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 VI

TRANSCRIPT OF PROCEEDINGS

March 10, 2008 - Pages 1 through 226

BEFORE THE HONORABLE MARK RINDNER
Superior Court Judge

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

For the Plaintiff:

STATE OF ALASKA
Department of Law, Civil Division
Commercial/Fair Business Section
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501-1994
BY: CLYDE "ED" SNIFFEN, JR.
Assistant Attorney General
(907) 269-5200
FIBICH, HAMPTON & LEEBRON LLP
Five Houston Center
1401 McKinney, Suite 1800
Houston, Texas 77010
BY: TOMMY FIBICH
(713) 751-0025

CRUSE, SCOTT, HENDERSON & ALLEN, LLP
2777 Allen Parkway, 7th Floor
Houston, Texas 77019-2133
BY: SCOTT ALLEN
(713) 650-6600

RICHARDSON, PATRICK,
WESTBROOK & BRICKMAN
1037 Chuck Dawley Boulevard, Building A
Mount Pleasant, South Carolina 29464
BY: DAVID L. SUGGS, Of Counsel
(843) 727-6522

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

For Defendant:

PEPPER HAMILTON LLP
301 Carnegie Center, Suite 400
Princeton, New Jersey 08543
BY: JOHN F. BRENNER
GEORGE LEHNER
NINA GUSSACK
(609) 452-0808
LANE POWELL, LLC
301 West Northern Lights Boulevard
Suite 301
Anchorage, Alaska 99503-2648
BY: BREWSTER H. JAMIESON
(907) 277-9511

PROCEEDINGS

THE COURT: We're on the record in State versus Eli Lilly and Company, 3AN-06-5630 Civil. We're outside the presence of the jury. Good morning to everybody.

A couple of pretrial matters. One, as you may recall from the voir dire, I think it was Ms. Shepherd had two teeth issues. She's at home with an abscessed tooth. I assume we're going to have to excuse her. Anyone disagree with that?

MR. FIBICH: The State does not, Your Honor.

MS. GUSSACK: No, Your Honor.

THE COURT: I mean, the alternative is to wait a day and to send everybody home for the day, but I realize that that may not be possible.

Mr. Suggs, did you have something?

MR. SUGGS: No, Your Honor.

THE COURT: Okay. Second, I received I guess -- I received this morning, but it was filed on Friday, a motion to intervene and unseal records by Bloomberg News. I assume, but perhaps incorrectly, that the Plaintiffs won't

oppose this and the Defendants will?

MR. FIBICH: That -- that is very accurate, Your Honor.

MS. GUSSACK: I'm not sure --

THE COURT: It may be accurate with them. We'll let them speak for themselves.

MS. GUSSACK: Thank you, Your Honor. Since we haven't yet seen the motion, it's hard to predict what our response would be.

THE COURT: The service indicates that the motions were served on -- by hand delivery on Mr. Jamieson and Mr. Sanders, so --

MS. GUSSACK: It hasn't yet found its way to us, Your Honor.

THE COURT: Mr. Treptow is -- or Davis Wright is filing the motion, Mr. Jamieson, if you want to check.

MS. GUSSACK: We'll look for it.

THE COURT: I'm not going to expedite ruling on this, so we'll wait until you get me your response.

MS. GUSSACK: Thank you, sir.

THE COURT: A couple of other things.

I just want to make a record. Over the weekend both on Saturday and Sunday I met and received from the parties deposition counterdesignations and objections to deposition designations and cuts of deposition designations, and made rulings which either on Sunday or today have been distributed to the parties as to the depositions of Jack Jordan, Bruce Kinon, Gary Toleffson, Denise Torres, I guess the additional -- request that additional information of Denise Torres be included in the Plaintiff's part of playing that deposition. Michael Bandick, Charles Beasley, Robin -- help me again.

MR. ALLEN: Wojcieszek.

THE COURT: -- Wojcieszek, and I think there was also some questions about Mr. Lechleiter and what portions would be included in his. I have now ruled on all of those including what should be included in the deposition, what exhibits would come in, and what objections would be sustained or overruled to the thing.

I've also received from both parties -- the State filed a, what I'll call a letter memorandum, explaining their position on

perhaps certain of the objections and some of my preliminary rulings. I think primarily both as to this off -- the question of what evidence I'm allowing in off-label uses that might go to warnings and what I'm not letting in. And the -- the -- Eli Lilly has filed a response to the State's letter motion to the Court regarding off-label promotion. The material that was originally filed by Eli Lilly hadn't yet been signed by local counsel, but my understanding is they have now filed all the signed versions, three-hole punched. Thank you very much.

MR. LEHNER: Two-hole-punched.

THE COURT: Two-hole punched; thank you very much.

And I don't want to take too much time from the jury right now to go over this. We'll maybe take this up at the end of the day for a short period of time before my next hearing to sort of discuss that issue.

The -- but I just wanted the record to reflect that those matters had been filed and received by me over the weekend. And I made certain rulings that I distributed over the weekend. I don't believe the rulings, or the --

most of that stuff has been docketed yet.

Finally, before we bring in the jury and discuss if there are issues that you wish to discuss before we bring in the jury -- and I hope I'm not sending anybody down rabbit trails, which I sometimes do.

Over the weekend when I was thinking about this, my understanding is that, basically, there are two types of claims in this case, one of which has two parts. We've got the common-law products liability warning claims. We've got -- and then we've got the UTPA claims both where the State is suing on its own behalf and will in that regard eventually have to prove ascertainable loss if we get to that part of the case, but the State is also suing as the State, the sovereign, seeking an injunction and -- under its authority under the Consumer Protection Act to seek injunctive relief.

Am I correct about that?

MR. ALLEN: Yes.

MR. BRENNER: That's not our understanding, Your Honor. I thought that was the legal issue that was presented from the very beginning of the case that the State was not

seeking injunctive relief. I think that was a legal issue Your Honor ruled on that even though they were not, they could still proceed for civil penalties. We thought the construction of the statute was to the --

THE COURT: Okay. Well, I won't even get into whether it's injunctive relief or not. They're seeking several penalties as the sovereign --

MR. BRENNER: That's it.

THE COURT: -- and that follows from their ability to get injunctive relief. Let's put it that way, correct?

MR. BRENNER: Yes, I think that's correct.

THE COURT: My simple question in all of this, since I recognize that those civil penalties probably have the most juice in this case, is is that a judge question or jury question? In other words, is the jury deciding this whole case, or am I deciding part of this case as to the predicates for getting those civil penalties?

MR. BRENNER: We thought ultimately that, imposition of penalties, if any, are with

the Court, not with the jury.
THE COURT: That's my --
MR. SNIFFEN: Well, Your Honor --
THE COURT: Go ahead.
MR. SNIFFEN: -- that's a tricky question. We think there's--
THE COURT: That's why I probably -- probably like dawned on me over the weekend and why I'm asking it now.
MR. SNIFFEN: Sure. Well, the rule on penalties is generally Your Honor will have the discretion to decide the amount of the penalty, and that amount is set by statute within a range. Whether or not a specific act is something subject to the penalty is a more amorphous question, that is: Is it up to the judge or the jury to decide what exactly is a violation? And we would take the position that the jury can probably answer some of those things.
In the Nissan case that was tried up here ten years ago, the special verdict form presented to the jury was exactly along those lines. It asked the jury to decide which conduct, was in fact, a violation. So that may

be a way to address that and we can --
THE COURT: Again, I'd like the parties to think about that. The reason it occurred to me is because the civil penalties follow from the State's ability to seek basically to enforce or preclude the behaviors for which the civil penalties are sought and that turns on injunctive relief, which generally is the province of the Court, which might mean that I have to make findings. That's kind of what I'm asking.
And so, that question doesn't need to be answered now, but it certainly needs to be answered by the end of the case, which is why I'm raising it now. So I'd like the parties to think about that and I don't want to say at your leisure, but maybe by -- well, as I understand it, if all goes well, the Plaintiffs are hoping to rest by Monday.
MR. FIBICH: We think we'll be through this week, Your Honor.
THE COURT: And -- so, certainly -- and then how long is the defense likely to be?
MR. LEHNER: Your Honor, we're probably going to be four or five days as well.

And I think we ought to be talking a little bit about the schedule in light of sort of who is coming this week. We began this conversation and we've had some scheduling issues on both sides on how the trial is going to unfold for the remainder of the week, I think is still subject to discussion and if the Court would like to have us --
MR. ALLEN: We should probably go ahead and put Dr. Gueriguian on and discuss it when he's done.
THE COURT: Right. We'll discuss that this afternoon. I'm just trying to figure out. Maybe by -- well, maybe I'll give you a weekend if you need the weekend. So maybe by Monday if I could get everybody's views on who decides what in this case and will I have to make findings along with the jury doing a verdict. It may well be a special verdict and my findings could be informed by that verdict, but I'm not even -- that's way premature, I suppose, for even me to throw that out.
I just want that to be -- I just want everyone to start thinking about that now so we can make a decision before we run up on top of

the jury going out to deliberate. And so we'll take up this afternoon the issue of -- issues that were raised in the letter that the State filed and the response that the -- that Lilly filed to that as well as scheduling issues.
MR. ALLEN: We'd ask that all matters be taken up after Dr. Gueriguian --
THE COURT: We will.
MR. LEHNER: As you recall, Mr. Allen handed you another letter yesterday at noon, again in response to the motion -- our response. We prepared a brief response. We can give you -- it's being filed with two-hole punches, but he raised a couple new issues. But if you'd like a courtesy copy in the meantime, I'm happy to hand it up.
THE COURT: I've got a lot of paper and it's probably best to give me the original filed with two-hole punches.
MR. LEHNER: That's be fine. Let me get it.
THE COURT: And I'm a little worried about the amount of paper I'm trying to deal with and finding things like that.

MR. LEHNER: That's why I raised it.
THE COURT: But I'll take a look at that, too.
Why don't then we -- anything else we need to take up --
MR. FIBICH: Yes, sir. We have some additional exhibits we want to offer into evidence, if I may approach the bench. One of which is 1941.
THE COURT: This is -- you want to offer these with --
MR. FIBICH: Dr. Gueriguian.
THE COURT: Okay.
MR. LEHNER: We had filed an objection to this on the basis of relevance, Your Honor.
MR. FIBICH: It's the No. 6 point, I believe, Your Honor, on the back. It goes to whether or not that constitutes marketing within the label, and the doctor says what about diabetes, the trained response.
THE COURT: This is Exhibit No. 1596?
MR. LEHNER: No, 1941.

THE COURT: 1941? Oh, I see, 1941. I'll overrule the objection and allow the exhibit into evidence.
MR. FIBICH: Your Honor, we're also offering 7971. May I have that one back, Judge, the one you admitted?
Thank you.
THE COURT: 7971? Mr. Fibich, why don't you point me to what the --
MR. FIBICH: We're on 7971.
THE COURT: Yes.
MR. FIBICH: Dealing with the issue of no blood monitoring on multiple places on the second page. Here's a highlighted copy that may help you. And, again, the --
THE COURT: I understand.
MR. LEHNER: Your Honor, our objection again would be on relevance as well as cumulative. There's enough evidence on blood monitoring I think that they've introduced. As well as the fact that this goes particularly to the objection we made about marketing documents that you've heard us on numerous times as being outside the scope of the -- the claims that are now being presented.

THE COURT: Mr. Allen, let -- one --
MR. ALLEN: I'm the one that knows this document.
THE COURT: Okay. I'll overrule the objection and admit 1596.
MR. ALLEN: Your Honor, you called that 1596.
THE COURT: 1596.
MR. LEHNER: Yes, that was 1596.
MR. ALLEN: I have it --
THE COURT: The MDL -- the MDL number is 7971 -- is that -- is that the number? Then it's 7971 that's being admitted.
MR. ALLEN: Yes, sir. Thank you.
MR. LEHNER: Too many numbers on these.
THE COURT: Did you guys want that back?
MR. FIBICH: Your Honor, 3738 -- 3387. I'm sorry.
MR. LEHNER: I think that's one of our exhibits. That's fine.
MR. FIBICH: That's admitted.
MR. LEHNER: That's admitted. No

objection.
THE COURT: I just want to -- Eli Lilly Exhibit 3387 is admitted without objection.
MR. FIBICH: That would be another one. We can just confirm for the record, that's admitted.
MR. LEHNER: Admitted over objections, we previously filed. You've ruled on this one previously.
THE COURT: This is -- what's the exhibit number since it's got -- 9739, Plaintiff's Exhibit. Mark, do we have that as admitted?
MR. FIBICH: That's previously been admitted.
THE COURT: Any objection?
THE CLERK: I've got 9731, not 9739.
THE COURT: I see the stuff about reduce negative impact of diabetes issue on the Zyprexa business so I'll admit 9739.
MR. LEHNER: Your Honor, I think we had previously filed objections to that one so it had been previously admitted over our objections.

THE COURT: Okay. I'm just trying to go off Mr. Borneman's -- you might check with Mr. Borneman sometime in the next day or two to make sure that he agrees with what you think has happened and clear that up.

MR. FIBICH: I think that's 1961, Judge.

THE COURT: 1961. I assume you have the same objection?

MR. LEHNER: Same objection, Your Honor.

THE COURT: I'll overrule the objection and admit 1961.

MR. FIBICH: Thank you, Your Honor. That is all we need this morning.

THE COURT: Why don't we get the jury in.

THE CLERK: We have issues. Another juror called in.

THE COURT: Another juror called in.

THE CLERK: Lynn didn't say which one it was.

THE COURT: I hate to do this to you, but I'm just advised that another juror

called in. I do not know which one, and has advised us that she has bone marrow cancer. And so I'm going to try and see if I can get some information as to who it is and what, but do you want to reconsider whether we're going today given that if we lose that juror and we lose Ms. Shepherd, we're a week into trial and we're down to 12.

MR. FIBICH: Your Honor, we have to go today because Dr. Gueriguian has a wedding, his son's wedding in India.

THE COURT: I understand that and I understand that and if we have to go today, we have to go today. But everyone ought to think about if we lose one more on this basis, we're going to be down to 11 and this case, unless we get some agreements, is going to mistry. I'm not going to decide what the parties are going to do with that, but --

MS. GUSSACK: May we have a minute?

MR. FIBICH: Can we go off the record and discuss this?

THE COURT: Sure.

(Off record.)

THE COURT: Please be seated.

We're back on the record. All members of the jury are present. Good morning, ladies and gentlemen of the jury. And I appreciate you all being here on time. The record should reflect that juror No. 12, Ms. Shepherd, has been excused from the jury due to a health problem.

We will resume with Dr. Gueriguian.

MR. FIBICH: May it please the Court. We'd recall Dr. Gueriguian to the stand.

THE WITNESS: Good morning, Your Honor.

THE COURT: Doctor, you realize that you're under the same oath you took when you began your testimony and are bound by the same obligations of that oath at this time?

THE WITNESS: Yes, I do, Your Honor.

THE COURT: Thank you very much. Please be seated.

MR. FIBICH: May I proceed?

THE COURT: Please, Mr. Fibich.

Q. (BY MR. FIBICH) Dr. Gueriguian, when we broke for the weekend, we were discussing Exhibit 10094. Would you tell the ladies and gentlemen what that exhibit is?

A. It's the post-New York Times response by the FDA to what the article alleged or contained or whatever.

Q. And what drug products does this letter involve?

A. The atypical antipsychotics and, in particular, Zyprexa.

Q. Doctor, you're a little soft-spoken today. If you could speak up or move the microphone.

A. Yes.

Q. You indicated that this was a post-New York Times article. Without going into anything of substance with respect to the New York Times article, why is that article important for the purposes of this letter?

MR. BRENNER: Objection, Your Honor. It's beyond this witness' knowledge and expertise.

THE COURT: If you know.

A. I do, Your Honor.

And the reason is that the FDA -- I only looked at the FDA response to that article and the FDA thinks that that article is important.

Q. (BY MR. FIBICH) Okay. Could you glean from this letter what the importance was as stated by the FDA?
A. Well, the FDA says that Lilly at its invitation, the FDA's invitation, responded to the New York Times and now the FDA letter in this particular one, 10094 exhibit says, Your response, meaning Lilly's response, has not been helpful. And then the FDA goes on to say what would be helpful to it and to the adjudication of the case.
Q. So, if you would, read the last line of the second full paragraph on the second page if you have that in front of you, sir. The second page, the second full paragraph, the last line.
A. Your recent February 20th, 2007 response to our January 12th, 2007 letter regarding the New York Times story has not been particularly helpful in addressing these concerns.
Q. What concerns is it that the FDA has expressed to Eli Lilly and Company?
A. Well, I can give them by number.
No. 1, the FDA has decided that the safety information is not complete.
No. 2, that the justification for

obtaining -- for being reassured on the safety information and its completeness is biased based on the facts, as the FDA, that we have to inform the prescribers about what's happening with the drug, Zyprexa.
No. 3, and that is very clear in the letter, we need, says the FDA, from you, Lilly, all the information from all the clinical trials of any sort, not only with Zyprexa alone, but with Zyprexa plus Symbyax.
Finally, there is another point of information that is important: The FDA is asking Lilly to explain any and all differences that may exist in its label in the United States and in foreign countries. So, as far as I'm concerned, this is the substance of the letter.
Q. And why is it important that physicians have all information that is complete?
A. There is no other way for a given physician treating a given patient to do his or her job properly in the -- and protect the health of his or her patient without having all the proper and important information emphasized in the label in an orderly and comprehensible fashion.

Q. If a label is inaccurate or incomplete, what effect does that have on a patient's ability to make an informed choice as to whether to take a drug?
A. Well, for the same reason then the prescriber does not, in the absence of the proper information make a considered decision, the same thing applies to patients who are prescribed the drug and who, after all, it's their life, they have to make the final decision.
MR. FIBICH: I'd like to publish 10094 to the jury, Your Honor.
THE COURT: 10094 may be published.
MR. FIBICH: If you would put on the screen Exhibit 9739.
Can you blow that up? And if you would, show the title of it, please, first.
Q. (BY MR. FIBICH) Dr. Gueriguian, do you see this document which has been admitted into evidence?
A. Yes, I do.
Q. Entitled "Project Bad"?
A. Yeah, I see that.
Q. And then go down to the -- under the project context. There's an amount that is

budgeted. You see that, sir?
A. Yes, I do see it.
Q. And how much is budgeted for this project?
A. $10 million.
Q. And then go down to "Defining Success." You see that, sir?
A. Yes, I do.
Q. What does it appear that this money is being used for?
A. Well, realize upside --
MR. BRENNER: Objection, Your Honor; speculation.
THE COURT: I'll allow the witness to testify.
A. Well, the Defining Success, the bottom line is precisely the bottom line, accelerate Zyprexa's growth. And then there are subsections of how to accelerate the growth. Realize the up side means realize the good things, realize the efficacy, realize the use of the drug and, of course, these things, in order to improve the bottom line have to be overstated, if that's the case.
Then the second part is to reduce

the negative aspects of what is known, and by what is known, I mean that Eli Lilly had found out that almost 100 percent of physicians were concerned to prescribe Zyprexa because they were concerned with the problem of diabetes mellitus. So, that, you have to understate or minimize in order to improve the bottom line.

Q. Dr. Gueriguian, is the statements here consistent or inconsistent with the requirement of our Food & Drug Administration that drug companies give fair balance when promoting their products?

A. They are inconsistent inasmuch as the DDMAC document that was introduced on last Friday did state very clearly in this particular case the general principles. Fair balance means do not overstate your efficacy and do not minimize your toxicity.

Q. This letter or this memorandum entitled Project Bad is dated 2002. When did the DDMAC first advise Lilly that they were promoting the drug without fair balance?

A. If memory serves, that was pretty soon after the initial approval of the drug, which was sometime in 1996. That's our -- what I remember.

MR. FIBICH: Your Honor, we offer this exhibit or -- may we publish this exhibit to the jury?

THE COURT: You may.

MR. FIBICH: If you would, 7971, please.

Q. (BY MR. FIBICH) Doctor, do you see this document?

A. Yes.

Q. Entitled "A Zyprexa Implementation Guide"?

A. Yes, it is and it concerns the -- it's a primary resource guide.

Q. And if you would, sir, down at the bottom of the first page the highlighted provisions says "Proven Safety"?

A. That's right.

Q. And is there anything in this paragraph which would indicate to you that Eli Lilly is using fair balance in the promotion of their product, Zyprexa?

A. Well, the -- the implication or the implying very strongly that Zyprexa is -- is at a low risk of certain serious medical complications and that the safety is proven by five years of

use and over 5 million patients treated.

