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 3

EXCERPT OF PROCEEDINGS

March 5, 2008 - Pages 1 through 168

BEFORE THE HONORABLE MARK RINDNER
Superior Court Judge

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

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THE COURT: State of Alaska versus Eli Lilly and Company. 3AN-06-5630. We are outside the presence of any members of the jury panel. Counsel are all present.

I understand there are a couple of pretrial motions to take up, and I'm going to just make some rulings on some of the preadmission issues.

I'm going to overrule the objections and admit Noesges 12 Exhibit. I'm going to overrule the objections and allow the 2000 Annual Report in. I'm going to deny the motion to preclude use of the Eski deposition. I will allow the deposition portions that were requested -- there's a few discrete things to be used in opening statement. I am not ruling that the entire deposition can be admitted. It's a deposition that in looking it over, I think, has both admissible portions and portions that probably aren't relevant. And I'm not making -- I'm just ruling that the portions that are requested to be used in opening statement can be used, but I'm not ruling the entire deposition can be used. Although I am ruling -- I am overruling -- or I am denying the motion to

preclude any use of the deposition that was filed.

I think that -- I'm a little afraid I missed one exhibit. Does that take them all?

MR. ALLEN: Eski's call note, comparable rates.

THE COURT: Actually -- thank you. I need a little more information. Maybe you can find it. It's not clear to me from what was attached, part of the notebook and stuff, what those really are. It said Eski 8, but from the portions that were attached, and I probably left it in chambers --

MR. ALLEN: Your Honor, I will -- I have the -- actually -- I'm not going to use all of Eski 8. I'll show the other side and show you. My glasses -- well, let me take it to the Judge -- let me read it in the record. It's Eski's call note of October 24th, 2001 where she says: I led the presentation with diabetes data. And she talks to the doctors and she concludes: All should have walked away thinking and saying comparable rates.

Comparable rates, Your Honor, is what we will contend in this case is a -- was one

of the unfair trade practices involved, and that is that Eli Lilly misrepresented the safety and side effect profile of Zyprexa compared to its competitors. That, in fact, Zyprexa had additional risks of hyperglycemia, diabetes and weight gain and, in fact, the risks were not comparable to the other agents.

And in their documents which you have admitted, which I will use in opening that had already been admitted into evidence, Your Honor, one of the messages concerning the warnings about Zyprexa was it had comparable rates to other antipsychotics, which we contend is not true. I need to show that that message that got out was not just out somewhere else, but it was right here in Anchorage, Alaska. And you've admitted comparable rates documents.

THE COURT: And Mr. Brenner.

MR. BRENNER: Your Honor, please, I believe this would have been covered by Your Honor's ruling of the exemption of UTPA. This is a statement allegedly made by a sales representative. As was addressed and really incorporated in Your Honor's ruling, we understand that the law is that those statements

by sales reps, if made, are covered by the comprehensive and pervasive federal regulatory scheme. And as I understood Your Honor's order, because there is a federal regulatory scheme that prohibits those acts, the exemption under the UTPA would be invoked and, therefore, that statement, allegedly made, is not relevant.

THE COURT: I understand the issue. Again, I've ruled previously that while I dismissed the claim for the UTPA, that evidence can be used for more than one purposes. And that evidence that might also be relevant would have been relevant to the call notes UTPA claim is relevant to the warnings common-law claims. And as I recall, I specifically indicated that if that kind of evidence of call notes was going to come in for that purposes, I need to have some kind of tie-up to showing that there was something was done in Alaska and those warnings were made in Alaska. This appears, at least on its face, to be that kind of information, and so I will allow the exhibit to the Eski deposition to be used.

MR. ALLEN: Thank you.

MR. SUGGS: Your Honor, I

realize you have ruled -- I would like to point out one thing for the Court with respect to this issue of statements by -- by sales representatives and the argument that we had. I believe the Court relied on the actions in the Zeneca case and some dicta in that case that said that advertisements also come in the form of physician-directed pitches by sales representatives, and then it cited 21 CFR Section 202.1(l)1. I went on that -- I actually dug out that CFR, and there's no reference in there whatsoever to sales reps. I'd like to hand up for the Court's review or consideration if you want that CFR.

THE COURT: You could give it to me, but if you're making a motion for reconsideration, that's sort of what it sounds like.

MR. SUGGS: I'm not making a motion, Your Honor, but we keep hearing the same argument again and again and again. I thought the Court should be aware of what the regulation actually says.

MR. BRENNER: I'm not sure Your Honor wants any more argument on that.

THE COURT: I don't.

MR. BRENNER: Very good, Your Honor. I would raise one other issue, if I would -- if I may, because of the comment about portions of the Eski deposition in opening and I'm not privy to what the opening is going to be. We would raise this argument in advance. There was discovery taken of Ms. Eski about activities by Lilly regarding the creation of the so-called Preferred Drug List in the State of Alaska, efforts made to talk to legislators or others to express Lilly's and others' views on that.

That is classic petitioning activity under the First Amendment to the Constitution. You cannot under Noerr-Pennington and a whole lot of cases use that even to buttress the claim. And if the State is going to do that, we object.

THE COURT: My understanding is that those portions of the Eski portions are not using --

MR. ALLEN: I'm not using those portions of the deposition, Your Honor, but I will argue in response to their claim the State has not taken any action, that, in fact, the

State has taken action and every time the State tries to take action, they form what they call an Alaska State Action Committee to fight those efforts.

THE COURT: Well, again, nobody has filed a Noerr-Pennington First Amendment -- I hesitate to invite it, but I guess I am if it is going to be an issue. There's no motions on that that I recall seeing. And I suppose -- I suspect that somebody may have seen that I recently issued a decision, at least in a UTPA context on Noerr-Pennington, and if there's a motion to be made, it ought to be made formally. I'm not going to make advance rulings on Noerr-Pennington issues without some better briefing --

MR. BRENNER: I understand.

THE COURT: Any other -- I heard there may have been one or two other pretrial motions?

MR. JAMIESON: One issue, Your Honor. With regard to Ms. Peterson, Virginia Peterson, there was questioning yesterday about her -- her relationship with an individual at Lilly. We have since gone back and have determined that this is the -- Alex Azar is

her first cousin, who she is close with and who she spends at least major holidays with --

THE COURT: And doesn't talk at all about his business.

MR. JAMIESON: Right. But he is a senior vice president of Corporate Affairs and Government Relations with Lilly. He's one of the top five or six people within Eli Lilly and Company. He has direct involvement with state governments and, in particular, with Medicaid/Medicare issues. And he is -- so he is a very, very senior member of Lilly's executive team. He reports directly to the CEO. He is one of the top five or six employees in a company of over 41,000. Your Honor, under Rule 47(c)9 --

THE COURT: Doesn't it say parties or attorneys?

MR. JAMIESON: Yes, it says parties or attorneys --

THE COURT: Is he a party?

MR. JAMIESON: He -- Your Honor, given that his stature within the executive team --

THE COURT: Is he named in the Complaint?

MR. JAMIESON: He is not named in the Complaint.

THE COURT: He's not a party. It doesn't say senior employees. It doesn't say employees. It says parties or attorneys.

MR. JAMIESON: Well, but the party here is Eli Lilly, a corporation. A corporation can only act through its employees and if this were the case of a low-level employee, even a junior executive, we would understand that position. Given his -- his stature within the company, reporting directly to the CEO, top five or six in the company, we think that Rule 47(c) forms an absolute basis, just because of the relationship between him and this prospective juror. And we want this jury to be fair and impartial for everyone. And we think on that basis she -- she should be stricken for cause.

THE COURT: I'm not going to strike her for cause. We're -- the Rule talks about parties and attorneys, and Mr. Azar is neither. She's been extensively questioned and has quite clearly indicated that there's nothing in that relationship that affects her ability to be a fair and impartial juror. If he was even a

low-level employee and she said that it might affect her ability, she would have been struck -- it would have been struck, but there's no basis for a cause. Based on her testimony, the only basis you're making is because she says she has a relationship that she says doesn't matter, and I don't believe the rule requires because she has a cousin who is an employee of Lilly's. Even if he's a high-level employee, he's not going to be a witness in this case, correct?

MR. JAMIESON: No, Your Honor.

THE COURT: And so based on that, I'm going to deny the application to strike her for cause.

Again, were there evidence that this relationship would have affected her ability to be fair and impartial, that might have been a reason, but I'm not doing it just because she's a cousin when her own testimony indicates it doesn't have any effect.

MR. LEHNER: One housekeeping matter, Your Honor. I know you're looking at some deposition designations that the parties gave you. They informed us that they would probably play either Dr. Lechleiter or Denise

Torres as their first deposition witness. When we looked last evening at trying to do what Your Honor suggested, that is, first play their designations and then play our designations, the way the designations were made and the counterdesignations just doesn't seem to us to make any sense. They were so garbled and so jumbled up that I think it would be confusing. We've prepared a motion to look at that or if you're prepared to sit down and look at this --

THE COURT: I'm going to look at the deposition designation booklets of, I think there were cuts for two people. That's tonight's work.

MR. ALLEN: That was our presentation of Dr. Lechleiter, who is their CEO, then COO, or Denise Torres, the head of global marketing.

MR. LEHNER: And what we'll do then is give you our counterdesignations and you can see what it will sort of sound like and if it makes sense whether or not to play them in a more sequential order or we'll also be making an argument about completeness, but we'll provide you those this afternoon so you can spend your

evening looking at them.

THE COURT: Early this afternoon. Well, it doesn't have to be early this afternoon, because I'm pretty full this afternoon, and it's not going to be gotten to until after hours.

MR. LEHNER: We'll have them before that.

MR. ALLEN: Your Honor, on that issue, I just want to remind the Court it's already ruled on this matter, and a deposition is just like live testimony. You're entitled to put on your witness; do your direct examination and then they can put on whatever they want. Garbled or not, they're not entitled to interrupt your examination to ask a question. And a deposition is just like live testimony at trial. And what they're trying to propose is can we interrupt in the middle of your exam and ask our questions when we want. And the Court's already ruled on this and I just would ask the Court to maintain its ruling.

THE COURT: I'll look and see what Lilly files and wait until then to rule on Lilly's motion.

When are you going to get the

motion so -- I mean, can I pretty much take this to be your response to the motion?

MR. ALLEN: Yes, sir, you pretty much can. Also, I think the Court should recognize that they were at the deposition. If they wanted to conduct a direct examination of their witness at that time, they could have. These are experienced counsel, the deposition was noticed and they were their witnesses. But I would cite the rules and the orderly presentation of evidence just like a witness live at trial.

THE COURT: I just want to make sure -- I mean, they're going to be filing a motion, and I normally would wait for your response --

MR. ALLEN: But that's my response.

THE COURT: That's just what I'm trying to ascertain.

MR. LEHNER: I don't think there will be a lot of argument in the motion, Your Honor. I think it really goes to the point that you made about earlier on about completeness. I just think -- we sat down and I think we'll have a little bit of disagreement about what would be the definition of completeness and we're going to

ask you to look at that with that in mind.

THE COURT: Okay. Is this really an argument about completeness, or is this an argument about the order that completeness gets done in? In other words, nothing I hear the Plaintiffs saying they can put on whatever testimony of this gentleman. Is it a gentleman?

MR. ALLEN: Yes, sir.

MR. LEHNER: A gentleman and a lady.

MR. ALLEN: One of each.

THE COURT: One of each. These people. That you can be as complete as you want, you've just got to wait your turn. That's, as I understand, their position. And your position is kind of we shouldn't have to wait our turn to get the -- to allow the jury to understand the context of everything.

MR. LEHNER: No, I think what we're trying to do -- as I understood your order the other day or your discussion about this, you indicated they would play their deposition designations, we would play ours. If there were portions that were required to make their deposition designations complete in some sense,

and I'm not sure what the Court meant by that --
THE COURT: I guess I meant comprehensible more than complete -- I mean, it's not going to do any good to play a portion of a witness' testimony if the jury doesn't really understand the context that it's given in, and I don't want the context to mislead anybody but I've got to read the deposition. I'm not saying that would happened.
MR. ALLEN: Your Honor, on that response, I guess, truly if I put a live witness on and it was incomprehensible, that's my problem and they're entitled to cross.
THE COURT: It is your problem if it's incomprehensible, but to the extent the context gives a false sense to what's going on to the jury, that's part of what I'm trying to avoid. But I'm not saying I'm going to. I'll read the deposition, read the motions, and then I'll try to do this in a way that gives people a chance to put on their cases the way they want to put on their cases, but also to make sure that in doing that I don't feel the jury is being confused.
MR. ALLEN: Misled.

Okay. Your Honor, one response to that. That's classic cross-examination. If, in fact, the other party, the adverse witness is on the stand feels that it's misleading, they're entitled to conduct a cross-examination.
THE COURT: Well, I understand that. But this was not a perpetuation deposition, right?
MR. ALLEN: Yes, sir, it was.
THE COURT: It was a perpetuation?
MR. ALLEN: Yes, sir, all the depositions were. They were ordered in the MDL and I had one day to take them. And they had notice and they --
MR. LEHNER: They were discovery depositions, Your Honor.
THE COURT: Were they discovery depositions or perpetuation depositions?
MR. ALLEN: Your Honor, there were no difference. It was perpetuation of their testimony. I had one day to take it. I could only take one day and the Court limited me to one day. It was good for all time and all cases, thousands of cases in the MDL. This was a perpetuation deposition.

MR. LEHNER: Your Honor, we could show you the case management order. There was depositions that were scheduled. There had been a hundred discovery depositions. There was no application to take a deposition, preserve testimony for trial. I understand you had -- as you had indicated with Ms. Eski, that's what you do.
MR. ALLEN: These depositions were ordered by -- in the MDL. We had one day to do them for all the cases across this country. Some tens of thousands.
THE COURT: And you were precluded from doing follow-up perpetuation?
MR. ALLEN: Yes, sir. I was not only precluded, I had to take one day and I had a maximum -- I can't remember -- eight hours, including the time not of examination when they were reading documents.
MR. LEHNER: Your Honor, the time limit had been negotiated with the counsel in the MDL early on. There was no application to take a perpetuation deposition. They were not precluded. Judge Weinstein never precluded anybody from taking any perpetuation deposition,

because nobody ever asked to do so.
THE COURT: I'll read the deposition and I'll rule after I've read the deposition.
Anything else?
Then why don't we bring the jury panel in, and we'll try to get our panel selected and move on to openings. Let me just ask: As I'm sure everybody here saw there was an article in the Daily News today. Does anybody want me to question the panel to make sure nobody read it before we swear our jury?
MR. FIBICH: Your Honor, on behalf of the State of Alaska, we think that that sort of thing just encourages it. As you used the phrase yesterday, don't think about the pink elephant in the room. We don't feel the necessity. You've given them that instruction yesterday. I presume when they're seated, you're going to give it every day at the close of testimony.
THE COURT: Well, I am but we haven't seated a panel yet and don't we want to make sure that nobody inadvertently read -- I mean, if somebody says I read something, I have

no doubt that everybody is going to want to question that person to find out what they remember and what they saw privately. Isn't it better to do that now than to have it come up in the middle of trial and we may lose a juror?

MR. FIBICH: We'll go along with whatever you decide.

MS. GUSSACK: Yes, Your Honor. We'd appreciate that.

THE COURT: I'll just ask a general question of everybody and hopefully, there's not going to be a problem, but if there is, I'll let some additional questioning get made of whoever might have seen it. Why don't we then -- we'll bring in the panel -- go off record, bring in the panel. When we've got everybody seated, we'll move along.

THE CLERK: Off record.

(Voir dire.)

THE COURT: And the record should reflect -- please be seated -- that we're outside the presence of the jury. Counsel, what we're going to do is get rid of the extra chairs. I want whatever the Plaintiff's doing for opening argument to be set up, and so we'll be ready to

go when I give the initial three or four instructions and start opening arguments for that. Let me ask about timing.

It's 20 after 10:00 now. We've got to do -- reorganize the courtroom a little bit. We've got to get things moved.

I can go through until -- my next hearing is now at 2:30 today, so that's what I'll go to if we need to, but we need to do that, but that may mean that each side is going to have to shorten up their opening a little bit.

Yes. Is that doable that if I give everybody an hour and a half instead of two hours?

MR. ALLEN: I actually need a little more time than that, but I'll have to do it --

THE COURT: Again, if you don't -- what's going to happen, this is your choice, you can take the more time, but it almost inevitably if that happens, it means we're not going to get all openings done today and the Defendants will go first thing in the morning. And I know you've already indicated that you'd prefer that doesn't happen.

MR. ALLEN: Wouldn't they have to start today to finish out the time --

THE COURT: I'm not going to make them do half an opening. We'll either get all the openings in today or one opening in today, and the second one tomorrow, but I'm not going to make the Defendants do half an opening, particularly given that -- the problem for tomorrow --

MR. ALLEN: Let me consult with my counsel.

