not clear whether

you've got an agreement about what -- I certainly am clear that you don't have an agreement that all documents or questions should come in.

What's being agreed to that the jury could hear a stipulation on I'm less clear on.

MR. ALLEN: Your Honor, in promotion of this 3 by 3 campaign -- your Honor, I have to take the case as it lies. I cannot redraft their documents. They have what they call a 3 by 3 message. It's very important, Your Honor. The 3 by 3 message is mood, thought and behavior, safety and ease of use. And I'm entitled to present that.

Now, let me go on to say you struck this. This is an on-label document. One of our theories in our case of failure to warn is that they overemphasized the benefits -- and let me find this for you, Your Honor. Let me find this.

And we know that this is improper, because we remember the November, 1996 FDA letter. The November, 1996 FDA letter says: You must engage in appropriate balance. And it is false and misleading to not do so, and, in fact, they said -- and it goes directly to the heart of

what they're doing now. They said -- the FDA has said, not Scott Allen, that the labeling pieces identified above contain one or more of the violations enumerated. They are all lacking in balance relating to adverse events and precautionary information and present a misleading impression of Zyprexa as -- this is what they said then -- as a superior, highly-effective, virtually free of side effects, easy-to-use product.

This impression is contrary to the labeling. That is precisely what they did in the Viva Zyprexa campaign. And we should be able to introduce evidence that their goal was not to warn. You ask: How does this relate to the failure to warn claim? How does it relate? That was a question the Court asked.

It relates to the claim because we're entitled to show that they engaged in efforts not to warn, but in unfair balance and they misrepresented the characteristics of the product. And they, through their campaign went out and did it on a concerted effort to doctors and their words of their song 24 hours a day -- they wish there were 40 more -- we can't rest,

I've got to run, might tell a doctor 50 times, 50 times, it says, I might tell a doctor. Now, hold on, and I'm -- here's -- this is a document they want stricken and they want taken out of the Jordan deposition.

This is a Zyprexa product knowledge conference call. This is an on-label campaign now. Here's the question that's asked: Here's the question -- they're teaching their sales reps and people in the field how to use and promote Zyprexa. It says: What if a doctor says, I don't see these types of patients, and it says the doctor is thinking he does not see schizophrenic or bipolar patients, but he probably does see patients with symptoms of behavior -- which they just said is on-label, mood, on-label, or thought disturbances. We need to focus on symptoms and patient types of Martha, on-label, David, on-label, Christine, on-label.

Even if the doctor does not have diagnosis, he should treat anyway. He needs to treat the symptoms until the patient can see a psychiatrist. Ask him if he uses drugs like Haldol or Risperdal and Zyprexa has less side effects than either of them. They're asking you

to take this document out of the Jordan deposition.

THE COURT: Again, right now that document is in, so the taking out is a different, it's a separate question that I haven't gotten to.

MR. ALLEN: Yes, sir, I totally understand your position. Let me show you one thing, and I've never been good with paper, but I want to show you something so the Court understands where I am coming from as we move forward. I apologize. Bear with me one second, Your Honor.

Here it is. You remember that last exhibit and that last statement? It is precisely what Ms. Gussack told this jury on opening statement. It says: A lot of bipolar patients -- and that's mood, thought and behavior disorder -- don't see psychiatrists. That's exactly what that doctor said -- I mean, what that document said.

A lot of patients with schizophrenia don't see psychiatrists. And that can be for a lot of reasons, not the least of which is in large portions of the country, like

Alaska, there is not a psychiatrist on every corner. In fact, a lot of our mental illness is treated by -- is treated by primary-care physicians or nurse practitioners, and we are lucky -- she says, we're lucky, because every time -- that's very important, every time a physician who is trained and educated to identify serious mental illness does and then treats it, people are on the road to reintegrating the quality of their life with what they are capable of. That is why when Lilly received approval in 2000 we moved into the PCP market.

So, Your Honor, I beg of the Court, and I plead with the Court to go back and look at the depositions of Denise Torres, Michael Bandick, and Mr. Jordan, and see where you have stricken -- or I can identify if the Court would like --

THE COURT: No, I've got my rulings.

MR. ALLEN: Okay -- and look at it and see whether or not you have stricken claims concerning -- and evidence -- evidence of mood, thought and behavior disorders. I just ask you to do it because mood, thought and behavior

disorders, Mr. Brenner and this team and Ms. Gussack to this jury said it's on-label. So this is no longer an issue. It's no longer an issue if I'm trying to get in off-label evidence. It's just an issue of whether I'm getting in evidence of what they said about the risks and what they said about the benefits.

Now, let's talk about Alzheimer's and children.

I have the document from Dr. John Lechleiter, the head of this company, a CEO of this corporation, Dr. John Lechleiter. He wrote an e-mail back in March of 2003. Let me get this focused.

There you go.

And he wrote it regarding notes from a day in the field with a neuroscience sales representative. And he says -- not Scott Allen -- I have highlighted -- and this is his e-mail. I have highlighted in bold the inputs that I consider -- this is the CEO of the company -- to be most significant or that came up most often, and would appreciate it if the global and U.S. teams for Zyprexa would follow up as appropriate.

And here is what he says. He says, Dr. John Lechleiter, CEO of Eli Lilly says: It appears to me that the fact that we are now talking to child psychiatrists -- I want to go to this, Your Honor, risks versus benefits, you have to look -- in order to determine if they properly warned about the risk --

THE COURT: I understand.

MR. ALLEN: Okay. Since we're now talking to child psychiatrists and pediatricians, that's short for pediatricians about Strattera, that's a whole other drug that they market, means that we must seize the opportunity to expand our work with Zyprexa in this same child-adolescent population.

Your initial ruling in the deposition of Dr. Lechleiter was to allow me to present this evidence.

They came to you this weekend, after you had ruled in my favor and asked you to reconsider. And you struck it. You did the right thing the first time, Your Honor.

We are entitled -- it may -- it doesn't go to off-label promotion --

THE COURT: Sure sounds to me like

it does --

MR. ALLEN: Dr. John Lechleiter was engaged in off-label promotions?

THE COURT: That's another question. That's part of what goes on here. Part of the reason -- I mean, it's an interesting box you're putting the defense in and we'll talk about that in a bit, but when I strike -- most of the questions I strike is because regardless of what positions people may be taking now, a lot of these questions sound like they may -- there's at least enough smoke that there may have been off-label promotion and I'm sure that's why the government is looking into this.

MR. ALLEN: Your Honor, you said I put them in a box. I have not put these people in a box -- but here's the point -- the jury's going to be asked to consider this question, though, Your Honor. It's not because Scott Allen put them in a box. Did they give an adequate warning? When ordered to determine if they gave an adequate warning, we have to look at who they knew they were warning. This was not a matter of speculation for them.

You struck this question. Denise

Torres admits in her deposition that 40 percent of the use of Zyprexa was off-label. That's just a fact. That has nothing to do with promotion. That means they knew, they knew 40 percent was off-label. So when you know it's off-label, you know it's being used in children, you know it's being used in $500 million worth of business, $500 million a year in dementia, then you know you have a duty to warn those doctors and you have a duty to not make misrepresentations. It's not because Scott Allen put them in the box. It's because they knew how the product was being used.

THE COURT: Let me ask the defense team: If the testimony of Denise Torres is, as Mr. Allen relates it, that 40 percent of the use was off-label, and to the extent that there is a lot of stuff about risk/benefit analysis, don't the -- doesn't that risk/benefit analysis change if the benefits are different than -- if they're not -- in other words, if there's off-label use being done and you've got a witness of your own that's saying there is, don't you look at that risk/benefit analysis differently depending on what use the benefit is for?

In other words, if it's for schizophrenia and you've tried two other drugs and this is the one that's -- the miracle pill for these patients, that's a very different risk than common depression, I'll just use as an example, when there's lots of other things that maybe you won't take a drug with -- I think you understand.

MR. BRENNER: I do, Your Honor. You could draw an even more dramatic hypothetical. Some doctor gets it in his mind that it's a useful for treating the common cold.

THE COURT: Well, I'm not worried so much about some doctor getting it into his mind. I'm worried about Lilly -- what Lilly tells -- that if Lilly is -- if there's off-label use being gone on by Lilly and these questions seem to go to that in my mind, do you have different obligations than with warnings and what your sales force are telling people on that basis?

MR. BRENNER: I think there we're back to that's more the off-label claim that's been taken out of the case. I think, Your Honor, we've gotten a little off track on risk/benefit.

Risk -- the core issue before the Court now in Phase 1 is adequacy of the warning. Shanks gives us the definition of that. Its: The warning should be sufficient to put the physician on notice of the nature and extent of any scientifically knowable risks or dangers inherent in the use of the drug. Risk/benefit goes to how the doctor uses or doesn't use the warning and it's the same as Mr. Allen -- talk about overemphasis -- that's proximate cause; that's not adequacy. That's a different -- that's a different issue for a different day.

THE COURT: But your opening statement -- or Ms. Gussack's opening statement, I guess, Lilly's opening statement clearly suggested that this had to be all looked at in the context of what this pill does for people. And to the extent that that's going to be the defense, don't you have to know what people you're talking about this drug does something for?

MR. BRENNER: I'm not sure I would characterize it as the defense, Your Honor.

I mean, the notion of risk/benefit, first of all, that was presented to the jury

first by Mr. Allen where he said at page 110 in his opening they wanted to eliminate the risk, eliminate the issue of diabetes from the risk/benefit equation. They don't want to warn. They want to eliminate this risk from the doctor's mind when he makes the decision to use this drug.

THE COURT: There's lots of testimony about that already.

MR. BRENNER: Sure and as Your Honor has pointed out to us today and to the jury, opening argument is not evidence. If there's evidence that we put in that needs to be rebutted, that's why you have a rebuttal case. It doesn't need to come in in the State's case right now.

Risk/benefit, of course, can change a doctor's mind given what he or she is prescribing it for what the condition of the patient is or is not, and how the risks stack up against those benefits. But, again, Your Honor, respectfully, that is not under Alaska law part of how one analyzes the adequacy of the warning. It is useful or relevant, if at all, in a proximate cause context. What was the impact of

the warning on the doctor and that, of course, is not for this phase.

As to the State's suggestion that, well, this is all on-label, okay, but proving on-label use is not part of the State's case. It's not part of any element of their case. They have no need to prove that. And so with all respect, and it's -- it's marvelous advocacy and lawyering. They're trying to drag back in that which has been ruled out, which is off-label. We should be direct and candid. This is a back-door way to try to get in what the Court says they may not. The State has no obligation, nor desire, nor would it be useful to advance their case to prove to the jury that Lilly engaged in on-label promotion.

THE COURT: To the extent that it's Lilly's position that they didn't violate the law and everything was on-label, then don't you have to know, as the jury, to evaluate whether the risks were adequately disclosed, the purpose for which the pill is being used and the populations that it's being used for?

MR. BRENNER: The indicated uses, that's right, Your Honor. The reality, of

course, is this has come up in other proceedings, we note, yes, off-label prescription occurs. That's a legal right of doctors. We say we didn't promote to it, but in all events it's out of the case. To drag that back in is a very collateral matter and not germane to the core issues that I think Your Honor's trying to put before this jury.

MR. ALLEN: Your Honor, can I answer those charges?

First of all, he read you the warning and then his quote and I wrote it down, the issue of a warning is how the physician uses the warning. How he uses the warning. He said it's relevant. Let me quote to you from Ms. -- and then he says how he uses it is not important. Here's what they said on opening -- talking about their expert, Dr. Kahn. So when Dr. Kahn comes and tells you, how do I think about what to prescribe for my patient, he has to think about what are the risks that this patient presents and the needs of this patient. And what are the risks of the medications I choose?

He's going to explain to you how he makes that risk/benefit analysis every time he

prescribes Zyprexa, and he will tell you that one of the reasons he prescribes Zyprexa is because the benefit will outweigh the risk in a particular patient. They said that's relevant, and it is.

And so when we're looking at risk/benefit analysis and the issue of failure to warn, it is not Scott Allen and the State of Alaska that has brought this issue up. It is the defense. And -- and it's not in just a broad sense; it is in regard to each patient every time.

And when they know that their product is used for schizophrenia, bipolar mania and almost half -- Your Honor, as I did the math, 4.6 million prescriptions of the 23 million that they touted, 4.6 million of the 11 and a half million, which are in the United States, 50 percent, 4.6; it is a substantial number, 4.6. It wasn't 100 -- was for purposes other than that.

And so when they know that their duty and responsibility to warn and to not only -- and we're not just talking about a common-law cause of action. We're talking about

the Alaska Consumer Protection Act that's by very definition is to protect consumers. They know, so they have a duty and responsibility to tell the truth and we say they didn't. They said they did. So they said it, Your Honor, on opening statement. Every time a doctor makes this decision he has to weigh it in balance.

THE COURT: I'm prepared to rule.

Again, whether this evidence becomes relevant at this point is partially a timing issue, and what other testimony it is. I'm not -- I will -- if you give me the citations to the portion of the Torres deposition that you said I struck where she talks about there being a certain percentage of Zyprexa use for off-label without it going into whether Lilly promoted that or not, I'll reconsider -- I'll take a look at that portion of the testimony again.

But as -- as a general rule, I am adhering to my private -- my prior rulings in keeping that testimony out at least right now from being played at this point in the deposition. But I want to make very clear, depending on the testimony of the Lilly witnesses, particularly the witnesses from the

company, but possibly other witnesses, this all may be proper grounds for cross-examination, and if I think that there's arguments being made in terms that that would lead me to think the door's open, this may all come in on rebuttal.

I'm not foreclosing that at all, which is whether you're putting them in the box or I'm putting them in the box, there's a very difficult line I think I'm giving you in terms of what to bring up with your witnesses and whether they're allowed to cross-examine or put on rebuttal testimony. And I may be giving you a line that's going to be very difficult to adhere about, but that's right now the line I'm giving you.

I just am not inclined at this point -- I still feel that most of these questions really go to establishing off-label use despite the different -- the positions that people may be taking at this point. That's how I read the questions, and I think it interjects that whole issue into the case, and at least at this point, I'm not going to interject that issue into this case on the warnings thing.

On the other hand, to the extent --

which I certainly didn't appreciate when I read the Torres deposition at first -- there was off-label use that would have nothing to do with Lilly promoting an off-label use. Just establishing that there is that use, I think that's -- I'll look at the questions again if you give me citations.

MR. ALLEN: I understand, and of course, we agree -- we disagree. We'll abide by the Court's ruling. Let me ask this: But I take it by your comments that you then -- they have already said what they said about mood, thought and behavior. You had already made your rulings on Jordan, and you stand by the rulings on Jordan --

THE COURT: Right. I tell you -- sometimes I reveal these things and wish I hadn't, or suggest things. When I read the Jordan deposition, it was kind of like, there were a few things in and I struck a lot of the deposition, and I was thinking why don't you wade through the whole deposition. That's your case, not mine. That certainly came to my mind.

MR. ALLEN: We're going to call Mr. Jordan as our first witness this morning by

videotape.
MR. LEHNER: We have an offer of proof yesterday. And I think we still had some reconsideration with respect to Mr. Jordan. We were told that we were going to hear first from Dr. Beasley; we were told to concentrate on that. Mr. Jordan was not on the list. There are some matters with respect to Mr. Jordan in front of you, if you could rule on those.
THE COURT: I'll have to take a look at this.
MR. ALLEN: We'd ask you to do it here on the break, Your Honor, because it's back on this point he just did it. And he's not telling -- I have an e-mail which I've saved. I e-mailed him yesterday when I got back to the hotel and said we're going to play Jordan today. And he knows it.
MR. LEHNER: I said that we had some objections with respect to that. I e-mailed him back with respect to that.
MR. ALLEN: In a trial there can be objections but if they're overruled, I'm entitled to proceed.
THE COURT: I ruled on the on

Jordan other than this reconsideration. I'll look at the reconsideration thing before we bring the jury in.
MR. ALLEN: Thank you.
THE COURT: And we'll know what we're doing with reconsideration on Jordan.
MR. ALLEN: Thank you, Your Honor.
MR. LEHNER: Your Honor, while the jury's out and maybe you want to do it now or at the break, I think we really do need to talk about some of the order of proof going down the week so we can make some plans. We haven't been able to get a lot of clarity about that.
Now we know Mr. Hopson is apparently coming tomorrow. I really would like to know whether or not we're going to be required to put a witness on by the end of the week. If they're going to finish their case by the end of the week --
MR. FIBICH: The answer is no, they do not have to have a witness here this week.
THE COURT: Okay.
MR. ALLEN: The order of proof, 24 hours' notice, I am calling Dr. Hopson tomorrow.
MR. FIBICH: Your Honor, one other

matter if I may, while we're outside the presence. Yesterday at the conclusion of Dr. Gueriguian's testimony there was a question about labels. We have had notebooks put together, 12 of them with the labels by year.
THE COURT: PDR?
MR. FIBICH: PDR.
THE COURT: Have the defense had an opportunity to review this?
MS. GUSSACK: No, Your Honor, and we would object because the PDR is not the official label, the package insert presented by the company is.
THE COURT: I understand that, but there was a question from the juror yesterday and I suggested that maybe we can give everybody all and everybody nodded no problem.
MS. GUSSACK: Your Honor, I think that what we -- I recall the discussion of the PDR. I think that what was clear there were questions about what the publication date that would have incorporated or not incorporated the label and there are supplements.
THE COURT: One of the jurors wanted a PDR label actually read.