Q. Is that statement true?

A. That statement is not true, and, therefore, that statement tends to overstate the safety.

Q. Let's go to the second page, if we could.

Doctor, you see the paragraph that begins "As we know, compliance can be an issue for some patients". You see that?

A. That's correct.

Q. And here the salespeople are being instructed to point out efficacy again?

A. That's true.

Q. What about ease of use?

A. Well, they're saying that one of the major selling, if you will, points of using Zyprexa from the doctors' viewpoint is that no blood monitoring is necessary. And this means that they are not -- implicitly, they're saying there's no blood sugar monitoring -- monitoring necessary.

Q. Doctor, as a physician and as a medical director that has surveyed many products, do you think it's appropriate for a manufacturer of a

product that has a relationship to substantial weight gain, hyperglycemia, diabetes to promote its product by suggesting no blood monitoring as an attribute?

A. With respect, Mr. Fibich, I'm just a medical officer, not a medical director, but to answer your question, no, it's not.

Q. Why not, sir?

A. Because in this particular case, it is the wrong thing to say because you do need blood monitoring from the very beginning for glycemia and other measurements.

Q. Is there any other way to determine whether you're having elevated glucose findings or elevated blood sugars other than to do blood monitoring?

A. Short of somebody going into a diabetic coma or ketoacidosis, no, there isn't. And there are several methods of blood monitoring and they could be used and they should be used.

Q. Is blood monitoring recognized around the world that we live in as an effective way of determining whether there is elevated blood sugars?

A. Yes, the methods are usually largely

available. They require very little implication of the patient. They're not expensive, by and large. So everything is fine. They've been a mainstay of protection of public health for a long, long time.

Q. Is an adverse blood glucose diagnosis something that can be used to prevent hyperglycemia and diabetes?

A. Yes, of course. It's one of the major essential tests. One, I may add, that was introduced by Japan in order to determine whether the patient had diabetes or not, and if he had to contraindicate the use of Zyprexa in such patients.

Q. So, with respect to this guide if I understand what you're saying, is we have a downplaying of the risk of diabetes in taking away the tool for diagnosing hyperglycemia, diabetes; is that correct?

A. Well, it's not downplaying. It's worse, because you are not allowing the prescriber to find out whether there is a risk and that's not downplaying. Downplaying would be, well, do the blood monitoring, but if it's below a certain level, don't worry about it. Here it's saying,

no blood monitoring and the prescriber doesn't know whether the patient that should or shouldn't use Zyprexa is diabetic or not, whether he or she has glucose intolerance and so forth.

MR. FIBICH: If we could go to page 12. Go to 11 first.

Q. (BY MR. FIBICH) Part of the same document, Doctor, is a section entitled Frequently Asked Questions. Do you see that?

A. Yes.

Q. If you would now go to page 12, and one of the questions that's being suggested to the salespeople for Lilly is: Do I need to do any blood monitoring with Zyprexa?

A. That's correct.

Q. And what is the answer that they are telling physicians?

A. No.

Q. You consider that to be appropriate?

A. No.

MR. FIBICH: I'd like to publish this document to the jury, Your Honor. This is 7971.

THE COURT: The document may be published.

MR. FIBICH: Let's pull up 1941.

Q. (BY MR. FIBICH) Doctor, this is another document which the Court has admitted into evidence entitled "Zyprexa Frequent Areas of Concern" or FAOC. You see that, sir?

A. I do.

Q. And these are potential questions that salespeople are being advised that may be asked of them?

A. Yes.

Q. If you would, sir, turn to No. 6, and the question is: I am concerned about diabetes, and the response is their cushion, thank you for sharing this concern with me. Then the salesperson is ordered or suggested to clarify, is this something you have seen or heard about? And then the address the area of concern. You see that, sir?

A. I do.

Q. Would you read that proposed answer to physicians who indicate they are concerned about diabetes?

A. In every study examining the subject, no causal relationship has been established between patients being treated with Zyprexa and the onset

of diabetes. The incidence of diagnosed treatment-emergent diabetes with patients taking Zyprexa was comparable to those patients treated with Risperdal, Haldol and Depakote in every clinical study conducted by Lilly or by our competitors.

Q. Go ahead.

A. These facts suggest that you should choose a medication based on its efficacy in treating complicated mood symptoms, but to be aware of the incidence of diabetes in this population and address it appropriately.

Q. You -- and I think you left off the first sentence which says: The incidence of diabetes is two to four times more common in mentally ill patients than in the general population.

My question to you, sir, is this fair balance in this product?

A. No.

Q. Your Honor, we'd like to publish.

THE COURT: 1941.

MR. FIBICH: And then the end of that it says get back to selling. At the end of that suggestion, after the salesperson makes this

response, it says, get back to selling. You see that?
A. Yes, I remember that. It caught my attention that sentence. It says, Good luck and good sell.
MR. FIBICH: Let's put 3387 up.
We have that in the database?
Can you block the screen?
Q. (BY MR. FIBICH) Dr. Gueriguian, you have the document there in front of you?
A. I do.
Q. Do you see this is a Hyperglycemia and Diabetes Data on Demand Resource Guide?
A. It is.
Q. If you would, sir, turn over to the -- page 5. Do you see this, sir?
A. I do.
Q. And we go through an introduction dealing with the sales sheet for objections regarding data messages from Janssen and Pfizer. And, Doctor, as represented to this jury in opening statement, that this document was used to get salespeople to probe doctors about the issue of diabetes. And I want you to read this paragraph that I'm highlighting here on the right

side of the page.
A. Yes, it goes, quote, Active probing is an effective strategy to employ as you prepare to implement the new hyperglycemia/diabetes pieces.
Q. Does it indicate to you that they are actually probing doctors so that they know about diabetes, or are they trying to suggest something else?
A. Well, first of all, it is probing since the paragraph, the preceding paragraph in that same column says that in April, 2001 the number of physicians who believe that there was a link between Zyprexa and hyperglycemia/diabetes has increased to 100 percent of physicians, so the probing was successful in determining what was the problem.
Q. Well, what I'm referring to, sir, is down at the same paragraph where it says, We now have substantial new data. It shows the same conclusion, comparable rates of hyperglycemia and diabetes. Do you see that?
A. Yes, I do.
Q. Is comparable rates an appropriate message to give if one is probing for diabetes and hyperglycemia?

A. No.
Q. Your answer's no?
A. Yes, it's "no."
Q. I want to go to the next page where it talks about the relationship of diabetes and how that's perceived by psychiatrists. Diabetes is scary for most psychiatrists, in part, because they do not deal with it on a daily basis and therefore fear the unknown. Risk factors, diagnostic criteria, and treatment standards are not fresh in psychiatrists' minds, and they are fearful of causing a disease that can lead to permanent physical complications.
These doctors have dealt regularly with potentially severe side effects such as tardive dyskinesia for many years. However, diabetes and hyperglycemia as a side-effect risk are relatively new on the horizon. Because of this, psychiatrists are generally less comfortable diagnosing and treating these conditions and are actively looking for more information. You are in a position to provide it to them. In recent market research, most physicians admitted they have seen no really credible data on hyperglycemia or diabetes. The

good news is that you do have data from credible large-scale studies to support the comparable rates message.
Do you see that, sir?
A. Yes.
Q. So, whereas doctors may have some knowledge about the relationship as referenced in the earlier paragraph, this would suggest that they really don't know much about that; is that correct?
MR. BRENNER: Objection, Your Honor. Leading and as we commented earlier, he's not qualified in psychiatry.
THE COURT: I'm going to sustain that objection.
Q. (BY MR. FIBICH) Let's go back to the top. If you would, read the sentence starting with "It is imperative."
MR. ALLEN: You need to put it on the screen, Tommy.
Q. (BY MR. FIBICH) Do you see that, Doctor?
A. Which part are you indicating, please?
Q. The highlighted part, middle of the sentence, where, "It is imperative that

physicians believe."
A. Yes, the document states that, It is imperative that physicians believe that Lilly is adequately addressing their concerns and that they internalize the comparable rates message.
Q. If you would keep reading, sir.
A. This strategy -- this strategy presents a great opportunity for you. Neutralizing the hyperglycemia issue with just a few key customers could result in a dramatic growth in prescriptions, and ultimately big premier rewards for you.
Q. Sir, is it ever appropriate for a drug company to neutralize an adverse event?
A. I think they're trying to neutralize the perception of -- the possible adverse events, and to answer your question, it's improper.
Q. You indicated in reading this that there's big premier rewards if the hyperglycemic issue is neutralized.
Do you see that, sir?
A. I do.
Q. Do you feel that that is appropriate for a drug company that has an issue with a side effect of its drug to be offering that kind of a

stimulus?
THE COURT: Just one second.
MR. BRENNER: Objection, Your Honor; that's a personal opinion, and not within the qualification that this witness has been offered for.
THE COURT: I'll overrule the objection.
A. Well, to be very direct, the FDA doesn't want anyone to be rewarded in a research of saying something that is not true. Those are FDA rules. We are interested in knowing this. DDMAC is interested in knowing such things. This is totally inappropriate.
Q. (BY MR. FIBICH) Sir, I want to go to page 7 of the same document. It says: What do we mean by neutralizing physicians' concerns about hyperglycemia and how do we go about this? By neutralizing we mean leveling the playing field, setting the record straight with the comparable rates message. In order to be successful, we must do the following.
Again, do you feel that that's appropriate for a drug company to be suggesting a neutralization of the issue of hyperglycemia,

weight gain and diabetes?
A. If it addresses a concern with proper tools and data, then there's nothing wrong with it. If, on the other hand, it is neutralizing a perfectly legitimate perception by physicians who were never given any indication by Lilly that the drug could cause diabetes, then it's totally inappropriate.
MR. FIBICH: Your Honor, at this time, we will pass Dr. Gueriguian.
CROSS-EXAMINATION
Q. (BY MR. BRENNER) Good morning, Doctor.
A. Good morning, sir.
Q. Doctor, you own or run a company called PharmaGenesis; is that right?
A. Yes.
Q. And that's a business you run out of your home?
A. Yes.
Q. And would you agree, sir, that the business of PharmaGenesis consists of you supplying experts to clients when clients seek you out for the purpose of finding an expert?
A. That's only one of the purposes, but that is true.

Q. And is it true, sir, that in some years about two-thirds of the income of PharmaGenesis has come from your testifying on behalf of Plaintiffs' lawyers in pharmaceutical cases?
A. Yes, and I have always been open to any client as long as they accept my rule that I'll say things as I see them. And I haven't had too many defendants asking for my expertise.
Q. And I know Mr. Fibich asked you whether you were being paid for your time here today, and these days. How much are you charging for your time?
A. $6 -- $600 per hour.
Q. And could you tell us how many hours you've devoted to this case so far?
A. No, I can't. I have to look at my records.
Q. I think at your report, at the time of your report, you said you had put 60 hours in; is that right?
A. Sixty hours? I think it was 63, but I may be wrong. 63 hours at that time, and I don't recall when that invoice was sent. And there's been more since.
Q. And how much more? Ten hours, 20?

A. I haven't done the computation yet because I sell -- send my bill once a project is finished or part of it is finished.
Q. And you've testified many times in court, haven't you, Doctor?
A. Yes.
Q. And you've given many depositions, sir?
A. Yes.
Q. Now, Doctor, over the course of this morning and Friday you've talked about a number of different documents, some of them internal Lilly documents, correct?
A. Yes.
Q. I take it you never saw those documents before the State's attorneys shared them with you, did you?
A. I don't know who showed them to me, except to say that the clients that retained me, which are Mssrs. Allen, Suggs and Fibich are the ones who transmitted these documents to me. That's the totality of my knowledge.
Q. Sure. And some of them you've commented on and interpreted some of them in terms of what Lilly people said or meant or were thinking; correct?

A. No, I interpret things, sir. I base my conclusions on factual statements.
Q. And then you share your impressions with the jury?
A. I don't share impressions. I share facts. I analyze them; I arrive at a conclusion and I defend my conclusion. I don't deal with anything.
Q. With respect to e-mails, you haven't spoken to the people who authored or responded to those e-mails, have you?
A. I didn't need to, and I haven't.
Q. And Doctor, do you have a sense of how many millions of pages of documents the State's attorneys have had access to in connection with this litigation?
A. Sir, you're talking to an ex-FDA medical officer who has had tons of documents piled up on his head. Yes, I do realize very well and I do realize that nobody can read all that and survive.
Q. And the ones that you shared with the jury over the last two days were the ones that the State's attorneys asked you to talk to them about, right?

A. No. The State attorney, as I told you, I don't know what was his or her role. I know only my clients and it's through them that I have been given a number of documents and I was told -- I told them when they asked me if I was interested in helping them, that I would do so only if they would accept my conclusions right or wrong, the conclusions that I arrived at.
Q. Yes, sir, and the documents that you've been talking about over the last two days, were those that you selected or did the attorneys here today select them for you?
A. Both. Theirs were documents -- you have to understand, Counselor, that an expert consultant is not a -- is not an adversarial individual. He's an expert and he has to be or she has to be objective. And when I received documents from the clients, I spend a sizeable amount of my time of searching documents on my own for the purpose of being objective. Because if you want to be objective, you have to analyze both sides of the question before you decide who's right and who's wrong. That answers your question, I believe.
Q. Were there documents, Doctor, that

you've looked at in preparing for your appearance here today that you didn't talk to the jury about?
A. I can't recall. There were an awful lot of documents that I looked for by myself. I chose a number of them for their pertinence, but I certainly cannot recall which ones were not retained and which ones were utilized, but I have -- I have extracted from the ones that were important on either side of the case in my notes, and moved on from there.
Q. Yes, sir. But when you say from either side of the case, you didn't ask for any documents from my client, you didn't make any request for documents from my client, did you?
A. No. When I say either side of the case, I mean scientifically. That is to say, you find out in the literature, for example, opinions that are agreeing with one side and disagreeing with the other or vice versa. And, again, this is important for anybody who portends to be objective.
Q. And you've made a literature search in connection with forming your opinions in this case?

A. Yes.
Q. You found, I believe, four pieces of medical literature you felt were important?
A. You must be kidding. I found many, many more.
Q. Doctor, you wrote a report in this case, didn't you?
A. Yes.
Q. And you understand the purpose for writing a report as an expert witness is to give the other side, my client, a fair opportunity to understand your opinions and their bases; is that correct?
A. Yes.
MR. BRENNER: May I have 10131 brought up, please.
Q. Doctor, that's the cover page of the report you issued in the Zyprexa litigation, isn't it?
A. That is correct.
Q. And could I see page 10, Mike -- could you find Exhibit B for me.
Yeah. Doctor, these were the four pieces of medical literature you felt were important and that you've said in your report you

had reviewed?
A. Yes. And this is exactly what I'm talking about. These are the important parts. You asked me the question, how many have you reviewed? I said I have looked at and reviewed many. But I'm not going to put everything here. What I considered unimportant was eliminated offhand, scientifically unimportant, uncontributory. What I put aside as important was a longer list, but I had to boil down to the more important issues. But I did review many more than these, namely these four, namely other things that I have looked at, namely other literature that I found to be of some importance. And, also, mainly an awful lot of things that I found to be noncontributory and not helpful.
Q. But the four pieces of medical literature you thought were the most important, worthy of including in your report, were these four?
A. I didn't say most important.
Q. You've selected these four to include in your report, right, Doctor?
A. Yes, Counselor, but you do know that selection is according to different criteria.

MR. BRENNER: I understand that.
THE WITNESS: The selection that I've used here is its contribution to clarify the scientific matters. It has less to do with importance because if they are important only from that point of view. But I can cite you, if you are interested, a much more important article that I have seen.
Q. (BY MR. BRENNER) Well, I would rather you've done that in the report when we had the opportunity to take your deposition on it.
A. Whatever you want, Counselor.
Q. We'll get to that, Doctor.
Doctor, in your report you wrote that Zyprexa has been approved by the FDA for schizophrenia, right?
A. Well, I didn't report that. I just took that as a fact.
Q. Right. And it had been approved by the FDA for acute mania and bipolar disorder?
A. Bipolar disorder, it wasn't for all indications of bipolar disorder, if my memory serves.
MR. BRENNER: Why don't we -- let's

have page 10 of 10131. If we could blow up that bottom paragraph.
Q. (BY MR. BRENNER) This is your writing about your olanzapine overview, right, Doctor?
A. That it is, and it's simply an overview.
Q. Okay. And what you said in your report was olanzapine, that's Zyprexa, of course, has been approved by FDA for the treatment of schizophrenia, correct?
A. Yes.
Q. Acute mania and bipolar disorder, correct?
A. Yes.
Q. Agitation associated with schizophrenia and bipolar disorder, correct?
A. Yes.
Q. And as maintenance treatment in bipolar disorder, correct?
A. Yes. These approvals were done at different points in time, not necessarily as a one-time deal.
Q. It's also true, though, Doctor, that at one time Zyprexa had been approved by the FDA for management of the manifestations of psychotic disorder; isn't that correct?

A. It may be, sir, but an overview is not something that is supposed to be comprehensive, exhaustive and ultimately boring and missing the point of an overview.

MR. BRENNER: Could I have EL2954A, please. Let's just blow up that first page a little bit, Mike. Just scroll down to the bottom.

Q. (BY MR. BRENNER) Doctor, this is the 1996 FDA-approved package insert for Zyprexa, correct?

A. Yes.

Q. Could we go to page 4, please? The Indication section, Mike, the very first sentence.

Doctor, am I reading it correctly that as of this time, the FDA had approved Zyprexa for the management of the manifestations of psychotic disorders?

A. Yes, you're correctly reading.

Q. Thank you.

MR. BRENNER: We can take that down.

Q. (BY MR. BRENNER) Doctor, you've expressed the opinion here that Zyprexa causes

diabetes; is that correct?

A. Yes, and I'm not the only one to express that opinion. The Japanese regulatory authorities share that opinion.

Q. Thank you. And is it also your opinion that Zyprexa causes diabetes at a rate higher than other atypical antipsychotics?

A. It is my opinion that treatment-emergent hyperglycemia dash diabetes have been shown to my satisfaction that they are much more frequent for olanzapine/Zyprexa as compared to other antipsychotics, namely first-generation, such as haloperidol, and second-generation typical or atypical, exception for clozapine, which is the worst offender in that category.

Q. Did you review any of the clinical data for any of the second-generation antipsychotics such as Geodon or Seroquel or Risperdal?

A. I have reviewed the Lilly documents where such comparisons were made from -- from around 1995 when the NDA was sent to the FDA and already at that point, the difference between Zyprexa and, for example, haloperidol or placebo or other atypicals was there was a strong signal that olanzapine was worse except, again, for

clozapine. And it had gotten over the years the -- the evidence was -- was -- got clearer and clearer that this was so -- Lilly was given time and time again notice by very respectful scientists with studies of their own that this was the case. In fact, all the Lilly documents say that at the end of the day most prescribers knew -- it wasn't most prescribers, let me correct that; 100 percent of the prescribers were worried that there was a link between the Zyprexa and diabetes. So it is the cumulative evidence that counts and not an individual piece of evidence.

Q. Let me try again, Doctor: Have you reviewed the clinical data for Risperdal?

A. I seem to remember I did, but I can't remember what it is right here today.

Q. Do you have access to Janssen's clinical data?

A. Why should I have access to Janssen's clinical data? Don't you know that there are publications in the public domain who refer to studies with Risperdal?

Q. Did you review all those, sir?

A. I cannot recall which one I reviewed. I

know I have evidence to that effect.

Q. Have you reviewed the clinical data for Geodon?

A. No, not that I remember.

Q. Have you reviewed the clinical data for Seroquel?

A. What was that again?

Q. What have you reviewed the clinical data for Seroquel?

A. Quetiapine?

Q. Yes. Quetiapine.

A. Not that I remember.

Q. Have you read the clinical data for Abilify?

A. Well, if you're asking me if I had the insights or access to confidential files at the FDA for these drugs, I couldn't review them because I couldn't have access to them, so I wonder why you're asking the question?

Q. Nevertheless, though, sir, I gather you didn't and you're confident though that you can make comparisons between Lilly's clinical data and the clinical data of all these companies that you've never seen?

A. As I said, on the basis of the

cumulative evidence that I was privy to, there is no doubt in my mind that this was the case. And since I couldn't have access to the rest, I certainly couldn't be expected to have read it for whatever reason and nevertheless --

Q. Would you agree with me, Doctor, that there are hundreds of published papers addressing the risks and benefits of atypical antipsychotics?

A. I suspect that perhaps there were more than that.

Q. Do you know Dr. Brancati who was here last week?

A. I know of him. I don't know him personally.

Q. Dr. Brancati said he had reviewed over 100 papers to make his opinions in this case. Have you reviewed over 100 papers to reach your opinion?