THE COURT: Okay.

MR. ALLEN: Do I have to consult now or can we rearrange the courtroom?

THE COURT: You can rearrange the courtroom and we'll go. Before we bring the jury back, we'll talk about it. Ms. Gussack?

MS. GUSSACK: Your Honor, I appreciate the Court's concern for Defendant's opening. We certainly wouldn't want it split, and, frankly, unless we are held to some constraints on openings, I fear that we would not be able to manage given that the Court had initially told us that we would each have two hours --

THE COURT: Again, recognizing that if we get started, for example, at a quarter to 11:00, the Plaintiffs do -- we go until 2:30 today. The Plaintiffs -- I figure you'll need another 15 minutes after the opening to reorganize and stuff, so that, basically, gives us 11:00 to 2:30, which is three-and-a-half hours --

MS. GUSSACK: Your Honor --

THE COURT: -- counting into break, so that's really an hour and 45 minutes a side. We're assuming that we get started on time and go well.

MS. GUSSACK: As long as the Court can indulge us for that time in between the Plaintiff's opening and --

THE COURT: I'm assuming that, A, I don't want the jury to have to sit through an hour and 45 minutes of opening and then not have a break so we'll give them a break, we'll reorganize the courtroom for you, but I'll sort of -- it'll be a 15-minute break.

MS. GUSSACK: Thank you, sir.

THE COURT: And if that happens and

we get started reasonably on time for these things, we seem to have an hour and 45 minutes a side.

MR. ALLEN: Hour and 45.

THE COURT: Is that doable?

MR. ALLEN: I just pulled three things out.

THE COURT: We'll take a break now while the jury is getting oriented and stuff and you get the courtroom set up. We'll get the extra chairs out of the way as soon as Mr. Borneman can do that. We'll be off record.

Is there anything else?

We'll be off record then.

(Break taken.)

THE COURT: Please be seated. We're back on record and all members of the jury are present.

Ladies and gentlemen of the jury, now that you have taken your oath, you are ready to serve as jurors in this case. To assist you in your task, I'm going to explain how a trial is conducted.

There are five parts to a trial. The first part will be opening statements. Each

party will make an opening statement outlining its case. What is said in opening statements is not evidence. The purpose of opening statements is to provide you with a preview of the evidence which the party intends to present.

The second part of the trial is the longest part of the trial, because it is the presentation of evidence by each party. Most of the evidence will be either testimony by witnesses or exhibits.

The third part of the trial will be closing arguments. During closing arguments, the parties will tell you what they believe the evidence has proved and urge you to draw certain conclusions from the evidence. What is said in closing arguments is not evidence.

In the fourth part of the trial, I will instruct you about the law which you must apply to reach your decision.

The fifth part of the trial will be jury deliberations. This is the time when you meet together to discuss the evidence, to decide what the facts are, to apply the law, and to make the decisions required to arrive at a verdict.

I will rely on you to determine the

facts. This must be done by relying solely upon the evidence received in this trial. You must not be governed by mere sentiment, conjecture, sympathy, passion, prejudice, public opinion or public feeling and must base your verdict only upon a fair consideration of the evidence.

The evidence should be considered and viewed by you in light of your own observations and experiences in everyday life, but you may not consider any other source of information not presented to you in this court. It will be my duty to decide what law must be applied. In so doing, I will look to a number of sources, such as the statutes and regulations of the State of Alaska and the decision of the Alaska Supreme Court or other courts, and the law offered by the attorneys who appear before you.

You must apply the law as I give to it you. You may not apply the law as you think it is or should be, or as another may have told you it is. The instructions I will give you are the only law that you may apply. You may not rewrite the instructions in your own words.

At no time during the course of the trial will it be my intention, by anything I say

or do or by any questions I may ask to intimate or suggest that you should find to be the facts on any questions submitted to you, or that I believe or disbelieve any witness. If anything I do or say seems to so indicate, you will disregard it and form your own opinion.

What the verdict shall be is your sole and exclusive duty and responsibility. Each side will have an opportunity to present evidence. In our system the Plaintiff is entitled to present its evidence first, then the Defendant presents its evidence. Then each party may have an additional opportunity to present rebuttal evidence.

Some of the evidence may be sworn testimony by witnesses. This testimony may be presented in person, telephonically, by videotape, or read to you from a sworn statement. You must evaluate all sworn testimony regardless of how it is presented. Each side will have an opportunity to question each witness twice. This process is why we call our system an adversarial system.

We begin with direct examination, followed by cross-examination, then redirect and

recross. The party who calls the witness will start the questioning. Some of the evidence may be exhibits, such as documents, pictures or objects. The exhibits will be identified for you by number or by letter.

There are three other kinds of evidence that may be presented during the trial. The parties may agree that certain facts are true; this is called a stipulation. There are also certain facts that the law requires you to accept as true; this is called judicial notice. The Court will clearly identify stipulations and any facts of which the Court takes judicial notice. Finally there may be facts that the law requires you to accept as true unless the other party proves that they are not true. These facts are called presumptions. I, again, will identify any presumptions for you.

I have told you about the sources of evidence. I will now tell you what is not evidence.

Nothing the attorneys say is evidence and nothing the Court says is evidence. If there are any exceptions to this during trial, I will clearly identify them for you. Remember,

you must decide this case based only on the evidence presented here in court.

Again, some housekeeping matters. Our trial day will start at 8:30. You must be here every morning by 8:20. We cannot begin until all of you are here. The trial will continue until 1:30 each day. As I indicated, we will be going a little bit late today and if we are going to be going late, I'll try to let you know that early in the day. We will not take a lunch break so you should plan to bring something to snack on during recesses.

Mr. Borneman is the in-court deputy, and he will escort you from the jury room when the trial is in session. During the recesses that we take during the trial day, you will retire to the jury room together. Coffee and rest rooms are available in the jury room. When we recess at the end of the trial day, you will not be required to remain together. This is not a sequestered jury.

However, you must obey the following instructions during each and every recess of the court and that includes recesses at the end of the day. First, do not discuss this

case either among yourselves or with anyone else until the end of the trial. In fairness to the parties of this lawsuit, you must keep an open mind throughout the trial. You must not reach your conclusions until final deliberations, which will be after all the evidence is in, after you've heard the attorneys' closing arguments and after my instructions to you on the law. During deliberations you should reach your conclusion only after an exchange of views with the other members of the jury.

Second, do not permit anyone to discuss the case in your presence. If anyone tries to do so, you should tell him or her to stop. If they persist, report that fact to the in-court deputy as soon as you are able. You should not however, discuss with the jurors either the fact that someone tried to talk about the case or any other fact that you feel necessary to bring to the attention of the Court.

Third, although it is a normal human tendency to talk with people with whom one is thrown in contact, during the time you serve on this jury, please do not talk in or out of the courtroom with any of the parties, the attorneys

or the witnesses. By this I mean, not only do not talk to them about the case, but do not talk with them at all, even to pass the time of day. Parties and attorneys have been instructed likewise. In no other way can all parties be assured of the absolute impartiality they are entitled to expect from you as jurors.

Fourth, do not conduct any investigations on your own or do any research concerning this case outside of the courtroom. Do not visit any locations where any of the events of the case have occurred. You must decide the case based only on the evidence presented here in court.

Fifth, do not read newspaper articles about the case or watch or listen to television or radio news stories about this case until the trial is over. Do not read about this case or any matters related to this case on the Internet.

We will now proceed with opening arguments.

Mr. Allen.

MR. ALLEN: May it please the court, opposing counsel, members of the jury,

good morning. How are you?
My name is Scott Allen, and I'm from Houston, Texas, and I am here today on behalf of the State of Alaska. Mr. Sniffen, your Assistant Attorney General of this state, honored me about four months ago by asking me to come here and represent the State of Alaska against Eli Lilly in this lawsuit. I want to tell you now that I am honored and humbled to be here. And it is my goal to do Mr. Sniffen and the State of Alaska proud, and I hope and I will strive to do so.
Now, let me tell you right off the bat that the Judge has just given you an instruction that we cannot talk, obviously, throughout these proceedings. I must admit to you I'm one of those people that like to talk, and I guess that's why I became a lawyer. And it often makes me feel kind of bad as an attorney throughout the course of a trial when I see you in the hallway and I can't speak. And I feel that that -- I'm being rude, and I hope you don't take it that way and understand.
Because I can promise you, on behalf of myself individually as a lawyer, and on

behalf of the State of Alaska, we understand what sacrifice you make to be here as jurors. We understand that you've taken time away from your families, your jobs, your social life, your hobbies, and we appreciate that. And if -- if you want to know what I would like to say to you every day throughout the course of this trial when I see you in the hallway, I'd like to say thank you. And I sincerely mean that.
Now, let's talk about this case.
What are we contending? What is the State of Alaska contending?
The State of Alaska is contending that Eli Lilly violated Alaska's Consumer Protection Act. It's an Act intended to protect consumers from unfair and deceptive trade practices. These are the things we're contending in this case.
No. 1, that Eli Lilly committed unfair and deceptive acts in their sale of Zyprexa in Alaska.
No. 2, that Eli Lilly made representations concerning Zyprexa and said it had characteristics that it did not have. And the main thing I want to talk about that is

something you'll become to understand at the close of this opening statement -- the representation that Eli Lilly made concerning the characterization of Zyprexa is that it was, quote, comparable rates; quote, comparable rates of adverse effects and side effects to Zyprexa to the other drugs in its class. And you'll understand that better as we go along.
But the fact of the matter is that Zyprexa's side effects of serious adverse consequences of diabetes, hyperglycemia, increased cholesterol, and weight gain. And we're not talking about cosmetic weight gain. We're talking about severe, significant weight gain that had devastating health effects on the individuals who took it, that those side effects were greatly more than the other drugs in its class that could have been chosen.
Thirdly, we are contending in this case that Eli Lilly committed fraud, deception, made false misrepresentations and, importantly, knowingly concealed, suppressed or omitted -- and this is a key phrase, a material fact with the intent that the people who purchased or used Zyprexa would rely upon those misrepresentations.

And I'll tell you simply put what that means: Eli Lilly did not tell doctors, the State of Alaska Medicaid system, or patients what they knew about this drug.
Rather than that, Eli Lilly made a decision that what they knew about this drug would require a warning on the pack, but if they put a warning on this product their sales would fall and they would lose money, people would choose another drug. And they decided not to disclose what they knew.
Lastly, we are contending in this case that Eli Lilly failed to give an adequate warning concerning the side effects of this drug.
Now, why is the State of Alaska involved in this matter? I represent the State of Alaska because the State of Alaska's Medicaid system has to pay for these medications, and they have to pay the Medicaid patients' future medical care, and medical care costs if they contract these diseases of diabetes, hyperglycemia, hyperlipidemia, and extreme obesity that carries with it cardiovascular risk. And it is not fair and it is not proper and it is not right for the State of Alaska to bear that burden when the

Defendant, Eli Lilly, failed to disclose to the State of Alaska and all the users of this product what they knew about this drug.

Now, it will, I think, always be helpful to keep in mind, and -- before I get into the evidence, we need to know what we do not need to prove, so we do not get confused as we go along and listen to the evidence. What is it Alaska and the State Medicaid system does not have to prove?

No. 1, we do not have to prove that any individual person has, in fact, been misled or even damaged. Not one.

Why is that, you might ask? First of all, that is what the Alaska Consumer Protection Act says, and if you think about it, it makes a lot of sense. Alaska, like a lot of states, wants to protect its consumers, and it does not want people coming into the state and using falsehoods, deception, untrue statements or hiding -- hiding things that it knows in the sale of its product, and then if they get caught coming forward and saying, well, it didn't matter, nobody really listened to me anyway.

So the State of Alaska does not

have to prove that one person has, in fact, been misled or damaged.

No. 2, in this trial, the State of Alaska does not have to prove there are any damages or what the damages are. You heard about this, I think, when Mr. Fibich gave us our little opening description of the case.

Judge Rindner has divided this trial into two phases: Phase No. 1, you're going to look at Eli Lilly's conduct and determine whether or not they, in fact, told -- told the consuming public and told the Medicaid system about what they knew. You're going to look at Lilly's conduct. In another phase that may take place, other people will have to worry about damages. So you do not need to worry about it in this case.

And, lastly, what does the State of Alaska not have to prove? We do not have to prove causation for certainty.

Now, what does that mean? And I wrote these words down last night, you see confusing and controversy and debate.

Ladies and gentlemen, it is our contention in this case that Eli Lilly's drug,

Zyprexa, causes hyperglycemia, increased blood sugar. It causes severe obesity. It causes diabetes and it causes hyperlipidemia, but the standard of proof on these allegations does not require us to prove that point, and here's why: All we need to prove is that Eli Lilly had evidence concerning its product. Whether they agreed with that evidence or not, because I -- we anticipate the evidence will show, well, we had evidence, but it was confusing to us. We had evidence, but it was a controversy to us. We had evidence that was in debate. I anticipate they will say.

But the law of the State of Alaska requires a drug company and any seller of a product -- remember, Mr. Fibich asking you the hypothetical about the car seller and if he thought there might be a problem with the brakes? Whether he agreed with it or not, he had the duty to tell the consumer about the potential problem? The same thing applies to Eli Lilly.

So -- and let me tell you why else we do not have to prove causation. Because the FDA, federal regulations which govern Eli Lilly specifically say Eli Lilly has the responsibility

to prepare a warning -- and a warning is a literal term, and you'll discover that in a minute -- a warning in this book, which is the package inserts. They must include a warning under this heading, the labeling shall - that's mandatory -- describe serious adverse reactions and potential safety hazards, limitations and use imposed by them and steps that should be taken if they occur. The labeling shall -- that means you must -- be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug. A causal relationship need not have been proved.

So when I tell you that if Eli Lilly has evidence in its files that it suspects a problem with this drug, that it believes it possibly can cause hyperglycemia and diabetes and severe obesity and hyperlipidemia; as soon as they know that, and not one second less, they have the duty to advise the consuming public in a label.

I'll leave that up there. And we say they did not.

Now, I'm going to tell you, I'm going to put this in Scott Allen's words. What

does this all really mean? I submit to you that it all comes down to this: Was Lilly fair? Did they disclose what they knew? Did they come forward and give a real warning as soon as they had evidence that they had a problem?

I'll submit to you the answer is not -- no, they did not. See, this is my handwriting. I'll bet you all expected maybe fancy exhibits, but this is what I wrote down. And I submit the answer to you, no, they weren't fair; no, they didn't disclose; no, they didn't come forward. But why are they required to do so?

Let me write in the answer. Informed choice. Informed choice.

That's what this case is about. Ladies and gentlemen, you're going to hear evidence, I am certain, statements from this counsel, well, we disagreed with the evidence, what we saw, so we didn't think we needed to turn it over. Or that evidence was speculative and we didn't need to turn it over. Or when we found out about the reports or any other labeling changes in other countries that took place on this drug, we didn't agree with it so we didn't

change our package insert in the United States.

You know what? Nobody -- and the evidence will show this -- is entitled to make a choice for somebody else. There's nothing wrong with them disagreeing with what they know. If they find evidence they don't agree with, fine and dandy. But they can't keep that evidence to themselves. They have a responsibility to the people who take this drug, the evidence will show, to share it with us, and let us make our own choice. And you know what? It may be the evidence will show some people will go ahead and choose to take the drug. But it may be that some people will choose not to.

Informed choice. This case -- we're not trying to tell people what to do. That's not what we're here about. The evidence will show that we're here to require this drug company to come forward and allow people to make their own choice, whether they agree with it or not.

I'm going to go through the documents in a minute -- and you will have no question -- and these documents are real paper. We're not going to be looking -- these are just

some of them. You're going to have a lot more than this. We're going to put some of them up on the screen, and you'll have no question that this company had plenty of information in its files, the evidence will show, that it did not share. That it did not share.

All right. Let's talk about this. Antipsychotics. And by the way, I am -- I don't know -- I think this is spelled correctly. I am a very poor speller, so if you look at any of my writing today and say, Mr. Allen, I'll say I plead guilty.

This case is about antipsychotics. And in order to understand the case, I'm going to give you some definitions as we go along, because when you see the documents as we display them, I hope this will help you understand them.

Antipsychotics, and in this case, Zyprexa in particular, Zyprexa in particular is indicated for two things: Schizophrenia and bipolar mania. It is a hard-core medication. It is -- it is not indicated for depression or anxiety for children or the elderly with Alzheimer's. It's not indicated for that. It's indicated for two things -- and there's --

there's a lot of medications that are sold in the United States and we'll talk about this in a minute. But a lot of them are right in here -- that can treat those conditions and they're generally referred to and you'll see the language as first-generation and second-generation antipsychotics. The first-generation antipsychotics we'll talk about some is Haldol and Thorazine, and I put et cetera because there's a lot more of them, but that's some background. Haldol and Thorazine. The second-generation antipsychotics are Clozapine, put on the market in 1989, Risperdal in -- Risperdal and Clozapine are made by other manufacturers. Risperdal, made in 1993; Zyprexa, put on the market in 1996. Seroquel, 1997; Geodon, 2001; and Abilify, 2002. And all together they're all antipsychotics. We call these the first-generation and these the second-generation antipsychotics.