MR. FIBICH: Your Honor, why don't we go ahead with the jury.
MR. ALLEN: Go make your rulings and reconsider because we need to play Mr. Jordan.
THE COURT: I'll go look at Jordan and make rulings on that. Let me ask before I go on break: I got objections to somebody this morning.
MR. LEHNER: Breier --
THE COURT: Was the Breier -- when are you likely to use Breier? I'm not sure I would get Breier tonight.
MR. ALLEN: Breier will be one of our last witnesses.
THE COURT: I've got a little time with Breier?
MR. ALLEN: You have a little time.
I also have cuts for Toleffson --
MR. ALLEN: Toleffson --
THE COURT: Two T's. Two T's. There was a list of five cuts when you gave me your list. You give me six on Sunday, your handwritten list. You gave me six people and one of the T's was missing. Maybe it was Toleff- --

I'll take a look. That witness seems to have gotten a little lost.
MR. ALLEN: I think this -- this may be the case -- I'll have to check. It may be Sidney Taurel who was a former CEO. I don't think we're going to play him. I think we're not. And so if that's the issue, I will check it --
THE COURT: I think that is -- I just noticed that -- as of this weekend. I had seven of these cuts and you had only listed six people, I think on your list, and that was where my question is.
MR. ALLEN: All right, Your Honor, I believe that's the case. I'll tell you if I'm wrong.
THE COURT: I'll go read the Jordan thing and then we'll get the jury in. I'll give you my ruling and then we'll get the jury in.
MR. FIBICH: How long do we have, Your Honor, ten minutes?
THE COURT: Yeah, I think so.
MR. ALLEN: Thank you. Thank you, Your Honor.
THE CLERK: Please rise, Superior

Court now stands in recess.
Off record.
(Off record.)
THE COURT: Please be seated.
I've reviewed Eli Lilly and Company's motion for reconsideration of rulings on objections to affirmative deposition designations of Jack Jordan, and I'm overruling all of the objections. I'm sticking with my original rulings on the subject.
We'll give the jury a few-minute heads up. And then is today all TV day?
MR. ALLEN: It's all movie day.
THE COURT: The jury has asked if they're getting out at 1:30. And I've got a 1:45; so, I'm telling them yes. Plus, as I recall, Ms. Mitchell has an appointment that I want to be sure she keeps.
MR. ALLEN: No problem.
THE COURT: We'll be off record.
THE CLERK: Off record.
(Break.)
(Jury in.)
(Bench conference.)
MR. BRENNER: We decided to play

our counterdesignations in our own case, at least with respect to Jordan. Beasley, we'll play Beasley in our own case as well. I don't know how you want to explain the process.
THE COURT: I was going to give this instruction, which is kind of the normal instruction I give on videotaped depositions.
MR. ALLEN: You can explain what Mr. Lehner wants you to explain. That's perfectly fine.
THE COURT: Okay. I'll explain then.
(End bench conference.)
THE COURT: Good morning, ladies and gentlemen of the jury and the record should reflect that we are back on the record and all members of the jury are present. We're going to begin our presentation today. I got a message that some of you inquired whether you were going to get out of here at 1:30, and the answer is yes.
Today is going to be a day where you're going to -- all the testimony today is going to be coming through videotaped deposition testimony. There aren't going to be any live

witnesses. The deposition testimony -- when a deposition is taken -- and a deposition is just an interrogation of a witness under oath just like you see in the courtroom.
And when a deposition is taken, the witness takes an oath that is identical in purpose to the oath given to the witnesses to testified before you in the courtroom. All parties are given an opportunity to ask questions of a witness during a deposition. You should weigh the testimony of the witness whose testimony was videotaped in the same way that you weigh any other testimony. However, you may consider that the witness did not actually testify in your presence. It is for you to decide whether this is significant in light of the fact that the witness could be seen and heard on the videotape.
And the way the process works in this case is the Plaintiffs can choose which portion of the videotaped deposition they want to show you. Once they're done, the Defendants will have an opportunity, if they wish to, to present, as you would, cross-examination, their own testimony that they want to present. But the

Defendants can also decide that they may want to wait to do that until they start putting on their case in chief after the Plaintiff rests in their case.

So my understanding at least for the first witness is that you're going to see that the Defendants have decided that rather than put on cross-examination, they're going to wait and may show you portions of that witness' testimony when they put on their case, and that's entirely up to them as to whether or not they want to do so.

So at this time we're going to start with our deposition testimony. And why don't you identify the witness for the jury, Mr. Allen.

MR. ALLEN: Yes. We are going to call as an adverse witness, Mr. Jack Jordan, U.S. Marketing Director for Zyprexa for Eli Lilly taken on October 6th, 2006. We offer Mr. Jordan's testimony.

VIDEOTAPED TESTIMONY OF JACK JORDAN

Q. Good morning.
A. Good morning.
Q. How are you this morning?

A. I'm fine.
Q. Can you tell the jury your name, please?
A. My name is Jack E. Jordan.
Q. You have an MBA?
A. It's called a Master's of Science and Management; it's an MBA equivalent.
Q. Right. And after you completed your -- the equivalent of a master's in business at Purdue University in 1988, what did you do next?
A. I went to work for Eli Lilly and Company.
Q. And you worked for Eli Lilly from 1988 until when, sir?
A. Until April of 2004.
Q. You were the brand leader for the drug Zyprexa for Eli Lilly from when to when?
A. From May of 1998 until about August of 2003.
Q. We will, of course, explore it in some detail.

Can you tell us, as an executive, as a brand leader for Zyprexa from May of 1988 to August of 2003, can you tell this jury in laymen's terms what it means to be a brand leader in that position?

A. It's -- it's really two areas of responsibility. One was to be responsible for the marketing strategy for the U.S., and the second area was to make sure there was alignment across the organization around that strategy.
Q. You were Mr. Bandick's superior, were you not?
A. When he was the Zyprexa brand manager for the year and a half he did report to me, yes.
Q. Now, you -- during this time period from 1998 to 2003, where -- where were you physically located in your job? Here in Indianapolis?
A. I was, yes.
Q. From 1998 to 2003, you told us your title regarding Zyprexa, were you responsible for the marketing or brand leadership of any other Lilly products during that time period?
A. I -- during that time period, I did have responsibility for a period of time for the Symbyax -- the Symbyax marketing team.
Q. Symbyax, for the jury -- tell the jury what that product was.
A. Symbyax was and is a combination of Zyprexa, olanzapine and Prozac, fluoxetine.
Q. At its height, at its height, during the

time you were brand leader and marketing director for Zyprexa in the United States, how many sales representatives were involved in the promotion and representation of Zyprexa?
A. Approximately a couple thousand sales reps.
Q. And the sales division -- was there different sales forces in Eli Lilly?
A. Yes.
Q. Sigma sales force?
A. Yes.
Q. The -- of course we know, and you agree, you tell the jury the sigma sales force promoted Zyprexa, correct?
A. They were the launch sales, primary care, yes.
Q. Then you have a neuroscience sales force; is that correct?
A. Yes.
Q. And that's a separate sales force from the sigma sales force, is it not?
A. Yes.
Q. And, then, the neuroscience force was -- had job responsibilities for promotion and using of Zyprexa, did they not?

A. That was part of their responsibility, yes.
Q. Then you had a long-term care sales force, did you not?
A. Yes.
Q. And that was a separate sales force from the sigma sales force and the neuroscience force; is that correct?
A. Yes.
Q. Can you testify whether or not, in your opinion, as the marketing director and brand leader for Zyprexa as to whether or not Zyprexa was the single most important product for Eli Lilly from at least the fall of 2000 until the time you left in 2003?
A. Our CO had highlighted, I believe it was four or five products that were going to be the priority during those years.
Q. Did any product take a priority over Zyprexa?
A. Not that I know of.
Q. Zyprexa was the biggest profit-maker for Eli Lilly from at least the fall of 2000 until the time you left; is that correct?
A. Yes.

Q. Let me -- before I do that, let me ask this: The on-label indication of schizophrenia is a diagnosis, is it not? Schizophrenia is a diagnosis?
A. It is, yes.
Q. Bipolar mania is a diagnosis, is it not?
A. Yes, it is, yes.
Q. Just so the record is clear, Zyprexa was never indicated for bipolar disorder, was it, sir?
A. No, it wasn't, no.
Q. Sir, I'm going to hand you what's been marked as Exhibit No. 5. This e-mail concerned a conference call of December the 9th, 2000, did it not? Hi, Crew, wanted to give you a summary of the Zyprexa conference call that was held today, right?
A. Yes.
Q. Now, in this question-and-answer document, it says what if the doctor says -- this is question No. 8 following question No. 7 -- what if the doctor says, I don't see those types of patients. You see that question?
A. I do.
Q. The document says, the doctor's thinking

that he does not see schizophrenic or bipolar patients. Continue with reading the document, please, sir?
A. But he probably does see patients with symptoms of behavior, mood and thought disturbances.
Q. Or thought disorders -- disturbances, right?
A. Yes.
Q. Okay. So is there a difference between schizophrenic and bipolar patients and patients with behavior, mood or thought disturbances?
A. There might or there might not be.
Q. Okay. Continue reading the answer to the question, what if the doctor says, I don't see those types of patients?
A. Need to focus on symptoms and patient types of Martha, David and Christine even if the doctor does not have a diagnosis, he should treat anyway. He needs to treat the symptoms until the patient can see a psychiatrist. Ask him if he uses Haldol, Risperdal and Zyprexa has less side effects than any of them.
Q. Sir, do you recognize Exhibit No. 8 as coming from your files?

A. I don't know if it did or didn't. My handwriting is there, so.
Q. Your handwriting is there at the bottom, correct?
A. Yes.
Q. Sir, do you remember the primary-care physician launch in October of 2000?
A. I do.
Q. Were you intimately involved in that launch?
A. The person that reported to me, Mike Bandick, was responsible for the launch, yes.
VENIREPERSON: Your Honor.
THE COURT: Hold on a second. I cannot see --
VENIREPERSON: The text thing is out of focus.
MR. ALLEN: We're not going to put it up anymore because you can't get it focused and we're going to have the documents to publish when the examination's over.
THE COURT: Thank you.
VIDEOTAPED TESTIMONY CONTINUES
Q. You had to approve his work, right?
A. Yeah, I had a good feel on what was

going on, yes.
Q. You not only had a good feel, you appeared at the launch itself and spoke to the audience in Orlando, Florida; correct?
A. I did.
Q. This was a -- by the time of the launch of Zyprexa, year X was upon you, correct, by that time?
A. It was.
Q. You had lost your patent on Prozac?
A. We had, yes.
Q. You were anticipating generic competition, correct?
A. We were.
Q. You knew you would have decreased revenues in Prozac, right?
A. We did.
Q. Prozac was your No. 1 selling multi-billion blockbuster as of that time, right?
A. It was.
Q. Isn't it true your entire company was geared up around the Viva Zyprexa primary-care physician launch? Wasn't it true, sir?
A. It was an opportunity that we certainly were excited about helping that patient group and

increase revenues, yes.
Q. Okay, sir. Anyhow, the position that -- tell the jury again, if you haven't already, can you explain to the jury what a position is in regard to a medical product such as Zyprexa, what a position is?
A. A position is ultimately how you want your customers to think about your product.
Q. Right. And the position listed in this document is the safe, proven solution for mood, thought and behavior disorders; is that correct?
A. That's how Mike wrote it in this document, yes.
Q. The very next sentence says -- begins: We will emphasize safety to address the barriers to adoption.
Did I read that correctly?
A. You did.
Q. And when you say, we'll emphasize safety, that means we in positioning the product for our customers, including the doctors, will emphasize to them that this product is safe, right?
A. As written in this document, yes.
Q. Then, going down under position it says,

quote, mental disorders, closed quotes, is intentionally broad and vague, providing latitude to frame the discussion around symptoms and behaviors rather than specific indications.
Did I read that correctly?
A. You did.
Q. Now, after the launch of Zyprexa into the primary-care market, you didn't -- you in the marketing as the brand leader didn't just leave things to chance, you wanted to see if the proper message was getting out to the doctors, didn't you?
A. We did do message recall, yes.
Q. And you wanted to see whether or not your campaign had been successful and doctors were responding to your message; isn't that true?
A. Almost all our segments we did do message recall, yes.
Q. Who is Zohar Porat?
A. She was a market research associate.
Q. Sir, I'll hand you what's been marked as Jordan Exhibit No. 13.
This is entitled, Qualitative Telephone Focus Groups, Sales Rep and DM. DM stands for district managers, doesn't it, sir?

A. It does, yes.
Q. Sales Rep and District Manager Topline Reaction to PCP Launch, December 2000, Zohar Porat, Lilly, Answers That Matter; is that correct?
A. Yes.
Q. Of the Sales Rep and District Manager Topline Reaction to the Primary Care Physician Launch, can you read for the jury out loud, the first bullet point under recommendations?
A. Now, I'm going to assume this was a summary given, you haven't given it to me, of the first part of the detail where they talk about the symptoms and then go on to the diagnosis as part of the message, which is what I saw trained. So in that context continue focusing on patient symptomology and having PCPs identify specific patients rather than on patient diagnosis.
Q. Let's see if I could read this a little slower for the jury. The first bullet point under Recommendations on the last page of Exhibit 13 reads as follows: Continue focusing on patient symptomatology and having primary-care physicians identify specific patients rather than on patient diagnoses.

Did I read that correctly?
A. Your reading is correct, but I don't know -- I don't know that it's represented correctly without seeing everything.
Q. Donna -- you remember Donna, do you not, sir?
A. I do, yes.
Q. Now, sir, let's go to Exhibit 15. Are you there at Donna?
A. On page 4, yes.
Q. Yes, sir. We have a circle next to Donna that says: Anxiety, irritability, mood swings and disruptive sleep, right?
A. Yes, those are what symptoms --
Q. Now we go to the page on Donna. It says, Donna, single mom in her 30s, presents in drab clothing and seems ill at ease, quote, I feel so anxious and irritable lately, closed quotes. Her history is reports she has been sleeping more than usual, has trouble concentrating at work and at home. Several appointments earlier she was talkative, elated and reported little need for sleep. Next bullet point: You had treated her with various medications including antidepressants.

Did I read that correctly?
A. You did.
Q. Are you at the page Zyprexa Primary Care Vision and Strategy?
A. I am, 71?
Q. Yes. In the vision for the PCP launch was Expand Zyprexa's market by redefining how primary-care physicians treat mood, thought and behavioral disturbances.
Did I read that correctly?
A. You did.
Q. And in fact, the Zyprexa, page 72, Strategic Intent says, Zyprexa can and will become an everyday agent in primary care, correct?
A. Given that antidepressants are one of the most frequently used products by primary care physicians, and if you think about potentially up to a third actually have bipolar disorder, there was the opportunity that doctors would write it every day. Primary care physicians would write it every day, yes.
Q. You're familiar with the 2001 marketing plan, aren't you?
A. I am, yes.