A. I don't see what that has got to do with it. I don't remember the number of papers I reviewed. I reviewed sufficient papers on both sides of the question to arrive at a good and solid and objective opinion.

Q. And when you say on both sides of the

question, does that mean that you reviewed medical literature that did not support or took a position contrary to yours?

A. I reviewed two types of documents. I reviewed Lilly-originated documents who maintained that point of view. And I reviewed some other piece of evidence where the -- to be -- to be precise, the issue was sometimes not addressed satisfactorily to the satisfaction of the author of the publication, that is, and that is very understandable because not all studies have sufficient power to arrive at a conclusive evidence in and by themselves, particularly in this case since Lilly didn't do the proper studies.

Q. When you say -- you say Lilly -- you mentioned that the other day, but you also told me you didn't read the entire NDA for Zyprexa, have you?

A. Sir, the medical officer in charge, I can assure you, in charge of Zyprexa didn't read all the NDA.

Q. Thank you. That's not my question.

Did you read the entire NDA?

A. If they didn't read it, how could I read

it since I didn't have access to it on top of it?

Q. So I guess the answer is, no, you haven't read the entire NDA?

A. You got it.

Q. Okay. But nevertheless you're confident in knowing all the clinical trials Lilly performed?

A. I didn't say that. I said that with the information that was supplied to me, which contained an awful lot of Lilly documents, there are two things that were apparent to me. One, that within those documents, in my opinion, as an ex-medical officer, Lilly didn't do proper studies.

The second side of the document is that they do state themselves in internal as well as external documents that there's no difference between placebo and Zyprexa, for example, in terms of their diabetic-inducing toxicity. And that is an opinion that I looked at because it's the other side of the story, and the right side of the story is that nobody really of any competence agrees with that statement. That's how an objective person goes around.

Q. Do you know how many clinical trials

Lilly has conducted on Zyprexa, Doctor?

A. I'm sure a great many.

Q. Yes, sir. You told us you haven't reviewed all of them; correct?

A. I don't need to review all of them, therefore, I did not review all of them.

Q. Having not been able to review all of them, you nevertheless feel able to say that the studies Lilly conducted were inadequate?

A. I'll explain it to you, and I'll be happy to explain it once more. If in its public document which is its labeling, for example, Lilly says that in a head-to-head comparison of Zyprexa against placebo, there is no sign of hyperglycemic or diabetic complications excess frequency, and I know that that is wrong statement on the basis of the available evidence. Why do you want me to go and lose my time and my client's money and the jury's time and the Court's time to go on a wild goose chase? I have obtained my goal. They're saying something that is proven wrong by everyone who knows anything about the subject.

MR. BRENNER: Can I have TG115? We'll talk a little bit more about the

literature, Doctor.
Q. (BY MR. BRENNER) Do you know if you read Dr. Barner's article on Diabetes Mellitus and Antipsychotic Drugs?
A. I don't remember this article.
Q. Did you read Dr. Cavazzoni and others' articles on Risk Factors in Patients with Treatment-Emergent Diabetes During Trials in Antipsychotic Medications?
A. I may have. I don't remember.
Q. How about Dr. Cohen and his colleagues, Prevalence of Diabetes Mellitus in Chronic Schizophrenic Inpatients in Relation to Long-term Antipsychotic Treatment?
A. No, but I have others -- I've read other articles that address this issue very appropriately.
Q. Next one. Dr. Hardy's article specifically about Zyprexa. Did you read that?
A. Well, it's an abstract and I don't remember reading it, but I read other articles in the same journal on schizophrenic research.
Q. Let's see if any of them are on the list. Did you read Dr. Henderson and colleagues' article?

A. I don't remember. I may have.
Q. Next one. How about Dr. Leslie and Dr. Rosenheck? Their article about diabetes attributable --
A. I would imagine, sir, without further ado that if you choose any number of articles in the literature, which contains tens of thousands of articles for the few ten years, most of them I haven't read.
Q. How about Dr. Lindenmayer's article on Changes in Glucose and Cholesterol Levels in Patients With Typicals and Atypicals?
A. I don't remember reading it. I may have, but I don't remember.
Q. Take that back.
Doctor, for doctors and scientists the word "cause" has a very specific meaning, doesn't it?
A. Yes. And that meaning is defined by pharmacology, which is my discipline, one of my areas of expertise.
Q. And doctors and scientists differentiate cause from association, do they not?
A. Well, epidemiologists do that, yes. It's not association; it's correlation.

Q. Sometimes that's referred to as association, though?
A. Sometimes it's referred as any way people want to refer it. It's a free country.
Q. Dr. Brancati, when he was here with us last week, he told the jury that association does not necessarily mean causation. Do you agree with that statement?
A. Well, in absolute terms he may or may not be right, but generally speaking, this is the -- what people -- experts think on the subject.
Q. And I think Dr. Brancati gave the jury an example of gray hair being associated -- being associated with an increased risk of stroke or cardiovascular disease; but that that would not be a causal connection, rather it would be an association? Is that a fair assessment?
A. I don't know. I wasn't here when the doctor -- the good doctor made that statement. I assume that he's saying that perhaps. Now I'm speculating -- that --
Q. Well, he -- I'm sorry. I didn't mean to interrupt.
A. That's all right. That white hair

causes -- means old age and it's old age does -- maybe that makes sense.
Q. Would you agree Dr. Brancati's example is a fair, good example of the difference between causation and correlation or association?
A. There are many examples to prove -- I mean to illustrate that point, and not knowing exactly what the good doctor meant, I cannot offer an honest and objective opinion.
Q. It is well known, though, Doctor, isn't it, that association does not necessarily imply causation?
A. You mean the correlation doesn't imply necessarily causation?
Q. Sure. That's well known?
A. Well, that's what people say. And -- which is one way of saying, if you have a drug, you'd better do the studies that try to establish the existence or nonexistence of causality.
Q. Doctor, it's not just people who say that association doesn't imply causation; it's doctors and epidemiologists?
A. They are people, you know.
Q. They are. That class of people, epidemiologists --

A. I'm not class conscious, sir.
Q. I'm pleased for that, sir.
Isn't it true, Doctor, that scientists, epidemiologists, physicians agree that association does not necessarily imply causation?
A. Yes, they do say that correlation does not imply causality, but that means that the person in charge of a drug when the signals are there, has the duty and the mandate to perform those studies that will show whether there's causality or not, and as a pharmacologist, I can tell you how this could be done.
Q. Doctor, doctors and scientists sometimes identify risk factors for disease, don't they?
A. Yes, and risk factors can be dependent or independent.
Q. Meaning they may or may not be directly causal or causal at all of the disease?
A. No, it means that they may either be a risk by adding something to another risk or have an independent by themselves being a risk. For example, a very high triglycerides are an independent risk for cardiovascular disease and if you had only -- just to illustrate what I'm

saying, the meaning of what I'm saying, if you had only very high tryglycerides, you stand at a higher risk of cardiovascular disease.
Q. But because a person has a risk factor for a disease, it doesn't mean that person will get the disease, does it?
A. The pharmacologists and the drug companies and the FDA do not deal with persons; they deal with statistics and epidemiological data. And what you can say is that in the general population, a drug will affect some patients and those patients cannot necessarily be identified as having had that risk and having gotten the toxicity -- the toxic effect of the drug.
Q. I'm not now limiting my question to drugs, Doctor. Because a person has a risk factor for a disease, it doesn't mean that person necessarily will get the disease, does it?
A. But the population -- within the population, a certain number of people will. Sir, what you're saying is correct, but it's not the whole truth.
Q. There are many risk factors for diabetes, aren't there?

A. One of them is life, yes.
Q. And one of them is elevated blood glucose levels, right?
A. One of the things.
Q. By the way, Doctor, you can have an elevated blood glucose level and not be diabetic, correct?
A. Well, in order to ascertain that, you have to make a proper glucose test, blood glucose test or glucose-intolerance test, yes.
Q. And sometimes people are called prediabetic?
A. That's when they are in between the two, and that can be determined by the performance of glucose tolerance test.
Q. When Dr. Brancati was here with us last week, he testified that many prediabetics don't go on to develop diabetes mellitus; is that a correct statement?
A. Seems to be a correct statement, yes.
Q. Doctor, age is a risk factor for developing diabetes. I think that's what you meant when you said, life is a risk factor for it, right?
A. That's true.

Q. But of course not everyone gets diabetes as they age?
A. Well, according to Lilly's statements there is an awful lot of people having diabetes so I assume that it's a very great risk.
Q. We know there's an epidemic of diabetes in the United States, isn't there?
A. Well, I wouldn't -- use Madison Avenue words. There is a concern, area of concern and an important concern, but let's forget the epidemic story.
Q. There's been an increasing rate and incidence of diabetes within the United States within the last 10 or 20 years, has there not?
A. Well, maybe, maybe not. There are two ways of explaining that. Either the methods of diagnosing and the desire of the population to be diagnosed is a reason. It may be a major reason. Now, on the other hand, yes, weight gain has been going up over the last several decades, and weight gain has a very strong association with diabetes. Most of the type 2 diabetic patients are elderly, overweight individuals. So, you're right.
Q. But just to be clear, Doctor, not

everyone gets diabetes as they age?
A. More and more people who have a risk factor get diabetes on a frequency scale, but not everyone gets it, which is not a reason to say since everyone is not going to get it, I'm going to prescribe a drug that is toxic and may lead to diabetes.
Q. And as you just told us, of course, being overweight is a risk factor for diabetes?
A. Yes, weight gain is an important reason for being overweight and this fact was denied by Lilly.
Q. And the -- overweight being a risk factor for diabetes, that's been known by physicians for a very long time, hasn't it?
A. Yes, but not if you tell them what you should have told them that in this particular case the drug was causing above and beyond the risk of normal weight gain.
Q. Doctor, when you were in training as a medical student, did you understand that being overweight was a risk for developing diabetes?
A. No, I was in France and we were all lean and beautiful.
Q. You never learned that in your training?

A. Yes, I did.
Q. Okay, you did learn that. And of course, that's for 20 years or more, physicians have been telling us to watch our weight, in part, because it's a risk factor for diabetes, correct?
A. That risk factor is increased that a certain drug may be increasing that risk factor, for the same amount of weight gain you have a greater frequency of having diabetes.
Q. Being physically inactive is a risk factor for diabetes?
A. Well, inasmuch as it may be related -- sedentary habits are risky for any number of health issues.
Q. And having a first-degree relative is a risk factor for developing that disease?
A. That depends. The issue of the problem of genetics of diabetes is very much in the air and I would not as a prudent expert hazard to toss my hat in either side of the debate.
Q. Doctor, do you remember you give a deposition in this case, Zyprexa litigation in April, 2007?
A. Yes.

Q. And the deposition is a proceeding where you're put under oath and you answer questions before a court reporter; correct?
A. That's right.
MR. BRENNER: May I have the April, 2007 deposition blown -- just blow up that front page for a moment.
Q. (BY MR. BRENNER) Doctor, this is going to be a portion of your deposition that was taken in connection with Zyprexa litigation taken in Philadelphia back in April.
MR. BRENNER: May I have page 67, Mike? Bring up lines 8 through 10, I think.
Q. (BY MR. BRENNER) Here, Doctor, you were asked the following question and gave the following answer. Okay. First-degree relative with diabetes would be a risk factor. And your answer was, yes, that's what the experts believe. That was your answer, correct?
A. That's correct.
MR. BRENNER: Okay. Thank you. Take that down.
Q. (BY MR. BRENNER) Doctor, it's not possible based on risk factors alone to determine whether someone is ultimately going to develop

diabetes, is it?
A. Are you talking or are you referring to a specific case causality?
Q. Yes.
A. Well, I'm not here to address a specific case, so I would say that in order to answer your -- first of all, forgive me, I don't understand the question quite. Would you be kind enough to repeat it?
Q. Certainly. It's not possible based on a number of risk factors alone to determine whether someone is ultimately going to develop diabetes, is it?
A. Well, in general, diabetes or in drug-related diabetes questions?
Q. I'm talking about general issue or principle of risk factors and their ability to predict causation in an individual.
A. You have to satisfy me with answering my request --
THE COURT: No, he doesn't, Doctor. You need to answer his questions and all he's asking you is, if somebody has five risk factors for diabetes, you can't look at this person and say he's going to get diabetes or she's going to

get diabetes; maybe they will and maybe they won't.
THE WITNESS: Thank you, Your Honor. You're right.
THE COURT: Is that correct?
THE WITNESS: Yes.
Q. (BY MR. BRENNER) In fact, somebody could have no known risk factors and not have diabetes, right?
A. I haven't seen a case like that, but it's possible, especially type 1.
Q. What causes type 2 diabetes is not entirely known to medical scientists, is it?
A. That's what I was alluding to when you asked the question about genetics of diabetes.
Q. So I am correct. What causes type 2 is not known.
A. Well -- what causes diabetes. You're right, probably.
Q. Doctor, last week Dr. Brancati told us that the best evidence, the best scientific evidence to determine causation typically comes from long-term clinical trials. Would you agree with that statement?
A. I don't know what Dr. Brancati was

talking about, therefore, I cannot offer a considered opinion.
Q. Does the best evidence on causation typically come from long-term clinical trials?
A. I don't know. I have seen -- would you please repeat that?
Q. Sure. Does the best evidence on determining a causal relationship between a substance, an event and the result come from long-term clinical trials, typically?
A. It may, in most cases. Some cases, no.
MR. BRENNER: Would you put up TG148, please. Could you blow up that first -- could we blow up that first part of it. The abstract and the title, Mike?
Q. (BY MR. BRENNER) Doctor, this was one of those papers that I put up on a slide a few moments ago. I think it's one you told me you do not recall reading. Do you recall reading this article -- this paper by Dr. Barner?
A. I think you're right in that I said I don't recall reading.
Q. And the title of this is obviously "Frequency of New Onset Diabetes Mellitus and Use of Antipsychotic Drugs Among Central Texas

Veterans," correct?
A. Yes.
Q. And if we look at -- the first part is Study Objectives. That's where the authors lay out what it is they sought to study in their research typically?
A. Yes, that clearly specifies the question -- the scientific question that they're going to address by a yes or no answer.
Q. And the study objective for Dr. Barner and his colleagues was to determine whether the frequency of new onset diabetes mellitus differs between patients taking atypical antipsychotic agents and those taking typical agents, correct?
A. That's what it says.
Q. And whether the frequency of new onset diabetes differs among those taking the atypical antipsychotics, right?
A. Yes, that's what it says.
MR. BRENNER: Now, Mike, if you could scroll down a little bit to the conclusions.
Q. (BY MR. BRENNER) Am I correct, Doctor, that Dr. Barner and his colleagues found that among veterans taking antipsychotic agents, no

difference was noted in the frequency of diabetes between patients who took typical agents and those who took atypical agents, right?
A. That's what it says, and this is what the experts call a negative study. And the negative study is not as important as a positive finding for the following reason.
The negative study implies two different things: Either there's not enough statistical power to see something that exists or that there's enough power to observe that, indeed, something does not exist. Negative study.
In this particular case, we're talking about diabetes mellitus caused by -- that was the end point, diabetes mellitus. And diabetes mellitus is in a large population not a frequent event. Therefore, not knowing the detail of this study, I cannot tell whether they had enough statistical power or not.
On the other hand, I have to address the issue, it's only fair, and I have made -- I have told about a study which, to my satisfaction, showed a positive finding and that was enough for me because a positive finding for

any referee of a publication -- a medical journal, a positive finding is much more important, more credible than a negative finding.

MR. BRENNER: Can I go to page 5, Mike. And on the right-hand -- blow up the right-hand column -- no, the other one. And the sentence --

Q. (BY MR. BRENNER) Doctor, the fourth line says -- the chi square results show there was no significant difference in frequency of new onset diabetes among the atypical agents. Was that the finding of these researchers?

A. Yes, and again, that's a negative finding, and what I said on negative finding applies perfectly. I'm not surprised.

MR. BRENNER: And if we could go, Mike, to page 9, the Conclusion section.

Q. (BY MR. BRENNER) Again, Doctor, in the second sentence, these authors reported that they found no significant difference in the frequency of new onset diabetes between patients taking typical agents and those taking atypical antipsychotic agents or among those taking atypical antipsychotic agents, right?

A. That's correct.

Q. And further on, in the next sentence they found no significant differences noted among the antipsychotics, right?

A. Yes.

Q. And finally, the last sentence was: Nevertheless, patients who are taking antipsychotic agents and have diabetes or are at risk for diabetes should be monitored for any adverse effects related to diabetes, right?

A. Yes, that's what they say and that's very good advice.

Q. Yes. And that was out in the medical literature, correct?

A. Yes.

Q. Sure. Doctor, one other question on this. If they found -- in this study these researchers found no differences in treatment-emergent or new onset diabetes among the atypical antipsychotics, that would be a comparable rate, wouldn't it? No differences?

A. Of course not. Comparable rate means that the -- the statement can be conclusively proven to be correct. As I told you, a negative finding is not conclusive. And as I told you, I have a positive finding that says exactly the

opposite.

Q. And what was the name of that positive finding study again?

A. De Hertel. D-e space H-e-r-t-e-l in Schizophrenic Research.

MR. BRENNER: May we approach for a moment, Your Honor?

THE COURT: You may.

(Bench discussion.)

MR. BRENNER: Your Honor, I believe the study is a recent study and not available at the time he was deposed to provide in his report, and I don't want him to talk about that --

THE COURT: Don't ask questions --

MR. FIBICH: Your Honor, he's opened the door on it, Judge.

THE COURT: I don't think so. I mean, this witness -- I haven't heard an objection, but if he doesn't -- if he wants to get out of here tonight instead of on Thursday, this witness is going to have to start answering the questions he's actually asking him instead of throwing in all the extra stuff that isn't really responsive to the questions.

MR. FIBICH: When are we going to

take a break?

THE COURT: When we take a break -- we'll probably take a break in about ten minutes. I'm just concerned that the longer he goes on with this, we're just going to be here, because there are a lot of easy questions.

MR. FIBICH: How long can we go today?

THE COURT: I'm trying to remember what the -- I think her doctor's appointment is tomorrow, not today, Ms. Mitchell.

MR. FIBICH: We want to get through -- I'll deal with that.

THE COURT: I want to get the jurors' questions, too.

MR. FIBICH: I understand.

MR. BRENNER: Thank you, Your Honor.

(End of bench discussion.)

MR. BRENNER: Mike, could I have EL3267, if we could show the title for that.

Q. (BY MR. BRENNER) Doctor, I put up in front of you a study titled A Retrospective Cohort Study of Diabetes Mellitus and Antipsychotic Treatment in the United States.

You see that, sir?
A. Yes, I see. And I see that it's a joint research between my UNC where I was a faculty and Eli Lilly.
Q. And that's Dr. Buse is from UNC?
A. I beg your pardon?
Q. Dr. Buse, the lead author, he's from UNC?
A. Well, I'll take your word for it. Probably.
Q. Dr. Buse, in fact, he is either the immediate past president or about to be the president of the American Diabetes Association?
A. I just attend some of their meetings. I'm not interested in the internal politics.
Q. So you don't know Dr. Buse's reputation in the world of diabetes, I take it?
A. Well, as a matter of fact, you're right.
MR. BRENNER: Could I show -- could I show the introduction, please.
Q. (BY MR. BRENNER) Doctor, the first thing these authors note is that studies over several decades have suggested that diabetes mellitus, impaired glucose tolerance and insulin resistance are more common in patients with

psychiatric disorders, including major mood disorders and schizophrenia.
Do you see that?
A. Yes, I do.
Q. And that's a correct statement, isn't it?
A. Well, the suggestion may or may not be correct. But it is correct that they are suggesting that this is the case.
Q. And in the next sentence, would you agree that there -- have been literature reports have associated treatment-emergent glucose intolerance with both conventional antipsychotics and atypical antipsychotics?
A. Yes, it's true. Like most issues that are difficult to resolve, the number of publications is universally proportional to the quality -- to the complexity of the issue, rather.
Q. But you would agree with me, Doctor, wouldn't you, that there were many, many researchers looking into this question as to whether there were treatment-emergent glucose abnormalities associated with all the antipsychotics?