Now, why is this important? Choice. The freedom to choose. The right to have a decision made upon good information. And if -- and it's sad to say, but the evidence will show -- and you see -- I put stars by Clozapine

and Zyprexa. The evidence will show if you have this much competition in the marketplace, you certainly don't want your drug product being thought of as having more risk than another. Because if that's the case, then you won't sell as much of your product.

And I will tell you the evidence will show in this case that what motivated the Defendants from failing to warn about their health risks was money. And it was the risk that they thought if, in fact, we warn about our product's risk, we wouldn't be as good against the competition. And I thought this morning, I'm going to skip to way back -- is our screen on?

By the way, we're about to enter a -- a adventure. I've never done this in my entire career. I've always used blow-ups and this drawing board, but they convinced me that we could use this and this thing is supposed to bring up exhibits. I'm going to show you right now an exhibit from Eli Lilly's file. Here we go. There it is. I got worried right there. I told -- I said, man -- all right.

This was 2003; June the 12th, 2003, after the product had been on the market almost

seven years. And they're having a meeting -- this is their internal memo, by the way. They thought no one would ever see this. This is their private, internal memo. They were thinking -- in 2003, by the way, they still hadn't warned about diabetes. They still hadn't warned about hyperglycemia. They still hadn't warned about severe weight gain leading to those problems, and they still hadn't warned about hyperlipidemia. But they knew -- they knew that that they needed to. And they knew a warning was going to be on its way.

And they met, and they asked themselves: Well, what would be the best-case scenario for us? And see where it says the best case is if we had simultaneous class warning. That means if everybody got the same warning we got, then that would be good for us. Best case. You see the worst case? Differential labeling for Zyprexa only. And they knew if they had to give a warning that was different than the other antipsychotics, people in making their informed choice were likely to not take this medication, this first-line treatment.

Where's the gun? All right. It

worked.

All right. The reason I also starred Clozapine, as the evidence develops in this case, you'll learn as the studies were done and the information came in about these second-generation antipsychotics, it turned out that Clozapine or Clozaril, either way, and Zyprexa had the worst two safety profiles concerning these matters and that the other medications, Risperdal, Seroquel were less, and these two medications, Geodon and Abilify don't appear to have a severe or problematic metabolic profile with these problems.

Words. This is just a dictionary. I've already used some of these words and I want you to know as we go along and look at the documents. Olanzapine. O-l-a-n-z-a-p-i-n-e, that means Zyprexa. When you look at their documents, they often call it by its generic name as opposed to its brand name. Olanzapine means Zyprexa. Package insert, label, PDR. I have a bad habit because I just assumed everybody knew what this was.

This is the PDR. It's called the Physicians' Desk Reference. It's published --

that has every medication available in the United States. And what the manufacturers do is they have to prepare labels or package inserts on their drugs and they can update them anytime they want or anytime the FDA tells them to, and they can be given to the pharmacists, et cetera, but once a year they can be put in this book and so a doctor can have this information handily available to him.

So if you hear me use the word label, package insert, or PDR, by the way, that's what we're saying, that's where the warnings are supposed to be and that's where the warnings weren't. OWC in their documents means olanzapine weight changes. You may see the word detailing in the documents. That means sales representatives, for lack of a better word.

I used to think before I got involved in this type of work as a lawyer that the manufacturers research a drug, they put it on the market and they let everybody choose for themselves, the doctors and the patients. No, no, no. They have sales forces, and they have sales forces go out to hospitals and institutions and doctors and nurse prescribers, and they have

them, quote, detail on the drug.

And that is where -- by the way, I think in this case, and I may get the number wrong, by 2000, I think they had over 2,000 sales reps in this country. They had what they called the sigma sales force, beta, gamma, long-term care, institutional. They had a lot of sales forces. So if you see the term detail -- and you will see in this case evidence shortly that when the detailers went out and talked to the doctors and the people who would look at this drug, they did not give a fair warning to them either.

Glucose, that just means blood sugar; you'll hear a lot of us talk about glucose or high blood sugar. I'd talk more about diabetes, but you heard about it yesterday. It's a killer, one of the leading causes of death in this country. You literally can go blind, get your legs amputated, you can have all kinds of extreme medical risks, cardiovascular problems and here is the long story short why. When the blood sugar gets enough in your body, it interferes with your circulation. I don't know if you've ever heard of diabetic retinopathy. Or you've heard of people getting foot sores and

their feet are cut off. It puts you at great risk. I think somebody said recently I'd rather have cancer than diabetes. It's a devastating disease and you measure diabetes by looking at blood sugar.

You may see this word, AEs or safety database. What that means is adverse experience reports or safety database. The company is required to keep a log, and sometimes the FDA keeps it when people begin to experience side effects, a small minority of those will be turned in. You'll hear -- you'll see a memo from Dr. Beasley, I think, in October of 2000 who worked for the company when he estimated the number of people with problems just with severe obesity caused by Zyprexa, 90 pounds or more. He estimated that would be 100,000 people in the United States due to Zyprexa; 100,000 at 90 pounds or more and if you see that AEs or safety database, you'll see that.

FDA. The FDA, the Food & Drug Administration. Ladies and gentlemen, we predict that the defense will rest its case a lot on the FDA. They'll tell you, well, we turned everything over to the FDA. Well, the FDA had

this. Well, the FDA had that. What are the facts about the FDA?

The facts are they do not do independent testing on these medications. None of them. They don't do their own research. They don't do their own studies. They're not set up to do that.

They must depend on the drug manufacturers to give them what they have, and if the FDA doesn't give the drug manufacturers what they have, then the FDA can't act with full knowledge. Now, here's what you'll have them say next. I'll bet you they may bring in 40 boxes, 50 boxes, all filled, and they'll say, look, we turned over all this information.

First of all, use your common sense. That much information on every drug, there ain't no way.

Second of all, it's not about what they gave the FDA; it's about what they didn't give the FDA. What they didn't give the FDA is a lot of what you're fixing to see in a minute. It's their internal, private, confidential conversations, memos and discussions that they never, ever thought anyone would ever see. And

the FDA didn't ever get to see it, and you'll see in a minute when the FDA finally got ahold of a lot of what you're going to see, guess what they did? Guess what they did? They said, Lilly, change your warnings. You and you alone are going to have to change your warnings in this case.

And Lilly has recently had to do so. Well, let me tell you, when everybody has mentioned the FDA yesterday, I'm going to show you in a minute, in this case, the FDA is on our side. It's on the State of Alaska's side. It's on your Attorney General's side. I'll show it to you in just a second.

Finally, I wrote this: Psychiatrists are not a cure. Really, I wrote that for a reminder to me. That's the last thing I wrote when I was leaving my room this morning.

As I told you, this medication was supposed to be serious medication for schizophrenia and bipolar mania only. It was not indicated for bipolar disorder, bipolar depression or anything else. It was a psychiatric drug, psychiatric drug for psychiatrists who specialize in that area.

The evidence will show you in this case that not only did Eli Lilly fail to warn about the dangerous side effects of Zyprexa, but once their company was having some financial problems on another front, they went and tried to expand and did succeed in expanding the market for this drug to family practitioners and general practitioners all in the name -- and you can quote me on this -- corporate performance. All in the name of corporate performance.

I will show you that they even wrote in a slide show that it was so important to them to sell this drug with no warnings that they bet the company farm on this drug.

Finally, not a cure. I always forget that, you know when I got involved in the case, sometimes I lost sight of that fact.

This drug doesn't cure schizophrenia. It doesn't cure bipolar mania. It treats it. I think that's important. None of these drugs cure it. And so when they're trying to make a decision, when people are trying to make a decision, that informed choice, let us know what you know, it's important to keep in mind it didn't cure anything.

And so, if you let us know, we can choose the first generation, they're still on the market and you'll see some recent studies that indicate that some of them are just as effective as the second generation.

This didn't cure a thing.

All right. I'm going to keep this up here. The question is: Was Lilly fair? Did they disclose what they knew? Did they come forward like the hunter the other day who knew he violated the law and said I want to come forward and -- no, they did not. And they didn't give people an informed choice.

Now, let me find my water. I hope you don't mind.

How long have I been going, Your Honor?

THE COURT: You've been going 30 minutes.

MR. ALLEN: Man, have I been talking too fast?

Okay. Thank you.

Let me -- before I get into the evidence -- and remember, what I say is not evidence. It's not evidence. I'm going to tell

you and you're going to see in a minute the things that I just told you are going to be right up on the screen from their files. Let me just assure you that we don't stand here by ourselves. The Attorney General and the State of Alaska has gone out and you're going to see some of the top doctors in this country have evaluated the evidence that we -- I have discussed with you. And they will be here in this trial.

I will tell you, as often happens in many trials -- I hope it doesn't happen here, but it could happen, it happens sometimes -- scheduling and whatnot, but I believe these gentlemen will be here to testify to you to confirm the things that I told you. Dr. Fred Brancati, he's a doctor of internal medicine, specializing in the field of epidemiology, of diabetes, in particular. He's a world-class, world-renowned expert. Let me tell you about epidemiology, and I will do it a disservice. But epidemiology is when you study the causes of disease by looking back at studies both in the past and in the future, and you look at statistics and medical articles and trust me, I have done it a disservice - but Dr. Brancati, let

me tell you, he's not only a specialist in epidemiology, he's a specialist in epidemiology of diabetes.

He's a professor at one of the finest medical schools in this country, and I'm sure you've heard about it, Johns Hopkins University. Basically what I have written down here in my notes -- he's going to give us all an education and I hope you enjoy it. What I wrote down is Diabetes 101. He's going to talk to you about diabetes. He's going to explain to you what it is. He's going to tell you after he explains it, that he agrees with me, he agrees with the State of Alaska that Zyprexa causes diabetes.

I submit to you, ladies and gentlemen, the evidence will show that he will testify to that. And I submit to you a doctor of epidemiology in diabetes at Johns Hopkins University is not going to risk his reputation or come into this courtroom in Alaska and tell that Zyprexa -- excuse me -- that Zyprexa causes diabetes unless he's telling the truth. And you'll get to hear it from Dr. Brancati. He will also, importantly, tell you that the incidence of

Zyprexa is -- of diabetes is greater with Zyprexa than it is the other drugs in its class. And therefore, remember I said they represented the characteristic of the risks of Zyprexa as being comparable to the other drugs? Dr. Brancati will testify under oath that that is not true.

We will then bring you Dr. John Gueriguian. Dr. Gueriguian is a medical doctor who worked at the FDA, the Food & Drug Administration, for 20 years. For 20 years he worked at the FDA and he approved or was involved in the approvement of over 100 drugs. He will come in and testify that, yes, Zyprexa causes diabetes, and that they had credible evidence dating back to as early as 1995 -- "they" being Eli Lilly -- that their drug could cause diabetes, but yet failed to warn the doctors and the public about that risk.

We will bring you Dr. David Allison. He is a psychologist from the University -- professor at the University of Alabama. He specializes in weight-gain issues, and he has been used by the Defendant, Eli Lilly, as a consultant. They thought enough of Dr. Allison to consult with him on their

business. Well, he will come in here and testify on behalf of the State. He'll testify that Zyprexa causes diabetes, that the weight gain with Zyprexa has the same consequences as weight gain due to other factors, and that it is not possible, not possible for most patients to manage their weight when you gain weight on Zyprexa.

You're going to see in a minute that this type of weight you gain on Zyprexa is what you call metabolic weight gain. When they test it in animals, they gave the animals Zyprexa and left them on a fixed diet; in other words, they couldn't eat any more or they couldn't eat any less. They had to eat the same amount of money -- same amount of money -- same amount of food, and when they did, they still gained weight. This was metabolic weight gain. Metabolic weight gain.

Lastly, we will bring you Dr. William Wirshing. He's a psychiatrist. He's formerly a professor at UCLA. But more importantly, he has conducted research on all atypical antipsychotics and was an investigator for this company, this company. Eli Lilly

thought enough about Dr. Wirshing that he was a clinical investigator for them. Unfortunately for Eli Lilly, he believes Zyprexa causes diabetes and he told Eli Lilly this in 1996, the year that they put the product on the market.

You will see that he wrote articles in the field and you will see it prompted internal e-mails within the company, and I will tell you now I anticipate that Dr. Wirshing is not as popular with Eli Lilly as he once was.

Now, I want to get directly into the evidence. If I find that --

MR. FIBICH: It's on your podium.

MR. ALLEN: There it is. I told you, this is a new thing for me. All right.

All right. Now, your Attorney General and the State of Alaska brought this case approximately a year ago. Early 2000 -- two years ago -- 2006, I can't believe it's 2008 -- approximately two years ago, early 2006. At the time they brought this lawsuit, based upon the information that they knew, they believed that Zyprexa's warnings -- yes, were deficient.

I was thinking last night, how could I show you these documents? Should I go in

order through the years and show them to you and should I not?

I decided not to. What I'm going to do before we go through all the documents year by year by year -- they're not all the documents, but the ones we can review in this time period. I'm going to tell you, as Paul Harvey used to say, the end of the story, the end of the story so you can evaluate what you know has happened. And when we go through the remaining documents in the case, then you can see how they add up.

Let's go to 2007. Now, you'll see down here it says May. It's not May. This letter's actually written in January. What this is called is called Bates stamping, a legal term. When these documents are produced, they have to put dates on them. This letter was shown when this letter was written in January of 2007 by the FDA to Eli Lilly. And here's what the letter said. Now by the way, ladies and gentlemen, I forgot to mention this. You can, of course, read that while I'm talking.

We're going to show a lot of documents today. I can't read every word and I have read them. I'm going to paraphrase them to

you. You'll have the documents yourself to review, as the Judge has told you, the documents admitted into evidence, by the way, every document that I'm going to show you has been admitted into evidence already.

You'll have them at your counsel table -- your counsel table -- I mean your jury deliberation room. But understand when I'm going through the documents and paraphrasing, understand that I'm doing so because I only have limited time, but you'll have these documents in your files.

Now, remember, the Attorney General of Alaska filed this lawsuit in 2006. He believed in 2006 that Lilly had not given an adequate warning. He has turned out to be absolutely, 100 percent correct. He has done the State a service. And it is proven by this exhibit and more.

In January of 2007 the FDA wrote Eli Lilly a letter and said to Eli Lilly: Concerning your application on Zyprexa, we have seen recent articles in the New York Times reporting on clinical trial data that showed that patients taking Zyprexa experienced higher blood

sugars and weight gain and it differed from the information Eli Lilly had revealed publicly and had previously given to the FDA.

It goes on to say: If you're in the possession of this information or other information that has not previously been submitted but would be helpful to us, give it to us now.

Now how did that happen? As I told you before, the FDA doesn't conduct its own tests. It doesn't conduct its own research. And this company, when it turns over the data, doesn't turn over the internal memoranda. However, the newspapers get ahold of things, and the New York Times got ahold of these things. When they saw it, it surprised them. They said, give it to us. We want to see it.

Well, I'll tell you, they did. They responded to the letter in February. If they want to show you their response, they can. And the FDA -- is that back up -- no, let me see here. The FDA wrote Eli Lilly back in March, on March 28th. That stamp right there is the actual stamp from the document, March 28th, 2007. The FDA wrote Eli Lilly back after they received

their response and here's what they said. They said -- look under updated information on the risks of weight gain, hyperglycemia, and hyperlipidemia.

Now if you'll see, it actually refers to a product called Symbyax, which is another product Eli Lilly made that had both Zyprexa, remember, olanzapine and fluoxetine, which is another Eli Lilly product -- Prozac, you'll hear more about it. So they were looking at both Zyprexa and Symbyax, which contained Zyprexa. And they wrote them a letter in March of 2007 and said this -- and these are not Scott Allen's words, not the State of Alaska's words. It says:

A primary concern with your application and a primary basis for our not taking final action is our view that we lack important safety information needed to adequately update the label, the thing in the PDR with all the relevant risk information. In particular, we are concerned that the labeling is deficient -- that's what the Attorney General of Alaska had said the year previously -- is deficient with regard to information about weight gain,

hyperglycemia, hyperlipidemia that is associated with olanzapine. And then -- sorry -- I drew the red line bad. It says whether taken alone or in combination.

The letter went on to say: Your recent letter -- this is Lilly's letter of February 20 responding to our letter of January concerning to New York Times -- has not been particularly helpful in addressing these concerns. And the FDA tells Eli Lilly in 2007 concerning the product Zyprexa, we do not feel that the current labeling for either Symbyax or Zyprexa provides sufficient information on the risk, and we fully intend to ensure that these labels are enhanced with the best available information to characterize these risks.