Q. Okay. You signed the letter attached to the 2001 marketing plan, did you not?
A. I did, yes.
Q. I will read your letter, portions into the record. Turn to the first, your letter, Dear Zyprexa Teammates, Last year you often heard me say 2000 is the critical year. Now that 2000 is complete, we can be proud that we delivered outstanding results in the critical year, all caps, the, exclamation points. We had many successes, not the least of which that we fulfilled our promise of selling $1.7 billion of Zyprexa, we launched into new markets, launched a new indication, launched new formulations, forged new relationships with a broader range of customers, improved our internal alignment and reestablished the Zyprexa team as truly incredible. Thanks for the outstanding performance in 2000, exclamation point. The "blank" patent expiration; that would be the Prozac patent expiration, wouldn't it?
A. I'm assuming.
Q. The Prozac patent expiration presents Lilly with even greater challenges than anticipated and provides new opportunities for

the Zyprexa team. Oddly enough 2000 may now be all caps, the critical year. 2001 is different. It's not just a critical -- it's a chance to do the extraordinary. Yes, we face challenges, we have to deliver over $400 million of incremental net sales in the same that Zeldox is launching and our current competitors will continue to challenge us.
Did I read that correctly?
A. You did, yes.
Q. The title of the -- or the theme of the Zyprexa marketing plan was Limitless; isn't that true? Limitless?
A. It was, yes.
Q. That's why you positioned your marketing plan for the year 2001?
A. It was -- the position for what I would hope that people would have a year of top-level performance.
Q. The high-level position of the position on diabetes is as follows: I'm reading, quote, Diabetes may occur in patients taking antipsychotics and/or mood stabilizers. Zyprexa and other agents have a comparable rate of diabetes.

Did I read that correctly?
A. You did, yes.
Q. I've handed you Exhibit 22. It's Issues Management Planning, Diabetes. You've seen this document before, have you not, sir?
A. I don't know.
Q. Do you see on the second page, Diabetes Our Position? Second page, Diabetes Our Position?
A. Yes.
Q. And doesn't it say just like the 2001 marketing plan: Our position is stated as diabetes slash hyperglycemia may occur in patients taking antipsychotics and/or mood stabilizers including Zyprexa at comparable rates with a possible exception of clozapine.
Doesn't it say that?
A. It does.
Q. And isn't that consistent with the stated position on diabetes as contained in the 2001 marketing plan?
A. Yes.
Q. And the rationale for the position as stated in Exhibit 22 is: Showing that diabetes is a common occurrence for all antipsychotics and

not just Zyprexa will help reduce the perception that diabetes is linked to specifically to Zyprexa and, in turn, will help to eliminate this risk from the risk/benefit equation.
Isn't that what it says?
A. It does say that, yes.
Q. Yes. And so wasn't Eli Lilly trying to reduce the perception that diabetes is specifically linked to Zyprexa?
A. Again, as -- as our medical folks did extensive analysis, we saw diabetes as an issue in this patient population because of its incidence and because they reviewed the data is that it was comparable across products. The concern was if the confusion in the marketplace made choosing a product just on one specific attribute and not see the entire -- all the data for all the molecules, we were concerned that physicians might make an inappropriate choice for that specific patient.
Q. What is Project BAD? Do you remember Project BAD?
A. I do, yes.
Q. Okay, sir. Exhibit 25 is Project BAD, August the 2nd, 2002. Defining Success. Do you

see that, sir, Defining Success, the second category?
A. Yes, I do.
Q. The third bullet point under Defining Success on Project BAD, can you read that out loud for the jury, please?
A. It says, Reduce negative impact of diabetes issue on the Zyprexa business.
Q. Yes, sir. Now, did you or did you not in marketing try to reduce the negative impact the issue of diabetes was having on the Zyprexa business?
A. Insofar as customers were -- there was a lot of confusion in the marketplace, and we felt like if we could clear up that confusion through good data, we thought it would have a positive impact on the business, yes.
Q. What was the confusion?
A. A lot of -- I shouldn't say -- we were hearing from the marketplace through market research that they were hearing that Zyprexa was causing diabetes, even went so far as some customers saying they heard that Zyprexa was going to be pulled from the market because of the diabetes issue.

MR. ALLEN: Your Honor, that concludes our offer of Mr. Jordan, and we'd ask the Court to allow publication to the jury. I believe these documents have previously been admitted, but Plaintiff's Exhibit 5073.
MR. LEHNER: Your Honor, can we just take a quick look --
THE COURT: Yeah, why don't you show him the whole pile of exhibits and make sure they're the ones we've previously made rulings on.
MR. LEHNER: Thank you, Your Honor. Those are all preadmitted.
THE COURT: Subject to Lilly's previous objections, those documents may all be published to the jury.
MR. ALLEN: Your Honor, I publish to the jury, Plaintiff's Exhibit 5073; Plaintiff's Exhibit 8479, the Primary Care Strategy and Implementation Overview; Plaintiff's Exhibit 5846, Zyprexa Launch Meeting, Viva Zyprexa; Plaintiff's Exhibit 8632, December 2000 Zohar Porat Qualitative Telephone Focus Groups; Plaintiff's Exhibit 284, the Zyprexa Novel Psychotropic Detail Piece For Physicians;

Plaintiff's Exhibit 1301, the 2001 Zyprexa U.S. Marketing Plan; and Plaintiff's Exhibit 9739 concerning Project BAD.

Thank you, Your Honor. That concludes the offer of Mr. Jordan.

THE COURT: And as I understand it, Lilly will reserve any further examination by videotape of Mr. Jordan for later on in the case?

MR. LEHNER: That's right, Your Honor. Thank you.

MR. ALLEN: Your Honor, can we approach?

(Bench conference.)

MR. ALLEN: I can do it now or outside the presence. I want to make a formal offer of the rejected portions of my Jordan testimony so I can preserve my record for appeal. Do you want me to do it off the record?

THE COURT: Off the record -- or outside the presence of the jury.

MR. LEHNER: We're going to move in light of what you saw in the first half of that testimony, to move to strike the first 12 pages. I think you saw what the back door approach when you saw that. I'd like to preserve the record.

THE COURT: I'll give everybody a chance to make their record.

(End bench discussion.)

MR. ALLEN: Thank you, Your Honor. Are we ready for the next?

THE COURT: Mr. Suggs.

MR. SUGGS: Your Honor, the State of Alaska next calls Dr. Charles Beasley whose deposition was taken on July 26th, 2006. At the time of the deposition he was the chief scientific officer for global product safety.

VIDEOTAPE TESTIMONY OF DR. CHARLES BEASLEY

Q. Good morning, Dr. Beasley. Would you state your full name for the record, please?

A. Yes. My name is Charles M. Beasley, Jr.

Q. And how old are you, sir?

A. I am 56.

Q. And are you currently employed by Eli Lilly?

A. Yes, I am.

Q. And what's your current job title?

A. My current job title is distinguished Lilly scholar and chief scientific officer for global product safety.

Q. And you received your medical degree in

1983 from the University of Kentucky College of Medicine; is that correct?

A. That's correct.

Q. And then you did a three-year residency in psychiatry at the University of Cincinnati in Ohio between 1984 and 1987; is that correct?

A. That would be correct. I completed the residency in June of 1987.

Q. Okay. And I believe you became board certified in psychiatry in 1988; is that correct?

A. That would have been correct. It's a two-step process, and I believe that I completed the second part -- I believe it was October of 1988.

Q. Okay. And you joined Eli Lilly as an associate research physician in July of 1987; is that correct?

A. That's correct.

Q. Were you ever in private practice in psychiatry after you completed your residency and before joining Eli Lilly?

A. No, I was not. I came directly from -- to Lilly from my residency.

Q. Okay. I'm going to hand you what has been previously marked Plaintiff's Exhibit

1349 -- by the way, for the record, this appears to be a PowerPoint presentation. It's 24 pages. The first page has a heading Human Metabolism, and I'd like to direct your attention to page 5, if you would. And there there's a heading entitled Development Milestones.

Do you see that page?

A. Yes, I do.

Q. Okay. And it indicates there that the molecule olanzapine, which was later marketed under the trade name Zyprexa, was first synthesized in April of 1982; does that square with your understanding?

A. That would be my understanding.

Q. Okay. And, in this case the first double-blind placebo-controlled dose was given in November of 1991; is that correct?

A. That's correct.

Q. And I believe you said you started working with Zyprexa in 1991. Were you involved in that very first clinical testing?

A. Yes, I was. Although I did not design those -- those clinical trials, I took over responsibility for the supervision of the molecule as those trials were beginning.

Q. Okay. And then the document indicates that the completion of core studies occurred in February of 1995. And can you describe for us what is meant by the term "core studies"?
A. Yes. These would have been the studies that would have been included in both the New Drug Application, the NDA, in the United States as well as the regulatory submissions in other countries.
Q. And am I correct that the largest of the core studies that was done was a study that was referred to as HGAJ?
A. That was the largest.
Q. Okay. And it had approximately how many subjects?
A. It had 1,996 subjects.
Q. Okay. And was it the largest, by far, of the various clinical studies that were done in connection with the drug?
A. It was.
Q. You've described various testing that was done on Zyprexa before it was -- went on the market. That testing was done by Eli Lilly, correct?
A. I would characterize it as being done by

the -- by the investigators. It was designed and administered by Lilly.
Q. Now, I understand, sir.
A. The FDA didn't actually do the studies or contract to have them done.
Q. Am I correct that Lilly employed an outside advisory panel with respect to Zyprexa?
A. There was -- there was -- there was both an international and a U.S. advisory panel for the molecule during its development that I'm familiar with.
Q. And back at that time, in December, 1995, were you reporting directly to Dr. Toleffson, then?
A. Yes, I was.
Q. And about the middle of that paragraph, four lines from the bottom, it states: For all patients treated with olanzapine for any amount of time, 40 percent gained greater than or equal to 7 percent body weight.
Do you see that language?
A. Let me just -- yes, I do.
Q. And it's generally accepted that an increase in weight of 7 percent or more is clinically significant, correct?

A. This has been a criteria established with the FDA for which the term is used potentially clinically significant.
Q. And that paragraph goes on that patients who remained on olanzapine for 12 months gained an average of 24 pounds at the end of 12 months, correct?
A. That's correct.
Q. Okay. By the way, if 40 percent of the people who took the drug for any period of time had more than -- had equal to or more than 7 percent body weight, that means that 40 percent of the people who took the drug for any length of time had potentially clinically significant weight gain, correct?
A. That's correct.
Q. Okay. And then there's a paragraph below that that's in italics which states, quote, Several advisers commented on the association of olanzapine with weight gain and encouraged Lilly to subject the data to a full analysis. Clinically significant weight gain is a risk factor for other conditions such as increased blood pressure, increased cholesterol and type 2 diabetes. The advisers also noted that Lilly has

an opportunity to develop strategies to help manage the weight gains.
Do you see that language?
A. Yes, I do.
Q. But if you step away from the individuals and look at the population, it's a virtual certainty that if you increase the risk of an adverse reaction that some people within that group will, in fact, contract the adverse reaction as a result of using the drug, correct?
A. That is certainly the -- the theory that would be intuitive and logical. What I am pointing out is that one would then need, as I think these advisers were doing, suggesting, scrutinizing our data and looking for whether or not those phenomena were observed.
Q. Your labeling also did not specifically inform physicians that patients who remained on olanzapine for 12 months gained an average of 24 pounds at the end of those 12 months, correct?
A. No, it did not.
Q. Okay. On page 8 at the bottom there's -- the last paragraph, there's a heading that says, Laboratory Anolytes?
A. Yes.

Q. And what does that phrase mean?
A. This would refer to all of those things that are measured in blood or urine. Specific measurements or things such as sodium, glucose, or white blood cells that are measured in a laboratory.
Q. And, in fact, the laboratory testing that was done on HGAJ subjects show that there was a statistically significant increased incidence of high glucose and also high cholesterol; isn't that correct?
A. Again, without benefit of looking at the -- at the entirety of the data, my only recollection is with regard to a analysis of the -- what we call the categorical incidence of elevated glucoses relative to haloperidol based on what we call anytime data, I recall this number as being statistically significant. That is, one number that needs to be appropriately put into context of actually about nine analyses.
Q. You say based on what we call anytime data, I remember this number as being statistically significant. What was this number that you were referring to?
A. I believe it was the percentage of

individuals who showed a -- a shift from a normal glucose to what would be considered a high glucose.
Q. Okay. And you were aware of that at what point in time?
A. I -- I don't know the specific point the data were analyzed.
Q. Would it be fair to say that if computer analyses were done of the data from the HGAJ study back in June of 1995 that you and Dr. Toleffson would have been aware of the results of those analyses?
A. Yes, we would have been.
Q. Okay. I direct your attention to page 11.
A. Yes.
Q. Do you see there there's a heading for lab tests of glucose nonfasting?
A. Yes, I do.
Q. In this study, HGAJ, there were actually two groups of patients, some of whom were taking olanzapine or Zyprexa. The other group was taking another drug referred to as a first-generation antipsychotic drug called Haldol or haloperidol; is that correct?

A. That's correct.
Q. And what you were doing in this study was comparing the incidence of these different types of laboratory anolytes between those folks that took Zyprexa and those who took Haldol, correct?
A. That's correct.
Q. And on page 11 here, this portion of the printout regarding glucose, nonfasting shows a statistically significant increased incidence of high glucose in the Zyprexa group as compared to the Haldol group, correct?
A. Yes. I'm seeing an incidence of 2.6 percent high for olanzapine; 1.1 percent for haloperidol, and the P value there by this test is .031 which is less than .05, which is generally considered the standard for statistical significance.
Q. Dr. Beasley, could I get you to look at page 12 of Exhibit 1605? And you see that at the top of the page there, there's the results of some laboratory testing on cholesterol, correct?
A. Yes, I do.
Q. And it also shows a statistically significant increased incidence of high

cholesterol, correct?
A. Yes, that's correct, 2.3 percent versus 0.8 percent.
Q. When Zyprexa came on the market in 1996, in October, am I correct?
A. I believe that was the case; 13 months after the NDA filing.
Q. And the labeling that was in effect at that time when the product came out in the market did not warn physicians that your clinical studies had found statistically significant increased incidence of high glucose in Zyprexa users, correct?
A. That is correct.
Q. Do you recall that by 1998 Lilly had almost 200 reports of blood sugar elevations?
A. Are you speaking about spontaneous adverse event reports?
Q. Yes.
A. And the year was --
Q. 1998.
A. 1998. I cannot give you the -- the specific number in 1998, but that would seem to me to be approximately correct.
Q. I'm handing you Exhibit 988. For the

record, this is a 26-page document bearing on the title page, the title, Census of Spontaneous Reports for Olanzapine During the First Two Years of Marketing, September 27, '96 to September 30, 1998. It was apparently prepared by Ken Hornbuckle and Man Fung, of the Worldwide Pharmacovigilance and Epidemiology Department at Eli Lilly and Company and it is marked Confidential.

And are you aware, sir, that it's generally estimated that only 1 percent, maybe 10 percent of the number of adverse events that actually occur in the use of the drug ever get reported?

A. The literature that I am familiar with estimated between 1 in 5 and 1 in 30 cases would be reported. This was in this time frame when I was more involved with Drs. Fung and Hornbuckle. I believe that more recent literature has suggested it may be as low as 1 in a hundred.

Q. If I can direct your attention to page 14, and I'm referring to the bottommost number of page 14.

In any event, whoever prepared this report, Dr. Hornbuckle and Fung have a bold

heading there entitled Blood Sugar Elevation, correct?

A. That's correct.

Q. And then below that, they have six different subcategories, including hyperglycemia, diabetes mellitus, diabetic acidosis, diabetic coma, ketosis, and glucose tolerance decreased, correct?

A. That's correct.

Q. And then below that, they have another bold heading that says Unduplicated Reports, correct?

A. That's correct.

Q. And that -- and it shows that if you looked at all four corners or, I guess it's actually eight quarters from '96 to '98, there were a total of 194 unduplicated reports of what they had grouped together as blood sugar elevation, correct?

A. That's correct.

Q. Okay. And, again, using the numbers we talked about before, if we multiply it by -- well, the numbers we talked before in terms of what the range might be with respect to what's happening out in the real world, if we multiply

the 194 by 5, that's almost 1,000 and if we multiplied by 100, it would be almost 20,000 cases of blood sugar elevation, correct?