A. Sir, if one scientist said water boils at 100 degrees centigrade and 10,000 said it boils at 50 degrees centigrade, science is not a democracy. On article that is positive contradicts and eliminates all the other literature that was negative.
THE COURT: Let me ask you why, Doctor. Maybe it was bad research for that one article.
THE WITNESS: No, sir. These are good people.
THE COURT: But I'm just saying, I mean, just the fact that one is positive, if it isn't replicated, doesn't that call into doubt the one article?
THE WITNESS: Not if the article is positive and well done. But you're right that to ask the question why is it so despite the fact that these are good people. Because it is difficult issue. All difficult issues take a long time to be resolved precisely because they're difficult.
At the beginning of the study, any study, you cannot imagine what degree of statistical power is needed to achieve a good

result, a positive result because you don't know what the -- the degree of risk is, the degree of toxicity is. That's the major reason why so many complex issues have so much contradicting literature and at the end of the day, it is the ones that are more rigorous and are positive that make it at the podium.
THE COURT: Okay.
Q. (BY MR. BRENNER) But until that time, Doctor, research goes on. Until that time that a definitive answer is provided, research is done and published, doesn't it?
A. No, sir, in this particular case --
Q. Not in this particular case. In general.
A. No, sir.
Q. Let me take you back to your example. No one is going to publish a paper today that water boils at 50 degrees, because we know the answer to that question, right?
A. Yeah, you'd be surprised.
Q. We know the answer to that question, right, Doctor? So there's no studies being published on when water boils, is there?
A. That's right.

Q. Okay But there are lots of questions in science, including an association between glucose abnormalities and atypical antipsychotics that have to be continually researched, because there has not been a definitive answer; isn't that true?
A. It is not true, sir, in this case, because the De Hertel study published in 2008 could have been and should have been performed in 1998 or 2002 by Lilly.
MR. BRENNER: Your Honor, I'd move to strike that comment.
THE COURT: Ladies and gentlemen of the jury, please disregard that.
MR. BRENNER: Can I go to page 4, Mike, of that study. Go back to Dr. Buse's study. The discussion section in the lower right-hand corner. If we can highlight the bottom five or six lines starting with "Of."
Q. (BY MR. BRENNER) Doctor, in this paper Dr. Buse and his colleagues found that of the atypical antipsychotic cohorts, only the risperidone cohort was associated with a significantly greater risk of diabetes than the haloperidol cohort, right?

A. Yes.
Q. And direct comparison of the olanzapine and respiradone cohorts indicated no significant difference in the risk of diabetes during treatment with these agents.
That was their finding, was it not?
A. That was their finding.
MR. BRENNER: Could I turn to page 6, please, Mike? The right-hand side.
And if we could highlight in the second paragraph four lines in, "The risk of developing diabetes." Thank you.
Q. (BY MR. BRENNER) And another finding that Dr. Buse and his cohorts made was that, I'm quoting here, the risk of developing diabetes was comparable between conventional and atypical antipsychotic cohorts. That's their finding, right, Doctor?
A. Yes, it is in this study. And I don't want to be dogmatic. What I'm saying is that there are two sides to the story in the literature --
Q. I agree.
A. -- and since there are two sides to the story, nobody can say that the opinion of

somebody who is in agreement with that company is the only study. They should say the issue is not concluded. That's not what Lilly did. So without being dogmatic, without insisting that the De Hertel article tells the absolute scientific truth, the absolute scientific truth is that we don't know for sure at the very least. Therefore, Lilly does not have the right to push one side and ignore the other side.
MR. BRENNER: Your Honor, I move to strike the comments about what Lilly should or Lilly shouldn't have done.
THE COURT: Again, Doctor, we're going to get through this a lot quicker if you listen to the question that he asks and answer that question. I'm going to instruct the jury to disregard the last statement because it wasn't responsive to the question.
THE WITNESS: I'm sorry, Your Honor.
Thank you.
MR. BRENNER: Could I have EL3801, please. If you could bring up the title and the Aims section.
Q. (BY MR. BRENNER) Doctor, you see this

is a study, the lead author is Dr. Cavazzoni, Dr. Buse is also an author. Its title is Retrospective Analysis of Risk Factors in Patients with Treatment-emergent Diabetes During Clinical Trials of Antipsychotic Medications, correct?
A. Yes.
Q. And the aim of these authors was to assess the short-term risk of treatment-emergent diabetes among patients with schizophrenia during clinical trials of atypical antipsychotics, right?
A. That's correct.
Q. And treatment-emergent diabetes is sometimes abbreviated in this article as TED, right?
A. Yes.
MR. BRENNER: If we could go to page 5, Mike, the Discussion section, the first six or seven lines.
Q. (BY MR. BRENNER) Dr. Cavazzoni and Dr. Buse and their colleagues, one of their findings was that the annualized rates of treatment-emergent diabetes were about 3 percent for patients treated with olanzapine, haloperidol

and risperidone, right?
A. Yes.
Q. And to they had occurred at an equal rate among those three agents, right?
A. That's correct.
MR. BRENNER: Your Honor, I don't know when you want to take a break.
THE COURT: Maybe this is a good time to take a break.
Ladies and gentlemen of the jury, we'll take our first break for the day. Before you go, I'll again remind you, please don't discuss this case or let anyone discuss it with you. Please try to keep an open mind until you've heard all the evidence in this case. We'll be in recess for about 15 minutes.
(Jury out.)
THE CLERK: Off record.
(Break.)
(Jury in.)
THE COURT: On the record, and all members of the jury panel are present.
Counsel.
Q. (BY MR. BRENNER) Doctor, I believe last week you testified a bit about the FDA's Drug

Marketing Advertising and Communication, sometimes called DDMAC, correct?
A. Yes.
Q. One of DDMAC's jobs is to review anything that's put out by pharmaceutical companies to make sure that it complies with the FDA's regulations regarding promotional and advertising activities, correct?
A. Yes.
Q. One of the things that DDMAC can do if it finds an offending article is to send what's called a warning letter to a company?
A. Yes.
Q. You saw those in your career with the FDA, didn't you?
A. Sometimes, yes.
Q. A warning letter is a fairly significant step for the FDA to take to formally advise a pharmaceutical company that it's out of compliance or violating a regulation, isn't it?
A. Yes.
MR. BRENNER: Could I have EL2113, please? If we could blow up the top part of that for the moment.
Q. (BY MR. BRENNER) Doctor, do you see this

is a warning letter to Janssen Pharmaceutica, Inc.?
A. Yes.
Q. It involves Risperdal, correct?
A. Yes.
Q. Risperdal is an atypical antipsychotic, correct?
A. That's correct.
MR. BRENNER: Now if we could bring up the rest of that first paragraph actually, Mike.
Q. (BY MR. BRENNER) And here, Doctor, if we look at the first sentence, you see that DDMAC is writing regarding a Dear Healthcare Provider letter that Janssen had sent regarding Risperdal, didn't it?
A. Yes.
Q. And one of the things that DDMAC is advising that Janssen is that they found that that letter to doctors was false or misleading in violation of federal law, correct?
A. Yes.
Q. And more particularly, if we look down at the bottom, the specific problem DDMAC had with the Janssen letter is that it misleadingly

claims that Risperdal is safer than other atypical antipsychotics, and it starts about the fourth line from the bottom.
A. I see it.
MR. BRENNER: See where it says -- you could highlight that maybe, Mike. See where it says --
THE WITNESS: I see it.
MR. FIBICH: I'm going to object to the relevance of this document and this inquiry.
MR. BRENNER: I'll think I'll get there in about a minute, Your Honor.
THE COURT: I'm going to overrule the objection.
Q. (BY MR. BRENNER) So, Doctor, DDMAC was finding at this time -- advising and putting Janssen on notice that they had made a misleading statement that Risperdal was safer than other atypical antipsychotics, right? That's what they are setting out in their first paragraph.
A. That's what they're saying.
Q. Now if we could go over to page 3, please, and that middle section says, Minimization of Risks, Misleading Comparative Claim?

A. Yes.
Q. In this paragraph, DDMAC is excerpting from the Janssen letter what they found thought violated federal law, right?
A. It says, The letter states.
Q. One of the things Janssen said in its letter to doctors, if you look at the last sentence of the Janssen letter, evidence also suggests that Risperdal is associated with a lower risk of diabetes than some other studied atypical antipsychotics. That's what Janssen said to the medical community, right?
A. That's correct.
MR. BRENNER: If we flip over to page 4, Mike. The first full paragraph at the top. That one, thanks.
Q. (BY MR. BRENNER) And now in this part of the letter, DDMAC is explaining why they found that statement to violate federal law, right, Doctor?
A. That is correct.
Q. What the FDA said is: FDA is not aware of substantial evidence or substantial clinical experience to support Janssen's claim that evidence also suggests that Risperdal is

associated with a lower risk of diabetes than some other studied atypical antipsychotics, right?
A. Well, the key word here is conclusive evidence, because the FDA, after the marketing of a drug has the burden to prove that the drug is unsafe.
Q. I'm sorry, it doesn't say conclusive evidence. It says it's not aware of substantial evidence or substantial clinical experience. That's the words they use.
A. Substantial is also a point where the FDA cannot ignore.
Q. Right. And then if we look at the lower part of this finding by the FDA's DDMAC it says, FDA's conclusion regarding the lack of evidence to support a ranking of risk among the atypical antipsychotics is reflected in the following statement from the warnings section of the package insert for Risperdal, Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.
That was the FDA finding as reflected in the FDA-approved package insert for

Risperdal, right?
A. Well, the precise risk estimate was not available at the time, that's correct.
Q. And so the FDA basically goes on, the FDA tells them they can't use that letter and they can't make the statement that Risperdal posed less of a risk for hyperglycemic-related events than other drugs. That was the FDA's finding, right?
A. According to the strictures of the regulation under which the FDA functions, that's the proper decision.
MR. BRENNER: If we could go two pages beyond that, Mike. This is the letter -- bring that, the electronic signature.
Q. (BY MR. BRENNER) This was a position stated by the FDA as of April of 2004, correct?
A. That's correct.
Q. Doctor, are you familiar with something called head-to-head clinical trials?
A. Yes.
Q. Head-to-head clinical trials are where two or more drugs or compounds are compared against each other, right?
A. Yes, it could be drugs or placebo.

Q. Fair enough. But typically when the phrase head-to-head is used, that's, for example, where one drug company wants to compare its drug against another company's drug; that's typically the way it's used, correct?
A. You're correct.
Q. Now, Doctor, you're aware that nowadays major pharmaceutical companies put a lot of their, even much of their clinical trial results on the web for everyone to look at, right?
A. What do you mean by major --
Q. Major pharmaceutical companies.
A. I'm sorry, I didn't hear the question.
Q. Let me repeat it. You're aware that nowadays many major pharmaceutical companies put the results of their clinical trials on the web?
A. Some or all?
Q. Many, some, many.
A. Fine. That sounds reasonable.
Q. Sure. And it's a way scientists or for that matter, the public now, can go and look at the results of any of these clinical trials, right?
A. Perhaps not many and depends what drug, what company. I can't address a specific

question.
MR. FIBICH: I'm going to object to the question unless we can put it in a time frame as to when they're contending that clinical trials were put on the web.
THE COURT: That's a fair question.
Q. (BY MR. BRENNER) Do you know, Doctor?
A. No, I don't.
Q. Did you look at any head-to-head clinical trials involving Zyprexa?
A. Well, I looked at the -- I went to the CEDR web site and I didn't find any of the things that you're talking about.
Q. This wouldn't be the CEDR web site. This would be a web site run by pharmaceutical companies themselves. Did you do any of that kind of research?
A. No.
MR. BRENNER: Could I put up TG167.
MR. FIBICH: I'm going to object to the question unless he can put it in a time frame. He's suggesting --
MR. BRENNER: I'll do that right now, Judge.
THE COURT: I think he's trying to

do that.
MR. FIBICH: That's my objection.
MR. BRENNER: I think I can cure that in about 30 seconds, Judge.
Well, let's answer Mr. Fibich's question. On this document, let's go to the very last page, shall we?
Just bring up the date of report, which is December 22, 2005.
Now, if we can go back to the front page of the report.
MR. FIBICH: Your Honor, I'm going to object and I want to approach the bench on this one.
THE COURT: We got this a little confused. The date of the report may be the 22nd of December of 2005, but it's not clear to me whether it was put on the web or what the date would have been when it was put on the web and that's --
MR. FIBICH: Here's the problem, he's suggesting in his questioning that the drug companies put these clinical trials on the web. It's my understanding that there's a recent legislation that now may require that they be

published. But to suggest that clinical trials are on the web for all these companies is misleading the jury.
MR. BRENNER: I don't mean to that and my point is not when it was on. It's the data I'm interested in.
THE COURT: Well, again, the question is a report -- was the report available in the public domain as of this date?
MR. BRENNER: My understanding is yes but my point is not so much the date. I just want to talk about the data. The data irrespective of the date --
MR. FIBICH: I'd like an instruction striking that questioning about the web, because it's not on the web.
MR. BRENNER: That's okay with me. I need the substance not the form.
THE COURT: Ladies and gentlemen of the jury, we're going to be talking about this exhibit in a second. There's questions about documents being now put on the web by pharmaceutical companies, and it's unclear from the testimony or even the question as to when this might occur.

I would tell you, at least at this time, to disregard any questions or discussions about documents being put on the pharmaceutical companies' and the web. As of this time, that has no relevance to the issues in this case. It may later on, and I'll let you know if it does.
MR. BRENNER: Mike, could you pull up the front part of that from the title of the study on down. There you go.
Q. (BY MR. BRENNER) Doctor, this is a synopsis of a clinical study report of a study sponsored by Bristol-Myers Squibb Company, right?
A. If you say so, sir. I don't have any knowledge of this document except as you present it, and I accept your representation.
Q. I thank you for that.
Abilify, the product, the name of the finished product that's identified there, that's a second-generation atypical antipsychotic, right?
A. That's correct.
Q. And Bristol-Myers Squibb is the company that sells it, right?
A. Yes.
Q. And then if we could look at the title

of the study, this particular study. This study was what's called a Multi-center Randomized Double-blind Safety and Tolerability Study of Flexible Doses of Aripiprazole and Olanzapine in Patients with Acute Schizophrenia, right?

A. Yes, this reminds me of the NDA contents that I've seen oodles of times when I was at the FDA.

Q. And I think actually everybody knows this now, but just to be sure, aripiprazole is Abilify and olanzapine is Zyprexa, right?

A. That's correct.

Q. Do I recall correctly, when you were here on Friday you told us about something called a hemoglobin A1(c) test?

A. Yes.

Q. Is that sometimes call a glycosylated hemoglobin test?

A. Yes.

Q. Do I recall correctly that you told us that was the gold standard for blood glucose determinations that is currently available?

A. Inasmuch as it gives a very good idea of a 60-day accumulated knowledge about glycemic changes.

MR. BRENNER: Could I go to page 5 of this document? The top paragraph, Mike.

And the very last sentence.

Q. (BY MR. BRENNER) Doctor, do you see that in this study Bristol-Myers Squibb ran a hemoglobin A1(c) test for both the patients on Zyprexa and the patients on Abilify?

A. Yes.

Q. And they came up with an exactly equal number who had a potentially clinically significant value for that test, for both those compounds?

A. But not the exact frequency.

Q. Right. But it's the same number?

A. That has no meaning.

Q. Actually, the frequency was lower in the olanzapine group, 19.2 percent, as opposed to 35.7 percent in the aripiprazole group, right?

A. Yes.

Q. Okay.

MR. BRENNER: You can take that down, Mike.

Could I have TG169, please? If you can pull up the title in the first part. Thank you.

Q. (BY MR. BRENNER) Doctor, am I correct that this is reporting on the results of another study done by Bristol-Myers Squibb.

And if we go down to the methodology section, Mike, a little further down.

In about the middle of that, you see they're describing their methods and they say that at one point in the study during this phase, patients were randomized to either open-label aripiprazole or olanzapine, correct?

A. Yes.

Q. So some patients were put in the Abilify group and some patients were put in the Zyprexa group, correct?

A. That's correct.

MR. BRENNER: And then if we could go to page 5 of this document. The middle paragraph and the very last sentence of that.

Q. (BY MR. BRENNER) Doctor, one of the findings that came out of this study conducted by Bristol-Myers Squibb was that an equal number of patients in the Abilify and Zyprexa groups had abnormal glycosylated hemoglobins, right?

A. Yes, but I have to know the total number of patients in order to have an opinion as to

what it's worth.

Q. Thank you. Another finding from this study was that in the Bristol-Myers Squibb's words there were no statistically significant differences between the treatment groups in mean change from baseline in glycosylated hemoglobin at any timepoint. That's another one of their findings, right?

A. Yes and again, it depends on statistical power to decide whether it's good evidence or not.

Q. Okay. Doctor -- you can take that down. Thanks.

Do you know what a poster presentation is?

A. Yes, I made a few in my days.

Q. It's a way, for example, at scientific meetings and conventions for researchers to present their data literally in a poster form to the other scientists and doctors, right?

A. To be very clear about it, if you're not given a spot to deliver lectures to scientists, then you get a poster.

Q. It's one way to share a researcher's data with other researchers and scientists.

A. Sometimes it's the only way to share at a meeting.
MR. BRENNER: Could I have TG164, please?
Q. (BY MR. BRENNER) Doctor, I want to show you some documents from a poster presentation just last month at the Biennial Winter Workshop on Schizophrenia and Bipolar Disorder in Switzerland.
Page 2.
THE COURT: Can counsel please approach?
MR. BRENNER: Yes, sir.
(Bench discussion.)
THE COURT: If you're going to ask him about 2008 stuff, I'm going to let them ask about post-2007 stuff.
MR. BRENNER: I made my record; I understand, Your Honor. I'll take it down. For the record, when we talk about issues of causality, it maybe becomes less relevant but I hear Your Honor's direction, and I'll follow it.
MR. FIBICH: You got to help him, Judge.
THE COURT: I'm just trying to keep

it fair.
(End bench discussion.)
MR. BRENNER: Could you pull up for me, P-10151.
Q. (BY MR. BRENNER) Doctor, you recall earlier in my examination of you we talked about the four papers that you referenced in your report for this case?
A. Yes, I do.
Q. And this case report by Dr. Ramankutty, that's one of the four that you mentioned, isn't it?
A. Yes.
Q. And as you see, this is a case report, right?
A. It is a case report.
Q. And a case report is a report as the name suggests here about a single patient, observations made by a physician about a single patient; isn't that right?
A. That is right.
Q. When Dr. Brancati was here with us last week, he was explaining that you have to use some caution in drawing conclusions from single-patient case reports. Do you agree with

that?
A. Not always.
Q. In general, one has to exercise some care before you draw too many conclusions from a single-patient case report?
A. Depends on the conclusion. If you're looking for a signal, then it's okay. If you're thinking that it's conclusive, it's not okay.
Q. How about for Dr. Gueriguian in this case? Was this a case report that you cited conclusive, less than conclusive or something else?
A. Well, for me it was interesting because this was a patient who was lean and wasn't gaining weight while on Zyprexa, and yet the -- there was a destabilization of diabetes, as they say. So this is such a -- a unique case that it says something, and the something that it says is: Weight gain is not the only reason for -- is not the only reason -- the only cause of increased hyperglycemia. And this is also, to me, important because it provides evidence to the fact that it's nature's experiment, as we call it in science, okay? And the nature's experiment says that the observation in monkeys that

hyperinsulimia was increased, therefore, they were insulin resistant, maybe this would be a case to prove that point. So it was important for that reason.
MR. BRENNER: Could you pull up the introduction section, Mike.
Q. (BY MR. BRENNER) Doctor, I do want to be clear about one very important thing. This patient has diabetes before she ever took Zyprexa?
A. I know that.
Q. Okay. And Dr. Brancati, when he was here with us last week, talked about something temporality, that if you want to say A causes B, A has to happen before B. That's an accepted concept in epidemiology, right?
A. Yes, but A can be diabetes, and B can be worsening of diabetes.
Q. I understand that. But in this case this particular woman had an 18-year history of diabetes before she ever took Zyprexa, right?
A. Yes.
MR. BRENNER: If we could -- Mike, show me the second column of data. Yeah.
Q. (BY MR. BRENNER) And, Doctor, in this

briefcase report, what happened here is this woman was started on risperidone and switched to chlorpromazine, right?
A. That's what it says.
Q. But her psychotic symptoms persisted, according to this doctor, right?
A. According to what it says, yes.
Q. Then she was switched to olanzapine, at which time she had a full remission of psychotic symptoms, correct?
A. Yes, that's what it says.
MR. BRENNER: Thank you, Mike. You can take that down.
Q. (BY MR. BRENNER) Doctor, is it true that antipsychotic drugs have been known to cause weight gain for decades?
A. Well, yes, that they've been known for quite a while. I don't know if it's decades and what you mean by how many decades, but for a big while, the perception has been there that they seem to do that.
Q. Okay. And, Doctor, weight gain was observed during the clinical trials of Zyprexa, wasn't it?
A. Yes.