And they wrote Eli Lilly one more time in August of 2007, after Eli Lilly submitted the data they were asked to submit. And they said, we have reviewed the data you have submitted as well as the available literature, and we would like to request that you make the labeling changes below pertaining to the effects of Zyprexa and Symbyax on body weight, lipids and glucose. And they conclude, we believe it is in

the best interest of the public health to make the interim labeling changes now based on the data that we already have available.

Members of the jury, I'll pause right now and tell you, in my entire legal career, my 24 years, I've never had the honor of representing, obviously, the State of Alaska. But when they brought this case, and I'm sure when you hear them talking a lot, they're going to say this suit doesn't have any merit, this suit's wrong, they're confused. We're not confused.

The FDA has said time and time again in 2007, this company did not warn properly. They did not give us the information we needed and it is in the best interest of the public health that Eli Lilly change its label, change its package insert and warn about the side effects of Zyprexa. And on October the 5th, 2007, you will see Eli Lilly, after the FDA request, wrote this letter and changed the warnings -- and I want you to notice this word, change the warnings and we'll talk about that in a minute, changed the warnings on Zyprexa as they should have done years before that.

One -- and I'll talk to you about the changes, the labeling. I'll show you the warning changes in a second. One of the other things they were required to do besides change the warning on the package insert in the PDR and in the label, they had to give new information for patients, and it said: Patients should be advised of the potential risk of hyperglycemia, elevated blood sugar, related adverse events and importantly, it said patients should be monitored regularly for the worsening of glucose control. It said patients should be counseled that olanzapine is associated with weight gain and patients should have their weight monitored regularly.

Now let me point out something: Patients should be monitored regularly for worsening of blood glucose control. There's only one way to effectively monitor for blood glucose, and that is to draw blood and take blood samples. You heard people talk about it. You see it advertised on TV. People will take their blood. Or if they don't have diabetes, they can go to the office after they've taken the medication and a doctor can take their blood.

Ladies and gentlemen, what Eli Lilly did in this case, not only did they hide the information, not only did they not tell the truth, but they did something even worse. They used on -- they used to, before the FDA made them change its label -- and you'll see the documents -- they used to try to sell their product and use as a selling tool telling doctors you don't even need to monitor blood. They used it as a selling tool. The very thing that would allow doctors to discover on their own, by themselves whether or not their patient had hyperglycemia or diabetes, this company in the detailing pieces that it provided to doctors advertised to them right in the detailing piece? No blood monitoring required. So they not only hid the risk; they told the doctors who would use their drug that the very tool that would allow them to find out about this on their own, you don't need to do it. You don't need to do it. You'll see evidence of that.

Now, what is the label change? Ladies and gentlemen, this is -- it's too big and too tiny and too much, and we don't have time -- what the judge gave me, but this is the new

warnings. You see the warning at the top. And they go on for pages -- that's the same page, page 2, page 3, page 4 -- did I get it up there -- and page 5.

Five new pages of warnings that the FDA made them put on their product.

Now, did any of the other second-generation antipsychotics that we discussed, have they been required? Clozapine, no; Risperdal, no; Seroquel, no; Geodon, no; Abilify, no.

You remember that comparable rates message I told you about that they went around and told doctors and other providers, we had comparable rates of side effects? That message was false. It was untrue, and it did not allow people to make an informed choice on their own.

Remember, ladies and gentlemen, we're not required to prove in this case that some doctors would use it still or some patients would take it still. That's their right. That's their right and that's not at issue in this case. There's other people that don't want to take it when they have five pages of warnings and when they know there's other medications that don't

carry the risk. And who would ever want to deprive the people of the right to make their own choice? And the law in the State of Alaska, the fine state that you're from, specifically says, we shouldn't deny people that choice. That the people who sell products of all kinds in our state have a responsibility to give us the facts.

So, that's the end of the story. In 2007 your Attorney General has been proven correct for filing this lawsuit, and if I go home to Texas, that's where I'm from, as you know, after this trial, and I have lost, I'm going to hang up my hat. I'm going to put away my briefcase, and I'm going to find something better to do, because evidently I ain't worth salt as a lawyer.

THE COURT: Ms. Gussack.

MS. GUSSACK: Your Honor, an instruction would be helpful.

THE COURT: Ladies and gentlemen, what Mr. Allen intends to do depending on the outcome of the verdict and what you should do has nothing to do with Mr. Allen's going back to Texas and you should disregard that last statement.

MR. ALLEN: I apologize.

I'll put away my briefcase when I go back, but let's move on.

Let's see what Eli Lilly knew back before this product came on the market. 1995, they did what's called clinical trials and they'll tell you -- I'm sure they'll talk a lot about clinical trials. The biggest one they did was the HGAJ study that had approximately on -- this is the Zyprexa patients, olanzapine, that's OLZ on the left and Haldol, remember that first-generation antipsychotic on the right. They did studies comparing the two drugs and they looked at all types of parameters and the HGAJ data, by the way, was turned over to the FDA, turned over to the FDA. And what they found out, right down here, right off the bat in 1995 before the product was on the market, you see glucose nonfasting. If you go down, it has 1284 patients. You see the percent. What it means is 2.6 percent of the Zyprexa patients ended up with elevated high glucose and 1.1 percent of the Haldol patients had elevated blood glucose.

Now, what's particularly important about this is this number, this P value. I think

Dr. Brancati can explain it to you better than I have but in order to have what they call statistical significance, this number has to be .05 or less. And so what they determined in this study, .03 is less than .05, that they had, right off the bat. statistically elevations in blood glucose on Zyprexa. What is that -- where is it? A time and a half, one-and-a-half times that of Haldol. They knew that before they put the product on the market, that the blood glucose in Zyprexa was greater than Haldol.

Not only that, in the same study, you will see that they had elevated cholesterol, which is lipids, which they just require them to warn about -- of 2.3 and .08; 2.3 for Zyprexa; .08 for Haldol. And remember statistical significance, .02. So that's less than .05. So we had a three times greater incidence of elevated cholesterol related to Zyprexa versus Haldol. So right off the bat, they knew that.

And let me show you an interesting fact that I forgot to mention on the first page. You see -- and this is going to be relevant later when I show you the package insert. You see this

low -- this is also -- they also look for low blood sugar, okay. And they determined that it looked like Zyprexa had low blood sugar different than Haldol, but look at the number; .25, that's a lot more than .05. So that's hypoglycemia, but when you look at the number it's not statistically significant. By the way, I have a hard time saying that word, statistically significant. So they knew, right off the bat, prior to the time Zyprexa was put on the market.

Find this slide for you.

I think I took it out. They went down to Puerto Rico. This is a meeting in Puerto Rico in December of 1995 that Charles Beasley and Gary Tollefson had. They worked for Eli Lilly. Now let me do this, which I forgot to do -- because when we're going to look at their memos, you need to know who these people are. I guess it's kind of like going to a play. You need to know the characters.

These are the people that worked on -- some of the people, which I think it's 41,000 employees. Eli Lilly is a Fortune 200 company. These are some of the people that you're going to see in these e-mails. John

Lechleiter, Dr. John Lechleiter. I believe he has a Ph.D. He is currently CEO and chairman of the board of their company. What you will see is that he was intimately involved with Zyprexa during the time before he became CEO, and, in fact, he was chief operating officer and second man in charge when I took his deposition -- you know, to be honest, I think it was March 28th of last year. I took his deposition last year and he was COO, and since then he's been promoted to CEO.

You'll see the name, which reminded me of Gary Tollefson. And, again, these are -- I'm not good on exact titles. They have fancier titles than this but Dr. Tollefson is what I call, and they call the neuroscience division -- and Dave, was he a psychiatrist? Dave is my co-counsel and he remembers this. Dr. Tollefson, a psychiatrist. Dr. Alan Breier -- you don't see his name here, but you'll see it in a minute. He was head of what Eli Lilly called its Zyprexa team. Psychiatrist. Dr. Charles Beasley, whose name you see right here, he was what they call the global Seroquel physician, a psychiatrist.

Dr. Robert Baker, who worked on the

Zyprexa for Eli Lilly he was head of Zyprexa's hyperglycemia diabetes --

MR. SUGGS: In charge of diabetes.

MR. ALLEN: I do need his help. He was in charge of diabetes. He was a psychiatrist. Dr. Bruce Kinon, he was in charge of the issue of weight gain. He was a psychiatrist. You're also going to see the name of Denise Torres. She's head of global marketing for all their marketing on Zyprexa. Jack Jordan, he's the head of U.S. Zyprexa marketing.

Mike Bandick, B-a-n-d-i-c-k, I took his deposition. He was brand manager for Zyprexa. He also had a title -- if I get it wrong I apologize -- head of marketplace management or something like that but he was involved in the marketing of Zyprexa. And Dr. Patrizia Cavazzoni -- if I mispronounce it -- who has been designated by the Defendants as an expert in this case and who also works for Eli Lilly, you'll see her name in these files.

So with that in mind, this is 1995, before the product's on the market. Eli Lilly goes down to Puerto Rico and they pay a group of psychiatrists to be what they called -- I think

they called it a schizophrenia advisory board. But it was called an advisory board and remember that data, the HGAJ study I showed you and they took it to the doctors that they hired -- here's the slide right here.

December 10th, '95, and what they reported to the doctors is that in the HGAJ study on Zyprexa that three adverse events were reported at a greater weight with Zyprexa compared with Haldol: Dry mouth, weight gain and increased appetite. The doctors who Eli Lilly hired to consult told them -- and we can't read this whole thing -- but they determined that patients who remained on Zyprexa for 12 months gained an average of 24 pounds at the end of 12 months. You'll hear testimony from our side in this case that if you gain 24 hounds in 12 months, you increase your risk of developing hyperglycemia and/or diabetes by four or five times.

Right here in the report done at this meeting in 1995, before the product comes on the market, the advisers told Lilly that the association of Zyprexa -- and I'm going to use Zyprexa when I see olanzapine -- of Zyprexa with

weight gain, they commented on it and encouraged Lilly to do a further analysis. They told them that clinically significant weight gain is a risk factor for conditions such as increased blood pressure, increased cholesterol, and Type II diabetes. Guess what? The FDA in the 2007 letters we just saw, required Eli Lilly to warn for the first time ever about increased cholesterol and about increased weight gain, and they were told back in 1995 on the very first meeting with advisers of this problem --

THE COURT: Mr. Allen, you've been going an hour.

MR. ALLEN: Thank you, sir. Thank you. I appreciate it.

One other finding, '95. Just read that preclinical pharmacology. You see where they say the compound appears to have an atypical activity profile similar to that of Clozapine. Why is that interesting? As the studies ultimately turn out, the two products that have a greater risk of hyperglycemia and diabetes are Zyprexa and Clozapine. Eli Lilly knew and reported in its own report back in 1995 that our product was similar to Clozapine.

Now, I want to talk to you about the package insert. And before we do, I need to show you testimony so we can understand it together. This is testimony I took of Dr. Lechleiter in March of last year and I asked him about a package insert. We're going to see one right here in a minute. And I said, Dr. Lechleiter, by the way, you understand there's a difference in the law, and in fact, between a warning in a package insert and a listing in the adverse reaction section. He testified: Those are two different parts of the label.

I said: You understand what changes being effected is, do you not? He said, I know what that refers to, and the long story short, you see what he says: The company, Eli Lilly has the right and authority to make changes in its label. They can change their package insert on its own without FDA approval and here's what he said: Yes, we can do that and we've done it many times.

So if you hear this company and their lawyers tell you, well, the FDA told us what to put in the label, the FDA told us what we

needed to say. They had the right; Dr. Lechleiter's admitted it. If they needed to improve their label, they can do it themselves, they can do it on their own and they've done it many times.

Deposition of Joey Eski, I took that last Friday here in Anchorage. Ms. Eski is -- I think her exact title is the executive sales representative for Zyprexa in Alaska. She's one of those detailing people. She was designated by the Defendants as their witness. I asked her to tell me the difference between a warning and an adverse reaction section in the label. This is her answer: Typically it's the rate of incidence, as I understand it, and the likelihood of occurrence. She's told you there's a difference between the warning and the adverse reaction section.

She went on. And so I said: So it's a big difference when something's in the warning section, right? Her answer: It's a big difference in terms of -- that we go and proactively alert people, yes.

Ladies and gentlemen, right there, not from my mouth, from the mouth of Eli Lilly's

employees, they have told you that there is a difference, a big difference between the warning and adverse reaction section. That the warning section acts as an alert, and that they can change -- the CEO of this entire company of 41,000 employees says, we can change our label anytime when we want and we've done it many times.

Remember I said the evidence will show that the reason they didn't change their label on Zyprexa was because it was money? Looky here. This is up there. This is the deposition -- I believe I got it -- of Denise Torres. I can't see that -- yes, there it is. Denise Torres, the head of global marketing. I took this deposition. And I asked Ms. Torres: You personally -- you personally wrote down in memoranda that label changes on Zyprexa could threaten Zyprexa's sales; is that right?

She said: Yes.

I asked her: Can you remember or tell this jury when you knew that a warning about hyperglycemia or diabetes, when you knew that warning would impact sales in regard to Zyprexa? Can you tell us an approximate date or year? She

could have said anything she wanted.

Here's what she said: I think, as I mentioned earlier, I know a date or year, absolutely not. I could have said that the first day I started work that, you know, again, something in the warning has the potential to impact sales.

So you've learned from the testimony of Eli Lilly's witnesses, the CEO of the company, the executive director, I think her name is, for sales representatives right here in the State of Alaska and the leader of global marketing and Zyprexa about this label and what it means.

Let me show you the first package insert or label that came out in '98 in the PDR. They got it out the label in '96 when the product came on the market, but it got published in the book the first time in '98.

This is what they look like. Warning right here on the first page. We'll talk about that in a minute. But one of the things, remember I said it's not a cure for anything -- I lost my glasses -- here it is. One of the things and they're governed by their label. Their

people will testify they can't promote outside their label. The label tells you what it controls, their drug. That's what they'll testify to. It's illegal for them to promote or go outside their label. And what it says here is that the mechanism of action of Zyprexa, as with other antipsychotics, is unknown. That's very important.

This drug doesn't cure anything, and nobody knows how it works. Don't you think when they find out about side effects or potential side effects for a drug that doesn't cure a thing that nobody knows how it works, that they should at least give all the information they have about the side effects? I'd like to know -- that's what their label says.

And then they have a warning section. Testimony here -- you've heard the difference between a warning section and it can affect sales. You can look high and low in their initial package insert from '96 all the way to about 2003 -- we'll talk about that -- you can look high and low. No warning on weight gain. No warning on hyperglycemia. No warning on diabetes. No warning on cardiovascular risk. No

warning on hyperlipidemia. Zip, zilch, nada, none.

From the time this product came on the market until the FDA made them change the label for the first time in 2003, no warning.

Ladies and gentlemen, when you have to determine in this case, was a fair and adequate warning given, there can be only one conclusion we submit the evidence will show. How could they give an adequate warning? They gave none. None.

Now, what they did -- and I want to explain this, I highlighted this. Tardive dyskinesia; they warned about that. And what the FDA, the label says is whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown. Tardive dyskinesia, and I'm just using Scott Allen words, the scientists and the doctors can discuss it, is an involuntary muscle movement problem that can be permanent. It can be severe. And on all of these medications, Haldol and Thorazine, the first generation, that was a problem. It's listed as a warning on all of their medications.

They try to tell you in this case

that their drug can't cause tardive dyskinesia. The product, read their insert. Read their insert. And it's also important regarding warnings and adverse reactions here in a second. So, no warnings, nada, zip, nothing.

Now, the evidence will show in another section of the label, remember the testimony, and let me get it up for you, of Ms. Eski here in Alaska, the sales rep. There's a big difference if something is in the warning section. She said, yeah, we go out and alert people. Well, they did have in the adverse effects section, they did list weight gain here back here. What they said here, the below things in the adverse reaction things did not result in a discontinuation rate of the drug much different than a placebo, five to six percent. And where they list weight gain is back there with headache, fever, constipation, dry mouth, increased appetite, cold, cough, sore throat. It's back there, though, but you can search high and you can search low and guess what you won't find? You won't find a statement by their company back here in the adverse reaction section that says this weight gain can result in

hyperglycemia or diabetes or hyperlipidemia. And if they try to tell you, well, that was just common knowledge -- let me see if I can find that document now. Let me see if I can find it now, because I have limited time. Let me see.