A. That is correct.

Q. With respect to Exhibit 988 -- let's see -- the one we had there, it's marked Confidential on every page. Was it standard drill at Eli Lilly to mark reports of adverse event reports as -- as Confidential?

A. Actually, I don't know whether all such reports would be so marked. Clearly, these are -- these are information that are -- the reports themselves and -- and analysis similar to this are not confidential because they are shared with Food & Drug Administration and other regulatory bodies.

Q. Do you recall that by December of 1998, just a couple of months after the cutoff period for this report, Lilly was struggling about what to say regarding the link between weight gain and diabetes?

A. Again, in the -- I don't recall any specific information or discussion about what Lilly was going to say in any specific context in that time period.

Q. Let me hand you what's been previously marked as Plaintiff's Exhibit 6890.

For the record, this is an e-mail from Mary Ann Adams to Michael Bandick, Charles Beasley, Dr. Alan Breier, Alan Clark, Ann Marie Crawford, Charles Feehan, there may be another name that's cut off, and the subject is Agenda Zyprexa Medical Marketing Meeting. And it's -- the agenda is dated December 9, 1998.

A. Yes.

Q. Do you see that under the agenda there is -- there's several bullet points. The middle one is Weight Gain and Link to Diabetes, question mark. What Does the Data Say and What is Our Action Plan, question mark.

Do you see that reference?

A. Yes, I do.

Q. And then there's a handwritten note at the bottom relating to weight gain, correct?

A. Yes, there is.

Q. By the way, do you recognize that handwriting?

A. No, I don't.

Q. The handwritten note says, weight gain and genetic vulnerability lead to hyperglycemia,

correct?
A. Yes, it does.
Q. Do you recall talking to people in the marketing department in December of 1998 about the issue of weight gain and diabetes?
A. I don't recall specifically. I may well have -- have done so in the process of trying to educate individuals that were specializing in neuroscience as opposed to diabetes care, about sort of the basics of -- of diabetes.
Q. Do you recall telling the people in the marketing department back in December of 1998 that the use of antipsychotic drugs could result in weight gain and that people who gain weight may develop insulin resistance which can lead to hyperglycemia and diabetes?
A. I may have been explaining that -- that there are these associations.
Q. Okay. Was it your belief at the time, back in December of 1998, that antipsychotics -- that the use of antipsychotic drugs could result in weight gain?
A. Yes, I think the data for -- for that are rather clear as reflected in our package insert, specifically for our drugs, and I think

the -- the David Allison article that, I think was published by this time to which we had contributed, looked at antipsychotics in general and suggested that.
Q. And was it your view back in December of 1998 that people who gained weight may develop insulin resistance which can lead to hyperglycemia and diabetes?
A. I would characterize it as a -- as a risk factor for developing.
Q. And if someone has a risk factor, that means that they may develop that problem, correct?
A. That -- that puts them at increased risk -- to be very precise, that puts them at increased risk relative to patients or individuals without that risk factor.
Q. Would you agree, sir, that if you have a group of people who are at increased risk of having some adverse event occur, that it is more probable than not at the end of the day, that some of those people will, in fact, develop the adverse event as a result of using the drug that increased their risk?
A. All I can say is that there is increased

probability among those individuals with that risk factor of developing the condition if they -- if they did not have the risk factor.
Q. Let's talk a little bit about the teams that were working on Zyprexa. I'm going to hand you what's been previously marked as MDL Plaintiff's Exhibit 8042 which, for the record, is a November 29, 1999 e-mail from Michelle Sharp to Gail Uminger which then copies several other e-mails.
The first of which is an e-mail on November 28th, 1999 from Edmundo Muniz to Michael Clayman and Timothy Franson with copies to Gregory Brophy, Kenneth Hornbuckle, Kenneth Kwong, correct?
And I believe you said earlier that Mr. Muniz --
A. Dr. Muniz.
Q. That he was the member of the pharmacovigilance department; is that correct?
A. That is correct.
Q. Who is Michael Clayman, one of the recipients of this?
A. He was -- I believe at the time he would have been the international director for

regulatory.
Q. Okay. And who was Timothy Franson?
A. And Timothy Franson at the time, I believe, was the head of regulatory for the United States.
Q. Okay. And who was Gregory Brophy?
A. And Gregory Brophy would have been one of the regulatory people for the United States that interacted specifically with the neuropharmacology division of the FDA.
Q. And in his e-mail, Dr. Muniz says, Mike and Tim, below you will find the summary of issues discussed this week regarding hyperglycemia and Zyprexa. There are two types of initiatives and then he lists what those two different types are, correct?
A. There are two types of initiatives, yes.
Q. And the first was a -- what he refers as a cross-functional action team led by Alan Breier. You see that?
A. Yes, I do.
Q. He states that the goal of this team is to bring to the same table all the groups and functions working to address the hyperglycemia issue, correct?

A. Yes.
Q. And the hyperglycemia issue was the fact that by November of 1999 there were published medical articles linking hyperglycemia with Zyprexa, and you also had a number of adverse-event reports linking hyperglycemia and Zyprexa, correct?
A. Yes. That would be correct.
Q. And then Dr. Muniz states under that section, while Val Simmons, Man Fung, Kenneth Kwong and Charles Beasley have been working closely together on this issue, it was felt that a broader involvement of regulatory pharmacovigilance Mike Clayman, Tim Franson, Greg Brophy and Edmundo Muniz was needed to evaluate a short-term plan.
Did I read that correctly?
A. Yes.
Q. Would it be fair to say, sir, that by this -- this memo reflects that in November of 1999 the hyperglycemia issue had -- with Zyprexa had become quite an issue, correct?
A. I think what this reflects is the company had very clearly intended to increase the resources, both number and level of resources

that would bring -- were being brought to bear to assess the topic.
Q. It's pointed out by Dr. Muniz in the background section of this e-mail that the discussion regarding hyperglycemia slash weight gain and antipsychotic drugs goes back as far as the early 1950s, and for more than two decades until the 1980s there was a large number of publications, but the interest of the scientific community and the regulators decreased until very recently. Do you see that language, sir?
A. Yes, I do.
Q. And were you aware of that discussion of hyperglycemia and weight gain being linked with antipsychotic drugs going back to the early 1950s?
A. This was actually part of my -- my residency training.
Q. And right below that section in item B in the background, Dr. Muniz states: Two regulatory agencies, EMEA and Canada, have proactively asked questions about hyperglycemia and Zyprexa?
A. Yes.
Q. And were you involved in responding to

those questions raised by the regulatory agencies and EMEA in Europe and Canada?
A. I certainly would have been involved along with the pharmacovigilance people who would have developed the responses.
Q. Were the regulatory agencies in Canada and Europe concerned with hyperglycemia and being linked with Zyprexa?
A. They had certainly asked us to conduct specific evaluations of our post-marketing surveillance data.
Q. And, in fact, by this point in time, November of 1999, the European regulatory agencies had already requested that hyperglycemia be a precaution in the Europe labeling; is that correct?
A. I -- the -- the European label does not make a distinction between warnings and precautions. There's one unified section. I don't have specific recollection of when they requested that it be included as a warning.
Q. If I were to suggest to you that it was requested in late 1998 and that Lilly finally added it to the warning slash precaution section of European labeling in July of 1999, would that

refresh your recollection?
A. I could well believe that that was correct. Again, I don't remember the specific --
Q. You don't have any reason to doubt those times I stated there, do you?
A. No, I do not.
Q. Okay. And regardless of the precise month, you would agree with me that at least by this point in time, November of 1999, hyperglycemia had been added to the precaution slash warning section in here, correct?
A. That's correct.
Q. Okay. In fact, there's even a handwritten note at the bottom of this e-mail saying Precaution in Europe, correct?
A. Yes.
Q. Okay. And by this point in time, hyperglycemia was mentioned in the U.S. labeling, but only in the adverse reaction section, correct?
A. Hyperglycemia, among other diabetic-related terms, yes.
Q. In the adverse reaction section, not in the precaution section, not in the warning section, correct?

A. That's correct.
Q. And am I correct that GPLC stands for global product labeling committee?
A. That's correct.
Q. And what was the global product labeling committee?
A. This is a committee made up of a number of individuals holding fairly senior positions within the company at the time it was chaired by, I believe, Dr. Clayman, so --
Q. I'm sorry?
A. Dr. Clayman, so it was a -- it is essentially a regulatory committee. But members from various components of medical, toxicology, ADME, manufacturing and other individuals that would ultimately make decisions, approve or disapprove labeling changes.
Q. And was the Zyprexa label the subject of a GPLC session in the weeks or months following this e-mail?
A. I don't recall.
Q. Let me hand you what's been previously marked as Plaintiff's Exhibit 990. For the record, this is a seven-page document, the first page of which is labeled Confidential, do not

forward, to be distributed only by global operations labeling department in Indianapolis, Attachment E. And, Dr. Beasley, if I can refer you to the second physical page of the document.
A. Uh-huh.
Q. There is a heading towards the top of the page, below the Confidential label that says, Olanzapine Labeling Change on Hyperglycemia for February 21, 2000 GPLC Meeting. Do you see that?
A. Yes, I do.
Q. Dr. Beasley, if I could refer you to the second physical page of the document.
A. Uh-huh.
Q. There is a heading towards the top of the page, below the Confidential label, that says Olanzapine Labeling Change on Hyperglycemia for February 21, 2000 GPLC Meeting.
Do you see that?
A. Yes, I do.
Q. Regardless of whether you personally drafted the text that's in here, would it be fair to say that you not only reviewed but approved this language?
A. Yes.
Q. Okay. So your analysis is reflected in

this document for the clinical trial data yielded results that showed that the frequency of hyperglycemia was common or frequent, correct?
A. Yes, by -- by this nomenclature, absolutely. And in our preliminary set of analyses.
Q. Okay. And then there's a box below that says: How has this proposal arisen?
A. Yes.
Q. And the language of that says: Recent review of random glucose levels of patients in olanzapine clinical trials reveal that the incidence of treatment-emergent hyperglycemia in olanzapine group 3.6 percent was higher than the placebo group, 1.05 percent, for common events incidences from clinical trials provide more meaningful information. Did I read that correctly?
A. That's correct.
Q. Okay. Now, this recent review that's being referred to there was the review that you and Dr. Kwong had done on your own initiative because you felt it was important to do; is that correct?
A. That's correct.

Q. And then there's a box below that that says: How has this proposal arisen?
A. Yes.
Q. And the language of that says: Recent review of random glucose levels of patients in olanzapine clinical trials reveal that the incidence of treatment-emergent hyperglycemia in olanzapine --
MR. ALLEN: Sorry for that. That's a technical --
Q. -- was higher than the placebo group, 1.5 percent, for common events incidences from clinical trials provide more meaningful information. Did I read that correctly?
A. That's correct.
Q. Okay. Now, this recent review that's being referred to there was the review that you and Dr. Kwong had done on your own initiative because you felt it was important to do; is that correct?
A. That's correct.
Q. And that incidence in the olanzapine group was almost three and a half times higher than in the placebo group, correct?
A. The number is in excess of threefold.

Q. Almost three and a half, correct?
A. Yes.
Q. Okay. Now, that language there could have been added to -- you could have suggested that that language be added to the label, correct?
A. Yes, we could have.
Q. If I can direct your attention to the following page, you also indicate in here that there were a number of literature reports published regarding hyperglycemia and olanzapine, correct?
A. I'm seeing the literature reports and I think these would reviewed -- briefly summarized such reports.
Q. Okay. And you also make reference to Dr. Daniel Casey from Oregon presenting a seminar at Lilly at the end of 1999 in that box, correct?
A. That's correct.
Q. Is this the same Dr. Daniel Casey who is one of the expert advisers who you spoke with at the December, 1995 meeting in Puerto Rico?
A. Yes, he was.
Q. The section of the document goes on to say that Dr. Casey performed chart review of 136

veteran patients who have been exposed to olanzapine therapy for at least four months with an average of 1.4 years. Of the 39 patients who had normal fasting glucose levels before olanzapine therapy, seven or 18 percent had fasting glucose levels of 126 milligrams per deciliter or higher during olanzapine therapy, and then it notes that threshold met the 1998 ADA diagnostic theory for diabetes?
A. Yes.
Q. The ADA refers to the American Diabetic Association?
A. That's correct.
Q. So, what he found during that review is that 18 percent of the people who had normal fasting glucose levels before they started using Zyprexa had thresholds that met the 1998 ADA diagnostic criteria for diabetes after they used Zyprexa, correct?
A. That's correct.
Q. I'm going to hand you what's been previously marked as Plaintiff's Exhibit 4858. For the record, this is a May 9, 2000 letter to FDA from Gregory T. Brophy. Now, it has in the upper right-hand corner, the first page, a bold

label that says Special Supplement Changes Being Effected. Do you see that?
A. Yes, I do.
Q. And am I correct that there is a provision of the FDA regulations which permits a drug company to add a warning to the labeling without prior FDA approval as long as the -- the label change strengthens the warnings?
A. That's correct. Or provides new information on safety, as I understand.
Q. In any event, this label change which was made in May of 2000, without prior FDA approval had three elements to it, correct?
A. I focused on the glycemic numbers, but I believe it also had a change to the NMS section and then the -- the term diabetic coma was also added.
Q. The second numbered item in this letter refers to the change that was actually made regarding hyperglycemia; am I correct?
A. It's with reference to the laboratory findings of hyperglycemia.
Q. Just with respect to the language that was used in the label change, did you tell doctors that the incidence of hyperglycemia was

common or frequent? Did you use those words?
A. We did not use those words; we provided the numbers.
Q. Can you -- would you read for the jury the -- the language that is -- was used?
A. Yes. In the olanzapine clinical trial database as of September 30, 1999, 4,577 olanzapine-treated patients begin, paren, representing approximately 2,255 patient-year exposure, end paren, and 445 placebo-treated patients who had no history of diabetes mellitus and whose baseline random plasma glucose levels were 140 milligrams per deciliter or lower were identified. Persistent random glucose levels greater than or equal to 200 milligrams per deciliter, paren, suggestive of possible diabetes, end paren, were observed in 0.8 percent of olanzapine-treated patients, paren, placebo 0.7 percent, end paren.
Transient paren, i.e., resolved while the patients remained on treatment, end paren, random glucose levels greater than or equal to 200 milligrams per deciliter were found in 0.3 percent of olanzapine-treated patients, begin paren, placebo, 0.2 percent, end paren.

Persistent random glucose levels greater than 160 -- greater than or equal to 160 milligrams per deciliter, observed in 1.0 percent of olanzapine-treated patient, begin paren, placebo, 1.1 percent, end paren.

Transient random glucose levels greater than or equal to 160 milligrams per deciliter but less than 200 milligrams per deciliter were found in 1.0 percent of olanzapine-treated patients, paren, placebo 0.4 percent, end paren.

Q. And that's the final language that went in the label, correct?

A. That's correct.

Q. We'll talk about that in just a minute. Let's finish up with this label change that you guys did in May of 2000. What happened five months later was that the FDA came back and made you take that language out of the label, is that correct?

A. That's correct.

Q. Let me show you what's been previously marked as Plaintiff's Exhibit 195 which, for the record, is an October 11, 2000 letter from Russell Katz, the director of the division of

neuropharmacological drug products at FDA to Gregory Brophy. And if we just cut to the chase here, what happened was FDA five months after you made that label change on your own without prior FDA approval, FDA came back on October 11th, 2000 and said you have to take that language out, correct?

A. That's correct.

Q. And the reason why they made you take that out was because the FDA said -- this is on the second page of the document -- the descriptive data that is provided expresses a certain level of implied safety with respect to treatment-emergent hyperglycemia.

Do you see that language, sir?

A. Yes, I do.

Q. And, in fact, that was the case, the data that you reported in there, the statements that you had in the labeling showed that there was essentially no difference between hyperglycemia and Zyprexa users versus placebo patients and the FDA concluded that that expresses a certain level of implied safety; isn't that correct?

A. I think you've asked me two questions.

With respect to the FDA's impression, that is correct.

I view these data, quite frankly, as not reassuring, although not ominous, not reassuring because of the difference. I clearly felt it was important to report these incidences.