Q. And Lilly reported those findings to the Food & Drug Administration, did it not?
A. I don't know what -- that's a difficult question.
Q. Well perhaps -- I'm sorry, were you finished? I didn't want to interrupt.
A. Well, I'll agree with you.
MR. BRENNER: Can we have EL2731, Mike? Blow that up a little bit.
Q. (BY MR. BRENNER) Doctor, this is a document called Review and Evaluation of Clinical Data, and it was performed by Dr. Paul Andreasen in 1996. Do you see that?
A. Yes.
Q. Dr. Andreasen, he's a medical officer at the FDA?
A. Yes.
Q. He was there at the same time you were?
A. Yes.
Q. Did you know Dr. Andreasen?
A. Not specifically. I knew the division director and I knew the group leaders, but not Dr. Andreasen, directly.
Q. This review of clinical data, is that the kind of work that medical officers at the FDA

do?
A. Yes.
Q. Dr. Andreasen reviewed the Zyprexa NDA, then he issued -- I can tell you this report is about 90-some pages long. Would that be a sort of a typical kind of report done by medical officers at FDA?
A. Yes, I'd say it's in the ballpark.
MR. BRENNER: Could I have internal page 79, please, Mike? Bring up that first paragraph there.
Q. (BY MR. BRENNER) And is this the kind of format that medical officers typically follow in preparing their analyses for internal use at FDA with these subheadings and sections?
A. Yes.
Q. And one of the things Dr. Andreasen specifically found and noted in 1996 was that weight gain was an adverse event that was common and drug-related at least in that study, correct?
A. Yes. These were short studies. That's what the meaning of the word acute means. Six weeks, sometimes four weeks.
Q. But this was a finding that Dr. Andreasen was noting for the internal uses of

the Food & Drug Administration regarding Zyprexa, right?
A. Well, that's part of what it says, but it has to be taken strictly on its wording and not conclude anything from that.
Q. Doctor, from the very first day Zyprexa was marketed in the United States, its product labeling discussed and disclosed this issue of weight gain, didn't it?
A. Not appropriately, in my opinion.
MR. BRENNER: Can we have EL2954A, please?
Q. (BY MR. BRENNER) Again, shows the date, Doctor. This is the 1996 package insert for Zyprexa, right?
A. Yes.
MR. BRENNER: Can we go to page 16, please? And bring up the Weight Gain section.
Q. (BY MR. BRENNER) And in fact, Doctor, consistent with Dr. Andreasen's review, clinical trial results regarding weight gain in olanzapine-treated patients was included in the Zyprexa package insert from its earliest days?
A. Well, you have to give me a few moments to read this.

Q. Sure.
A. Yes.
Q. And, in part, Doctor, one of the things that was disclosed in the FDA-approved labeling was information about long-term therapy with olanzapine, 238 median days of exposure. Do you see that?
A. Are these two paragraphs following through?
Q. They do.
A. Okay. Then -- I agree with what you said.
MR. BRENNER: Could I have the next page, page 17? The endocrine section, Mike.
Q. (BY MR. BRENNER) Doctor, also in this early -- really the first package insert for Zyprexa it was noted that diabetes mellitus had been observed infrequently during the clinical trials, correct?
A. Yes.
MR. BRENNER: And page 18, please. I think it's the top line.
Q. (BY MR. BRENNER) And also that hyperglycemia had been observed during the clinical trials for Zyprexa. That was also

included in the package insert, was it not?
A. Yes.
MR. BRENNER: Could I have EL2559, please? Go to the next page of that one. Bring up the title and the abstract or the objective. Thanks.
Q. (BY MR. BRENNER) Doctor, do you see this article titled Antipsychotic-induced Weight Gain: A Comprehensive Research Synthesis.
Do you see that title?
A. Yes, I see it. It means that they're doing a review article if the meaning is understood well.
Q. I think you're exactly right. Do you see that the lead article is Dr. David B. Allison?
A. Yes.
Q. Do you know Dr. Allison?
A. Not personally.
Q. We understand he's an expert in this case for the State. If you look at the first line of the objective section. And am I correct, Doctor, that the objective of Dr. Allison and his colleagues in this article was to estimate and compare the effects of antipsychotics, both the

newer ones and the conventional ones, on body weight, right?
A. Yes, I suppose they're using some sort of method analysis.
Q. Okay. And then if we look down near the bottom of the Objectives section, where he says, Dr. Allison finds that both conventional and newer antipsychotics are associated with weight gain.
A. That's what it says.
Q. And clozapine was -- had the greater potential and ziprasidone the least according to their research, right?
A. That is correct.
Q. This appeared, Doctor, in the American Journal of Psychiatry in 1999?
A. Right.
Q. The American Journal of Psychiatry, that's the official publication of the American Psychiatric Association, is it not?
A. Usually when it says American Journal of, it means that there's an association behind it, you're right.
Q. And that's widely read among psychiatrists, is it not?

A. I suppose it is. I don't know personally, because I'm not in that particular area, but it sounds reasonable.
MR. BRENNER: Mike, if we could show the bottom part of that page.
Q. (BY MR. BRENNER) Doctor, in the little box to the left, the authors note that this paper or these data were presented in part at a meeting of the American Psychiatric Association in 1998; is that right?
A. That's what they say.
Q. Okay. So we know that this research and information about weight gain and antipsychotics was being discussed in the medical literature and at medical meetings, specifically directed at psychiatrists, right?
A. Well, discussed is too big a word because usually meetings -- what happens to meetings are as follows: You have, let's say, 15 minutes to present your work and there's about five minutes of discussion, so I don't know the venue. I don't know how it was discussed. It's been discussed some, at least.
Q. And they published their findings in the leading journal for American psychiatrists,

right?
A. Well, usually when you are at the meeting and you send the review paper, it has a better chance of being published and it's not a refereed article.
Q. You think this was not subject to peer review?
A. I think that it probably was not, certainly not as rigorous as usual, because it's just a meta analysis. It has been subjected, I assume, to some review, but not a rigorous review.
Q. Doctor, the very last words on the page -- we're going to go to the next page, the with the -- and then continues -- blow up that next sentence.
Dr. Allison and colleagues wrote, With the advent of new atypical antipsychotics extrapyramidal side effects are becoming less of a problem. That's a true statement?
A. That it's becoming less of a problem? It's the perception of the scientists in the field, yes.
MR. BRENNER: Could I have internal page 6, please?

One more. Yeah, Discussion, the first sentence.
Q. (BY MR. BRENNER) One of the conclusions Dr. Allison and his colleagues made was that most neuroleptic drugs were associated with weight gain, right?
A. That's what it says.
MR. BRENNER: You can take that down.
Q. (BY MR. BRENNER) Doctor, do I recall correctly that you were critical of Lilly in your direct examination regarding the use of so-called random or nonfasting glucose tests in its clinical trials?
A. I was more surprised than critical, being that Lilly is such an expert in glucose.
Q. To do a fasting glucose test it requires some cooperation on the part of the patient, right?
A. Yes.
Q. Because the patient can't eat for an extended period of time?
A. Well, usually just past the night and you do it the next morning, I suppose.
Q. And you've never treated schizophrenic

patients, correct?
A. No, that's correct. I have never treated a schizophrenic patient.
Q. Do you understand that it's often difficult to get the kind of cooperation one needs to do a fasting test from schizophrenic patients?
A. And that -- that difficulty is appreciated, but it exists in every single clinical trial.
Q. Doctor, surely FDA was aware of Lilly's use of the random or nonfasting glucose test in its clinical trials, wasn't it?
A. The FDA was -- I don't know when the FDA was aware, and you have to remember that this was a neurological agent and therefore, the weight gain issue became prominent when it was discovered that it was happening in Zyprexa. I'm not criticizing the initial finding. I'm criticizing that later on a proper study was not done with the proper methodology.
MR. BRENNER: Could we have EL2731 again, Mike.
Q. (BY MR. BRENNER) Again, there was Dr. Andreasen's review of the Zyprexa clinical

data?
A. Yes.
MR. BRENNER: Could I have internal page 79? And the top paragraph. Good.
Q. (BY MR. BRENNER) Would you look at that with me, Doctor? It's the one titled Adequacy of Assessment, Metabolic and Endocrine System.
A. Yes.
Q. And -- this is in part the summary of Dr. Andreasen's review of the data provided by Lilly in support of its application for Zyprexa, right?
A. Yes.
Q. One of the things in the second-to-last sentence, Glucose values were recorded as fasting or nonfasting as appropriate. This was adequate in the assessment of olanzapine's effect on the metabolic and endocrine system.
That was Dr. Andreasen's finding, right?
A. That's what he said. I don't understand exactly with what he means and he's not an endocrinologist, but I understand what he said.
Q. Do you know what his discipline is in medicine?

A. No, I assume -- since I told you that I didn't know him --
Q. If you don't know --
A. But I assume since he was a medical officer in the neurological division, he's not an endocrinologist. But I may be wrong. If I'm wrong, just correct me.
Q. But I think you told us -- when you were describing the workings of the FDA, of course one of the value of having many medical officers is that you can share your expertise with one another.
A. That is correct.
Q. And so that I think you had told us, for example, DDMAC would call on you or the office of the chief counsel and other divisions would call on you regarding endocrine issues, for example, right?
A. Yes, but the divisions -- going to another division for experts' review of certain matters in an NDA doesn't occur all the time and certainly rarely occurs when the issue is -- doesn't appear at the time to be of importance to the entire package.
Q. Doctor, we spoke a few minutes ago about

Dr. David Allison, one of the State's experts in this case. Did you know that Dr. Allison was invited by Lilly to review Zyprexa data including the random glucose measurements more than seven years ago?
A. No, not that I remember. I don't remember seeing that.
Q. Did you ever see a manuscript that Dr. Allison co-authored that contained his findings regarding random glucose measurements in patients treated with Zyprexa and other antipsychotics?
A. I don't recall, but I have my opinion on the subject.
MR. BRENNER: Could I have TG136, please.
Q. (BY MR. BRENNER) Do you see this manuscript of which Dr. Allison is the lead author and it describes changes in random blood glucose concentrations in patients in the schizophrenia clinical trials?
A. Yes.
MR. BRENNER: Could I have the second page of that, please? The bottom part.
Q. (BY MR. BRENNER) You see, Doctor, that

these findings were presented at a variety of medical conferences in 2001, basically conferences around the United States and around the world?
A. I see that.
Q. So I take it, then, you'd agree, Doctor, that Dr. Allison had no problem presenting research findings based on Lilly's random glucose measurements in Zyprexa trials?
A. It is perfectly all right to begin with nonfasting blood glucose, but when you see that there's a problem of power and a degree of precision that you cannot attain, the only thing I'm criticizing is that later on better methods ought to be used because the original methods, the results with the nonfasting were inconclusive in their totality. So I don't criticize, per se, the method. I say when a method is not sufficient to answer the scientific question, then you have to graduate to the better methodology.
MR. FIBICH: Your Honor, we're going to object to any further questions about this document unless Mr. Brenner can show us that it has been published and peer reviewed.

Otherwise then we have an objection to the entire line of testimony.
THE COURT: That objection is overruled.
MR. BRENNER: Go over to page 16, Mike. The bottom.
Q. (BY MR. BRENNER) The middle -- the middle sentence, one of the things Dr. Allison and his colleagues noted, Doctor, is of potential clinical importance, the likelihood of a glucose event was not significantly different between treatment groups, of course with the exception of clozapine-treated patients. That was one of his findings, right?
A. I don't know if it was his findings, but it was one of his conclusions and it goes back to what I said earlier. If you don't see the problem, if it's a negative result, then you'd better use a better method and have more statistical power to have a conclusive answer to the scientific question.
Q. Doctor, in evaluating data, can you find data that are statistically different but are not clinical significantly different?
A. It happens.

MR. BRENNER: Thank you. You can take that down, Mike. Thanks.
Q. (BY MR. BRENNER) Doctor, am I correct that in May, 2000, the FDA wrote to Lilly and all the other manufacturers of atypical antipsychotics and asked for further analysis of data about hyperglycemia and diabetes?
A. I don't know what documents you're referring to. I'd rather see it rather than --
MR. BRENNER: Could I have PE775?
Q. (BY MR. BRENNER) Doctor, this is a May 1, 2000 letter from the FDA to Dr. Brophy at Eli Lilly, right?
A. Right. May I have a few moments to read the letter?
Q. Yes, absolutely, sir. Do you need the part taken down so you can see the page? I want to make it more legible for you.
A. Oh, yes, yes. I can see it.
May I have the next page, please?
Q. Certainly.
A. Yes, I have seen this -- this letter and the -- what I got from it is that the FDA's requiring from Lilly all the data that they have.
Q. Actually, it was more a reanalysis of

data that had already submitted; is that right?
A. Not really. Not really when you think about what occurred in the future.
Q. Well, this letter was also sent to all the other manufacturers of atypical antipsychotics; isn't that right?
A. I understand that, and to all the manufacturers the question was you send everything that you have.
Q. And in response to that letter, Doctor, in July, 2000, Lilly submitted a 600-plus page response, didn't it?
A. I don't know. I have to see what you're talking about.
MR. BRENNER: Can we have EL2043. Blow up that letter.
A. What was your question?
Q. (BY MR. BRENNER) Yes, Doctor. Is it correct that in July of 2000 Lilly submitted a 600-plus page response to the FDA's request?
A. Well, the important notion is not how many pages Lilly sent. The important question, did they obey the FDA in giving them all the data.
Q. And did you have an opportunity to

review this July, 2000 submission by FDA?
A. No.
Q. You never looked at this?
A. Well, I cannot -- if I didn't review it, I didn't see it.
Q. Okay.
A. But I saw evidence later on.
MR. BRENNER: Could I have P4871, please? In fact, let's go to the last page, first, to set a date. I just want to show you this electronic signature line. Russell Katz, 12/16/03.
Q. (BY MR. BRENNER) Doctor, you know Dr. Russell Katz, don't you?
A. Well, I've heard of him. I don't know him personally.
Q. He's --
A. Division director.
Q. He's the division director in the neuropharmacologic section of FDA?
A. He replaced Dr. Leber.
MR. BRENNER: Now let's go back to the text of the letter. If you could expand that a bit.
Q. (BY MR. BRENNER) This is Dr. Katz's

writing in this letter to Lilly and advising them that you now must revise the labeling for Zyprexa, correct?
A. Well, to be very precise, Lilly has taken the initiative to propose an amendment to its label through the Changes Being Effected provision of the regulations, and the FDA in an unusual fashion is reviewing and then saying what it thinks about it. And I say unusual because it's usually a pro forma thing to accept Changes Being Effected label initiation for change.
Q. But, in fact, the FDA does have to accept -- does have to review even a Change Being Effected?
A. That's what I said. I said that most of the -- yes, the FDA has to approve it. Most of these are pro forma and it's rather rare that the FDA would do more than a pro forma review.
Q. But here they did?
A. Yes.
MR. BRENNER: Mike, if I can have blown up the text part of that letter. In this part --
A. Forgive me. I have to see the top part of this paragraph, because it means we

completed -- right. Thank you very much.
Q. (BY MR. BRENNER) And here, Doctor, Dr. Katz is directing the language that's going to be used in the warning regarding hyperglycemia and diabetes mellitus, right?
A. Dr. Katz is doing more than that. It's doing what you're saying, but it's doing more than that, saying the amendment is approvable, which is less than the amendment is approved. That's what I mean. This is unusual. It's not pro forma, and then it says before these applications may be approved you must perform the following corrections.
MR. BRENNER: And now if we can go to EL2945A, to page -- internal page 6. And blow up the warnings section, please.
A. Forgive me. Which year is this?
Q. (BY MR. BRENNER) This was 2004, January, 2004.
And my only question -- feel free to look at it, Doctor. My only question is Lilly, in fact, implemented the warning change directed by FDA?
A. If memory serves, it didn't implement it fully as the FDA wanted it to, but I have to look

at it to find out what that means.
Q. I would like you to look at that, because I believe this is verbatim the language provided by Dr. Katz in his December, 2003 letter.
A. For this section, perhaps.
Q. Yes, sir.
A. But not perhaps for others.
Q. Now we're just focusing on this section. Do you have any reason to disagree that Lilly included the exact language directed by Dr. Katz in his letter?
A. For this section?
Q. Yes.
A. No.
Q. And, in fact, FDA directed the same warnings going to all the other atypical antipsychotic drugs, didn't it?
A. Yes, it is.
Q. So that the Geodon package insert would have the same language, right?
A. I assume so.
Q. And the Risperdal would have the same language?
A. I also assume so.

Q. And the Seroquel would have the same language about hyperglycemia and diabetes, right?
A. I assume so.
Q. And so, Doctor, at least as of December, 2003, FDA did not conclude that Zyprexa had a different risk of hyperglycemia or diabetes from the other atypical antipsychotics?
A. That's not true. What is true is that given the regulatory constraints under which the FDA functions and they're good constraints, the FDA has to prove that what it wants the company to say is being conclusively proven.
Q. Conclusively proven?
A. Well, yes. It has to show -- it has to -- the data has to be sufficient -- what's the question here? The question here is what's the difference between the toxic effect that we're discussing here, hyperglycemia, et cetera, what's the difference between the various atypical antipsychotics? That's my understanding.
And the FDA at the time, and that's its decision, its opinion, didn't think that it had conclusive evidence or sufficient evidence to force the companies to say, in your case, you have to say this and to the others in that other

case you have to say that.
THE COURT: Let me just ask you because you've used two words, conclusive and sufficient. Something could be sufficient to require a change without it being conclusive. So what is it? Sufficient or conclusive?
THE WITNESS: They're -- the word conclusive has a different regulatory and scientific meaning. So scientifically, conclusive means scientifically proven beyond -- there's a consensus among experts that this is so. Now, for the regulatory world and the FDA, they -- it has to meet certain legal strictures, and I will not quibble about the words. I say substantial or whatever. I don't know exactly on what basis the FDA decided in this case.
THE COURT: Okay.
Q. (BY MR. BRENNER) Doctor, the use of the term conclusive, does that appear anywhere in the FDA regulations governing these matters?
A. Well, that's why the conclusive statement is usually a scientific statement, but sufficient is what the FDA considers that it needs to prove. It's the burden of the FDA in the post-marketing period.

Q. And that's sufficient evidence pursuant to the regulatory scheme under which FDA operates?
A. Yes.
Q. Thank you.
Doctor, I think on Friday you told us about two rhesus monkeys developing fasting hyperglycemia after being treated with clozapine. Do I recall that correctly?
A. Say that again.
Q. I think you testified about rhesus monkeys who developed fasting hyperglycemia after being treated with clozapine?
A. All the rhesus monkeys showed an increase in their HbA1c level, if my memory serves.
Q. These were monkeys that were treated with clozapine?
A. Correct.
Q. Clozapine is not the same as Zyprexa?
A. It's not the same -- it's the same for any number of definitions but not in terms of the toxicity with respect to hyperglycemia and diabetes, yes. It's worse.
Q. And also clozapine is associated with a

dangerous side effect called agranular cytosis; is that correct?
A. I did say, if you recall on Friday, having done that I thought that I -- I was surprised that immediately Lilly didn't perform the same rhesus monkey study with Zyprexa. I was forthcoming about that. It was clozapine.
Q. I understand, Doctor. I want to talk about agranular cytosis. This agranular cytosis is a condition in which the patient's white cells are basically destroyed, right?
A. Yes, Chloramphenicol in the old days was responsible for agranular cytosis. It's very rare, but it was enough to contraindicate Chloramphenicol.
Q. And because of the agranular cytosis risk for clozapine, clozapine carries a special warning that their patients be monitored, have the blood monitored to check for this fatal side effect, doesn't it?
A. I accept your representation.
Q. Doctor, when you were talking earlier this morning about some blood monitoring in Lilly's sales materials. What they're talking about is Zyprexa, unlike clozapine, didn't

require blood monitoring for agranular cytosis, correct?
A. I seem to have perhaps induced somebody in confusion. There are oodles of different blood monitoring because there are oodles of different parameters of laboratory tests. I was talking about monitoring blood glucose.
Q. Uh-huh. I understand that, Doctor. It is true that for Zyprexa and the other second-generation atypicals other than clozapine, there is no requirement for blood monitoring for agranular cytosis; is there?
A. That's correct, to my knowledge. As far as I can see.
Q. Doctor, would you agree that making an extrapolation from what happens in one species like a monkey to another species like a human can give us a basis for conjecture, but not a basis for a conclusion?
A. It is more than conjecture. There is a very good reason why the FDA requires animal studies. If there wasn't any reason, there is no reason to make animals suffer and spend a lot of money. The reason is very simply this: We want to have an idea of what's happening in the

animal, and we require two species, says the FDA, one a rodent species, rat or mouse, and the other one another species and usually you try to get closer in evolutionary terms to the human species.
Now, the only reason to perform a study is if you find out something in the animal. As a company you are required to perform during clinical trials what is necessary to find out whether this is happening in the humans.
MR. BRENNER: Could I have EL2121, please? Just blow up the top part of that.
Q. (BY MR. BRENNER) Doctor, do you see that this is another FDA review and evaluation of clinical data here of various drugs, including Zyprexa, and an association with diabetes mellitus?
A. It certainly appears to be that. I'm sorry, I didn't mean to interrupt.
MR. BRENNER: Not at all. And could I just go to the last page of that to show the signature?
Q. (BY MR. BRENNER) This evaluation was performed by Dr. Judith Racoosin, a medical officer at FDA?