Here it is. This is a document from January of 2001. This was a -- what they call a diabetes sell sheet that they train their sales representatives to use when they're training these doctors and telling them. Now, remember, if they try to claim that weight gain was -- everything's common knowledge, everybody should have figured it out on their own. Although they didn't put a warning in the pack, that they should have figured it out on their own, look what they wrote in their own training sheet. Currently, this is January, 2001, physicians are unaware of diabetes as an issue. They knew that. They knew that. Now, if your drug product has a risk of hyperglycemia and diabetes related to the drug and you write it down in the chart in your own files and you know it's a side effect of the drug, they knew that -- what do you need to do? Step up. Do the right thing. Give a warning. They didn't do it.

Now, original package insert didn't change, no warning -- but I've got to shoot straight. They did have continuing on the adverse reaction section, at the back of the insert; not in the front, not in the warnings, but on the back on the way out the door, they do have weight gain, and they talk about weight gain and they're going to talk about it. What they tell you is the average weight gain during long-term therapy was 5.4 kilograms. You recall that December, '95 meeting where it says the average weight gain over one year was 24 pounds; 5.4 kilograms is approximately 11 pounds. So even when they talked about it, their statement here didn't even match with what they had told the doctors back in Puerto Rico.

Now, they do have -- after you get past all that, under other adverse events observed, they have some more listings, and it says, by the way, under this listing -- it's important to emphasize, and I'm paraphrasing -- that this doesn't mean that any of this was caused by Zyprexa, and they have what I call a laundry list or a CYA list. And look what they put in here: The flu, increased salivation,

nausea, vomiting, thirst, gingivitis, mouth ulcerations, hip pain, decrease in libido, shortness of breath.

Look at this one, seborrhea, eczema, dry skin, and contact dermatitis. Sounds like a Head and Shoulders commercial. Dry eyes, ear pain, eye inflammation, and on and on and on. Also, back here in this other adverse effects, they do have tardive dyskinesia, frequent tardive dyskinesia. What does this tell you? What it tells is that when something is in the adverse reaction section, it does not preclude it from being put in the warning section. And there is a difference, as the witnesses have testified, between adverse reactions and warnings, because if there wasn't, then they could just stick tardive dyskinesia back in the adverse reaction section and said, we warned you, we told you.

They knew it wasn't in the warning. They knew where the warnings went. They knew where the warnings went. And tardive dyskinesia is up in the warnings. Now, what else did they put back here? Remember the hypoglycemia? That's the very opposite of elevated blood sugar. Look what else they put back here in the adverse

reaction section. Weight loss. The opposite of weight gain. So you've got dry mouth. You've got decreased libido. You've got weight loss. You've got low blood sugar. This isn't a warning. All right.

They did put, among all this listing, sometimes I have a hard time finding it -- where is it? I'll find it. Here it is. Hyperglycemia, it's in there in the same section with hypoglycemia. Unless they want to tell you their warning of hypoglycemia and their warning of the flu syndrome, this isn't a warning. They do also have infrequent diabetes mellitus and diabetic acidosis right there with eye inflammation and shortness of breath and fecal incontinence.

Ladies and gentlemen, this does not constitute a warning. Not because I say so, because the witnesses say so. And if you use your common sense, as the Judge gave you instructions that you should do, common sense tells you this is not a warning. So don't let them tell you.

And by the way, if it -- they know it wasn't a warning. Years later, 2001, they

record that physicians are unaware diabetes is an issue. They know the truth. Don't let them snow you now.

Let me find -- I'm trying to move. How much time do I have left?

MR. FIBICH: You've gone an hour and 15 minutes, Scott.

MR. ALLEN: I got 45 minutes.

THE COURT: No. Not 45, a half an hour.

MR. ALLEN: What? We were going to go ahead and use our time -- what do you want me to do? We were going to go ahead and use our full time.

THE COURT: The full two hours and have them go tomorrow?

MR. ALLEN: What do you want to do? I say yes, we're going to do that.

THE COURT: Okay. Then I'll let you use your full time and the Defendants can do their opening statement tomorrow.

MR. ALLEN: All right. Fine. Now. Judge, can you let me know? How much time do I have? Thirty minutes if I --

THE COURT: If you're going for two

hours -- you have 30 minutes, if you're going an hour and 45 minutes, and then I think we can both get in by going late. I mean, pretty much.

MR. ALLEN: I'll try to get it done in 30 minutes, if I can. Let me tell -- I know sometimes I speak fast, but I'm trying to get us all out of here, but I may not be able do it.

Right after the product came on the market, guess what? The FDA wrote them a letter and said, you're engaging in false and misleading acts concerning your Zyprexa. You're not telling the truth. You're not telling the truth about the events in your material. Right off the bat, within one month after the product's on the market this company is engaging in false, not because I say so, because the FDA says so, false and misleading acts.

What's one of the things they're accused of doing? Dr. Tollefson, the head of neuroscience, he was on a phone call, teleconference -- I think he was talking to investors and people like that -- that would invest in Eli Lilly. Remember, they tried to claim that they'd warned of weight gain. Within one month after this product's on the market,

Dr. Tollefson is on his phone and he's saying to the people on the phone and the FDA hears about this and writes them a letter and says, this is false and misleading.

He says, so we went back and analyzed our data and saw that the vast majority of weight gain reported initially as an adverse event, was in fact weight gain in patients occurring who had baseline, that's lower weight, before starting treatment had been below their ideal body weight. Dr. Tollefson went on -- in bold letters they put here -- so we, being Eli Lilly, really look at this with a majority of patients, majority, as being part of a recovery rather than an adverse event. And that data, I think, is fairly compelling because it was included in our label.

Their company right off the bat concerning this adverse reaction of weight gain was telling people that the majority of them, it was a benefit. Not a danger. FDA said, hey, cut it out. That ain't right. It's false and misleading. Stop it immediately.

Let me show you -- I'll skip ahead and see if I can get through. They're going to

tell you they follow FDA regulations. We would never do anything against the FDA. No. Ladies and gentlemen, the evidence will show they not only continued to do that, they did it years, years later.

Let me see. I'm going to find it. Here it is -- coming up -- if I can get -- there it is -- my glasses. You'll hear about something if we have time today called the Viva Zyprexa Launch, the Viva Zyprexa Launch. Remember I told you initially it was a psychiatric drug, but in 2000 when their company got in trouble, the evidence will show -- they lost -- what was the trouble they got into? It's in the document right here. They lost their patent on Prozac, their No. 1 selling drug. They call it Year X. That's their term for it. When they lost their patent on Prozac, they lost a billion dollar blockbuster. So what they had to do -- here's what they said. If I can find it -- I think it's right around the same location. Right around the same location. Here it is.

Yeah, here it is. This is their annual report when they lost it. So what are we going to do now? Well, we're going to use as our

front line, we're going to start replacing Prozac's business with Zyprexa business and make it into a billion-dollar blockbuster. Well, part of the plan to make it into a billion-dollar blockbuster was this: Let me show it to you -- here it is -- excuse me. I apologize.

Was this: Viva Zyprexa, you see I sing that because they have a song called Viva Zyprexa, and what they did was they decided to expand the market. They weren't happy now with just psychiatrists. Prozac's patent went off, they were losing money. They said, we've got to sell it to more people. We've got to get it to more doctors. Had the indications changed? Was it now for something else? No. Their needs had changed; they needed money.

So what they did is they went into the primary-care market -- by the way, if you think I'm -- there you go. They answered the question in the slide show. Why are we doing this? Their answer, not my answer, Zyprexa's success is crucial to corporate performance. Look. Here's another slide show they prepared in back July of 2001. You think it wasn't important to them to get this product out as far and wide

as they could? Their words, not mine. The company is betting the farm on Zyprexa.

The ability of Eli Lilly to remain independent and emerge as the fastest-growing pharma company of the decade depends solely, solely, only on our ability to achieve world-class commercialization of Zyprexa. This company bet the farm for money.

Oh, by the way, was there a warning on the pack about diabetes and hyperglycemia and adverse weight gain at that time when they bet the farm?

Answer: No. Did they know about it? Answer: Yes.

Now, let's see whether or not -- what the evidence will show. Remember the FDA said, '96, stop saying weight gain is a benefit. Stop it.

Now, let's see what Eli Lilly did. This is Dr. Alan Breier, the head of their product team. They recorded what he said at the Viva Zyprexa meeting. You know what, they put it on cassettes so sales reps can have it in their car so they can listen to it to get trained. This is what they wanted them to say. Look what

they said. '96, they said, stop it. He says, hey, we're going to grow sales in the elderly. Its attributes line up so beautifully in the elderly. One of our Achilles heels is weight gain. Achilles heel -- you know what -- That's a plus in the elderly, that's a plus because of the wasting of those individuals. And look what he concludes: and there's a huge amount of business in the elderly. That's what Dr. Tollefson said back in '96. The FDA said, stop it right now. They didn't stop it.

If they get up here and say, well, we would never do anything against the FDA. Well, they say, well, Dr. Breier may have used a little loose language; he didn't really mean it. He said it twice, not once. Twice. Weight gain is a side effect of Zyprexa. We knew it early on. It's reality. In certain conditions, like the elderly, it's a plus. It's an advantage because of the difficulty the elderly have maintaining their weight.

They not only didn't warn, they not only didn't put it in their package insert, they went around training their sales representatives to tell people it's a good thing. Reprehensible.

And not because I say so. The FDA says, stop it. They kept it up. You can't stop a moving train, particularly when you bet the farm on the product.

Let me show you -- how much more time do I have --

THE COURT: It depends. You've got until 12:45, if you're going to finish this in an hour and 45 minutes, in which case we'll get both openings in today. If you go beyond that, Lilly will do its opening tomorrow.

MR. ALLEN: I'm going to finish today and I'm sorry, again, if I talk fast. I could talk slow and I'm going to try to slow down. I want to get finished so these people can get up.

Now, let's look at some of the internal documents of the company which indicate that they knew there was a problem early on and they didn't tell and didn't warn. Let me find some. I've got a lot. They're all right there. I'm going to choose. Here's one in '98, in '98. All right.

This is written by a guy named Peter Clark. He's in marketing, okay. He's a

marketing guy. And he's aware of the fact that Dr. Wirshing, who ends up being our expert, who was their consultant at the time, has written and published an article saying Zyprexa was related to hyperglycemia and he wasn't the only one. A Dr. Goldstein had done so, also. The marketing guy says, look, you know, he wants to tell the truth. He wants to tell the truth. He says -- look at those two bullet points: We need to start telling everybody that use of antipsychotics may result in weight gain. No. 2, And patients who gain weight may develop insulin resistance which may lead to hyperglycemia and diabetes. You see the words may, may. That's fine. We're not sure, but it might. We need to start telling people that. Boy, that rubbed somebody the wrong way.

Dr. Bruce Kinon, one of the psychiatrists on the team, Zyprexa team, said, no, we don't want to make that connection. That's the bottom e-mail, says we don't want to make that connection. Well, Mr. Schmidt responds and says to Dr. Kinon, hey, don't get mad at Peter. He's only saying what Charles Beasley, the global physician on our product -- he's only

saying what Charles told him in this first attempt to establish what the scientific information is concerning diabetes and hyperglycemia. Remember?

Causation does not need to be proven. You needn't change the warning as soon as there's reasonable evidence. Dr. Beasley is quoted as saying, we're just trying to establish the scientific information. He got shut down. He got shut down.

Let's go on. You don't think they knew? This is '99. Head of the product team. Here's how they view the problem. They didn't look at it for patients; they looked at it for money. Olanzapine-associated weight gain and possible hyperglycemia is a major threat to the long-term success of this critically important molecule.

Weight gain -- it's a threat to the drug? It's a threat to patients. They had to form a team to try -- they formed a team and they said -- look what they said on the same memo. Dr. Breier: We're going to try to handle this issue. And look what he says, success of this effort will contribute to securing the future of

olanzapine and the financial health of our company.

Yeah, they were concerned. They were concerned about their pocketbook. Looky here. November, '99. This is a top secret. You see that box. Nobody is supposed to see this and by the way, the last two e-mails, private, internal, confidential, no one seen it. They didn't send it to the FDA. Looky here. November, '99. Briefly. We got trial data, we've got study data. This is Dr. Casey, one of their consultants. He did a review of charts and determined that 18 percent, almost 1 in 5 of patients who started with Zyprexa who had normal glucose, developed abnormal glucose. They had animal studies, post-marketing spontaneous adverse reports. Looky here. Right here. Discussion section. Post-marketing reports, animal studies suggest an association (indicating). See the word? An association. November, '99. Did they put a warning in the package insert?

No. But we know they don't -- we know they don't care what the FDA says. They wait until they make them do it. Let me find

another one.

I've got 15 minutes, Your Honor, if I get through early --

THE COURT: 20.

MR. ALLEN: 20 to get through early?

THE COURT: Yes.

MR. ALLEN: Look at this one. This is where they -- this is what I call -- really, I thought to myself, I have to be honest. This is when the heavy lift in the line really got hard for the company. It got hard. The heavy lift in the line, Attachment E, Global Product Labeling Committee. February, 2000, corporate internal private document. They didn't think anybody would ever see the global product physician and the head of pharmacovigilance, Kenneth Kwong. Let me put it this way. I don't know if he's the head. He's one of the men that worked there. That's who keeps up with the adverse experience reports.

Guess what they did? They came forward and said, we better change our label. We better change our label. You know, currently, and I'm doing a long story short, we're saying

it's very rare. Back in the back it said infrequent. Hyperglycemia is not very rare. It's common or frequent. We need to change our label, but look down at the bottom right there. Look down at the bottom. They were looking at their trial data internally, and they determined that there was a three-and-a-half times greater increase in blood sugar than patients on placebo. And they recommended a warning change.

Look at the other pages of this document real quick. We don't have time to study it. They talked about the fact we have history of observations. We have case histories in our files. We have other studies supporting the fact that there is a hyperglycemia with our product. Remember Dr. Casey? Remember that name? He came and did a seminar at their company at the end of '99 and reported on the 18 percent data.

They looked at it and said the pharmacology -- what we know about the pharmacology of the drug could explain why people are gaining so much weight and, look, there they say it again, olanzapine is classified and it has similar to Clozapine. They say it. What do they do? Do they warn? Do they change their label?

You know what, ladies and gentlemen, the answer is, yeah, they did. They changed their label when they got this information and they changed it to this: Remember, their internal data said we have a three-and-a-half times greater incidence of hyperglycemia than a placebo.

Now, I don't know if you ever remember -- I never get the quote right but Mark Twain said one time, there's statistics and there's dang lies. Well, they took and relabeled the data and they wrote in the label on their own, on their own. Look at it. They said, well, look, our hyperglycemia is comparable to a placebo, not greater than a placebo. Not greater than a placebo. And they did it, see, a change is being effected. They did it on their own.

I'll tell you what, let me show you something. Let me find it. 2001 PDR, they did it in May of '99. That change made it in the PDR.

One problem. Much like the teleconference, much like Dr. Breier at Viva Zyprexa, the FDA said, whoa, what are you all doing? They wrote them a letter in October of

2000, after they changed the label and they said -- this is the same language when you're trying to make it look like a placebo and you stick it in the package insert. Here's what the FDA writes them a letter and says, don't do that. It's not true. It's not right. The descriptive data that is provided -- that is provided expresses a certain level of implied safety with respect to hyperglycemia -- treatment-emergent hyperglycemia. And they said, this reassuring language is not appropriate.

What do we see now? Well, they took the adverse reaction of weight gain and tried to turn it into a benefit, and they take the adverse reaction of hyperglycemia and try to reassure you. You know what, this is 2000 when this occurs. Remember the heavy lifting and lying.

They took this reconfigured data. This company sells diabetes medication. Matter of fact, they describe themselves in documents right in record as a diabetes care company. And they decided, maybe we can take it down from our side of the neuroscience division, and we can take it down to Atlanta where our diabetes people

are going to have a meeting and maybe we can get them to look at the data and maybe they'll help us out and get us out of our jam. Here's what the diabetes doctor told them. Come clean. Come clean.

Now, there's a big series of e-mails that are written on October the 9th and 10th, 2000 on this topic. They start with Dr. Baker's around 2:30 in the afternoon. Here's what he writes on the 9th. Is that Dr. Baker's? Yes, it is.

He's reporting, he goes down to this meeting and he reports the diabetes doctors, that's endocrinologists, those are diabetes. One of the problems in this case, remember all the people that went down in charge of this product is psychiatrists? This is diabetes. That's not a psychiatrist problem; it's an endocrinologist problem. When they took it down to the experts, what did the experts say? You've got problems, you have a huge amount of weight gain -- the magnitude -- and I'm doing it by recollection. You have a lot of reports. We don't believe the data that you -- Dr. Brody -- Mr. Brody, he's not a doctor, who is at that meeting, the diabetes

side wrote Dr. Baker back 30 minutes later and said, look, this group of endocrinologists and those who spoke up are very concerned about what Lilly is doing. The board's recommendation is probably not the way Lilly does business. Lilly needs to come clean. Recognizing that's not the way we do business, Eli Lilly.