Q. In the proposed -- well, in the labeling that you guys actually put in in May 2000, which the FDA made you take out five months later in October, there was no indication of any statistically significant differences in hyperglycemia between Zyprexa and other patients, correct?

A. There is clearly not in this -- in this information that was added.

Q. Okay. Let me show you what's been previously marked as Plaintiff's Exhibits 5565. For the record, this is a series of e-mails and you had received a request from Ralph Dittman -- by the way, who was Ralph Dittman?

A. Ralph Dittman was a German -- he was a German psychiatrist in our German affiliate.

Q. And he was asking you for information on hyperglycemia, correct?

A. Let me, if I can --

Q. If you look at the top of the second page.

A. Yes.

Q. Okay. And you wrote back to him and you said, in part: Our continuous analyses show that olanzapine does result in statistically significant mean increases in random glucoses relative to placebo and haloperidol.

Did I read that correctly?

A. That's correct.

Q. By the way, if I forgot to point out for the record, the date of this e-mail is February 22, 2001.

A. Right. These would have been analyses that were conducted subsequent to those that had been done as part of the review of data by myself and Dr. Kwong.

Q. Then, would these analyses had been done before the May, 2000 label change or after?

A. I think they would have been done afterward.

Q. Three months later, you and others gin up language that goes into labeling under special supplement Changes Being Effected, which shows essentially no difference between the incidence

of hyperglycemia and Zyprexa users versus placebo users and five months after that FDA makes you take out that language because they say it gives an implied sense of safety, correct?

A. I agree with you with respect to the action of the FDA. In your question you characterize our actions in a certain fashion that I would disagree with.

Q. And then five months after the FDA makes you take out that language which they said was expressing a certain level of implied safety with respect to treatment-emergent hyperglycemia, you do another analysis which finds a statistically significant mean increase in random glucose for Zyprexa relative to placebo and haloperidol, correct?

A. That was my understanding at the time, having not been involved in those analyses.

Q. And, sir, if I can direct your attention to the remaining language in that paragraph you go on to state: These increases are occurring as early as week one, correct?

A. Yes.

Q. That would be week one after beginning use of the drug?

A. That's correct.

Q. And you say: These changes are accounted for in part, but not entirely by weight increase, correct?

A. I think you have excluded a parenthetical in the -- in this, but that states may not represent a true deterioration in glycemic metabolism but simply an increase in food intake since these are random and not fasting glucoses.

Q. And then you go on to say, These changes are encountered for in part but not entirely by weight increases, correct?

A. Yes.

Q. Then you say, Categorical analyses to values above a set of thresholds: 126, 140, 160, 200 milligrams per deciliter do not reveal significant findings, but trends are there except for the comparison of clozapine to olanzapine to the lower two thresholds. Clozapine more, correct?

A. That's correct.

Q. Sir, when you do categorical analyses like that, you are splitting the data up into different chunks, correct?

A. That's correct. We have been talking -- most of what we've been talking about so far has been categorical analysis. You define a certain value that makes a distinction between normal and abnormal. At this time 126 was the ADA criteria, so if you were 125, you would be considered normal. If you were 126 or above, you would be considered abnormal.

Q. And describe for the jury what the difference is between a categorical analysis and a continuous analysis.

A. A continuous analysis is where you take averages. You have a certain number of individuals who have a baseline, or a before treatment value, and each one of those patients has an individual value and they're observed to have multiple values that's measured while they're on treatment, and each of those patients will then have a change at each point in the observation, and those changes are taken as an average.

Q. And, sir, it was your continuous analysis that you're referring to here which showed that olanzapine does result in statistically significant mean increases in

random glucose relative to placebo and haloperidol, correct?

A. That was my understanding of the work that had been done at that time.

Q. And sir, it was continuous analyses which your company's own outside experts recommended that you needed to be looking at, correct?

A. Yes, and I think that was the reason they were looked at.

Q. Let's talk about that right now. Do you recall that in October of 2000 you and various representatives of Eli Lilly had a meeting with a group of outside experts in Atlanta?

A. Yes, I do.

Q. Okay. And those were -- the people that you met with, those outside experts were an academic advisory board, correct?

A. That's correct.

Q. Now, Eli Lilly is a drug company which makes not only psychiatric drugs but also makes and distributes a number of drugs for the treatment of diabetes, correct?

A. That's correct.

Q. And do you recall --

THE COURT: Can we stop for a second?
THE CLERK: Off record.
THE COURT: Are we doing okay? Do you want to take a break now -- how much longer do we have with the deposition, about? As I recall, it was about an hour and 12 minutes.
MR. ALLEN: We have about half-hour left. Forty minutes was -- this was the longest depo we had. So I think -- how much time?
THE VIDEOGRAPHER: Looks like about 40 minutes.
MR. ALLEN: He said about 40 minutes.
THE COURT: Do you want to take your break now? I see some nods. Let's take a 15-minute break now.
We'll be off record.
(Jury out.)
(Break.)
(Jury in.)
THE COURT: Please be seated.
And we're back on the record. All members of the jury are present.
Are we going to resume?

MR. ALLEN: Yes, sir. We resume with Dr. Beasley. Can we dim those lights behind? Thank you, Your Honor.
RESUME VIDEOTAPE TESTIMONY OF DR. CHARLES BEASLEY
Q. And do you recall that -- that people in Lilly referred to these outside experts as being in the Who's Who of diabetes?
A. I don't recall that characterization, but these are -- were certainly a number of very, very prominent academic individuals.
Q. Okay. And so -- and so you and Chris Bomba and Patrizia Cavazzoni and Suni Keeling and Robert Baker all went down there in October of 2000 to meet with them, correct?
A. That's correct.
Q. And did you give them a presentation?
A. I believe it was Dr. Cavazzoni that basically, presented the results of the work that had been represented in what Dr. Kwong and I put together.
Q. Would it be fair to say that the end result of the analysis and the research that you and Dr. Kwong put together was what was reflected in the labeling that was implemented in May of 2000?

A. Yes. Certainly, that work that Dr. Kwong and I have performed, obviously, with a lot of assistance led to the labeling change.
Q. Right. And fair to say that the results of your analysis at the end of the day were the numbers that we saw before that were stated in that labeling change that was made?
A. That's correct.
Q. Okay. That's the same labeling change that the FDA made you take out of the label five months earlier, correct?
A. That's correct.
Q. Okay. And, in fact, that letter that the FDA sent instructing you to take that language out of the labeling was dated October 11th, correct, 2000. It's in the upper right-hand corner.
A. There's a stamp here, October 11th, 2000.
Q. And that was just days after the meeting you had the meeting with the outside experts in Atlanta?
A. Again, I'm getting a bit confused on my dates -- I think it was October.
Q. I apologize. Let me hand you what's

been previously marked as Exhibit 6998. For the record, this is an e-mail dated October 9, 2000 from Robert Baker to Charles Beasley, Christopher Bomba, Alan Breier, Thomas Brody, Patrizia Cavazzoni, James Gregory, John Holcombe, Jack E. Jordan, Suni Keeling, Bruce Kinon, Michael Murray, John Richards, Eugene Thiem and Mauricio Tohen and Paula Trzepacz, correct?
A. Yes.
Q. And in this e-mail Dr. Baker states that in the first paragraph, For your information Lilly's -- Lilly's diabetes slash endocrine group held an academic advisory board meeting this weekend in Atlanta.
That would have been days before October 9, correct?
A. Yes.
Q. Okay. And we know that on October 11 the FDA comes out and says you've got to take that label language out, right?
A. Correct.
Q. Okay. So, within days after you meet with the outside experts, FDA tells you to take the label out, right?
A. Yes.

Q. Okay. Dr. Baker, in Exhibit 6998 goes on in his e-mail to say, they kindly allotted two hours for discussion of olanzapine's potential hyperglycemia risks and Charles Beasley, Chris Bomba, Patrizia Cavazzoni, Suni Keeling and I attended. Unfortunately, this consultation reinforced my impression that hyperglycemia remains quite a threat for olanzapine and may merit even further medical attention and marketing focus on the topic.

Did I say that correctly?

A. Yes, that's correct.

Q. In the second paragraph he goes on to state: They were, however, concerned by our spontaneous AE reports -- that's referring to adverse event reports, correct?

A. That's correct.

Q. And quite impressed by the magnitude of weight gain on olanzapine and implications for glucose. Much of their input for helpful steps came back to addressing weight gain.

Did I read that correctly?

A. That's correct.

Q. And you had been warned about the weight gain problem by another panel of outside experts

as we talked about right at the beginning of your deposition back in December of 1995, correct?

A. That's correct, and this was something that we described and from my perspective, given Dr. Breier's efforts, we were attending to.

Q. And continuing on in his e-mail Dr. Baker said, citing methodological questions at least the vocal members were not reassured adequately by our analyses such as the finding that relative risk was not higher than comparative drugs. Disconcertingly, one member compared our approach to Warner-Lambert's reported argument that Rezulin did not cause more hepatic problems than other drugs in its class.

Do you see that language?

A. Yes I do.

Q. Were you familiar with what Warner-Lambert was doing with respect to Rezulin?

A. No. I was familiar with the drug and I was familiar with the fact that it was ultimately withdrawn from the market.

Q. Okay. Because of safety problems, correct?

A. Because of the perception that it had a risk of hepatic dysfunction.

Q. Let me show you another e-mail regarding this meeting that you had with the outside experts in October of 2000. I'm going to hand you what's been previously marked as Exhibit 1449. I want to direct your attention, first, to that e-mail from Thomas Brody to Robert Baker and Eugene Thiem that starts in the middle of the first page.

First of all, who was Thomas Brody?

A. I don't know who Mr. Brody was.

Q. Do you know who Eugene Thiem was?

A. I think he was an individual involved in the marketing area in the U.S. affiliate.

Q. Okay. And the subject is the meeting with endocrinology consultants, correct?

A. Yes.

Q. And Mr. Brody says: Robert -- referring to Robert Baker -- clearly this group of endocrinologists who spoke up and I would rate those who did speak up as the leaders of the pack, are very concerned with the approach Lilly is taking towards the issue that Zyprexa leads to diabetes. I can only hope that you and all of the team who attended the NADAB meeting are gaining the ear of senior leadership and

articulating this finding. Although the board's recommendation is probably not the way Lilly typically does business, I do believe they made a very strong point that unless we come clean on this, it could get much more serious than we might anticipate.

You see that language, sir?

A. Yes, I do.

Q. Okay. Now, you did, indeed, have the ear of senior leadership within the corporation, did you not?

A. Yes, I would characterize my position as at least having their ear.

Q. And the man that you had the ear of was Dr. Gary Toleffson, correct?

A. That's correct.

Q. And did you have the ear of any others who would be regarded as senior leadership with the company?

A. I believe that I also was able to speak freely with Dr. Breier.

Q. And now, sir, if I could direct your attention to the third physical page. At the top of the page is an e-mail from Robert Baker to you, Alan Breier, Christopher Bomba, Patrizia

Cavazzoni, Suni Keeling, again referring to the meeting with endocrinology consultants, correct?
A. Yes.
Q. And in that e-mail Dr. Baker does two things, No. 1, he forwards to you and the others there that original e-mail that he'd gotten from Thomas Brody, the one where he said that although the board's recommendation is probably not the way Lilly typically does business, I do believe they made a very strong point that unless we come clean on this it could get much more serious than we might anticipate. Correct?
A. Excuse me. I was -- I was looking at this and I believe that was on page 1, as I recall.
Q. Sir, the language I just read was -- you're correct, in the e-mail at the bottom of page 1. It's also in the e-mail that's at the bottom of page 3, because on page -- what page 3 does is reflects an e-mail that Robert Baker sent to you and others forwarding that e-mail from Thomas Brody, correct?
A. Yes.
Q. And it was in that e-mail from Thomas Brody that Mr. Brody said that I can only hope

that you and all of the team who attended the meeting are gaining the ear of senior leadership and articulating this finding, correct?
A. That's correct.
Q. And so, in fact, by Robert Baker sending this memo on to Alan Breier, he put this in the ear of senior leadership of the company, correct?
A. That's correct.
Q. So, Alan Breier was informed in October of 2000 that these consultants were saying that they made a very strong point that unless we come clean on this, it could get much more serious than we might anticipate, correct?
A. That's correct.
Q. Okay. And then in his e-mail to Robert Baker -- pardon me -- in Robert Baker's e-mail to you and others at the top of this page, 3, he has -- he starts off by saying, my take was that this board of academic endocrinologists was impressed enough by the magnitude of weight gain and number of reports in the spontaneous report database that they were predisposed towards subsequent testimony to an analysis that did not find a hyperglycemia rates between olanzapine and comparators, correct?

A. That's correct.
Q. Then he goes on to have a message to you and also to Alan Breier, correct?
A. That's correct.
Q. And he says to you, do you think it's appropriate to look at secondary analysis that does not exclude baseline abnormalities and another looking at mean changes in glucose?
A. That's correct.
Q. And the looking at mean changes in glucose is the continuous analysis that we referred to earlier, correct?
A. That's correct.
Q. And that's the one that when you did it a couple of months later, your understanding in February, 2001 that it did, indeed, show a statistically significant increase in random glucose for Zyprexa relative to placebo and haloperidol, correct?
A. That is my -- that was my understanding of those analyses at the time. I am not -- I have no knowledge of the -- the ultimate outcome of what may have been continuing analysis here.
Q. Okay. Because by that point you were out of it, right? You were gone?

A. I was transitioning out of it, yes.
Q. They took you out of the Zyprexa group and they send you over to deal with Cialis, correct?
A. That's correct.
Q. Let's continue on with what -- was telling Alan Breier, senior management in October of 2000. Dr. Baker says: Alan, I believe that what Tom is referring to as, quote, not the way Lilly typically does business, end quote, are suggestions to more vocally assert that olanzapine may have a problem on the glucose issue. And rather than moving forward with our analyses turning all info over to an independent board for review, conclusions and dissemination. You see that language here?
A. Yes, I do.
Q. And so what Baker was telling Breier -- by the way, Breier was not at the meeting, correct?
A. No.
Q. So Baker's telling Breier that these experts were saying that you should actually assert that Zyprexa may have a problem on the glucose issue, correct? Is that what he says?

A. That was apparently Dr. Baker's recollection at the time.
Q. So he's saying that the experts are saying, hey, go out and tell doctors that Zyprexa may have a problem with glucose, right?
A. Again, that was apparently Dr. Baker's recollection at the time.
Q. I want to show you another e-mail -- a series of e-mails relating to this meeting in October of 2000. For the record, I'm handing you what's been previously marked Plaintiff's Exhibit 1453. Sir, would you agree with me that the e-mail that's at the bottom of page 3 of this exhibit is the same e-mail that we were just talking about in the prior exhibit?
A. I believe it is.
Q. Okay. And then what's above that, which actually starts on page 2, is your e-mail response back to Dr. Baker?
A. Let's see. I -- I haven't read it yet, but that would appear to be -- on the 10th at 8:43. He would have presumably sent that late in the afternoon and I would have seen it the next -- the next morning.
Q. And in this e-mail you're giving your

take on the situation, correct?
A. That's correct.
Q. And then in the second paragraph you say: These guys were solely concerned about the weight gain, not only because of the diabetes risk, but all the other potential health risks. They initially thought it might simply be a response to improvement and schizophrenia with a few outliers, rather naive view but they ain't shrinks. When they have seen this is not seen in nonpsychotic patients, and fixed diets, and olanzapine is the worst offender rather than clozapine, they advocated a different marketing strategy than we are taking. They believe we should aggressively face the issue and work with physicians to address methods of addressing weight gain.
Did I read that correctly?
A. That's correct.
Q. Now, when you make a reference to nonpsychotic normals, am I correct that you're referring to clinical studies done by Lilly which showed that normal people, nonpsychotics when they take Zyprexa, have significant weight gain?
A. Yes.