A. I don't recognize her name. I don't know which division she is.
Q. No one you know but she is a medical officer at FDA?
A. I accept it.
MR. BRENNER: Let's go to the page 2 of that report and preclinical studies.
Q. (BY MR. BRENNER) Doctor, preclinical means in animals, right?
A. Yes, in FDA parlance, that's what it is.
Q. And here, Dr. Racoosin is reporting her findings on her review of the preclinical studies for various atypicals, including Zyprexa, right?
A. Right.
Q. And one of her findings in the very first sentence of the second paragraph is risperidone and olanzapine preclinical studies did not demonstrate changes in serum glucose. That's Dr. Racoosin's conclusions?
A. Yes. That's in the rat, I assume.
MR. BRENNER: Take that down. Thanks, Mike.
Q. (BY MR. BRENNER) Doctor, when you were here on Friday, you talked about a federal regulation. That I think you called it a Change

Being Effected or CBE provision?
A. It's called Changes Being Effected.
Q. And I think you told the jury that that, in effect, allows a company to cut through red tape if it feels that it needs to change its package insert for something of importance?
A. Well, if time is of the essence, it is normal that the FDA offers this possibility. And it is absolutely normal for a company to take advantage of the possibility to protect its patients, but it can be used and it can be misused.
Q. Even under the CBE, the Changes Being Effected regulation, Doctor, a company never -- never falls outside the review of the FDA? That is, a company can try to make a change, but it also has to submit it at the same time for review by FDA?
A. Well, I stated already a few moments ago that this is the case, and I stated further that I have been involved in many of these Changes Being Effected, and I recall only one where we -- the FDA insisted on having more than a pro forma review and insist that this was not acceptable.
So it depends what it is.

Generally speaking, it's pro forma. If it's unusual, the FDA is not happy for whatever reason, then it becomes something else again.
Q. And perhaps that's the point I was trying to make. Even if you try to make -- even if a manufacturer tries to make a Changes Being Effected, it is still subject to FDA review and the FDA can tell you, stop, take away what you just did?
A. Yeah, but it rarely does so because most of these Changes Being Effected are well -- they address a time-related emergency, and the FDA facilitates that by being a very pro forma thing, very pro forma review of the submission.
Q. But would you agree that a manufacturer is not free simply to change warnings because it views the FDA's assessment of a particular risk differently than does the FDA?
A. Well, the manufacturer is not free to change things and to say things that are not in agreement with data and other scientific medical evidence. On the other hand, the manufacturer -- manufacturers as a class know very well that if they're saying something that is being expected by the FDA that has been pursued and stated

publicly by the experts in the field, then they know that it's going to be pro forma. It's going to pass easily. There's going to be no impediment. That's the way it works. I've been there; that's what I saw. That's what I participated in.
Q. And would it be fair to say, then, Doctor, that when the FDA is actively reviewing a particular issue or particular risk, or for that matter a benefit, its preference is for the manufacturer to wait for the completion of the agency's review before it attempts to take any action regarding the warnings?
A. Sir, I just told you that manufacturers know that if what they're saying makes sense and it is in consistency with the experts' consensus, and may I remind you that the statutes say a drug is safe when the experts agree it is safe. A drug is efficacious when experts agree. So when you have this expert consensus, the FDA just let it pass, doesn't even touch it. It is when, for whatever reason, it feels that there's something not quite right in this request from the manufacturer that it takes the time and time is precious for the FDA to say, no, this is not the

way it should be, that's the way it should be.
Q. And in fact, Doctor, starting in 2000, the FDA, commencing with its request from all manufacturers for data regarding atypical antipsychotics and glucose irregularities, the FDA was undertaking a very significant, an in-depth review of the issue for all antipsychotics?
A. The FDA could -- the FDA certainly was attempting to do a overview, but to call that an in-depth review is not in my opinion the proper usage, because in order to have -- to be able to make a deep review, the FDA had to have the assurance and the knowledge that it had everything that it had requested.
Q. But you don't actually know what FDA had before it starting in that 2000 time frame in response to its request to all manufacturers, do you?
A. You're precisely right. But in 2007, the FDA understood --
THE COURT: Doctor, if I could ask you not to talk about that --
MR. BRENNER: Thank you, Doctor.
Q. (BY MR. BRENNER) Doctor, we've heard

you comment several times during your direct the phrase comparable or comparable rates.
Comparable doesn't mean identical, does it?
A. Well, it depends how you use it.
Q. How do you use it?
A. I don't use it.
Q. Okay. Fair enough.
A. I have seen manufacturers constantly using words like "similar," "comparable". This is not something that should be used. The FDA defines terms. The scientists define terms. The approach is to say, here is the statistical P value in that comparison, and if you don't have a statistical P value, then the only thing you ought to say is we don't know as to the present whether it's identical or not identical, if it's greater or not greater.
Q. It would be better to present the data themselves, I gather?
A. Exactly.
MR. BRENNER: Could I --
Q. I'm sorry. I didn't mean to cut you off.
A. No, it's all right.

MR. BRENNER: Could I have EL3399.
Q. (BY MR. BRENNER) Doctor, yesterday you told the jury about a number of different Lilly marketing pieces. The first question to you was: Were you ever shown this by any of the lawyers representing the State of Alaska in this case?
A. I don't remember seeing this graph.
Q. Right.
A. But I'm sure I saw other things that --
Q. And do you see --
A. -- address the same issue.
Q. But this particular one I want to focus you on, one of the things it says there in the middle there is incidence of glucose elevations was comparable between and Zyprexa and placebo, right?
A. That's what it says but that's not what it is.
Q. And then they put the actual numbers in there, don't they?
A. Yes.
Q. The actual numbers put there for the doctors to put there was that the incidence was slightly higher among the Zyprexa treated than among the placebo?

A. I don't know that you can say that given the numbers -- I don't know that there's sufficient statistical power. You have more than 4,500 for Zyprexa and 445 for the placebo.
Q. Sure.
A. I don't know what that means.
Q. You can't read that graph for us,sir?
A. I can read that graph, but I don't know what it means.
Q. One thing it means as depicted here is that Lilly was telling doctors there was a higher incidence of random glucose elevations among the Zyprexa patients. That's the comparison of those two little bars, right?
A. Yes, and that statement goes against their using somewhere else here, there, everywhere the term comparable rate.
Q. It's certainly fair for Lilly to present their data to doctors and doctors can draw their own conclusions?
A. That's not what's being done here, is it?
Q. I think it is being done here, Doctor.
A. When you begin talking about the difference and characterizing it, then you can't

just cut off statements and messages to the prescribing community and ignore the entire universe and the context in which this was said. Comparable was told by the company to be constantly repeated and driven in the heads of prescribers.

Q. But if in Lilly's presentations comparable meant slightly different, that would be --

A. Comparable doesn't mean slightly different. I don't know what it means, and it shouldn't be used except to neutralize people.

Q. Is there any FDA regulation that prohibits use of the word comparable?

A. Yes. DDMAC knows that this is not the term to use, for example.

Q. Did DDMAC ever take any action against Lilly for using the words comparable rates?

A. I don't know the answer to that question, but I know there was at least one DDMAC letter to Lilly where it found an awful lot of false, misleading and in violative of the regulations.

Q. But nothing having to do with comparable rates, did it?

A. Well, I don't know.

MR. BRENNER: Can I have EL2018, please?

Second page of that. If you could blow up the middle section. Average.

Q. (BY MR. BRENNER) Doctor, this is another promotional piece by Lilly. I can show you the whole thing if you want. My first question is: Was this ever shown to you by the attorneys for the State of Alaska?

A. I don't recall that it was.

Q. Okay. And here what doctors are being told in part is that mean random plasma glucose levels in patients treated with Zyprexa increased, right? And that they increased greater than in patients treated with risperidone and greater than among patients treated with haloperidol, but below patients treated with clozapine?

A. That's what it says. I don't know what database they used.

Q. This is information Lilly was putting out for physicians; isn't that right?

A. Well, in this particular piece, yes. I don't know if it disagrees or contradicts other

statements made by the company.

Q. Okay. Thank you.

A. What it's saying is -- you're right.

MR. BRENNER: We can take that down.

Could I have P1111.

Q. (BY MR. BRENNER) Doctor, this is a document you testified about yesterday. If I can go to the next page, please. Highlight the first bullet point, the issues or issue.

One thing that -- one thing that was known was that diabetes was the No. 1 reason physicians were concerned about potential weight gain with Zyprexa, right?

A. That was the problem. That was the issue.

Q. So physicians knew both about weight gain and at least there was a potential link between weight gain and diabetes, according to the market research?

A. No, they didn't know that.

Q. They didn't know that?

A. No, they didn't know that. It took them a while to find out that there may be a problem and that message was contradicted by the

representations of the Lilly company.

Q. But nevertheless, diabetes was the No. 1 reason physicians were concerned about weight gain?

A. What is the date of this? 2001?

Q. 2000, I believe you told us yesterday, Doctor.

A. That's what the company says, and I agree that it's saying that.

MR. BRENNER: Good. Could I have the next page of that document?

Q. (BY MR. BRENNER) From this document you were shown yesterday, the 2000 document, Lilly's market research was showing that diabetes was associated most closely with Zyprexa in the minds of physicians, right?

A. Yes, those are marketing statements, yes.

Q. It's the information derived from the marketing component, isn't it?

A. Yes, and it doesn't address what is being told in the label and what is being told to prescribers.

Q. Look at the third bullet, apparently irrespective of what was being told, or what

you're saying was being told, the actual findings was doctors tend to look for diabetes with Zyprexa patients and not with other atypical antipsychotics. That's what the doctors were telling Lilly, right?
A. And Lilly shot back saying, don't think that this is true.
MR. BRENNER: You can take that down.
Q. (BY MR. BRENNER) Doctor, on Friday you told us a bit about the Japanese regulatory approach to Zyprexa, right?
A. Yes.
Q. Now, Doctor, labeling, prescription drug labeling around the world doesn't look the same, does it?
A. Well, very rarely it does. Often, more often than not, it should. And there are very few reasons that certainly in the Western world the -- there should be glaring differences between what a label says in the European Union, in Canada even more, and what it says in the U.S.
Q. But nevertheless, based on your experience, Doctor, there are differences. Different regulators around the world take

different approaches to the same problem; isn't that true?
A. In part. What is also true is that the negotiating power of companies with different regulatory agencies vary.
Q. And when you were at FDA, was it your perception that the Food & Drug Administration tried to have dialogue and communication with other regulators around the world to see how they were handling issues?
A. Well, when I was at the FDA, I certainly did that. My colleagues did that. But that doesn't mean anything about what a given regulatory agency -- what power it has to have a company accept what it thinks is right and what it thinks all other regulatory agencies believe and the consensus experts as well.
Q. In the case of Japan's treatment of Zyprexa, is it true that when Lilly learned of the Japanese health ministry's concerns it sent a team to Japan to evaluate the data that the regulator there was looking at?
A. I don't understand what you mean. Didn't they have the data? I mean, this is Eli Lilly-generated data, is it not?

Q. No, sir.
A. That's why I'm saying I don't understand what you mean.
Q. Do you know when Lilly learned of adverse event reports in Japan that were of concern to the Japanese Health Ministry it sent a team of physicians to go review those data with the Japanese Health Ministry?
A. I accept your representation.
Q. Did you know that based on its evaluation of the actual case reports there in Japan that Lilly scientists disagreed with the Japanese health authorities' evaluation of them?
A. And why would that be a surprise?
Q. It's also true that Lilly formally advised the FDA of this action by the Japanese health authority?
A. Well, not all the evidence seems to agree with what you're saying.
MR. BRENNER: Can I have EL244, please. The top part, blow that up.
Q. (BY MR. BRENNER) This is a Lilly internal document, communication with FDA, subject is communication regarding labeling change in Japan. You see that, Doctor?

A. Yes. And the date is 2002.
Q. Yes.
A. Thank you.
Q. Was this document shown to you by the lawyers representing the State?
A. Not that I remember.
MR. BRENNER: Could we go down to the bottom of that page, please?
Q. (BY MR. BRENNER) You see the discussion of details, Doctor, begins on Friday, April 12, 2002, Drs. Breier and Brophy contacted Dr. Laughren. Who is Dr. Laughren?
A. I think he worked in the neurology division.
Q. He's the division director, isn't he? He worked under Dr. Leber?
A. I only knew somebody else. I wasn't familiar with the position of Dr. Laughren.
Q. You know he's in the neuropharmacological division of FDA, right?
A. Yes, that, I know, but in April, 2002, I don't know. I had left the FDA.
Q. I understand. But you don't have any reason to dispute the fact that Lilly, on April 12, 2002 contacted Dr. Laughren to tell him that

the Zyprexa label in Japan was being revised to include information regarding hyperglycemia and diabetes in the warnings and contraindications sections, right?

A. That's what it says.

MR. BRENNER: Now can I have EL2629, please?

Q. (BY MR. BRENNER) Do you see, Doctor, this is a report submitted by Lilly to the FDA in April, 2002 entitled Analysis of Japanese Data on Hyperglycemic and Diabetic Spontaneous Serious Events Associated With the Use of Zyprexa.

Do you see that, sir?

A. That's the -- I see that this is the internal analysis by Lilly.

Q. It's not the internal analysis, sir. This was submitted to the Food & Drug Administration.

A. Yes, still, it was submitted to the FDA, but it was Lilly who prepared the analysis.

Q. Was this document shown to you before you formed your opinions in this case?

A. No.

MR. BRENNER: Could I have internal page 4 of that, please. Bring up the background.

Q. (BY MR. BRENNER) You'll see in this submission to the FDA by Lilly it advised that the Japanese Ministry of Health Labor and Welfare was requesting a label change. Not requesting, requiring to expand the previous language regarding hyperglycemia and diabetes, and is mandating a Dear Doctor letter be sent to physicians, right?

A. Yes, and I would like to know when Lilly found that out from Japan and when -- what is the date of this communication to the FDA.

Q. The date of that communication is April, 2002, sir.

A. Excuse me?

Q. The date of this communication is 2002.

A. And when did the Japanese tell Lilly about all that?

Q. I'm not sure. Do you not know that, sir?

A. No, I don't know that. I need to know the information.

Q. But you didn't need to know that yesterday when you used it to support your opinions against my client, did you?

A. It's not what I used to support, but now

I need the information, and I'll tell you why, if you want to.

Q. Not right now. Thank you. The FDA determined that this Japanese-type label was not supported by the data, did it?

A. No, this is an Eli Lilly analysis. My interpretation, knowing what the FDA does and how it functions, is entirely different.

Q. Certainly, Doctor, you would agree that the FDA did not require a label change based upon the Japanese regulators' approach to this issue, did it?

A. Because it was in the post-marketing period and it couldn't impose it on Eli Lilly.

Q. Did it ever request -- did it request a change at that time?

A. Sir, we at the FDA know very well what we can obtain and what we cannot obtain, and we have very few people working on compared to the people working for a company and we have many, many problems, and we have a management system. What we can't obtain, we will not ask.

Q. Doctor, you're not suggesting that FDA ignored this submission and this contact by Lilly, are you?

A. The FDA doesn't ignore anything except that which has not been sent to it. I'm telling you that in the real world the FDA's duty is to manage its time wisely so as to address as many public health issues that it can address.

Q. Okay.

MR. BRENNER: Could I have P4436, please.

Q. (BY MR. BRENNER) Doctor, this was another document you talked about Friday with the jury.

Do you recall that?

A. 1596, yes.

MR. BRENNER: Just --

A. No, excuse me. This is 1586 or 96. I asked the question yesterday.

Q. I'm not sure how it's treated.

THE COURT: I thought we got an agreement that it was 96.

THE WITNESS: Thank you, Your Honor.

Q. (BY MR. BRENNER) The first thing Doctor, the first thing I note it's a draft document.

A. Excuse me.

Q. It's a draft document?
A. Yes.
Q. So would it be fair to say we're not sure whether this was complete, whether everything in it was accurate; it was a draft, right?
A. Yes, and I'm sure if the draft -- the final document was different, you'd be kind enough to supply it.
Q. Did my friends on this side of the aisle, were they kind enough to supply you with the final?
A. Obviously not.
MR. BRENNER: Okay. If we could go to internal page 6, please?
Q. (BY MR. BRENNER) You talked to the jury about one particular page of this document but I want to talk to you about another. You see this is sort of a chart of the way different regulators around the world handled the issue of diabetes for different atypical antipsychotics?
A. Yes, and this is prepared by Lilly and you can expect that Lilly is not going to do anything that is contrary to its interests, therefore, the draft to final issue becomes moot.

Q. If we just first look at the adverse reaction block, the second block from the bottom?
A. Yes.
Q. Okay. One thing this chart is telling us is that diabetes was in the adverse reaction section of the package insert for Zyprexa, for Risperdal, for Geodon, and for Seroquel in the United States, right?
A. That's what it says, but I don't know the exact verbiage in each case.
Q. Okay. But if you assume just for the moment that that's a correct representation, then for all atypical antipsychotics except Clozaril, the FDA treated diabetes as appropriately placed in the adverse reaction section of the package insert?
A. That depends on the wording, but generally speaking, yes, but we cannot derive conclusions from the imprecision that is still in this document.
Q. But another thing that -- this table reflects, Doctor, is there's a wide variation in the way regulators around the world treat the same event, isn't there?
A. And maybe there's a good reason for it.

Q. But you'd agree with me that Japan treats diabetes differently than Denmark and differently than Ireland and Korea, they have a different approach among all those different countries, don't they?
A. Again, you keep saying diabetes, and I want to say that this is not the case. Most of the time they were talking about hyperglycemia, and just talking about hyperglycemia doesn't mean anything if you don't see -- if you don't know, if you don't present what is exactly said about hyperglycemia in each case.
MR. BRENNER: You can take that down, Mike.
Q. (BY MR. BRENNER) Doctor, on Friday you recall testifying about certain data from a study, a clinical trial called the HGAJ trial?
A. Vaguely, yes. I referred to one of the H series.
Q. And you looked at one piece of -- basically, one piece of data from that study about glucose levels; is that right?
A. Are you referring to the -- yeah, I was referring to the high-level increase, high glucose increase group and the fact that compared

to placebo or haloperidol, I don't recall. We have to see the document. There was a statistically significant difference, and I refer to that as a signal.
Q. And that was one piece of data, one slice of the data from one clinical trial; isn't that true?
A. No, there were other pieces of data with respect to cholesterol with that same file --
Q. I'm focusing on glucose levels now.
A. Fine, but, yes, and a signal is a signal. It's a positive finding. If you don't find anything anywhere else, you're obligated to resolve that issue conclusively.
Q. Did you know that other analyses from the same study were performed and they didn't repeat or replicate the findings that you talked to the jury about on Friday?
A. I don't know what you are talking about. Are we talking about that the same data from the same trial was analyzed again and found to be not statistically significant in that particular group?
Q. No, sir. I'm talking about the fact that the data you chose to show the jury did not

reflect how the patients did over time. It isolated them at one point in time, a high point. That's right --

A. A certain point in time. High point means high level, and the studies were six weeks and if in six weeks you see that difference, it's very important.

Q. But your data, the data you chose to show didn't show all the glucose levels for each patient that were measured over time by trial, did you?

A. I grant you that, but we have to look at the importance of positive findings.

Q. Because the importance is you need to do more research and see if you can replicate or confirm those findings?

A. A signal that cannot be ignored is a signal that has to be addressed.

MR. BRENNER: Can I have EL2043, please? Just to orient us, Doctor. This was a submission made by Lilly to the FDA. We've talked about it before. I'd like you to go, Mike, to internal page 71, and, in particular, Table 5.12. Yeah. Okay.