Guess what? Dr. Beasley, remember the global -- Zyprexa physician? He writes an e-mail the next morning. Ladies and gentlemen, I'm going to have to paraphrase this in order to cut back on time. But what he says is, first, he said we got two issues. The marketing approach and the scientific approach we've got to worry about. That's problem No. 1. We believe the evidence will show that's problem No. 1. There only should be one approach to these types of matters. Marketing, this is a drug that doesn't cure anybody. Nobody knows how it works, and they're concerned about marketing. They should only take the scientific approach.

He then says we've got two problems: Weight gain and hyperglycemia. And then he says: The guys, that's the endocrinologists were really concerned about

weight gain, not only because of the diabetes risk, but all the other potential health risks, when they understood that this was seen in nonpsychotic normals. Let me tell you one of the other things they try to do it, instead of taking the responsibility on themselves after they've been told to come clean. They're going to blame it on the victim. Blame the victim. Blame the patients.

They may try to say in this case, this really isn't a problem with the drug; it's the people taking the drug. Right here. It says right there. This occurs in normal people and animals on fixed diets. They can't eat any more or less. What do they say? Olanzapine is the worst offender.

Now, why is that important? The worst offender. They've identified themselves as a worst offender. They knew it. It goes on to say that diabetes doctors -- look at that data, you know, the data they stuck in the insert that the FDA said is false. They said these doctors say, looks like to me you're torturing this data. Torturing. Spinning the data. And they said, you know what, we want the continuous data.

Now let me tell you real briefly what that is. They gave these doctors what they call the categorical data and the doctor says that doesn't make any sense to me. You're trying to claim it doesn't have a diabetes problem. We're seeing all this weight gain. We're seeing hyperglycemia. This doesn't make any sense. They gave these doctors what they call categorical as opposed to continuous data.

I'm no scientist. Don't claim to be. Never was. Here's how you figure it out. Difference between categorical and continuous. If somebody asks you how Ichiro's hitting right -- what's Ichiro's batting average. Somebody says, well, he's one for 8 the last 8 at bats. That's 125. He says, No, I want the batting average. Well, he's 2 for 10 the last 10 at bats. Well, that's 200. No, I want to know the batting average. He's four for 20 the last 20 at bats. That's 200. That's what you call categorical analysis. But what if you ask the guy, he'll say all I want to know is his batting average. His batting average, oh, it's. 340. When you look at all the data on a continuous basis as opposed to chopping it up, it gives them

the full picture. If they give him the categorical data, he's one for 8, batting 125. Give us the full data and you find out Ichiro's batting average is .340. And the doctors asked for the continuous data, the company didn't give it. And look what it says down here.

These doctors say, look, don't be aggressively denying that this doesn't cause glucose intolerance or claiming that it's no worse than others. Don't be doing that. And look what Dr. Beasley wrote. He says that, looks like what Dr. Casey had been telling us. Remember Dr. Casey had been in their office in 1999. Dr. Beasley -- Beasley says they've been telling us for a long time. Did that stop them, Eli Lilly? No, it didn't.

I'll show you right now that they gave messages to doctors and after they were told not to do so -- let me show you this too, while I'm -- this is something they said. If doctors ask about weight gain, tell them it's due to increased appetite. It's not a metabolic response. Look, pill does not equal weight gain, okay?

That's what they told doctors in

January of 2001. If you go back and look at an e-mail -- let's see if I can find it. Here it is -- that Dr. Beasley wrote in March of 2001. It says: One thing -- this is writing internally -- one thing we can definitely say, definitely -- remember, you don't even need definite. But one thing we can definitely say is that olanzapine causes weight gain. For approximately 50 percent of patients in trials who remained on the drug greater than six months, the amount was greater than ten pounds. Some patients the clinical trials gain as much as 80-plus pounds lacking empirical data to the contrary.

You know what that means? Oh, we had some doubt. We were confused. You have reasonable evidence, without a doubt. He said, we can say definitely. Lacking empirical data to the contrary, it would be ludicrous -- this is their word, ludicrous, crazy -- to state that such a patient is not at a long-term increased cardiac risk relative to prior to gaining weight, especially if in temporal association with that weight gain, the patient developed increased in fasting glucose and lipid levels. They knew a long time. They knew a long time.

MR. ALLEN: What do you want me to do? Finish? Wrap up?

Let me see if I can find the note just to prove that it happened right here in Alaska. They say, so, well, it didn't happen here in Alaska. I apologize to you all. Oh, here it is -- by the way, this comparable rates message which is completely false, why did they do it? You don't need to ask me. Look at their documents. They want 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's making the decision to use the drug. Their words, not mine. This is the comparable rates message.

Look at here. Here's a sales note, right here in Alaska. Here's the date. October 24th, 2001. Sales notes -- they keep notes in the computer when they talk to doctors, lunch presentations. This is the sales rep -- led with diabetes data and she goes on, focused on weight gain chart and risk factors, all should have walked away thinking and saying comparable rates. If they ever say, well, that may not have

happened, the documents are confusing. Yeah, well it did happen. It happened right here in Anchorage. Look at this one. They say well, everybody knew. Isn't it just common knowledge on voir dire -- looky here. This is June 27th, 2002 right here in Anchorage. The sales rep tells the doctor, Pam Engel is the doctor or nurse, I don't know which one she is, was concerned about weight gain for Zyprexa patients, but we discussed proper diet and the fact if the patients are feeling better, perhaps they will be able to exercise. Also discussed the mechanism of Zyprexa and that the drug does not cause weight gain. Remember Dr. Beasley's e-mail in March of 2001? One thing we can say definitely is the drug causes weight gain. Definitely we can say that.

All right. Let me tell you real quickly, I got a written confession. They didn't do the right thing. I can't remember the exact day, August of 2002, the Japanese FDA made them change their warning -- and by the way, there's still no warning in the United States. Japanese makes them change their label extensively and what they say in the warning change, they say

causation can't be denied. They say that. They should have been telling them in the United States. They don't tell them. But they write this internal e-mail, this is a regulatory briefing, in the summer of 2002. This is as close to a written confession you're ever going to get that they knew they needed to change warnings. They say, we anticipate differential labeling.

They think they're going to get hit by the FDA. Do they discuss going out and doing it on their own? No. It says the analyst community -- that's the stock exchange -- that's the kind of talk they care about. The stock exchange community has indicated this could trigger a Lilly disinvestment. Our stock could fall if we change the warning. There is a substantial risk. You think they wanted the public to know about their problems? No, they say the substantial risk in opening Zyprexa to a Public Advisory Committee at the FDA. We don't want the public look at this stuff. No way. But it says -- we've got to try to influence this outcome. The better way is in private negotiations with FDA.

Down here, marketing people, investing people, they didn't want to warn. They would lose stock price.

Now, I'm going to tell you briefly. Guess what, remember the best case/worst case scenario? Well, they've got the best case. In 2003, FDA tells them, change your warning for the very first time, for the very first time, they have to put diabetes and hyperglycemia. But so did all the other manufacturers. Remember that was their best case. They could compete then. Nobody could put their product down. The problem with that was right after that there was a corporate crisis. The CEO, currently and COO at that time finds out about this --

THE COURT: You've got a minute to finish up.

MR. ALLEN: -- the ConSensus Statement. That's where our expert, Dr. Wirshing, their former consultant, our expert testifies against Dr. Cavazzoni, the FDA testifies, all the manufacturers testify. For three days they can put on anything they want and they determined in the conSensus conference -- and this will be the last thing I show you,

because the judge told me to wrap it up. These were experts from American College of Endocrinology, the American Psychiatric Association, the North American Association of Obesity and they determine, looky here, look whose drug carries the greatest risk, Clozapine and olanzapine. Remember the drugs that are similar that they knew were similar. Three pluses, they had the risk for diabetes. All the other ones in the class, all the other ones, no.

Zyprexa -- and when do they knew this, they knew it in January, 2004 before they ever notified the doctors in a March letter.

Ladies and gentlemen, facts on the table. They bet the farm. They were worried about money. They denied and never put a warning on the label. When they finally did in 2003, they were made to do so, but it was still not sufficient, because they still didn't tell all they knew. You saw that the first, your Attorney General was right, the FDA told them it's right. All the evidence is in. These people didn't warn. They chose to bet the farm, ladies and gentlemen. Chose to bet the farm. It's time to call their bet.

Thank you very much.

THE COURT: Ladies and gentlemen of the jury, we're going to take a 15-minute break while we reorganize the courtroom and have Lilly's opening statement. Again, we'll go a little bit late so we can finish these opening statements today and get right to the evidence tomorrow. And so I'd ask you now to return to the jury room again. Please don't discuss this case among yourselves or let anyone discuss it with you. We'll be in recess for about 15 minutes.

THE CLERK: Rise. The Superior Court now stands in recess.

Off record.

(Break.)

THE COURT: Please be seated.

We're back on record. All members of the jury panel are present.

Ms. Gussack.

MS. GUSSACK: Thank you, Your Honor.

Can you imagine how hard it is to sit waiting for your chance to get up and speak after a long presentation like Mr. Allen's? I

wanted to jump up, but I have to wait my turn and now you can appreciate why we took such care to pick a jury that could commit to doing exactly what Judge Rindner said, which is to keep an open mind until all of the evidence is in. And, of course, these opening statements are not evidence; you've heard that. We have a ways to go to put that evidence in.

But we appreciate that you made that commitment to keep an open mind and listen to the evidence. There is going to be some very important evidence coming from Eli Lilly and Company, its employees, its expert witnesses and we're looking forward to bringing it to you. Never, in all the time that I thought about coming to try a case in Anchorage, did I think I would feel warm in Anchorage. And here I am feeling warm because I'm ready to go. And I want to really express my appreciation for your time and for your attention.

Let me do a little bit of background, again, since it's been a while since we got a chance to speak. My name is Nina Gussack, and I am proud to be here on behalf of my client, Eli Lilly and Company. And my trial

team partners who are sitting over here, George Lehner, John Brenner, Andy Kantra and Brewster Jamieson are going to be working right alongside of me as we try this case and in fact, George will join me in making these opening comments to you this afternoon.

I want to talk with you this afternoon about Zyprexa, a prescription medicine made by Lilly for serious mental illnesses that you've heard described already, schizophrenia and bipolar disorder. This is no lifestyle drug. This is not about allergies. This isn't about erectile dysfunction. This is about serious mental illness.

When the Food & Drug Administration approved this medicine in 1996, doctors understood it was a breakthrough medicine, something that could help restore meaningful life to patients who were robbed of their dignity and their lives by their serious mental illness. Were there other medicines available before Zyprexa was brought to the market in 1996?

Yes. But those medicines had side effects that made patients unwilling to stay on them. And you're going to hear about some of

those side effects including tardive dyskinesia and very jerky physical movement.

Here's one thing you need to understand: No medicine can help people with serious mental illness unless they're going to take it, right? You have to take your medication to benefit from it. And Zyprexa was a breakthrough medicine for a lot of reasons, but not the least of which was that it had a better side effect profile on the kind of side effects that made it very difficult for patients to stay on.

But let's get something straight right now. It's a prescription medicine. There is no prescription medicine that doesn't have side effects. Every prescription medicine has side effects.

So what it is that our physicians are doing when they prescribe medicines for us? They are weighing the risks against the benefits. There is no one medication that is perfect for everybody, and there is no medication that doesn't have risks. But our physicians are making that hard choice every day to try to make sure that the prescription they're making is the

best one for us. And we're going to talk about that and this case is going to involve a lot of information about how doctors make those choices.

How important is Zyprexa as a medicine? You do not have to listen to me. You don't have to listen to Eli Lilly and Company about that. You have to listen to the State's expert witness, Dr. Wirshing, who Mr. Allen mentioned to you. The expert psychiatrist for the State of Alaska has said: The second-generation antipsychotics, including Zyprexa, are among the most powerful disease modifiers in all of medicine. They are a Godsend to most people. A Godsend.

And if you have a family member, you know someone or you know anything about serious mental illness, you can appreciate that the -- the class of medications that we're talking about, these atypical antipsychotics are what we call the second-generation of them, because there was an older group. And Zyprexa belongs to the more current group, are a Godsend.

I want to show you what Dr. Wirshing said when he testified before this trial, and he's going to come to trial.

Video: "They're the closest thing to magic that I have ever experienced in my professional life."

MS. GUSSACK: They're the closest thing to magic that I've experienced in my professional life. From Dr. Wirshing, the State of Alaska's psychiatrist who has made his career treating schizophrenic patients at the VA Hospital in California.

Before there were medications like Zyprexa to treat schizophrenia, and these -- and bipolar disorder, you know what treatment consisted of? Lobotomies, imprisoning people, electric shock treatment.

In the 1950s scientists discovered what we call the first generation of antipsychotics, and you saw them on the easel before, including Haldol, and you're going to hear a little bit more about Haldol. These medications were valuable because they were helpful, but they were not -- but the next generation of medications has proven. And these atypical antipsychotics, the second generation were a great leap forward in the treatment of these very serious diseases.

Scientists have been searching for more effective medications for serious mental illness for years. And over 20 years ago, 20 years ago, two Lilly scientists discovered a molecule and researched it and developed it, and the company invested in it, and in -- all in the hopes that it would make a difference in the lives of millions of people. That molecule is the medicine Zyprexa. That medicine has been prescribed to 23 million people since it was brought to market.

It is approved for use in over 80 countries. It is approved by the FDA in the U.S. It is used every day by the physicians who prescribe for patients in Alaska.

Why does Dr. Wirshing say they're the closest thing to magic that he's ever experienced in his professional life? Because he knows, as all physicians who treat these diseases know, there is no cure for schizophrenia. There is no cure for bipolar disorder. But we are searching every day to give people back a quality of life that will allow them to be with their families, to not be in hospitals, to not be in prisons, to have a quality of a life that allows

them to be functioning human beings in our society.

Zyprexa and medicines like Zyprexa can free the mentally ill from a hell that most people cannot imagine, from a hell that most people cannot imagine. That's how Dr. Wirshing, the State's expert, describes these illnesses.

So I guess it won't surprise you that the company is very proud of its development and manufacturing and selling of Zyprexa.

You will learn a lot about the diseases that Zyprexa treats. We're going to bring to this courtroom Dr. Kahn from Columbia University. He's a psychiatrist who lives in New York, and he's going to tell you about the patients he treats every day. He will tell you about what a typical patient with schizophrenia is like to treat.

Patients with schizophrenia which -- and schizophrenia has been called the cancer of the brain. That's how horrible a disease it is. These are patients who may suffer from paranoid delusions, thinking that people are out to hurt them; they may hear voices no one else hears; suffer from fear and obsessive

thoughts; not be able to hold a job; not be able to maintain the relationships with their families; and they may live on the street. They may not be able to operate in any constructive way in their life. They tend to be in and out of hospitals and, typically, doctors try multiple medications to help relieve their symptoms.

And they include all kinds of medications, antidepressants, antianxiety medications and antipsychotics.

This is the kind of patient Dr. Kahn treats, and he's going to tell you about the challenges of finding the right medication for each patient.

Schizophrenic and bipolar patients are at risk for diabetes regardless of what medication they use. It's been well known in medicine for quite a while. 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 can 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. Not in every patient. He may make the decision that in a particular patient it's not worth it. If a particular patient presents some challenges or has some medical background, he may choose not to prescribe it, but he is making that choice, that balancing every day.

Dr. Kahn sees, just as Dr. Wirshing did, testified, these risks that a medicine presents are tolerable sometimes when you're trying to get a very important impact in addressing illness.

Bipolar disorder is another devastating illness. You may know some people with it. You may have family members. Bipolar mania in which a patient can swing from depression to a manic phase where people can have delusions and think that they are more powerful than they are in their manic phase, they may engage in very aberrational kinds of behaviors. They may be obsessive drinkers or gamblers or other kinds of problematic behaviors. Bipolar

disorder is not just -- because some people do think about it about a kind of depression. Do not be confused about how serious this disease is. It has the highest risk of suicide of all mental illness.

And you know what is really challenging about bipolar disorder? It is really hard to diagnose. You will hear from the physicians that we bring to court how many, many patients with bipolar disorder go undiagnosed for a period of seven to ten years, or are misdiagnosed, three and four different times because it is a hard disorder to diagnose and a hard disorder to treat. And there is tremendous risk to patients who are -- who suffer from bipolar disorder because of the high risk of suicidality, and Zyprexa is effective in treating those patients.

A lot of bipolar patients don't see psychiatrists. 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 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 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 from FDA in 2000 for Zyprexa to be used in bipolar disorder, that's why it started to move into calling upon primary care physicians.

MR. ALLEN: Your Honor, could we approach?

THE COURT: Please.

(Bench discussion.)