Q. And when you refer to the animals on fixed diets in this e-mail, am I correct that that's referring to scientific studies conducted by Lilly which showed that animals on fixed diets also showed significant weight gain?
A. I don't recall the specific basis at this point 6 years later for this statement on my part. Dr. Breier, on toxicology, were conducting studies with animals and studies had been previously conducted, so I cannot recall the specific studies that I was referring to here.
Q. Okay. But if your -- if your e-mail is correct and you were the one that wrote this --
A. Right.
Q. -- that there were findings of significant weight gain in animals on fixed diets, that means that you were seeing weight gain in animals whose diet was controlled experimentally so that they were not just free to feed as they wished, but they were given a fixed amount of food, correct?
A. That would be correct.
Q. Now, did these experts give you any examples of what they meant when they said that Lilly should aggressively face the issue?

A. I can't recall any. Obviously, I have my impressions that -- of what they -- what they meant.
Q. Okay. You go on to say at the bottom of that first paragraph that, again, talking about the weight gain, when you translate 1 to 2 percent gain of 40-plus kilos into the absolute number based on 5 million patients, the number is 50,000 to 100,000; 100,000 people putting on 90 pounds of weight is a lot.
A. And that was a speculation on my part as a possibility to underscore this to the people we communicated with.
Q. Okay. How did you arrive at that calculation?
A. My recollection is that we had -- the number of analyses had been done looking at weight gain in our clinical trials, and I believe that Dr. Kinon was, in fact, the primary individual running these -- running these -- having these analyses run. And my recollection is that I would have seen listings that would have shown percentages of patients with different amounts of weight gain who had been treated for various lengths of time.

Q. And, sir, do you recall writing a memo some months later in which you said: It would be ludicrous to state that such a patient is not at long-term increased cardiac risk relative to prior to gaining that weight, especially in temporal association with that weight gaining the patient developed an increase in fasting glucose and lipid levels?
A. I don't recall that specifically, but I may well have written that. Gaining body fat is clearly recognized as a risk factor for cardiovascular disease. I think I learned that in my first year physiology course.
Q. For the record, Exhibit 6128 is another series of e-mails. If I could direct your attention to page 3 of the document. That's an e-mail from Ernie Anand and to Andrea Smith asking if there was a standby statement to clarify Lilly's position as to whether Zyprexa can cause cardiovascular complications due to weight gain and diabetes which are clinically recognized risk factors.
See that, sir?
A. Yes.
Q. And then this gets forwarded on to you

as reflected in -- on page 2 of the document which is an e-mail from you to Andrea Smith with copies to Ernie Anand, Patrizia Cavazzoni, Margaret Sowell, Anna Thornton in which you respond and say: One thing that we can say definitively is that olanzapine causes weight gain for approximately 50 percent of patients in trials who remained on the drug for more than six months. The amount of gain was more than ten pounds. Some patients in clinical trials gained as much as 80-plus pounds, lacking empirical data to the contrary, it would be ludicrous to state that such a patient is not at long-term increased cardiac risk relative to prior to gaining that weight especially if in temporal association with that weight gain the patient developed an increased in fasting glucose and lipid levels.
Do you see that language, sir?
A. Yes.
Q. Do you recall writing that e-mail on or about March 15, 2001?
A. No. I mean, again, I do not recall writing it.
Q. You don't dispute that you indeed did that, though?

A. No, not at all.
Q. Directing your attention back to Exhibit 1453 --
A. 1453.
Q. -- that's your October 10, 2000 e-mail to Alan Breier with copies to Robert Baker, Paul Berg, Scott Clark, John Holcombe, Roland Powell, Alvin Rampey, and Roy Tamura. You go on in your e-mail about ten lines down from there to say -- actually, it's one, two, three, four, five, six, seven, eight, nine -- ten lines from the top.
The problem is the arbitrary nature of the cut points and the potential for big shifts depending on those cut points and the fact that we chose the cut points, not really they came from the ADA web site. They specifically referred to the data as being tortured.
Did I read that correctly?
A. That's correct.
Q. Do you recall who it was that referred to the data as being tortured?
A. No, I do not.
Q. Dropping down to the next paragraph in the second sentence you say, They, referring to the outside consultants, they want the continuous

data using all data analyzed over time covarying for both static, diabetic diagnosis, baseline obesity, et cetera, and dynamic covariants, weight gain, alteration in hyperglycemic dose. Similar to David Allison one or two would be happy to take all our data and perform the correct analysis like we don't have competent statisticians.
Did I read that correctly?
A. That's correct.
Q. You go on to say towards the end of that paragraph, I will say that I believe we should have a full-time, dedicated, sophisticated statistical resource that does nothing but hyperglycemia. No meetings, no surveys, zilch until we have completely tortured the data.
Did I read that correctly?
A. That's correct.
Q. And did you completely torture the data?
A. Well, again, what I mean by torture the data here, a reference to the paragraph above where it was used in a positive context, we thoroughly analyzed the data. Coming out of this meeting, we had the two individuals that were interested in working with us. We had

Dr. Cavazzoni assigned full-time, and I believe, although I could be incorrect, that Dr. Breier took steps to see that additional statistical resources were added. We also increased the time commitment of the endocrinologist that was working with us on these matters.

Q. And additional statistical work that you did, at least your understanding of it, up until the time you left the Zyprexa project and later -- some months later in 2001 was that the continuous analyses that the outside consultants had asked for showed that olanzapine does result in statistically significant mean increases in random glucose relative to placebo and haloperidol; is that correct?

A. And that was my understanding at the time of where those analyses stood. I do not know if those were the final analyses of those data.

Q. I'd like to direct your attention to the last paragraph of your e-mail. It says: With regard to the marketing side of this issue of impaired glucose tolerance slash diabetes, the message was clear: Don't get too aggressive about denial. Blaming it on schizophrenia or

claiming no worse than other agents until we are sure of the facts and sure that we can convince regulators and academicians. WL with Rezulin was the example. Sounds like what Dan -- strike that. Sounds exactly like what Dan Casey was saying.

Did I read that correctly?

A. That's correct.

Q. Now, the WL that's referring to is Warner-Lambert, correct?

A. I believe that would be correct.

Q. We talked a little bit about that Rezulin example before. And when you said that sounds exactly like what Dan Casey was saying, when had Dan Casey told Lilly that you shouldn't be too aggressive about denial, blaming it on schizophrenia or claiming that Zyprexa was no worse than other agents?

A. Well, again, I don't recall specifically when Dr. Casey would have made those suggestions to us.

Q. Sir, in fact, despite these recommendations by your outside consultants, in fact, what Lilly did for years after this was to insist that the rate of hyperglycemia and

diabetes with Zyprexa was comparable to other drugs, correct?

A. I do not have specific knowledge of the marketing materials that were put together over time and have been used over time. I did recall -- I did review one initial marketing piece that did present the data that was presented in our package insert.

Q. This is the American Diabetes Association -- let me show that -- of course, see -- there it is. The title's All About Diabetes, and it's put out by the American Diabetes Association, Cure, Care and Commitment. You see that?

A. Yes.

Q. And you've already told this jury that they're much more qualified than you to discuss issues concerning the seriousness or lack of seriousness of diabetes, right?

A. I think that would be the generally held opinion.

Q. And, certainly -- this says diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that is needed to convert sugar, starches and other

food into energy such -- energy needed for daily life. The cause of diabetes continues to be -- let me see -- continues to be a mystery, although both genetics and environmental factors such as -- what, sir?

A. You're asking me to read the --

Q. Yeah, such as what?

A. As obesity and lack of exercise appear --

Q. Appear to play a role.

You testified under oath that diabetes is a known risk -- excuse me -- obesity is a known risk factor for diabetes, right?

A. That's correct.

Q. And, in fact, you testified that the weight gain that you saw in Zyprexa, I think your -- you can correct me, because you'll probably get it -- you testified that 40 percent of patients who take Zyprexa have clinically significant weight gain within six months?

A. Actually, I think the best representation -- that's from the HGAJ study. I think the best representation is actually the -- from the combining of the data which would suggest it's 56 percent of individuals.

Q. Have clinically significant weight gain within six months?
A. Potentially significant defined as 7 percent or greater.
Q. Which would put them at a increased risk of developing hyperglycemia and diabetes?
A. It would be a risk factor and might put them at risk.
Q. And you certainly, then, would agree with me that Zyprexa causes clinically significant weight gain, which is a risk factor for diabetes, correct?
A. I have said that -- that there is a strong association and I believe that in some patients Zyprexa can cause weight gain. I've also testified that weight gain is a risk factor for diabetes.
Q. Right. Now, you've also taken -- and you certainly -- it's not a preferable thing to increase your risk factor for diabetes since diabetes is such a severe disease, is it not?
A. Well, again, one does not want to increase any risk factor that would put one at -- at increased risk of any disease, including diabetes.

Q. Right. And diabetes, we know, and hyperglycemia itself is -- has numerous severe medical complications, does it not?
A. There are a number of complications that are associated with both hyperglycemia and more importantly, diabetes.
Q. Right. Such as heart disease and stroke. This is --
A. Yes, your page here --
Q. You probably don't need to read the page. You can just tell us. Diabetes carries with it the risk of heart disease and stroke, kidney disease, eye complications including blindness, diabetic neuropathy, that's loss of feeling and sensation in your periphery, right?
A. Yes. It's -- actually in diabetes it's actually a painful sensation.
Q. Nerve damage, foot complications, which I know can lead to gangrene and amputations. Skin complications and depression. It can cause depression in and of itself?
A. It has been associated with depression.
Q. Right. Just so we're all communicating now, you and I now agree and you can tell the jury under oath that diabetes and hyperglycemia

are serious medical conditions, are they not?
A. Diabetes clearly has very serious potential outcomes. The -- the condition can, therefore, be considered clinically serious. Many cases would not meet the regulatory definition of seriousness.
Q. Well, how about when I say you can get amputations, heart disease, loss of vision, peripheral neuropathy, are you telling this jury that doesn't meet the FDA regulation definition of serious?
A. Those things that you've just mentioned would meet the FDA criteria.
Q. Right. And aren't all those things as reported in this document, Beasley No. 1, secondary factors that occur following -- can occur following diabetes?
A. Can occur. Yes, sir.
Q. Okay. Sir, I don't think you need to pull it out. It's Exhibit 1453, but it is in that stack here. Just so the record is clear, this is your e-mail that you wrote on October 10th, 2000 following -- this is No. 1453. You knew that in the -- this is your words -- I'll read it. These guys, talking about after the

meeting, were really concerned about the weight gain, not only because of diabetes risk, but all the other potential health risks.
So we have right here a statement that the people at the meeting were concerned about weight gain and diabetes, right?
A. You know, that is my recollection of their main topic of interest was the weight gain.
Q. Sir, and I'm not trying to argue with you. You didn't call it a topic of interest. You said these guys were really concerned, isn't that what you said, not me?
A. Yes, that's correct.
Q. So, the doctors in Atlanta who talked about why they were concerned about weight gain were concerned because weight gain can lead to hyperglycemia, which is prediabetes, and diabetes can occur and all those risks such as peripheral neuropathy, amputations and blindness are concerns, right?
A. Those would be consequences for adverse outcomes of diabetes.
Q. And these -- and that's exactly what these doctors were concerned about --
A. I think my reference here is to the

other potential health risks, such as cardiac disease and those things.
Q. Let's go on. They initially thought it might simply be a response to improvement in schizophrenia with a few outliers, and you put this parenthetical, parens, a rather naive view, but they ain't shrinks.
A. Just a good old boy.
Q. You thought that was a rather naive view, correct?
A. That's correct.
Q. When they understood this is seen in nonpsychotic normals, which you told Mr. Suggs we see weight gain in individuals who are nonschizophrenic and psychotic?
A. That's correct.
Q. And animals on fixed diets, we see it on animals in testing when they have fixed food intake, correct?
A. That was clearly my understanding of preclinical studies at the time. I don't recall the studies.
Q. You were trying to be accurate when you wrote this e-mail?
A. Yes.

Q. Less concerned with animals and that olanzapine is the worst offender other than clozapine. They advocated a different marketing strategy than we are taking.
Did I read that correctly?
A. That's correct.
Q. And that's a long way it took me to get there is what you were saying is Zyprexa, as opposed to other second-generation antipsychotics such as Seroquel, Risperdal, Abilify, Geodon, Zyprexa is the worst offender concerning the issue of weight gain, true?
A. And these are certainly the -- what I wrote here and what they've characterized is the fact -- and, again, I would come back to the data analysis. It comes in No. 2. It's not necessarily far away from some of the other second-generation.
Q. It's No. 2 worst offender behind clozapine for causing weight gain, correct?
A. That's correct.
Q. And that's certainly what you wrote in your e-mail, Exhibit 1453, on October 10th, 2000 at 8:33 in the morning.
A. That's correct.

MR. ALLEN: Your Honor, that concludes our offer of Dr. Charles Beasley, but Mr. Suggs has some documents.
THE COURT: Okay.
MR. ALLEN: Mr. Suggs has some documents he would like to publish to the jury.
THE COURT: Before we do that, am I correct that the defense is going to defer playing any portions of Dr. Beasley's deposition?
MR. LEHNER: That's correct. We'll put that in our case.
MR. SUGGS: Your Honor, there were two exhibits that were referenced in Dr. Beasley's deposition that have not yet been formally admitted, although, Your Honor, I think has been on those. And those would be Exhibits AK6090 and 8042. And there were a number of other exhibits that had been admitted previously in one form or another, but they have not been published and those are Exhibits 1349, 1605, 988, 6998, 4858, 1449, 1453, 195, 990, 5565 and 6128.
And we'd request permission to publish all of these exhibits to the jury, Your Honor.
MR. LEHNER: Your Honor, with

respect to the two that you haven't ruled on, perhaps we should approach the bench and discuss those briefly.
(Bench discussion.)
MR. SUGGS: I believe Your Honor has already addressed these in the deposition testimony.
MR. LEHNER: I think the only objection is the handwriting on there, Your Honor. Should we publish them without the handwriting?
MR. SUGGS: Your Honor, the handwriting is the most critical part of the document.
THE COURT: I'm going to admit these for notice purposes. 6890. And what is the other one?
MR. SUGGS: 8042. That was the one that had an extraneous page at the back.
THE COURT: Okay. So that's been pulled, the extraneous page?
MR. SUGGS: Yes.
THE COURT: Based on my previous rulings in this matter, 6090 and 8042 are both admitted, and those two documents, along with

1349, 1605, 988, 6998, 4858, 1459, 1453, 195, 990, 5565, 6128, all of those are State's exhibits, I believe?

MR. SUGGS: Yes, Your Honor.

THE COURT: All of those may be published to the jury.

MR. SUGGS: Thank you, Your Honor.

(End bench conference.)

MR. ALLEN: Your Honor, we now have the deposition of Robin Wojcieszek -- I believe is how I pronounce it -- Robin Wojcieszek. It is 40 -- if my math is right, it's 49 minutes long. That might be a good time to end for the day.

THE COURT: Why don't we show the jury Robin Wojcieszek's deposition, and it sounds like we'll be able to let them go a little early.

MR. ALLEN: Yes, sir. Thank you.

MR. SUGGS: With this deposition we're going to try some of the documents contemporaneously while we're playing the deposition. I'll show them on the Elmo and put the screen up in front of Your Honor, if that's okay.

THE COURT: That's okay. It's fine to have the screen in front of me. Ladies and

gentlemen, we'll try to do the deposition --

MR. ALLEN: My sheet says 49 minutes two seconds.

THE COURT: Rather than take our second break, we'll try to get that played and let you go early.

MR. FIBICH: Your Honor, can we practice the screen before we start the deposition?

VIDEOTAPE TESTIMONY OF ROBIN WOJCIESZEK

ROBIN WOJCIESZEK,

having been called as a witness via deposition, testified as follows:

DIRECT EXAMINATION

Q. Good morning.

A. Good morning.

Q. Would you state your full name for the record, please?

A. Robin Pitts Wojcieszek.

Q. And what's your occupation?

A. I am a pharmacist, and I work at Eli Lilly and Company in regulatory affairs.

Q. And when did you begin working for Eli Lilly?

A. I began working for Lilly in August of

2002.

Q. Did you have any job responsibilities with Zyprexa after you came to Lilly?

A. Yes.

Q. Okay. If you can describe those for me?

A. I began working on Zyprexa in April of 2003 as a regulatory scientist.

Q. And who did you report to?

A. Greg Brophy.

Q. And who reported to you?

A. I don't have anyone reporting to me.

Q. Okay. How did you come to be designated as the person to testify on behalf of Lilly in this deposition?

A. I was responsible for some of the supplemental applications that are referred to in this communication or in this deposition. And I have primary responsibility for interactions with FDA regarding Zyprexa and labeling changes.