Q. (BY MR. BRENNER) Doctor, this is a

report of the incidence of high or low blood glucose levels at any time in the entire placebo-controlled integrated database with the Zyprexa NDA in the acute phase. That's a review of all the patients in placebo-controlled acute phase studies, right?

A. That's what it says.

Q. And if we look here, the glucose nonfasting section, there were 1.2 percent of the olanzapine patients had a high value. But 1.7 percent of the placebo-treated patients did, right?

A. Well, as a medical officer, that raises a big question. How come placebo is worse than any drug?

Q. Right. And you would want to look at all the data on glucose levels to try to --

A. No, I would discount this kind of presentation as being totally practically impossible as statisticians call this. It's almost certain -- almost certainty that it doesn't work. You don't have placebo being significantly and consistently more toxic than the drug, especially in the low one which says 3.5 percent for olanzapine and 7.1 percent for

placebo. Please.

MR. BRENNER: Take that down, Mike.

Q. (BY MR. BRENNER) Doctor, do you know how many trials Lilly conducted -- clinical trials Lilly conducted on Zyprexa?

A. Not the exact number, but I would say a lot.

Q. Do you know that they conducted clinical trials that have run up to 12 months in duration?

A. Yes, I know that.

Q. And do you know that there were open label extensions for some clinical trials in which patients were followed for three years?

A. Yes. Open label is fine but it cannot replace controlled studies because you don't have a comparison.

THE COURT: Can somebody explain the meaning of open-label extensions?

Q. (BY MR. BRENNER)

Thank you, Your Honor.

Doctor, an open-label extension -- I'll take a step back. In a randomized placebo-controlled clinical trial, one group of patients gets the drug, another gets a placebo, a nonactive substance, right?

A. Yes, and these groups have been put together in order that they are essentially -- in many essential respects similar or identical.

Q. When we say a clinical trial is blinded or double-blinded, it means that neither the doctors running the research nor the patients know whether they're getting the active drug or the placebo, right?

A. You're correct.

Q. The reason we do that is so that we try to minimize the risk of introducing bias into the study, right?

A. Precisely.

Q. When we talk about an open-label extension, the blind is broken?

A. Both of them are broken.

Q. Yes, so that the patient -- for example, doesn't it sometimes happen in a trial a patient actually does well on the drug, would like to continue on the drug, the double-blind phase comes to an end, and then you can say well, we want to continue to gather data about you. But now we'll now tell you you are getting the active drug and now both the patient and the doctor know that?

A. You're absolutely right, and there are very good reasons to do that. Once you have established the efficacy of the drug during the controlled section, it would be unethical, sir, to not to have anybody in that group who wants to benefit for the drug to be put on the drug in the extension which is open with respect to blindness or blindedness to be precise.

MR. BRENNER: I think I answered Your Honor's question.

Your Honor, I don't know if it's an appropriate time to take a break.

THE COURT: Actually, it is. Ladies and gentlemen, why don't we take our second morning break and we'll be in recess for about 15 minutes.

THE CLERK: Off record.

(Break.)

(Jury in.)

THE COURT: Please be seated.

And we're back on record and all members of the jury are present.

Please continue.

Q. (BY MR. BRENNER) Doctor, Friday you told the jury about FDA advisory committees?

A. Yes, we talked about them. I don't recall the exact context.

Q. Advisory committees, as I understand it, are committees of outside experts upon whom FDA can draw if they feel they need their expertise on a particular subject?

A. Yes.

Q. They hold meetings that are open to the public which they assess questions and data presented by the FDA?

A. And the company.

Q. And industry?

A. In fact, usually the industry presentations are considerably longer than those by the FDA members.

Q. And am I correct, Doctor, that those advisory committees are convened at the request of FDA?

A. Yes.

Q. I think you told the jury that these advisory committees help the FDA when it's facing a thorny or difficult question; is that correct?

A. Usually, and the FDA members can have different reasons to believe that it's a complex or thorny issue.

Q. I gather, then, if the FDA doesn't feel the need for expert outside assistance on a question they don't convene an advisory committee?

A. That's not necessarily following.

Q. They don't convene an advisory committee on every issue that's presented to the FDA, do they?

A. That's true.

Q. And it's true, isn't it, that in the case of atypical antipsychotics and issues of diabetes or hyperglycemia the FDA never convened an advisory committee, did it?

A. No.

Q. Am I correct in saying that?

A. Yes.

Q. Doctor, is one way the FDA communicates with doctors though something called medical letters?

A. Medical letters. There is a publication that is called Medical Letters.

Q. But is it the case, sir, in your experience that if a doctor has a question, a medical or scientific question, that pharmaceutical companies have letters that

address topics regarding their drugs that are directed to healthcare professionals?

A. And there are brochures or you can call them anything you want. That's fine. I understand what you mean.

Q. Thank you.

MR. BRENNER: Could we put the ELMO on, please?

Q. (BY MR. BRENNER) Doctor, do you know if you ever looked at or were shown medical letters that Eli Lilly provided or had available to doctors regarding Zyprexa?

MR. FIBICH: Your Honor, we'd like to have these identified. And if he's going to cross-examine Dr. Gueriguian on these, we would like them to have them admitted into evidence so the jury can see them in their totality.

MR. BRENNER: I'm going to go through them briefly.

THE COURT: They need to be identified. You don't have to move to admit them into evidence, but the Plaintiffs can move them into evidence if they want to and if there aren't going to be objections, but if there are going to be objections, then I probably should hear about

it if you're going to show them now and we'll have the jury look at them.
MR. FIBICH: For the purpose of optional completeness, the State of Alaska now moves that any of these letters that are going to be shown to the witness in some limited part be admitted for their totality.
MR. BRENNER: All I'm asking the witness at this point, Your Honor, is whether he's seen them.
THE COURT: If that's the only question, that's the only question. But we're doing more than that when we put them up on the screen, so that's -- if he says he hasn't seen them and you want to end the questioning there, then we're not admitting them and we're not using them. If you start asking him and putting them up on the screen, then I assume they can be admitted.
MR. BRENNER: I understand Your Honor's ruling.
THE COURT: So that'll be the rule.
MR. FIBICH: I'm sorry, Judge. Tell me the rule again.
THE COURT: My understanding is

we're going to go beyond just asking him has he's seen them --
MR. BRENNER: I do not intend to.
THE COURT: Okay. So I think all he's going to do is ask him if he's seen them. He can show them to the witness and he says he hasn't seen them. But if they haven't been seen and his answer is going to be no and that's going to be it then they're not coming into evidence but they shouldn't be on the screen. That's what I'm saying.
MR. FIBICH: We would like them identified.
MR. BRENNER: I can do that, Your Honor.
MR. FIBICH: And provide copies to us.
MR. BRENNER: I have them. Certainly.
THE COURT: That should happen as well.
MR. FIBICH: And if these are letters at any length, we want Dr. Gueriguian to see the entire letter.
THE COURT: To what?

MR. FIBICH: Dr. Gueriguian to see the letter. Putting up some small part of a letter may be a misrepresentation.
THE COURT: What I understand is he's going to show the doctor the letters without putting them up and the doctor is going to say whether he has seen them. If he says he's not seen them, that's the end of the questioning. If he says he has seen them, and you're going to want to further use them, then we'll admit them, and we'll take it one step at a time.
MR. BRENNER: Very good, Your Honor. May I approach the witness so we don't have it displayed?
THE COURT: Yes.
And this is EL2993.
MR. FIBICH: Do you have a copy for us?
MR. ALLEN: Do you have a copy for us?
MR. BRENNER: I'd be happy to give it to you after I hand it to the doctor.
MR. FIBICH: Well, Your Honor, if he's got another copy, we would like to see it while the doctor's looking along with it.

THE COURT: That's fine. I just want to tell you, everybody, that when we end this, if the doctor is not done testifying he'd better be here tomorrow.
MR. FIBICH: Well, Your Honor, as sensitive as I am to that issue, I'm equally sensitive to my responsibility to the State of Alaska.
THE COURT: I understand that.
MR. FIBICH: Thank you.
THE COURT: I'm just letting everyone know what the rule is going to be.
MR. BRENNER: Would counsel prefer that I show it to counsel first?
THE COURT: That's normally what I like to have done.
MR. BRENNER: I'll be happy to do that, Your Honor.
MR. FIBICH: Is this a copy?
MR. BRENNER: No. That's not a copy. That was my copy to put on the ELMO, but I understand the concern.
Q. (BY MR. BRENNER) Doctor, the only question I have for you is whether you have seen this medical letter before --

I'm sorry, let me get out of your way.
A. I don't remember seeing it.
Q. Thank you, sir. I'll show counsel EL2996.
Doctor, have you ever seen that medical letter before --
MR. BRENNER: Sorry, Your Honor.
A. No, this is not a letter that I have seen.
Q. Thank you, sir.
THE COURT: And you might speak up a little bit, Doctor.
THE WITNESS: Thank you, sir.
MR. BRENNER: EL2987.
Q. (BY MR. BRENNER) Have you ever seen or been shown that medical letter?
A. No, I haven't.
Q. Thank you, sir.
A. I don't remember seeing it.
Q. And last is EL3012.
A. Thank you.
Q. Doctor, have you ever seen or been shown that medical letter?
A. I don't remember seeing this either.

Q. Thank you. Doctor, in your time at FDA do you recall something called periodic safety update reviews, PSURs for short?
A. You're referring to annual reports or periodic reports?
Q. Yes, sir.
A. Yes, sir. The ones --
Q. Tell the jury what those are.
A. Well, you have first to say what they're not, because it's important. Some adverse event reports have to be sent from the -- based on regulations within a 15-day of their receipt by the pharmaceutical company to the FDA. Those are important ones that have to be known immediately.
Now, for the rest, and depending at the time, the chronology, what period it was and which division did it or -- and other such things, this is an obligation to send an annual report with everything else and there may be a mandate for certain drugs to have periodic reports that are more frequent and, again, to send either everything or things that the FDA wants to have.
Q. Did you know that with respect to Zyprexa, Lilly has submitted 12 periodic safety

update reports to the FDA?
A. I don't know that they have submitted how many reports, but I assume that they would have been, because the FDA was interested in having all the information.
Q. Were you shown any of those, sir, before you formed your opinions in this case?
A. Not that I remember, and they didn't affect my opinion one way or another.
Q. Are you familiar from during your time with the FDA, with something called a periodic adverse direct experience report, or a PADER?
A. I didn't have any of those. Now we go into area where division has its own nomenclature, so it's very confusing. All I know is that there are -- there is for every case a knowledge by the manufacturers, companies at the request of the FDA to either send them in a regular fashion, if you will, according to general regulations or for specific purposes, they have to send off more often and more detailed.
Q. Were you aware, Doctor, that with respect to Zyprexa, Eli Lilly has submitted 14 adverse drug experience reports or PADERs to the

Food & Drug Administration?
A. No, but I can understand why perhaps.
Q. Did you review them before you made your opinions in this case?
A. No, I didn't, but it didn't affect my opinion one way or another.
MR. BRENNER: Could I have EL2127, please? If I could just go to -- pull that up, first. If I could have internal page 9.
Q. (BY MR. BRENNER) Doctor, do you see this submission that Lilly made to the FDA regarding diabetes mellitus and antipsychotic treatment in the United States, a pharmacoepidemiological study?
A. I see it. I understand it to be in the year 2001, and I also understand it to be in response to an FDA request.
Q. Did you review that response, Doctor?
A. I have to see it before I can --
Q. What part would you like to see?
A. I think I need to see the entire document.
Q. Okay.
MR. BRENNER: May I approach the witness, Your Honor?

THE COURT: You may. Counsel are free to approach the witnesses without asking for leave of the Court.
THE WITNESS: Thank you.
What EL was this, you said?
Q. (BY MR. BRENNER) Whatever was on the cover letter, Doctor.
A. I don't see --
Q. I believe it's at the top.
A. I didn't say the date. I said the EL number of the exhibit.
Q. I'm sorry. I'll tell you. 2127.
A. 2127?
Q. Yes, sir.
A. Thank you. No, I haven't seen this, or at least I don't remember seeing it. I would have remembered.
MR. BRENNER: Thank you, Doctor.
Can I have EL2032?
Q. (BY MR. BRENNER) Doctor, were you aware that in October of 2002 Lilly submitted a 100-page-plus report to the FDA on olanzapine and glucose homeostasis?
A. No, I didn't know in specifics, although I knew that there were an awful lot of movement

of interactions between the FDA and Lilly.
MR. BRENNER: Doctor, EL2033, please.
Let me see internal page 10.
Q. (BY MR. BRENNER) Doctor, were you aware that March of 2003, Lilly submitted a report in excess of 600 pages regarding adverse event reports of glucose disregulation and olanzapine?
A. I can't answer that question, because I may have seen a summary or something like that, therefore, I can tell you that I didn't receive a 600-page report, but I cannot admit that I'm not somehow aware of the essential content of such package.
MR. BRENNER: Could I have EL2036, please? Could I have internal page 11.
Q. (BY MR. BRENNER) Doctor, were you aware that in June of 2003, Lilly submitted a 70-plus page report regarding diabetes and atypical antipsychotics to the FDA?
A. What is the number -- the exhibit number, please?
Q. EL2036.
A. I assume that Lilly sent an awful lot of literature to the FDA, and I haven't seen this

one either.
Q. Thank you, Doctor.
MR. BRENNER: Can you take that down, Mike.
Could I have EL2119, please?
Blow that part up.
Q. (BY MR. BRENNER) Doctor, do you see this is another review and evaluation of clinical data by Dr. Boehm of the FDA?
A. Yes, I do see that.
Q. Do you know if you reviewed this document before forming your opinions in this case?
A. Is this a voluminous document or may I have a look at it?
Q. Certainly happy to hand it to you. It's not voluminous.
A. For ex-FDA, this is not voluminous. I haven't seen this document, but I agree with the -- what the summary says.
Q. Okay. Thank you.
MR. BRENNER: Actually, can we go to page 7, internal page 7 of that document. And bring up the paragraph underneath the table.
Q. (BY MR. BRENNER) Would you also agree,

Doctor, that Dr. Boehm of the FDA found the glucose lab abnormalities were common, but potential diabetes events were relatively rare among olanzapine and placebo-treated groups?
A. The fact that diabetes -- treatment-emergent diabetes is rare is something that is accepted. Now there was no difference between -- there was no marked difference in risks between the treatment groups. I can agree with that because there wouldn't have been in all probability sufficient statistical power to do that. And I do agree with what the reviewer said in his or her summary that with that -- despite that you cannot say that there is not such an effect, which is perfectly reasonable under the circumstance.
MR. BRENNER: Could I have EL2121, please?
Q. (BY MR. BRENNER) And we looked at this for another purpose a little while ago, Doctor. This is -- I can show you -- this is Dr. Racoosin's review of data regarding various atypical antipsychotics in May of 2001. Do you see that?
A. Yes.

MR. BRENNER: Could I go to page 8, internal page 8 on that, Mike, and the -- that paragraph right there. And the first sentence.

Q. (BY MR. BRENNER) Doctor, am I correct that Dr. Racoosin of FDA, based on her review of the NDA data for the five atypical antipsychotics found that they were not implicated for obvious diabetes mellitus? That was her conclusion, right?

A. That was her conclusion and I would agree with it with the proviso that I have to see her summary before I can give a very -- I mean a considered opinion on the subject.

MR. BRENNER: Could I have EL2130, please?

Q. (BY MR. BRENNER) Doctor, do you see that this is another review by Dr. Boehm, completed in August of '01, regarding epidemiologic studies involving atypical antipsychotics and diabetes?

A. That's what it says.

Q. Do you know if you ever saw this document before forming your opinions in this case?

A. What's the exhibit number -- EL2130?

Q. Yes, sir.

A. Again, I would appreciate receiving the document to make absolutely sure that I didn't see it.

Q. I can do that.

A. Thank you. I quite agree with her conclusions.

Q. Have you ever seen it before, though, sir?

A. No, I don't remember seeing it.

MR. BRENNER: Could we pull up page 9 of that document, and bring up that first big paragraph.

Q. (BY MR. BRENNER) And the first sentence. Doctor, do you agree with that finding by the FDA reviewer, Epidemiologic studies results suggest a relationship between treatment with an antipsychotic and increased risk of diabetes, but an important remaining question is whether the evidence describes a causal relationship between drug and diabetes risk or whether it simply reflects an increased diabetes risk in schizophrenics?

A. It is not a finding. It is an opinion based on whatever literature has been reviewed,

and as such, at that period in time, without the proper studies being done, I quite agree with it.

MR. BRENNER: You want to take that down.

Could I have EL2737?

Q. (BY MR. BRENNER) Doctor, am I correct that this is -- I think it's what's referred to in FDA parlance as a consultation by Dr. Mosholder?

A. Yes, I know Dr. Mosholder.

Q. He's an epidemiologist at FDA?

A. That's right.

Q. He's called upon sometimes to provide assistance to medical officers and other FDA officials?

A. In fact, the epidemiologists work on every NDA with all the divisions.

Q. And if we just go down a little bit on that. Am I correct that what Dr. Mosholder was doing here was reviewing updated medical literature? Here he talks about a total of 44 new references regarding this issue of atypical antipsychotics and glucose abnormalities.

A. I respectfully ask for a few seconds.

Q. Sure.

A. Well, I quite agree. Yes, I understand what Dr. Mosholder is saying, and I agree with his conclusions.

Q. Do you know if you reviewed that document before you formed your opinion in this case?

A. That's correct. But it wouldn't have affected my opinion one way or another.

Q. What's correct is you did not review it --

A. Well, that was the answer to your question to begin with, and then there was the corollary.

MR. BRENNER: Could I have EL2133, please?

Q. (BY MR. BRENNER) Doctor, this is another review by Dr. Boehm of FDA completed in 2005; do you see that?

A. Yes, I do.

Q. Do you know if you reviewed this FDA review before forming your opinions here?

A. Would you please hand me the document, sir?

Q. Yes.

A. Thank you.

Yes, I haven't seen this document, but I do agree with its conclusions, which are very sensible and well-supported.

Q. Let's just turn to that, briefly.

MR. BRENNER: If I can have page 11, the very bottom.

Q. (BY MR. BRENNER) Dr. Boehm wrote this: There have been a number of published studies regarding atypical antipsychotics and diabetes in the two years since our last literature update, but considering all of the results, there does not appear to be clear evidence to support changes in our position about this relationship.

Dr. Boehm wrote: The clinical pharmacology studies document interesting findings, but it is unclear to what extent the observed changes in metabolic laboratory parameters predict the risk of diabetes mellitus outcomes in treated patients.

That's what he wrote, correct?

A. Yes, that's what he wrote, which means that if you want some monitoring, you have to do proper studies to resolve this issue.

Q. And then a little further down in his note, in his report, am I right that Dr. Boehm

wrote: Given the inconsistent findings and incomplete information, it appears appropriate to continue to advise in labeling that patients treated with any of the atypical antipsychotics be monitored for diabetes mellitus?

A. I couldn't disagree with this statement. I totally agree with it.

MR. BRENNER: Thank you, Doctor. That's all I have.

THE COURT: Mr. Fibich.

MR. FIBICH: May I proceed?

THE COURT: I'm happy to have you do redirect at this time, but one thing I'm concerned about is to make sure the jurors get their questions in before the doctor has to leave.

MR. FIBICH: May we approach the bench?

THE COURT: Sure.

MR. FIBICH: How long can we go?

THE COURT: 2:00.

MR. FIBICH: Until 2:00.

THE COURT: We can take their questions now and then you've got the rest of the -- well, I want to finish him up. 2:00 is what

we've got.

REDIRECT EXAMINATION

Q. (BY MR. FIBICH) Dr. Gueriguian, I want to ask you a few questions.

First of all, let's go back to Changes Being Effected, CBEs, that we've talked about throughout this trial. Can a drug company do that at any time as long as they are strengthening a warning?

A. That's true.

Q. Any time they desire to do that?

A. Absolutely.

Q. And in this particular case, Eli Lilly and Company did try to strengthen a warning -- or did try to do a CBE warning change, correct?

A. Yes.

Q. And what did the FDA do with respect to that and why?

A. They didn't agree with it.

Q. Why?

A. Because they felt that it wasn't -- what they were requiring wasn't consistent with what the FDA saw.

Q. Dr. Gueriguian, you've been asked a lot of questions about what you've seen and what you

haven't seen. Describe for the jury how many boxes, or any way you want to, of material that has been sent to you by lawyers for the State of Alaska in connection with your opinions in this case.