MR. ALLEN: There's no -- evidence. It's not approved for bipolar disorder. It's approved for bipolar I disorder. It's a major difference.

THE COURT: This is opening statement. You can point that out down the road.

(End bench discussion.)

MS. GUSSACK: Patients with bipolar disorder need help, and we want to make sure they get help wherever they can. That may be a primary care office; that may be a primary care

office; that may be in a nurse practitioner who can prescribe's office. We want to make sure that physicians and nurse practitioners have the information that they need to make those kind of diagnoses and make good prescribing decisions.

Physicians like Dr. Kahn, as well as the physicians in the State of Alaska, trust Zyprexa to help their patients who suffer from these diseases. That's why Lilly is proud to say we make Zyprexa. It is affecting the quality of life for countless patients. What doctors do every time they write a prescription, whether for an antibiotic, a cancer medication or for Zyprexa, is to balance the risks against the benefits. That's what doctors do. That's what you're going to hear about.

There is no question that this medicine is effective. As I said, not for everybody. And you're going to hear that and, of course, sometimes you have to take one or two medications until you find the one that works. It is not always so simple to say, you have this problem, therefore, you take this medication. You will hear about that.

The State has said that -- that

Lilly's label for Zyprexa was misleading or deceptive. But let's be clear, they are not saying that this medicine doesn't work.

Instead, they want you to believe that the label failed to warn doctors about the risks of Zyprexa even though Lilly's label for Zyprexa has been reviewed, approved, revised, amended, approved again by FDA on numerous occasions as more and more scientific information became available.

So in 1996 the medicine was first approved to treat patients. It received the approval again after Lilly submitted more information to FDA for bipolar mania four years later in 2000. It -- Lilly submitted more data later and asked for approval to market it for the maintenance of schizophrenia relief and received approval again. Lilly submitted data to FDA. All of the information it had about how effective Zyprexa was about used with other medications for bipolar disorder. And FDA approved it again in July, 2003. And then, again, in January, 2004.

And each time FDA made the decision that it was approved for these new uses, FDA looked at all of the information that Lilly

submitted and said, yes, we believe it is safe and effective for those medications. Not guaranteed safe. Safe and effective for the medications as described in the label.

And let's be clear, as we're talking about the label, we're not talking about the label on the bottle that you get from the pharmacy. We're not talking about that little piece there. We're not talking about the summary sheet that your family physician may give you. We're talking about that detailed small-print, lengthy requirement that FDA requires every manufacturer to use to develop, reporting all of the information about its medicine that has to accompany that medicine when it is provided to the pharmacy or to the physician.

But we know that doctors aren't taking out their magnifying glass to look at each section of this label. Where do these labels appear? In lots of places. In the Physicians' Desk Reference that you saw before, on web sites, in their handheld computers that they can type in the name of the medicine and find it. But each portion of this label is regulated by FDA. The size of the print is regulated by FDA. The

sections of the label and warnings is one section, adverse reactions is another, precautions is another, clinical pharmacology is another. Each of those sections are requirements that FDA has, and only when you have satisfied FDA's requirements for where the information goes and what you say are you allowed to market your medicine. That's what Lilly did starting in 1996 with Zyprexa.

I want you to think about for a minute what the State is asking you to do. The State wants you to believe that Lilly has fooled doctors in Alaska; doctors who are trained in the practice of medicine, doctors who use their best judgment every day to treat serious illness; doctors whose own patients tell them this medicine works. The State wants you to believe that for the past 11 years Lilly has pulled the wool over the eyes of physicians in the State of Alaska.

And the question you should be asking yourself is: What physician is the State of Alaska bringing to this courtroom to tell us how the State got bamboozled? Because I didn't hear anything about anybody coming from the

physician, no psychiatrist coming from the State to tell you how they were fooled by Lilly's label, about how it was misleading.

That's because the State is not bringing any doctors from Alaska to court to tell you that they were misled, that the label's inadequate or that they were tricked into prescribing Zyprexa.

Lilly is going to bring you the doctor from Alaska. In fact, you might think of him as the head doctor for Alaska, Dr. Duane Hopson, because Dr. Hopson is a psychiatrist. He is the president of the Alaska Psychiatric Association. He is also the medical director of the Alaska Psychiatric Institute, the only state-run psychiatric hospital in Anchorage, and he is an employee of the State of Alaska. And Lilly will bring Dr. Hopson to court.

You might think that the State would have brought him as a witness in their case, but they won't and we will.

And Dr. Hopson will tell you that he and others on his staff use Zyprexa regularly to treat patients at the Alaska Psychiatric Institute, and he will tell you that he has and

continues to prescribe Zyprexa to patients right here in Alaska.

He's also going to tell you that Alaska has no restrictions, no restraints on the use of Zyprexa. Two years this lawsuit has been pending and for two years the State has not imposed any restriction, any restraint, any limit on the use of Zyprexa. Does that sound like somebody who has been bamboozled? If they had a complaint two years ago, you need to be asking yourself, I think, well, why haven't they done something?

MR. ALLEN: Your Honor -- I object. It's argumentative. We're right here filing a lawsuit.

THE COURT: Again, these are statements of counsel. You'll hear evidence about things and you're going to determine facts based on the evidence. This is argument of Counsel. It's entirely proper.

MR. ALLEN: Okay, Your Honor. I just wanted you to know we filed a lawsuit.

MS. GUSSACK: You're going to hear from Dr. Hopson when he comes to court that he considers and evaluates each patient on an

individual basis just like Dr. Kahn's going to talk to you. And that the doctors on the staff of the Alaska Psychiatric Institute, State of Alaska employees in many cases, turn to Zyprexa in many cases after considering all the risks and benefits of the medicine.

You're also going to learn, because it's a serious medicine for serious disease, it's not advertised on television. You will not find it in magazines at the supermarket. It's not on the radio. It is a medicine that is prescribed by physicians and Lilly communicates its information about Zyprexa to physicians. Like I said before, Lilly cannot sell this medicine until the FDA has evaluated and studied it to determine whether the risks and benefits are appropriate and when they have approved the label for the medicine.

You will also hear, not just from Dr. Hopson, that people who work for the State of Alaska have not limited or restricted the use of Zyprexa. Not in State hospitals, not by doctors employed by the State, not by Medicaid patients, even though the State has the power and authority if they wanted to. You will hear that lawyers in

the office of the State Attorney General where Mr. Sniffen and his counsel have authority go to court on occasion and ask judges to order that certain psychiatric patients be administered medications, including Zyprexa, when the patient won't willingly take the medication themselves. The State comes and asks the judge to administer Zyprexa to patients when the patient won't take it themselves in certain circumstances.

That's how valuable the State thinks this medicine is. And why does the State do this? Because the medicine works. And two years ago when Alaska filed this lawsuit saying the label was deceptive or misleading, you might have thought something would have changed, but it hasn't. The State of Alaska's doctors continue to prescribe Zyprexa, and the State has done nothing to discourage it.

Why are we so sure that doctors haven't been misled? Because the label and all of the information that Lilly shares with physicians tells them about the side effects and the risks with -- associated with Zyprexa.

Since Day One that this product was marketed in the U.S., weight gain was described

in the label in the adverse reaction section. Doctors know the risks.

Before the FDA approves a medicine for sale -- and that label, I want to talk just a minute about the process, and you're going to hear much more about this, but the process that goes into developing a medicine and having it approved by FDA. Because it's not just a molecule that goes into becoming a medicine and gets accompanied by a label. There are studies that are done in the laboratory and then in clinical trials, and when the product comes to market as Zyprexa did, what is being labeled is what is learned from all of those studies. And that's what FDA is looking at, all of the information that Lilly submitted about what it learned from its clinical trials with Zyprexa.

Now, the FDA is not dumb or stupid, nor are they all-knowing. They are simply the cop on the beat. And when FDA says green light, that means we get to go ahead and market the medicine. And when they say stop, we stop. And you will hear both -- both times when FDA said stop, we don't think you should put that in your label, and you will hear times when they said, go

ahead, your label looks good. And you will hear about times that we have had communications with FDA and said, we see the data, the information this way, what do you think? But when FDA speaks, that's final. We can have views, but FDA is the cop on the beat and we listen to what FDA says.

FDA said when we first came to market in 1996 with Zyprexa that the weight gain information needed to be in the label, and ultimately they approved that label with that weight gain in the adverse reaction section.

Let's look at the label. Here's the label that was available in 1996, and as I mentioned earlier, it has lots of different sections to it. Let's look at the adverse reaction section, which is from the first time this product was approved. Lilly was explaining to physicians where weight gain was observed, and they told physicians in short-term clinical trials, meaning six-week trials, patients on olanzapine or Zyprexa gained 6 percent compared to those patients on placebo or sugar pill.

But that's not all they told doctors about weight gain. They also told

doctors that in long-term treatment with olanzapine, which is the generic name for Zyprexa, in long-term treatment, more than 50 percent of patients met the criteria for having gained a lot of weight. So everybody can just close their eyes for a minute and say, what's 7 percent of their weight? That's what doctors were told. Your patients, when they come in, may gain 7 percent of their existing weight. Significant weight gain, and doctors knew.

Did Lilly have an obligation to tell doctors what weight gain does? No, because doctors have gone to medical school and doctors know. All of us have had doctors tell us we need to lose weight or be mindful of our weight because weight gain or being obese or being overweight is a risk factor for a lot of diseases; diabetes, cardiovascular risk. Lilly was telling physicians, here's what we saw from our clinical trials about weight gain.

But that's not all. What else did the label say in 1996? It said: In other adverse events we saw infrequently hyperglycemia and diabetes. Infrequently meaning -- and that's a defined term by FDA -- 1 in 100 to 1 in 1,000

patients reported that they had diabetes or hyperglycemia. That's why it was reported as infrequent, and that information came from the information that Lilly had before it brought the product to market. But what happened? When the product comes to market, all the study doesn't stop. Lilly continues to look at all of its experience as it's being used in the market and so does FDA. And you're going to hear about that process of monitoring the safety profile of Zyprexa as it's in the marketplace.

What did this label do? It told physicians about weight gain. It told them about diabetes and hyperglycemia based on information known to Lilly in 1996. It alerted physicians. It told them these things were seen infrequently with respect to diabetes and hyperglycemia and here's what we know about weight gain.

But the label isn't the only source of information physicians have to get information about medicines. There were articles being published in medical journals and doctors were -- had those available to them.

Doctors have known for a long time, as I mentioned before, that patients with

schizophrenia and bipolar disease are at risk for diabetes. Doctors also know that there are risk factors for diabetes. They don't predict who is going to get diabetes, but we know if you have a family member, parent, brother or sister who develops diabetes, you're at increased risk. If you're obese or have substantial weight gain, you may be at risk for developing diabetes. Just getting older makes us at risk for diabetes. And it would be hard to imagine that anybody could be walking around not reading about the epidemic of diabetes in the population at large and the epidemic of being overweight in the U.S. but -- and you will hear this from Dr. Inzucchi, our endocrinologist who will be coming to testify. Everybody who is overweight doesn't get diabetes, so it's not so clear what it is that predicts who gets diabetes.

But Lilly was sharing its information with doctors about weight gain and sharing its information with FDA and it wasn't just relying on the label. From 1998 through 2002, Lilly made available 11 different medical letters about Zyprexa. And what are medical letters? They are detailed summaries of

information about various subjects. So there were medical letters that Lilly made available to physicians about body weight changes and medical letters about blood glucose changes and medical letters about how to manage weight, which is a challenge for everybody, and particularly those who may be impaired with mental illness.

Lilly trained its sales representatives who call on physicians to answer questions about weight gain and diabetes that doctors might raise, and Lilly's sales representatives were trained to ask questions during their calls to find out concerns doctors might have about the use of Zyprexa. I want to show you some of the materials that Lilly sales reps were given to be trained on. And they were told, probe your physicians in every call, even those customers who aren't voicing concerns. Remember, in 2001 they told their sales reps, many physicians do not proactively bring up the diabetes issue.

And what kind of information were the sales reps sharing with physicians when they made those sales calls? Here's some detailed information that sales reps provided to

physicians in 2000 about weight gain. And you can see that they're talking about the kind of information that Lilly knew about weight gain and Zyprexa. Lilly wanted to make sure that physicians had accurate information about these issues. What did they tell doctors about hyperglycemia and diabetes? They had information that the sales representatives provided to physicians about those subjects as well.

So you'll be, I think, not surprised at all to learn that when Lilly did market research -- and all companies do market research to understand what their customers are thinking or know and for Lilly as a pharmaceutical company its customers are the physicians who prescribe their medications.

What did Lilly's market research show in October, 2000? In October, 2000 60 percent of physicians surveyed said they thought there was a link between Zyprexa and hyperglycemia and diabetes. Does that sound like we were hiding that information from physicians? In April, 2001, the number of physicians who said in market research that they believe there was a link increased to 100 percent of

those physicians surveyed. Physicians knew about weight gain. They knew about the risks of weight gain. They knew about the fact that hyperglycemia and diabetes had been reported. There was an ongoing scientific debate in the medical community about whether these things are related or not. There is no one view that answers all of it.

But one thing that Lilly has done is to participate in trying to evaluate and research the questions. And provide information to physicians. And they have done that ever since they first started thinking this was a medicine that could help patient with serious mental illness.

Let me introduce my partner, George Lehner to tell you what the evidence will show that you're going to see over the next few weeks about how that scientific debate was informed and how Lilly shares information with physicians.

MR. LEHNER: Good morning. Ms. Gussack was talking a little bit about the labeling story and got up to 1996, but I want to talk a little bit more about that and what was happening between Lilly and the FDA in the years subsequent to 1996 because the labeling story

really didn't end there as you've heard, and I want to talk about that. Labels are not frozen in time. They evolve, they change. And why is that? It sort of makes common sense because as this product is used, as this medicine is used by more and more people, manufacturers who make these products gather more and more information about the experience people have with their product. And what a company like Lilly does when it gathers that information, it analyzes, it looks at it, it studies it, it provides it to the FDA, it sends it to physicians in medical letters, it continues to educate the community about that.

When there's enough information about that says here's something new, here's something different, then the label is changed. That's what happened in this case. Let's stop back for a minute because what was really happening was really clear by the 1999, really by May, 2000 that the FDA was not only the cop on the beat but they were really on active patrol.

In May, 2000, the FDA asked Lilly and all the other manufacturers who made the products that you saw up there, to provide

information to the FDA -- and I'm going to show you the letter that the FDA sent in May, 2000, because in some way was sort of the kickoff of the FDA letters to get very actively involved in what's going on here. And the FDA said to assist us, the FDA, in fully evaluating the possibility that atypical antipsychotics may produce disturbances in glucose metabolism -- that's a lot of fancy language for there's some increase in glucose control, sugar levels rising. We are requesting the sponsors of these agents, that's all the manufacturers, to provide us with more extensive safety information.

The FDA said that it had reviewed a number of adverse event reports that had been coming in, adverse event reports actually that had been provided to the FDA by Lilly, as Mr. Allen mentioned we do. And it said we need to know more. So Lilly spent the next couple of months gathering the data and in July 2000 it submitted a comprehensive report to the FDA. Now, remember, this is four years after the product has been on the market and now there are about 4 million patients. This is actually the report, I think we have a cover page on the

report -- I tried to save a little bit of paper, this is going to be presented into evidence, it's double-sided. This is the report that Lilly sent to the FDA in July 2000.

You're going to hear in more detail about this report from Dr. Patrizia Cavazzoni. She's a medical doctor, she's a psychiatrist, she works at Lilly and she's the chief detective at Lilly when it comes to understanding the safety of Zyprexa. That's what she spent her career at Lilly doing.

I said FDA was acting like the cop on the beat and were in active patrol. As you heard, in April 2000 the FDA wrote Lilly again and this time they told Lilly to remove information that Lilly had decided to add to the label in that year about hyperglycemia. Let's look at that letter. Mr. Allen showed it to you, and here's part of it as well. What FDA said, a more complete submission of glucose data is necessary before an appropriate review of treatment-emergent hyperglycemia and diabetes can take place. They didn't say the information we had put in the label was misleading. They didn't say it was false. They said it could imply -- it

could express a certain level of implied safety. What they said is, before we understand this more, before we can approve ultimately this language being in the label, we want to have more information from you. It was clear to -- it was clear to Lilly that the FDA had taken control of this issue.

Now, as a result of the FDA's interest, Lilly continued to submit annual and periodic reports to the FDA. In May, 2001, Lilly submitted its analysis of clinical trial data and two epidemiological studies. This is the report that they submitted in May, 2001. In October of 2002, Lilly provided a briefing document and this showed new Lilly studies and now talked about the kind of spontaneous adverse events that were reported after now 9 million exposures to the drug. Nine million patients had taken this drug by October, 2002.