Q. Okay. And how long have you had that responsibility?

A. Since 2003.

Q. Okay. Are you also the prime person responsible for communicating with FDA regarding Symbyax?

A. Yes, I am.

Q. Okay. Let's 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 Alaska litigation.

And I hand you -- I'll hand you what we'll have marked as Plaintiff's Exhibit 2.

This appears to be a copy of a fax of a letter that bears several dates on the front page. The earliest in time of which was March 28th, 2007, and I notice that on the very last page there is an electronic signature of Thomas Laughren that's dated March 28th, 2007.

Do you see that?

A. Yes, I do.

Q. Was this letter faxed to you on March 28th, 2007?

A. Yes, it was.

Q. Okay. 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?
A. That's correct.
Q. Or I guess the generic terms would be containing both olanzapine and fluoxetine, correct?
A. That's correct.
Q. 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, correct?
A. That's correct.
Q. 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 drugs?
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?
A. That's correct.
Q. And since those submissions occurred in the fall of 2006, the studies that contain that data would have been concluded sometime before that, correct?
A. That's correct.
Q. And do you know when it was 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 -- 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. I want to make sure I understand it. So that the submissions that occurred in the fall of 2006 to support the -- the additional indication for treatment-resistant depression included data from the 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. Probably 2001 sometime?
A. Some of them were, yes.
Q. Okay. So it'd be fair to say that the -- that the data that's being referenced here in this letter is 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 there's a bolded heading that states: Updated information on risks of weight gain, hyperglycemia, and hyperlipidemia. 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's associated with olanzapine use, whether taken along or in combination with fluoxetine. You 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?

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 can 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 -- in the labeling, correct?

A. What they or -- they're asking for is

regarding, if you look at the previous paragraph, it's an extension of 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 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, yes.

Q. Okay. And what they said in that paragraph was: Regarding data displays and overall strategy would be the subgroup patients on the basis of their status at baseline so that clinicians can better understand the risks associated with treatment of patients following 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 relative to glucose, paren, less than 140 milligrams per deciliter, end paren, i.e., 2.9 percent of such patients receiving OFC had on-treatment levels

greater than or equal to 200 milligrams per deciliter compared to .3 percent of placebo-treated patients.

Do you see that?

A. Yes.

Q. When they talk about OFC, that's another way of talking about Symbyax or the combination of olanzapine and fluoxetine, correct?

A. That's correct.

Q. And was it your understanding that blood glucose levels greater than or equal to 200 milligrams per deciliter was regarded as diagnostic for diabetes by the American Diabetes Association?

A. Yes, based on the kind -- the ADA guidelines.

Q. Okay. So what the FDA was saying here is the data that you had presented to them already indicated that 2.9 percent of the patients who had baseline random blood glucose of less than 140 wound up having on-treatment levels greater than or equal to 200 compared to .3 percent of the placebo-treated patients, correct?

A. That was an analysis included in the application.

Q. Okay. And was that an analysis that had been done by Lilly or by FDA?

A. By Lilly.

Q. Okay. So, Lilly itself had concluded, then, that 2.9 percent of the patients receiving the combination drug who originally had nondiabetic levels of blood glucose went over the -- the 200 mark, which is diagnostic for diabetes as compared to only .3 percent of the placebo-treated patients; is that correct?

A. What this is saying is this is a particular analysis, categorical analysis or a shift analysis that was done in the application. The overall conclusions would be something that are -- are -- our medical group would make. This is one of many analyses that we conducted.

Q. This particular analysis, however, showed essentially a tenfold higher rate of patients going from nondiabetic levels of blood glucose to -- to blood glucose levels over 200, correct?

A. For this particular analysis?

Q. Yes.

A. Yes.

Q. Okay. And do you know who within Lilly

did that analysis finding that tenfold increase?
A. That would have been done with our statistical group, with the medical group doing an evaluation of the results.
Q. Okay. And I'm presuming that at some point they provided you in regulatory affairs with that data or writeup of the data which you then submitted to FDA, correct?
A. That's correct.
Q. Okay. They then go on to say in their letter, FDA does: However, note that 46 percent of patients who are borderline to high baseline, 140 to 200, have such on-treatment levels compared to only 5 percent of placebo-treated patients.
Do you see that?
A. Yes.
Q. And it was your understanding they were say -- what they were saying there, that when you look at the data that Lilly had generated, it showed that those folks who had somewhat elevated levels of blood glucose in the 140 to 200 range, that when you look at those folks, about 46 percent of those people who were exposed to the combination drug went over 200 as compared to

only 5 percent of the placebo-treated patients, correct?
A. That's correct.
Q. Okay. And that, again, would -- I'm presuming would have been another analysis done by Lilly itself, correct?
A. That's correct.
Q. Okay. So in both of these statements here about what that data showed, FDA was really talking about what Lilly's own analysis had shown, and this was not some separate analysis that FDA had done; is that a fair statement?
A. That's a fair statement.
Q. Okay. Continuing down in the letter a couple of lines, the FDA said, I believe, making reference to that latter analysis where the 46 percent of patients had blood levels over 200 after treatment, they go on to say: In addition, we were troubled that this important finding was not included in your proposed label; do you see that?
A. Yes.
Q. And do you know who it was that made the decision not to include that information in the proposed label?

A. That's a decision that's made -- that's actually a very cross-functional group of individuals within medical, regulatory and global patient safety.
Q. I'm sorry. I don't know why that word came to mind.
Let's see here. Do you know -- that particular data that we've been talking about on which those analyses were made, do you know when they would have been -- when that data would have been generated?
A. That data would have been generated, you know, prior to our submission, so in the summer of 2006.
Q. Okay. I think you said that the -- that the data ranged from between 2002 and 2005.
A. Correct. But this -- this particular analysis is of a pooling of studies.
Q. Ah, okay. Okay. So this analysis was done, you believe, probably in the summer of 2006?
A. Yes.
Q. The analysis that was done in the summer of 2006 as referred to in this first full paragraph on page 2 was an analysis of data that

had been actually generated sometime between 2002 and 2005; fair statement?
A. That's correct.
Q. Okay. If I can direct your attention to the third full paragraph on the second page of the FDA's letter, the one that starts off, Our overall goal. You see that?
A. Yes, I do.
Q. It states, quote, Our overall goal is to improve labeling with regard to these findings so that clinicians will be better informed on what the risks are for their patients. They cannot make reasonable treatment decisions until they have such information. We do not feel that current labeling for either Symbyax or Zyprexa provides sufficient information on these risks and we fully intend to ensure that these labels are enhanced with the best available information to characterize these risks.
You see that language?
A. Yes, I do.
Q. Now, are you aware that in the Zyprexa litigation, not only in this case in Alaska, but in thousands of other cases around the country, Lilly has been asserting that its Zyprexa label

was already sufficient and adequate?
A. Yes.
Q. But at least the -- and Lilly has never, to your knowledge, admitted that its labeling was inadequate, has it?
A. Yeah, that's correct.
Q. But in this March, 2007 letter, FDA told the company that it felt that Zyprexa labeling was not adequate, correct?
A. That's correct.
Q. Now, after receiving this communication from FDA in March of 2007 that it did not believe that the Zyprexa label was adequate, the company did not change the label in April, did it?
A. No, it did not.
Q. Or May?
A. No.
Q. Or June?
A. No.
Q. Or July?
A. No.
Q. Or August?
A. No.
Q. Or September?
A. No.

Q. There was finally a label change in October of 2007, correct?
A. That's correct.
Q. The second full paragraph on page 2 of the FDA letter makes reference to a New York Times article. Do you see that?
A. Yes, I do.
Q. I gather that FDA was -- was wanting to know Lilly's response to the information that was presented in this article; is that correct?
A. That's correct.
Q. I'm going to hand you what we'll have marked as Plaintiff's Exhibit 4. Before I do that, am I correct that there were essentially three parts to Lilly's response to FDA regarding the New York Times article?
A. Yes.
Q. Okay. One was -- Part 1 was submitted in February of 2007. Part 2 was submitted in May of 2007, and Part 3 in June of 2007, correct?
A. Part 3 was in July.
Q. I'm sorry, July 9th of 2007, correct?
A. If I recall, it was July 2nd.
Q. Okay. Okay. I'm going to hand you what I've marked as Plaintiff's Exhibit 4, and I

realize this is Part 2, but at least the way the documents were presented to me, this is -- I have to refer to parts in here to try to track through the sequence.
A. Okay.
Q. For the record, Part 2 is a 77-page document produced to the State bearing the title Regulatory Response, Response to the FDA Query Regarding the New York Times Article, Part 2, and bears the date May 10, 2007.
Did I describe that accurately?
A. Yes, you did.
Q. And were you involved in preparing this response and then submitting it to FDA?
A. Yes.
Q. Okay. If I could direct your attention to page 41, they're numbered in the upper right-hand corner, this is on that page a copy of a letter from FDA to Lilly to the attention of your boss, Gregory Brophy, that is dated January 12th, 2007.
Do you see that?
A. Yes.
Q. And is that the January 12 letter that was referred to in the FDA's March 27 -- or March

28 letter?
A. Yes, it is.
Q. Did we mark that as 2, Exhibit 2?
A. It's 2.
Q. And in the second paragraph of FDA's January 12th letter they state, quote, Recent articles in the New York Times reported on clinical trial data from 70 clinical trials on Zyprexa that showed patients taking Zyprexa experienced high blood sugar levels and weight gain that may have differed from information Eli Lilly revealed publicly and to the FDA.
Did I read that correctly?
A. Yes.
Q. And if you could drop down to the last paragraph on the page, FDA says, By this letter we are asking you to ensure that you are in compliance with all applicable statutes and regulations, and we further request that you submit to the agency all data and information, including, but not limited to, those referenced in the recent New York Times articles that bear on the safety of Zyprexa. In particular, we are interested in receiving data and analyses bearing on these concerns about weight gain and

hyperglycemia that have not already been submitted to the agency. Additionally, if you're in possession of other information not specifically required to be submitted by statute or regulation, but that would nevertheless be useful to FDA in evaluating the safety of Zyprexa regarding these concerns of weight gain and hyperglycemia, we request that you please submit this information to us as well.

Do you see that language?

A. Yes.

Q. So, basically, what they were -- they were asking for was for Lilly to submit data and analyses about weight gain and hyperglycemia that have not already been submitted, and they were telling you to submit any other information that would be useful to FDA and analyze the safety of Zyprexa regardless of whether such information was specifically required to be submitted by statute or regulation; is that correct?

A. That's correct.

Q. At any time after receiving this letter in January of 2007, did Lilly tell FDA, no, we are not going to comply with your request to submit information bearing on this issue even if

it's not called for by statute or regulation?

A. What we did is we -- with receipt of this letter in January of this year -- shortly after receipt, we had a teleconference with FDA to get a better understanding and clarity of what they would like us to submit that we were not required to submit under the regulations, so getting clarity around that.

Q. But it's fair to say that Lilly never told the FDA, no, if it's not called for by statute or regulation, we're not giving it to you?

A. No.

Q. Lilly never said that, right?

A. No.

Q. Okay. So FDA would have been under the impression that if you had information that bore upon the safety of Zyprexa, you were going to provide it to them even if it wasn't specifically called for by regulation or statute, correct?

A. Post -- post this letter we -- we did commit and responded to this request.

Q. Suppose that there was a particular document that was found and it was come across, it indicated that Zyprexa was probably causally

related to higher blood sugars, who within the team that was working on responding to FDA's requests here, who on the team would have decided whether that was something to be included or not, what was submitted to FDA?

A. We had ultimately Dr. Charles Beasley was involved in determining what was deemed as potentially discrepant.

Q. You said he was involved, was he the lead play caller on that?

A. He was -- there were some additional physicians that were involved in the review. He -- he had the oversight of those definitions.

Q. He would have been the most senior person involved in making that decision as to what was discrepant and should be submitted versus what was not?

A. That's correct.

Q. Okay. I'm going to hand you what's been previously marked as Plaintiff's Exhibit 6128, and this is another e-mail chain, and I'm particularly concerned with the e-mail that is on the second page. I'd direct your attention in particular to the e-mail on the second page which is an e-mail from Charles M. Beasley on March 15,

2001 to Andrea Smith, Ernie Anand, Patrizia Cavazzoni, Margaret Sowell and Anna Thornton, the subject being olanzapine and cardiovascular risk. If I could direct your attention to the third line down on that e-mail it states, quote, One thing that we can say definitively is that olanzapine causes weight gain and for approximately 50 percent of patients in trials who remained on the drug for more than six months, the amount of gain was greater than ten pounds. Some patients in clinical trials gained as much as 80-plus pounds. Lacking empirical data to the contrary, it would be ludicrous to say that such a patient is not at long-term increased cardiac risk relative to prior to gaining that weight especially if in temporal association with what weight gain the patient developed an increase in fasting glucose and lipid levels. Could you see what language?

A. Yes.

Q. That e-mail was not submitted to FDA as part of the response, was it?

A. No, it was not.

Q. Okay. And have you ever seen that e-mail before I showed it to you today?

A. No.
Q. Okay. By the way, the Zyprexa labeling, even today does not state that olanzapine causes weight gain, does it?
A. No.
Q. Dr. Beasley said that he could say that definitively back on March of 2001, correct?
A. Not understanding the overall connection of what data he's remarking on or the situation, I don't feel comfortable answering what question.
Q. Okay. I'm going to hand you what's been previously marked as Plaintiff's Exhibit 7802. For the record, this is a one-page document, what appears to be a chart. I'll represent to you that the database that was provided to us by Eli Lilly says that document is dated June 24, 2000, and I'll also represent to you that the database provided to us by Lilly says what it contains are the files of Michelle Sharp, and I believe what Michelle Sharp was, at least once a colleague of yours in regulatory affairs, correct?
A. That's correct.
Q. And back in 2000, she had responsibility for Zyprexa, did she not?
A. Yes.

Q. Okay. And the title of this document is Listing of Treatment-Emergent Abnormal Lab Findings in Olanzapine-Treated Patients, Placebo-Controlled F1D-MC-HGFU studies one and two combined. You see that?
A. Yes.
Q. And then are a listing of various laboratory findings, abnormal laboratory findings, and do you see that there's a listing for glucose, nonfasting high?
A. Yes.
Q. And could you see what it indicates what the percentage of olanzapine patients who had high glucose was and that the percentage for placebo patients was 0 percent?
A. Yes, I could.
Q. And could you see what are to the right of that, several -- several A's, the letter A's?
A. Yes.
Q. Okay. And if you look down at the bottom there is a little legend as to what the letters mean.
A. Uh-huh.
Q. And it says, according to A, what the letter A means quote, event probably causally

related. You see that?
A. Yes.
Q. And this document was submitted to FDA as part of the response in 2007?
A. No, it was not.
Q. In fact, had you ever seen this document before I showed it to you this morning?
A. No, I have not.
Q. I'm going to hand you what's been previously marked as Plaintiff's Exhibit 8666, which is another e-mail chain. I'm concerned really only with the -- the one on the first page, which is the last one. It is dated June 27, 2002. It is from Dr. Simeon Israel Taylor to a number of individuals, and if I can direct your attention to the last two sentences in the first paragraph over towards the right. You see where it starts off, However, two lines from the bottom?
A. Yes.
Q. It states, However, I feel that we need to deal with the scientific facts, whatever they are. Ultimately, I expect that a fair-minded scholarly evaluation of the available data is likely to support several conclusions. No. 1,

Zyprexa, like other members of the class, causes weight gain.
Two, like other causes of weight gain, Zyprexa-induced weight gain probably increases the risk of diabetes.
Do you see that language?
A. Yes.
Q. And this was not provided to FDA in the response of 2007, was it?
A. Taking a minute to look through it.
Q. Sure.
A. No.
Q. Okay. And, in fact, had you ever seen this document before I showed it to you this morning?
A. No.
Q. Do you recall that about two months after receiving Part 3 of your submission --
A. Okay.
Q. -- and after having reviewed that prior submissions that Lilly made to the agency, the agency wrote to Lilly on August 28th, 2007 requesting that Lilly make substantial changes to the Zyprexa labeling to protect the public health?