In March, 2003, Lilly again updated and supplemented its prior reports. They did the same thing in June of 2003 with a new submission of data. And also reviewed all the literature that had been accumulated on diabetes and antipsychotics. That's what the evidence will

show. Lilly was forthcoming, Lilly was opening the books and saying here's what we know about this relationship that may or may not exist between our product and this condition.

Now, September, 2003 marked a very significant milestone in the life of this label. I've been talking about how the label evolved and changed when the FDA told all the manufacturers of the second-generation antipsychotics to add new information to their label. After three years of review and analysis of the data, remember, they sort of began this process in May of 2000 and it's now September of 2003, after three years of review and analysis of all the data that had been submitted by all the different manufacturers, the FDA told Lilly and all these other companies it's time to add some new information to the label. And what did they do? They said here's the information we want you to put in the label and, of course, Lilly did.

They wanted to put into the label that there is a increased risk of diabetes among schizophrenics. The label said and pointed to certain studies, epidemiological studies which suggest an increased risk of

hyperglycemia-related adverse events in patients treated with atypical antipsychotics.

They said, however, there's not enough data to show whether there is a difference of risk among the various antipsychotics. They said doctors, we want you to do some monitoring of your patients and, last, and hardly least, the FDA said: The relationship between atypical antipsychotics use and hyperglycemia-related adverse events is not completely understood. It's not Lilly's language, that's not Lilly trying to hedge its bets. That's the FDA language.

This is the FDA saying we don't really understand this, we don't know what this relationship may be if any. But we want to at least alert doctors that something may be going out there, put it in the label; and we did. It doesn't say whether or not it caused, it didn't say whether it didn't cause, it said you may be alert to the fact that there may be this relationship out there, but we really don't know what it's all about.

At the same time that the FDA made the label change request, it sent a letter to all

manufacturers that accompanied that request in September 1990 -- September 2003 and it told the companies what the FDA wanted to do next.

And that letter said in essence, that while the FDA believed that the language that it had just recommended to be put in the September, 2003 label adequately described the available information that then existed on antipsychotics and the use of diabetes (sic), it said we, meaning the FDA acknowledge -- acknowledge that additional labeling changes may be required as new information becomes available.

This is important because the FDA was telling manufacturers that the 2003 label isn't the last chapter, it's likely that this label is going to change again as more information becomes available. And what the FDA did was made it crystal clear what new information that it wanted to receive from the manufacturers. In essence the FDA said we're really on top of all this, we're all over this, and here's what we want you to provide us so that we can make the kind of decision we need to make about what should go in the label.

And so the 2 -- so in 2003, the FDA

sent a letter which said: We want information about those groups that might be at risk, we want more information about whether the risk is the same for all the groups or not, all the different antipsychotics or not. We want to see what kind of research you've done to determine if there's some kind of mechanism, how does this happen, if at all. Have you done any research about that?

And over the next three years Lilly pursued each one of the areas that the FDA told it that it should research and provided the FDA with new data on groups that might be most at risk, and provided FDA with a data it had on the comparable risks that it had among the various antipsychotics medicines and remember the FDA was also gathering this information from other manufacturers as well at the same time. Information to which Lilly, of course, was not privy. And Lilly provided data from what are call machinist tick studies, studies that Lilly conducted to determine whether or not when people would take Zyprexa it would have some kind of direct effect on the pancreas which is the main organ that's involved in diabetes.

So it's not surprising in 2007 when

the FDA informed Lilly that it wanted to change its label to reflect all the new information that the FDA had gathered from Lilly since the 2003 label change.

THE COURT: You have one hour left.

MR. LEHNER: Thank you. I think I will barely use it, Your Honor.

Let's look at briefly what the 2007 label said. The State has suggested that this 2007 label represented a major change in how Lilly described the relationship between blood sugar labels or blood glucose levels and Zyprexa since the label now stated that the increases in glucose levels appear to fall on a continuum. And the label now said, as the FDA -- excuse me -- and the label also said that olanzapine appears to have a greater association than some other atypical antipsychotics, and somehow the State is arguing that despite the many submissions that Lilly made to the FDA, the many analyses that Lilly and the FDA had conducted between 2003 and 2007, despite all the other information that had been submitted to the FDA by manufacturers of similar medicines and despite the ongoing debate in the scientific community

that Lilly had somehow up to this time, again, managed to mislead or deceive physicians, mislead the FDA, mislead the State of Alaska about the comparable rates that might exist with respect to this disease and these medicines.

In fact, as the evidence will demonstrate, the 2007 label was yet just another step in the evolution of this label. It was an effort to more fully describe and elaborate this relationship that was not completely understood in 2003 and it's still not completely understood. And you can bet, you can bet that there are likely to be more label changes in the future as what has happened over the last decade continues to happen, as more information gained -- is gained, as more information comes into the manufacturers, as the FDA learns more about this product, as other manufacturers learn more about their products, as all of that information is accumulated, analyzed, it's likely that the label is going to reflect other changes in the future as well.

That's the nature of prescription medicines; we learn a lot more as we go along and we learn our best what we try to know in the most

comprehensive fashion, but in a fashion that is the most accurate and hones to the truth.

Now, it's not surprising that the 2007 label does not say that Zyprexa causes diabetes. You won't see that in that 2007 label. It doesn't say Zyprexa causes diabetes, that's not surprising. Why is that? You've heard a little bit about that. We know that diabetes is a very complicated disease.

Ms. Gussack mentioned that Dr. Silvio Inzucchi, he is a diabetologist from Yale, one of the leading researchers on diabetes in the country will come here and doctors can predict who is most at risk for diabetes, but doctors really do not know why one person might get diabetes and another person, who is very similar and who has very similar characteristics, does not get diabetes. Many factors may be at work; family history, age, background.

We know that people with severe mental illnesses like schizophrenia and -- schizophrenia and bipolar are also more likely to get diabetes than people who don't have those conditions. But again, schizophrenia and bipolar don't cause diabetes. There are other risk

factors as well, events that might help us predict who might get diabetes, when, in fact, nobody really knows what causes diabetes.

What do we know about Zyprexa? We know and as you have seen that Zyprexa and we have told doctors Zyprexa causes weight gain, not in every patient, but in some. And in those who gain weight, some may gain a little, some may actually gain a lot. It's a doctor's decision to decide whether or not he or she is going to keep a particular patient on the medication while that person may be gaining weight gain. By the wail, it's very hard to hide weight gain, particularly substantial weight gain as you're visiting your doctor. As I said, weight gain also does not cause diabetes. We also know there appears to be an association with elevated blood sugar levels and second-generation antipsychotics. But, again, elevated blood sugar levels do not equal diabetes.

Elevated blood sugar levels are not even necessarily a natural next step to having diabetes.

Between 1996 and October, 2007, the Zyprexa label changed several times to add more

information to help doctors better understand the relationship between blood sugar levels and people who take Zyprexa. You've seen two of these changes. But the fact that a label changes over time does not mean that it is misleading, it does not mean that it is deceiving, does not mean that the label that came before that was necessarily misleading or deceiving either. What it means is that Lilly is gathering more information, communicating that information to physicians, trying to respond to the concerns of its customers and to the concerns of its author, the FDA. When you have heard all of the evidence, I think you will come to the conclusion that the right answer is not to say that Zyprexa causes diabetes. I believe that the right answer is what the evidence will show. It's namely that what Lilly has been doing over the last decade and is doing today; studying, monitoring, reporting, probing answers to hard questions.

Let me address for a minute some of the allegations that the State has made for you. You're going to hear a lot of our responses during the various witnesses that will come here today. You saw a lot of witnesses and I'm going

to address one or two to tell you what they didn't tell you. You heard Mr. Allen say that when the regulatory authorities in Japan told Lilly to change the label, Lilly made a change to this label in Japan. Lilly didn't agree with that change but it made it nonetheless.

What the State didn't tell you was that as soon as Lilly changed the label in Japan, it told the FDA. Called the FDA on the phone and said we're making a label change, this is a note to file from Lilly are from two doctors at Lilly talking to the FDA and saying we made a change in Japan to our label. That's not all Lilly did. Lilly promptly provided, yes, another report to the FDA, this time a comprehensive report analyzing everything that they had learned about why Japan had changed the label and it told the FDA why it disagreed with the conclusions that the Japanese regulators came to. Lilly also told the FDA, but you'll hear that Lilly told its sales representatives to go out and tell doctors that a label change had been made in Japan. The label change in Japan was no secret, but it was something that Lilly disagreed with. You will hear from Dr. Cavazzoni again, who went to Japan,

who analyzed the data, and who reached the conclusion that the label change that Japan made was not warranted because the data did not support the conclusion that the Japanese regulators for their own regulatory reasons, reached with respect to how the label should look in Japan. And that's not surprising.

Ms. Gussack said that this product has been used by 23 million people over the last 11 years; it's been approved for use in over 80 countries. Different countries have different regulatory regimes. The label that Mr. Allen showed you is not the label that is used in Japan. It's not the label that is used in Europe. It's not the label that is used in India. It's not the label that is used in South Africa. Different countries have determined what kind of information should go on labels and how those labels should be structured. Mr. Allen also told you about the ConSensus statement. He described that meeting where a number of scientists came together to look at whether or not and to examine this question of the relationship between second-generation antipsychotics and hyperglycemia and diabetes and

what that might be and they reached certain conclusions and he showed you a chart where there were a number of pluses on that -- you may remember that -- and it appeared to show that there were more pluses for Zyprexa than some of the other manufacturers with respect to the relationship between diabetes and hyperglycemia. What he didn't show you was that after that report was issued, the FDA took the step of writing to those people who put together the ConSensus statement, and I think we have that document as well. The FDA took the occasion to write to the editors that had published this ConSensus report and the -- it's important to look at what the FDA said. These are the people at the FDA who -- these are the people at the FDA who are responsible for the division that reviews these drugs. The neuropharmacological drug product center and it said that this division is not aware of evidence proving that the treatment-emergent diabetes risk for these drugs is wholly or in part due to treatment-emergent weight gain, although weight gain is widely recognized as a risk factor for diabetes in the general population, the clinical trial and

epidemiological evidence has not shown, has not shown, a direct link between these treatment-emergent side effects.

So here's the FDA, this is the group that has been collecting information from all the different manufacturers for, what, now, this was in 2004, at least very actively since May 2000 and even before, the FDA who had been analyzing all that, the FDA who had the scientists who were most knowledgeable about the range of these medications, they take this step of writing to this ConSensus panel editor, a ConSensus panel that met for three days to look at this issue and said you know we don't think you got that quite right. Based on the data we have, we don't see this direct link that you may be trying to talk about in your ConSensus report.

So, let me come back to the beginning. There's a question, I think that Ms. Gussack asked and I think it's one that we would like to ask you to keep in your mind. Why are we here? This case is called the State of Alaska versus Eli Lilly and Company. That would lead to you believe, as she said, that doctors who work for the State and prescribe Zyprexa

would be here to tell you about how they have been deceived, but that isn't the case. Where are the Alaska doctors, she asked? Where are the State officials? Remember Dr. Hopson? She talked about Dr. Hopson, he's the medical director for the Alaska Psychiatric Institute. He was never asked by the State of Alaska -- he never asked the State of Alaska to sue Eli Lilly. You may wonder why. You may also be surprised to learn that he didn't even learn about this lawsuit until after two months -- two months after it was filed. Who else did the lawyers not ask about suing Eli Lilly? Dr. Karleen Jackson, she serves on the Governor's cabinet --

MR. ALLEN: Your Honor, this is far outside the evidence. A lawsuit was filed by the Attorney General to fight this company for what they've done. Now he's making argument, not on evidence.

THE COURT: Again, this is argument of counsel, opening statements. I've told the jury that it is not evidence in this case. You're free in your closing statements, if they're unable to prove the things that they're talking about here. to point that out to the

jury.

MR. ALLEN: Thank you, Your Honor. There is no proof --

MR. LEHNER: Your Honor, the proof will be the testimony of Dr. Hopson --

THE COURT: The proof will be -- I can't tell whether there's going to be proof or there isn't proof. You will have to evaluate that. You're the determiner of facts in the evaluation of whether attorneys have told you things that are eventually proven in the case, and that goes for both sides.

Q. (BY MR. LEHNER) We took the deposition of Dr. Hopson and he told us that he didn't learn about the lawsuit until two months after it was filed. We also took the deposition of Karleen Jackson. She serves on the governor's cabinet. She told us that she was not asked about this lawsuit. In fact, she didn't learn about this lawsuit until over 18 months after it was filed, and it is her department that is responsible for making sure that Alaska pays its Medicaid patients. She's the Department that's most interested in the claim, I would assume, that the State has brought. And what about another

individual who works at the Department of Health and Social services, David Campana? He's the pharmacist who manages the Medicaid pharmacy program for Alaska. He was asked straight up and he's the one who reviews these drugs, September 19th, 2007: Has Eli Lilly ever made misrepresentations about the safety, efficacy, effectiveness of Zyprexa to the State of Alaska? Answer, not that I know of. Then he was asked whether the label, the package insert misrepresented the facts to the State of Alaska that Zyprexa was safe and effective. Straight up, no.

So what are we doing here? I'm going to be as straight as I can. I'm going to suggest to you that after you review all the evidence you will come to the conclusion that this case should never have been brought. It should not have been brought because Lilly has always provided physicians with the information they need to make appropriate decisions about treating their patients. There's simply no evidence to support the allegation that Lilly gave doctors an inadequate warning about the risks or the benefits of this product. It should

not have been brought, because Lilly always kept the FDA up to date with changes made to its label from around the world, whether or not Lilly thought those changes were correct or favorable. And it should never have been brought because no doctor or no State official responsible for purchasing Zyprexa in Alaska asked for this lawsuit to be filed. Neither the State's top psychiatrist nor the head of the department that paid for Zyprexa asked for this case to be brought against Eli Lilly.

We're going to have one more chance to talk to you at the end of this case. And when we do and when you have then heard all of the evidence, we're going to ask that you find that the lawyers for the State have proved no wrongdoing by Lilly. And we will ask you, on the other hand to keep in mind, the many benefits that this medicine has provided to some of the most seriously mental ill people here in the State of Alaska. And we are going to ask you at the end of the day to render a verdict for Eli Lilly.

I appreciate your time and we look forward to talking to you at the end of the case.

Thank you very much.

THE COURT: Ladies and gentlemen of the jury, that concludes the opening statements for today. And so I'm going to let you go for the day. I'd ask you to return here tomorrow at 8:20. And we'll try to get started at 8:30 again. It's possible there'll be pretrial matters and I'll try to keep them as short as I can. When we start tomorrow, I will give you some more preliminary instructions that will probably take ten minutes or so and then we'll begin the presentation of the evidence of the case. Once again, I would ask you to not discuss this case with anyone, nor let anyone discuss it with you. And to please keep an open mind until you've heard all of the evidence in this case until closing arguments and instructions are provided to you. Again, I thank you for your service, and I'll see you all tomorrow.

(Jury out.)

THE COURT: Please be seated. We're outside the presence of the jury. Are there any matters we need to take up before we recess for the day?

MR. LEHNER: Your Honor, we're

going to submitting to you those deposition designations. I think we have a motion to file -- it may have already been done, but we'll get to your chambers the transcripts for Dr. Lechleiter or Ms. Torres, either one of them will be the first to come up.

MR. ALLEN: I believe -- yes. It depends -- let me put it this way, Mr. Lehner, if it comes up tomorrow or Friday, it will be first. But things could change as we go into next week.

MS. GUSSACK: Your Honor, we've also received, I think, some demonstratives for Dr. Brancati. Would that be Mr. Suggs that we should -- we'll address those issues, I don't know that they'll be anything that we have to address to the Court in the morning.

THE COURT: I've gotten just filed a motion for clarification of instruction regarding presentation of video deposition testimony which I think deals with -- is that the submission you're talking about?

MS. GUSSACK: Yes.

THE COURT: All right. So I've already gotten that. So I consider that and I'm going to review that today, as I understand it,

the State has told me what their response is. So I know what that is.

MR. ALLEN: Yes, I have. I haven't read that, Your Honor. Unless there some new argument I'm not aware of. But you know my basic position.

THE COURT: I know your position. Again, I'll be taking both this motion up this evening as well as going over the two deposition designations that I've been asked to review, to issue rulings sooner rather than later on. So that's one of my tasks for tonight. If there's nothing else, then, if everybody would be here, we may not get started at 8:15. But if everyone could try to be here by 8:15 in case there are preliminary matters, I really would like to shorten up the -- the delay in getting the jury in and getting going, particularly since, as I understand it in the next two days we've got two witnesses who need to get in and get out. We'd prefer to try to get them in and out, but I'd prefer to keep my calendar and keep this trial ending at 1:30 instead of going as late as we're going. We'll see. If there's nothing else, then we'll be off record.

MR. ALLEN: Thank you, Your Honor.

(Trial adjourned at 2:10 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 5th day of March, 2008.

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