A. They sent us a communication on that date requesting labeling changes.
Q. And they did that because they thought it was in the best interest of the public health, correct?
A. That was a statement made in that particular letter.
Q. Let me hand you what we'll have marked as Plaintiff's Exhibit No. 8.
For the record, Exhibit 8 is a letter dated August 28th, 2007 from Thomas A. Laughren to Ms. Wojcieszek. In the third paragraph they said: We have reviewed the data that you have submitted thus far as well as the available literature, and we would like to request that you make the labeling changes listed below pertaining to the effect of olanzapine and Symbyax on body weight, lipids and glucose.
Do you see that language?
A. Yes.
Q. Okay. So, notwithstanding the fact that Lilly had taken the position that the labeling did not need to be changed and the FDA after reviewing all of the material that you had submitted thus far by August 28th, was of the

view that, indeed, the labeling did need to be changed, correct?
A. That's correct. The one point that we were also getting -- trying to get clarity is what data they were referring to that they had reviewed thus far.
Q. Okay. They go on to say: We anticipate that additional labeling changes will be necessary when we have reviewed the results of the additional analyses that we have requested.
Do you see that language?
A. Yes.
Q. Referring back to the FDA's letter in that same paragraph, FDA goes on to say, quote, Given that you're completing these analyses and our review of them will take some time, we believe that it is in the best interest of the public health to make interim labeling changes now based on the data that we already have available.
Do you see that language?
A. Yes.
Q. Okay. But then FDA proceeds to lay out the language that they were suggesting with respect to changes to the warning section,

correct?
A. Correct.
Q. Okay. But with the full contemplation that these changes might well only be interim and that there might be additional changes that may or may not come into play after you submit all of your other data, correct?
A. That's correct.
Q. Okay. And the first section that they have changes that they request have to do with the hyperglycemia and diabetes mellitus sections of the warnings of Zyprexa, correct?
A. Correct.
Q. Okay. What they show there is by strikeouts and underlining the language that they want eliminated and the language that they want to replace them, correct?
A. Correct.
Q. At the end of the first paragraph it states, quote, olanzapine and clozapine treatments have been associated with a greater potential to induce hyperglycemia than other atypical antipsychotics.
Do you see that?
A. Yes.

Q. And what does the word induce mean?
A. It means that there's some sort of a relationship of olanzapine and hyperglycemia.
Q. Well, in fact, the word "induce" indicates it's a causal relationship, does it not?
A. It could mean that.
Q. In fact, the ordinary definition, the ordinary dictionary definition of the word induce definitely indicates that it was a causal relationship. If I induce something, that means that I have brought -- brought about that result, correct?
You may answer.
A. Again, it could be defined that way.
Q. And then the FDA also proposed that on the following page a completely new section in the warnings section regarding weight gain, correct?
A. Correct.
Q. Up until this point in time, Lilly had never discussed weight gain in the warnings section of the Zyprexa labeling, correct?
A. At this time, it was not in our current label. However, it was being proposed in the

supplemental applications for TRD in adolescents.
Q. And when was that proposed?
A. That was in 2000 -- late 2006.
Q. And then also in this letter, the FDA was requesting a completely new section on -- in the warnings section regarding hyperlipidemia, correct?
A. That's correct.
Q. Now, hyperlipidemia refers to fats in the blood, correct?
A. It -- it refers to -- yes, things such as triglycerides, cholesterol, lipids, correct.
Q. That was what hyperlipidemia means, is altered levels of triglycerides and cholesterol, correct?
A. Correct.
Q. And after receiving this letter in which FDA laid out the language it wanted to see in the labeling, Lilly did not accept the language requested by FDA and, instead, sought to change the language, correct?
A. In response to this -- this communication, we initiated discussions and proposals with FDA shortly after receipt.
Q. Lilly did not accept the language that

was laid out by the FDA in their August 28th, 2007 letter, correct?
A. We provided our proposal in response to their request based on data that we had available short -- you know, during this time frame.
Q. Your response to FDA was not -- okay, we'll make the label change that you requested, correct?
A. Correct.
Q. Okay. If I could have -- we'll mark as the next exhibit Plaintiff's Exhibit 9.
And for the record, Exhibit 9 is a document entitled FDA Briefing Document. At the upper left-hand corner, it says Revised September 12th, 2007.
A. That's correct.
Q. And was this actually submitted to FDA?
A. It was -- the information included in this was e-mailed to FDA.
Q. Okay.
A. In preparation for our meeting on September 17th.
Q. And I'm going to hand you what I've marked as Exhibit No. 10, but keep Exhibit 9 handy.

A. Okay.
Q. A document which purports to be meeting minutes of a meeting between FDA and Lilly on September 17, 2007.
A. That's correct.
Q. And did you prepare the minutes that are in Exhibit 10?
A. Yes. In addition to my colleague Catherine Melfi from regulatory who was also in attendance.
Q. If I can direct your attention to the last two sentences of the warning language that Lilly had proposed after FDA's request. They start at the very, very bottom of the page, the last three words on the page, In contrast.
A. Yep.
Q. Okay. They say, quote, In contrast, the association between atypical antipsychotics and glycemic control appears to fall along a continuum although relative risk estimates have been inconsistent. Clozapine appears to have the greatest association while olanzapine may have a slightly greater association between quetiapine and risperidone and greater association than ziprasidone.

Did I read that correctly?
A. Yes.
Q. But what you have done in that -- what was done in that section was to take out any reference to a causal relationship, correct?
A SPEAKER: Objection to the form.
A. What we included was in response to FDA's request around that last statement that they made in their August 28th letter, that last paragraph around that statement of olanzapine treatments have been associated with a greater potential to induce hyperglycemia than other atypical antipsychotics. We were responding with data that we had available looking at our internal studies of head-to-head comparisons of olanzapine versus other atypicals and some other external literature that we felt was a more appropriate statement around changes in glucose measures.
Q. But you took about -- you took out any reference to language that indicates a causal relationship?
A. We -- we did not include that in our proposal.
Q. Okay. And, in fact, to this day, Lilly

denies that olanzapine can induce or cause hyperglycemia, correct?
A. We don't feel that the -- that we have data to support that particular statement FDA included.
Q. If I can have you look at Exhibit 10, please, which is the minutes of the September 17, 2007 meeting Lilly had with the FDA. And was this meeting at FDA headquarters?
A. Yes, it was.
Q. Okay. Would Dr. Thomas Laughren had been the leader of the FDA side?
A. Yes.
Q. Okay. And within the Lilly participants, was there one leader?
A. I facilitated the meeting and Dr. Corya was the medical lead, so the two of us co-facilitated the discussion.
Q. Okay. And the purpose of this meeting was to discuss Lilly's response to FDA's August 28, 2007 letter, and just so I guess the record is clear, the response that you're referring to there would have been what we had marked as Exhibit 9; is that correct?
A. Yes.

Q. Okay.
A. Yes.
Q. And if I can direct your attention to the following page. It appears that at this meeting Lilly outlined three main labeling concepts that Lilly wanted to have for an inclusion in the hyperglycemia warning; is that correct?
A. It outlines three of the main objectives of our proposal compared to what FDA had proposed.
Q. And those three main concepts are laid out on the second page of Exhibit 10, correct?
A. That's correct.
Q. Okay. And then the first one you note in your minutes that FDA requested removal of the statement regarding background risk for hyperglycemia in patients with schizophrenia, and Lilly believes that this is important information for labeling, correct?
A. Correct.
Q. And FDA agreed that that statement could be retained in the revised labeling, correct?
A. Correct.
Q. Point 2 was FDA's requested labeling

recommends that all patients on olanzapine should be monitored regularly for worsening of glucose control, and that was different from what had been before, correct?
A. That's correct.
Q. There had been -- the labeling change that was made in 2003 had suggested that there be monitoring of glucose for patients who had diabetes or risk factors for diabetes, correct?
A. Correct.
Q. And here FDA was -- was recommending that -- that all patients on olanzapine should be monitored regularly for worsening of glucose control regardless of whether they had diabetes or risk factors for diabetes, correct?
A. That's correct.
Q. Okay. And in the minutes here indicates that Lilly accepts the recommended monitoring, however, Lilly believes that the recommendation should cover the class atypical antipsychotics, correct?
A. That's correct.
Q. Okay. And as far as you know, sitting here today, you're not aware of any such change to the other labeling of atypical antipsychotics

saying there should be monitoring of every patient, correct?
A. That's correct.
Q. Okay. And then in italics at the bottom of that section, you note what FDA's response was, correct?
A. Right.
Q. And that was that FDA is not convinced that all patients on atypical antipsychotics require the same level of monitoring, but does agree with Lilly's assertion that all patients should get baseline glucose measurements, correct?
A. Correct.
Q. Okay. And then Point 3 stated that FDA's requested labeling places olanzapine and clozapine in the same category in terms of association with glucose disregulation. However, Lilly asserted that available data including both Lilly clinical trial data and the available literature support a differential association between clozapine and olanzapine and reiterated the belief that the association between antipsychotics and glucose disregulation appears to fall on a continuum.

Did I read that correctly?
A. Yes, you did.
Q. And then you note there that FDA agreed that there is a continuum on which the atypicals fall in terms of association with -- with glucose disregulation, correct?
A. Correct.
Q. By the way, with respect to the monitoring of all patients that FDA was insisting on here in 2007, that had been required by the Japanese label in -- as of April of 2002, correct?
A. That's my understanding based on the history. I was not involved in that.
Q. So, at least --
MR. SUGGS: Your Honor, that concludes the deposition of Ms. Wojcieszek.
THE COURT: Okay. Could we take the screen down, please.
MR. SUGGS: We do have some documents that we need to have admitted or -- and/or published. I don't know if you want to do that now --
THE COURT: It's five after, and I don't want to have the jury sit here and go

through the documents today.
MR. SUGGS: Very well. Thank you.
THE COURT: Ladies and gentlemen of the jury, this brings us to conclusion of our trial day. I'd ask if you'd be here at 8:30, 20 after 8:00 tomorrow so that we can resume -- again, I would remind you, please do not discuss this case among yourselves or allow anyone to discuss it with you, and please try to keep an open mind until you've heard all the evidence in this case. I also remind you to please not view any TV stories or newspaper articles or do any Internet searches concerning the subject matter of the lawsuit.
I'll excuse you for the day and I'll see you tomorrow.
(Jury out.)
THE COURT: If any documents are circulating, if you could leave them there on the corner of the bench.
Please be seated. We're outside the presence of the jury.
Mr. Suggs, what -- I want to briefly do this, because I have people coming in at a quarter of, so I need you to get your stuff

moved up quickly.
MR. SUGGS: Okay.
THE COURT: What are the other documents that need to be admitted?
MR. LEHNER: Do you want us to look at those this afternoon and just do it first thing in the morning?
THE COURT: Let's do it first thing in the morning. One question from myself: In Lilly's depositions counterdesignations and objections to the deposition of Dr. Breier, on the pages that deal with -- there's a number of counterdesignations and then there are some that are highlighted and have got checks with them. I'm assumed it's just the checked ones that you want included for review of completeness purposes?
MR. LEHNER: I think the checkpoint -- they are highlighted, but the highlighting didn't turn out so well. I went through and put the checkmarks.
THE COURT: You wanted to double-check.
MR. ALLEN: Not tonight, but tomorrow I'll work with them. I've taken a pen

and slashed some out prior in an attempt to try to get it shorter --
THE COURT: Again, I don't think I'll get to it tonight. If you have something that I have -- I don't review --
MR. LEHNER: Since it's now less than 24 hours, what's on the agenda for tomorrow, Your Honor?
MR. ALLEN: Dr. Hopson. I've got depositions of -- I'm going to look at it. Eski, Joey Eski, but I'm going to look at the Court's rulings to see whether I want to play it tomorrow, or hold until we see how the evidence develops. But potentially Joey Eski, Dr. Hopson, I would assume Dr. Lechleiter, Dr. John Lechleiter, the CEO's deposition and Gary Toleffson. And then, if time, is it Baker that we have?
MR. SUGGS: No.
MR. ALLEN: Kinon?
MR. SUGGS: Yes.
MR. ALLEN: Dr. Bruce Kinon. It's a matter of timing, Your Honor, on the clock.
THE COURT: All of those I made rulings on. Everybody. Hopson would be the only

live witness. That answers your question.
MR. LEHNER: That does answer my question.
MR. FIBICH: Your Honor, I have one final issue, if I may. We have gone to the trouble of having notebooks done, I think rather nicely with all the PDRs. We're still in the Plaintiff's case. We've marked this. I think it's a good way to present it so if there's any comparison needed, they can do it easily. We've marked this as State Exhibit 10160, and we offer it into evidence.
THE COURT: Okay and you were going to look that over tonight --
MR. LEHNER: Yes, we'd like to look it over, and then we'll let you know our views tomorrow morning.
THE COURT: Again, my understanding was that after the juror asked this question and rather than have the witness at that time read particular portions, there was a dialogue that we had about letting the jury have copies of the PDRs through the years so that there was no dispute about that, and I thought that's where we were all heading. But I'll let Lilly --

MR. LEHNER: I'm going to look at it for completeness.
MR. FIBICH: Whether we had that dialogue, which the Court is correct, we did, we're still offering it in spite of that.
THE COURT: I understand that. Whether we need a witness or don't or whether we can agree on this, we'll see, but --
I'll let you look at it for completeness. I thought there was an understanding subject to certainly that that what's we were going to give the jury.
MS. GUSSACK: Your Honor, just on that point. As I recall, Your Honor asked a question of the witness about the fact that the PDR wasn't within Lilly's control and wasn't that a publication issue. And we certainly have evidence that we can bring to the Court's attention tomorrow as to why the PDR -- and I think there's a concern about it being more confusing than clarifying for the jury.
THE COURT: Again, I won't preclude you from putting in evidence or even stipulations, because it would seem to me that it ought to be known to both of you as to what the

lag time is on these things. I certainly would be willing to include -- discuss including that to the jury as well so they know these are what the PDRs are but they know that there's an 8-month or 12-month, whatever the month period of time is for lags. It strikes me that that would be fair to both sides.
MR. ALLEN: They can make a proposal, Your Honor. Of course, as we said all along. We're in our case and we want to put something in. If they want to rebut it, I guess under 104(b) they can. But the evidence is clear. Just so I don't want any confusion with the Court, the various manufacturers do submit the information to the PDR and the PDR is published annually.
THE COURT: I understand.
MS. GUSSACK: My only point to the extent it was a question from a juror, we'd like to be able to frame a response and be heard on how that response should be handled so there's not confusion.
THE COURT: You may do that.
MS. GUSSACK: Thank you, Your Honor.

MR. LEHNER: Last but not least. We'll take up tomorrow morning, you wanted to do an additional proffer of the Jordan testimony. We had some objections in light of what we heard today but we'll let you know that for tomorrow morning.
MR. ALLEN: Your Honor, I'm going to have to get a record of what you cut out and have it reviewed.
THE COURT: Again, just like they have submitted to me, I guess, requests for reconsideration on some of my rulings as to what was in or what was out on a deposition, you are free to do that. And I guess I invited that to the extent there was something about the number of people that were off-label or weren't off-label when we were talking about numbers.
MR. ALLEN: Yes, sir.
THE COURT: Anything else?
MR. ALLEN: No, sir.
THE COURT: We'll be off record and have a nice afternoon.
THE CLERK: Please rise. Superior Court now stands in recess. Off record.
(Court adjourned at 1:32 p.m.)

REPORTER'S CERTIFICATE

I, SANDRA M. MIEROP, Certified Realtime Reporter and Notary Public in and for the State of Alaska do hereby certify:

That the proceedings were taken before me at the time and place herein set forth; that the proceedings were reported stenographically by me and later transcribed under my direction by computer transcription; that the foregoing is a true record of the proceedings taken at that time; and that I am not a party to, nor do I have any interest in, the outcome of the action herein contained.

IN WITNESS WHEREOF, I have hereunto subscribed my hand and affixed my seal this 11th day of March, 2008.

_____

SANDRA M. MIEROP, CRR, CCP
Notary Public for Alaska
My commission expires: 9/18/11