A. Several boxes.

Q. And how voluminous is that?

A. Well, the usual FedEx box.

Q. Let me ask you this way: Have you seen all that you need to see to come to the conclusions and opinions that you've expressed here today?

A. Yes.

Q. You've been asked about a number of things that you may have or may not have seen. Why are those unimportant in coming to the conclusions that you've come to?

A. Because based on the basis of important and clearcut evidence, you are able as an expert to form an opinion; that's what counts. And in fact, everything that has been shown to me that I had leisure to look at were FDA opinions with which I agreed, so it didn't make any difference in my opinion because --

Q. Is it more important to you in forming

the opinions that you did that you see what was sent to the FDA or what Lilly knew internally within the organization in the company?
A. Well, they're both very important for me to form an opinion, but it depends what we're looking at. Sometimes what the FDA has received is important, and sometimes the FDA's request to get more is equally if not more important.
Q. And what was it that triggered the FDA's request to get more information?
A. In which circumstance?
Q. In 2006 -- '7 --
A. It was a realization that they didn't have in all probability all the important information about this drug.
Q. That followed the publication of the story in the New York Times; is that correct?
A. Yes.
Q. Dr. Gueriguian, you were asked if hyperglycemia and weight gain was in the package insert which is synonymous with the label?
A. Yes.
Q. Is hyperglycemia and weight gain in the warning section?
A. Yes.

Q. The warning section?
A. Sometimes at the end of the --
Q. I'm talking about prior to 2007.
A. Oh, okay. It is not.
MR. BRENNER: Objection; that's misspoken, Your Honor but we can clear it up later.
THE COURT: You can clear it up later.
Q. (BY MR. FIBICH) Is hyperglycemia and weight gain in the warning section from 1996 to 2006?
A. I have the 2004 in my hand, and I'm looking at the warning section. It says neuroleptic malignant syndrome, tardive dyskinesia and that's it.
Q. Dr. Gueriguian, you've mentioned that different countries have different power to regulate pharmaceutical companies. Does the FDA have less power, in your opinion and experience, than other regulatory authorities in other countries?
MR. BRENNER: Objection, Your Honor, that's far beyond his knowledge.
MR. FIBICH: He opened the door on

it, Judge. He went all through it.
THE COURT: It's a question of expertise. There will be other witnesses, I assume, that can talk about these things, but I'll sustain the objection.
Q. (BY MR. FIBICH) With respect to the FDA's power, does the FDA have the power to make a company take a drug off the market once it's been approved?
A. No.
Q. How difficult is it for the FDA to make a drug company do anything, particularly with respect to strengthening a label?
A. Very difficult.
Q. Doctor, you were asked a number of questions about various studies that the company lawyers put on the board --
MR. FIBICH: Can we turn this on, please?
Q. (BY MR. FIBICH) And one of which was earlier talked about by the company lawyers, and this is a study in which the authors are Patrizia Cavazzoni, you see that?

THE WITNESS: Yes.

MR. FIBICH: Alan Breier and John Buse. Do you see that?
A. Yes.
Q. Do you see at the bottom this was a study done by the Eli Lilly and Company?
A. Yes.
Q. If we go to the back, sir, do you see that Ms. Cavazzoni is a Lilly employee and is going to testify in this case or has been designated to testify?
A. Yes.
Q. And we see that Dr. Breier is with Lilly Research Laboratories. Do you see that, sir?
A. That's correct.
Q. And we see that Dr. Buse is with the North Carolina school in Chapel Hill. You see that?
A. Right.
Q. But then there's a disclosure down here at the bottom that Dr. Buse has received honoraria, consulting fees and research grants from Eli Lilly.
Do you see that, sir?
A. Yes.
Q. Doctor, you're aware, are you not, of a

study that has been known as the CATIE study?
A. Yes.
Q. That was a study that was published in the New England Journal of Medicine?
A. That's right.
Q. And that study -- and what is the New England Journal of Medicine?
A. It's the premier journal, medical journal in the United States and the world.
Q. Okay. And are you aware that this study which looked at the effectiveness of any antipsychotic drugs in patients with chronic schizophrenia was funded by the National Institutes of Health?
A. That's right.
Q. And this study was performed to determine the effectiveness of second-generation antipsychotic drugs compared with older agents; is that correct?
A. It is correct.
Q. And the conclusion of this study published in the New England Journal of Medicine was that olanzapine was associated with greater weight gain and increases in measures of glucose and lipid metabolism; is that correct?

A. Yes.
Q. Now, Doctor, much has been said about -- that there are different studies with different conclusions, different evidence relating to this issue of causation. You've been examined about that earlier today, correct?
A. That's right.
Q. Once again, for a drug company to have a responsibility to strengthen a warning, is causation required?
A. No.
Q. What is required?
A. Required that there be sufficient evidence to consider that there's a risk.
Q. Okay. Now, sir, are you familiar with the ConSensus panel that was empaneled to look at the issue of antipsychotic drugs, obesity and diabetes?
A. Yes, I am.
Q. Okay. And that was a panel that was made up of organizations such as -- such diverse organizations as the American Diabetes Association, the American Psychiatric Association, American Association of Clinical Endocrinologists and the North American

Association for the Study of Obesity; is that correct?
A. That's right.
Q. And this consensus panel met for three days in November of 2003 on the subject of antipsychotic drugs and diabetes; is that correct?
A. That is correct.
Q. And this study ConSensus was paneled for what purpose?
A. For the purpose of addressing the question whether or not the Zyprexa and other such atypical antipsychotics, what was the opinion of experts on that subject.
Q. And, sir, presentations were made, were they not, by the Food & Drug Administration?
A. Yes.
Q. By representatives from AstraZeneca, Bristol-Myers Squibb, Janssen, Lilly and Pfizer Pharmaceutical Companies?
A. Yes. That's only fair to give both sides and the opportunity to talk and present their point of view.
Q. And the pharmaceutical companies that I just referenced; AstraZeneca, Bristol-Myers

Squibb, Janssen, Lilly and Pfizer are the manufacturers of those second-generation antipsychotics, correct?
A. Yes.
Q. Let's go back to who made up the ConSensus panel.
Do you recall who was on the panel?
A. Not off the top of my head, no.
Q. Here it is on the back. We had a panel that was comprised of one, two, three, four, five, six, seven, eight individuals, correct?
A. Yes.
Q. And then the support for this conference was actually paid for by grants from the manufacturers of the antipsychotic products that were being studied relative to their association with weight gain and hyperglycemia and diabetes, correct?
A. Yes.
Q. And then the panel members, the people that were deciding this had -- there's a disclosure that they had received grant support, honoraria and consulting fees from Pfizer, Lilly, AstraZeneca, Janssen, Novartis, correct?
A. Novartis, yes.

Q. Additionally, the presenters at the conference included again, Dr. Cavazzoni and Dr. Buse and many other people.
You see that, sir?
A. That's right.
Q. Now, in addition to giving everybody a fair chance to be heard and in addition to having representatives of the manufacturers present, they also were given something else. And that was the ConSensus panel was given copies of most of the known peer-reviewed English language clinical studies published in this area, as well as additional articles from animal studies, other papers, and abstracts.
Do you see that?
A. Yes.
Q. So everything that you've been asked about by these company lawyers and everything that was peer-reviewed, animal studies and the like, and all of the English language these people had, correct?
A. That's what it appears to be.
Q. And when it came down to the conclusion of this ConSensus panel, as referenced by this chart, what was their conclusion, sir?

A. Well, with respect to second-generations and their metabolic abnormalities, weight gain, from top, clozapine, to the bottom, ziprasidone, it was a lowering of the effect, that is to say, clozapine and olanzapine had the greatest weight gain in the opinion of these people. And diabetes was also clozapine and olanzapine. And the -- the evidence were not clear with respect to the ones that have a D on the column instead of a plus or minus or whatever. And worsening of lipid profile was exactly the same for clozapine and olanzapine up top, and the other ones still undetermined.
Q. So, the bottom-line conclusion was that there was not comparable rates of hyperglycemia, diabetes and weight gain; is that correct?
MR. BRENNER: Objection; leading.
MR. FIBICH: I'm trying to get this done.
THE COURT: It is to get it done, and I'll allow a little latitude.
A. I think it's very clear that that was the conclusion.
Q. (BY MR. FIBICH) Dr. Gueriguian, I also want to show you a policy committee meeting that

occurred on April the 12th of 2002 entitled Zyprexa Safety Overview.
You see that, sir?
A. Yes.
Q. And this is another internal Lilly document?
A. Yes.
Q. And in the introduction it says: Pfizer's Geodon and BMS --
A. Bristol-Myers.
Q. -- Bristol-Myers Squibb, Abilify appear to have less metabolic issues than other atypicals, correct?
A. That's what Lilly says.
Q. Would that be indicative that there's comparable rates as known by Eli Lilly and Company?
A. Not as Lilly sees it in its own document.
Q. Then it goes on to say, The results of two Lilly epidemiological studies analysis of advance PCS and GPRD databases indicate that the risk of diabetes mellitus is increased in patients treated with antipsychotics, including Zyprexa.

Do you see that, sir?
A. That's what it says.
Q. One of the analyses that you were asked about by the company lawyers was this study here. Again, a Retrospective Cohort Study of Diabetes and Antipsychotic Treatment. And, again, we have the Lilly consultant, Dr. Breier and Dr. Cavazzoni participating as authors.
You see that?
A. Yes.
Q. And would you read the conclusion that I've outlined here?
A. An increased risk of developing diabetes compared with the advance PCS general patient population was -- I don't see the edge --
Q. Observed during treatment with conventional --
A. Was observed during treatment with conventional or atypical antipsychotics.
Q. And this advance PCS is what was referred to in the prior document I showed you, correct?
A. That's right.
Q. Doctor, we've previously been talking about Exhibit 7971. I want to go back to that.

And in it this is another preparation to deal with issues and the question is: I have heard that Zyprexa causes diabetes, and it goes on to say in a large retrospective analysis, the incidence of treatment-emergent glucose elevations was comparable to placebo 3.1 to 2.5.

Do you see that?

A. Yes.

Q. Now, that is not what Eli Lilly had revealed in their proposed label change that they discussed internally, correct?

A. That is correct, 3.6 percent for olanzapine versus 1.05 percent for placebo.

Q. How did Eli Lilly go from 3.6 for olanzapine and 1.05 for placebo to the statistics that they used in this information to give doctors?

A. I have no idea.

Q. Do you recall the discussion about torturing the data?

A. Yes.

Q. Is it your understanding that this is what was done by means of a categorical analysis?

A. Probably.

Q. You're not sure?

A. Well, it's not a question of being sure or not sure. It's just that it is enough to show the -- the dichotomy, the difference to show that there's something totally wrong here.

Q. Doctor, this is another document that we've discussed earlier.

1901, hyperglycemia/diabetes data on demand resource guide.

A. Yes.

Q. And this is the document that indicates that certain doctors were concerned about the relationship between Zyprexa, hyperglycemia and diabetes, right?

A. Well it says that 60 percent of them answered that they believe there was a link between Zyprexa and diabetes.

Q. Let's go over their strategy. The strategy here, sir as set out in this -- as set out in this document is our goal -- our goal -- that means what they're trying to accomplish, right?

A. That's the objective, yes.

Q. -- is to continue to drive new patients starts on Zyprexa, keep patients on therapy longer, and ensure the appropriate doses

utilized. In order to maximize this effort, we must neutralize the hyperglycemia/diabetes issue, help physicians manage weight gain and continue to sell the unparalleled efficacy and dependability of Zyprexa.

Does this appear to you to be an effort to hide and downplay the risk of diabetes?

MR. BRENNER: Objection, Your Honor. It's not an area of expert testimony. It's his personal opinion.

MR. FIBICH: I'll rephrase the question.

Q. Is it appropriate for Eli Lilly and Company to have a goal to neutralize this issue? Is that in compliance with FDA regulations?

MR. BRENNER: Same objection.

THE COURT: That is overruled.

A. DDMAC objects to that, and as the FDA in its entirety would object to that.

Q. (BY MR. FIBICH) And it goes on to say, By neutralizing, to mean leveling the playing field, setting the record straight with comparable rates message.

A. Yes.

Q. Do you see that, sir?

Now, the FDA did not get this information, did they?

A. I don't think so.

Q. Let's go to Message Point No. 2: Many physicians think there is a logical link between weight gain and diabetes. In market research, we see that many of them even use these two words interchangeably. We believe it is essential to weaken this link in order to neutralize the diabetes/hyperglycemia issue.

Is that an appropriate thing for a pharmaceutical company to be doing with its sales force with respect to those that may prescribe this drug?

A. Totally inappropriate.

Q. It's illegal, is it not?

A. Well, I am not an expert in legality.

Q. It goes down, sir, and it concludes that, Neutralizing any concern from our customers is essential to the future growth of Zyprexa in the marketplace.

Do you see that?

A. That's what they say.

Q. Doctor, you've been asked a lot of questions about causality. I want to, again, ask

you: Does causality require as to when a company should change its label to a warning?
A. No.
Q. And when should Lilly have changed its label to a warning, sir?
A. When there was enough evidence to show that there may be a public health issue.
Q. When was that, sir, in your opinion?
A. I think it began -- the signals were clear in 1995, 1996. They strengthened, and I am of the opinion that by 2002, in the absence of Eli Lilly doing additional studies to settle the issue, Eli Lilly was obligated to err on the side of caution.
MR. FIBICH: Pass the witness, your Honor.
THE COURT: Mr. Brenner.
FURTHER CROSS-EXAMINATION
Q. (BY MR. BRENNER) Doctor, that regulation you were just shown, that guides the conduct of medical officers at the FDA, too, doesn't it?
A. Yes.
Q. Okay. Thank you. I want to clear up -- I think there might have been some confusion

about this label change. Let's make sure we're all on the same page.
Doctor, I want to show you -- this is from -- I'll show you the date.
This is the September, 2003 package insert for Zyprexa. That will take us to the Warnings section.
This begins the Warning section that starts with neuroleptic malignant syndrome, correct?
A. Well, let me get to this -- to the page. Warnings, yes. I'm there. I'm looking at the PDR.
Q. Okay. I'm not sure it's going to match up precisely. It may be easier to work off the screen.
A. Well, PDR is the one that makes the physicians aware of what's going on.
Q. Right. I think all I'm trying to establish is that as of 2003, that date in 2003, hyperglycemia and diabetes were addressed in the Warnings section of all atypical antipsychotics, including Zyprexa, true?
A. Could you go to the point where it says Warnings?

Q. Yes. It's on the previous page.
A. Well, could you please show me that and then let's move on.
Q. I'll have to flip the page, or I could show --
THE COURT: Show him the document.
A. That's right.
Q. (BY MR. BRENNER) We'll show you the document, Doctor. The Warnings are at the bottom of that.
A. Yes, tardive dyskinesia, yes. Yes, it makes the -- it is in the Warnings section, but it's not in the PDR, and it does say that there's a class effect. Zyprexa is not worse than any of the other atypical antipsychotics.
Q. Well, it actually doesn't say that in the Warnings. It's just that the FDA directed that warning go into all atypical antipsychotics.
A. It says that in the first sentence.
Q. It says it in the first sentence. The first sentence says, Hyperglycemia, in some cases extreme and associated with ketoacidosis --
A. Has been reported in patients treated with atypical antipsychotics, including Zyprexa --

Q. Yes.
A. -- which is the class effect. It's no different for any one of them. That's what I just said.
Q. Yes, and that's the direction that FDA gave to Lilly and the other manufacturers to include in the warnings.
A. With the information that they had or didn't have from Lilly, yes.
Q. Doctor, is it true that promotional materials are submitted to DDMAC for review?
A. They should be.
Q. Yes. You were asked about the ADA consensus statement. Do you recall that?
A. It's not just the ADA, but, yes, I know what you mean.
Q. Okay.
MR. BRENNER: Could I have, quickly, TG149, please. And if you could just blow up the center section.
Q. (BY MR. BRENNER) Am I correct, Doctor, that consensus statements issued by ADA do not represent an official Association opinion, according to their own internal guidelines?
A. Well, that's only normal because it

represents the consensus of all the expert scientists, but for whatever reason, one or another association wouldn't like for -- to associate with it. This is normal way of doing things.

MR. BRENNER: You can take that down. Can I have EL2001?

Q. (BY MR. BRENNER) Doctor, following the consensus statement that was published, there are a series of letters and responses from various entities, are there not?

A. That's right.

Q. And one of them was submitted by officers at the FDA, correct?

A. That's correct.

Q. By Drs. Boehm, Racoosin, Laughren and Katz?

A. Yes.

MR. BRENNER: Can we pull up that page? Yeah, it's right there. Let's blow that up.

Q. (BY MR. BRENNER) And you've told the jury before who those physicians are at FDA.

A. Yeah, we know who they are.

Q. Yeah.

MR. BRENNER: Can we just show the lines above that, please.

Q. (BY MR. BRENNER) And those officers, those officials at FDA wrote in response to the consensus statement and disagreed, right?

A. No, they didn't disagree. They agreed on one issue, which was the recommendation to monitor the patients treated with these second-generations, and they still didn't disagree, but they expressed their belief that as in a regulatory agency and its constraints, we do not believe that the available evidence allows the ranking of diabetic risk in the various antipsychotic drugs.

This is -- I agree perfectly with that. FDA couldn't do anything more than that.

MR. BRENNER: Thank you very much.

MR. FIBICH: Just a few, Your Honor, if I may.

THE COURT: I really want to get the jury questions in. I'll give you two minutes.

MR. FIBICH: Two minutes, I'll take it.

CONTINUED REDIRECT EXAMINATION

Q. (BY MR. FIBICH) Dr. Gueriguian, when the FDA wrote the letters that have just been referred to, did they have the same data that this jury has seen, the same information?

A. No, no, not to my knowledge.

MR. BRENNER: Objection.

Q. (BY MR. FIBICH) With respect to these training guides, these are internal Lilly documents, correct?

A. That's correct.

Q. This is not something that DDMAC would have purview over, correct?

A. Well, certainly not.

Q. It's not something that had been given to the FDA?

A. That's -- to the best of my knowledge, yes, these documents are internal managerial documents. In fact, some of the people at the -- of the people at Eli Lilly are not privy to this kind of thing.

Q. In the package -- or the product label package insert that you were just asked about, what year was that?

A. 2003.

Q. Would you compare that to the 2004 and

see if that language is in there?

A. Warnings, warnings. No, it ain't.

MR. FIBICH: Pass the witness, Judge.

FURTHER CROSS-EXAMINATION

Q. (BY MR. BRENNER) Is that -- are you looking at the PDR, Doctor?

A. But, of course. I mean, why would it be in the PDR in 2003 and suddenly magically disappear from the PDR in 2004?

Q. That's my point, sir. The package insert in 2004 had the same information as in 2003 regarding hyperglycemia and diabetes.

A. Well, here it is.

THE COURT: Let me see if I can do this. Changes to a packet insert in 2003 when they got included in the PDR would depend on the publication schedule for the PDR; wouldn't that be true?

THE WITNESS: That would be true for 2003 as well as 2004.

Q. (BY MR. BRENNER) You don't -- Doctor, you don't know the lag time between changes that are sent out to the medical profession and when they're published in the PDR, do you?

A. What I'm saying is the 2004 PDR publication doesn't show the -- what was present in the 2003 PDR publication.

THE COURT: But you aren't looking at the 2003 PDR. You were looking at the 2003 package insert. They're different, aren't they?

THE WITNESS: Yes, they may be in terms of date, but I'm looking only the PDR here and their chronology.

THE COURT: So you see in the PDR for 2003 these warnings, but not for 2004; is that what you're saying?

THE WITNESS: That's what I see, yes.

THE COURT: Okay. Do you have both PDRs in front of you?

THE WITNESS: Yes. Here it is.

MR. BRENNER: Nothing further.

THE COURT: Any questions from the jurors?

THE CLERK: Anybody else?

THE COURT: Could the counsel please approach?

(Bench discussion.)

THE COURT: Two questions.

MR. BRENNER: I don't have any objection to No. 1, Your Honor.

THE COURT: Well, I need to see the exhibit for me to know what you're being asked.

MR. FIBICH: May I see the first question again?

THE COURT: I don't know what the verbatim means -- here it is. I'm going to let him answer question No. 1.

Can we give them copies of the PDRs?

MR. FIBICH: We can give them all.

MR. BRENNER: Your Honor pointed out correctly there's this time lag --

THE COURT: I understand that. You guys can explain it. But rather than have him reading the warning, it would be better for them to see the warning.

MR. FIBICH: Give them all the PDRs.

THE COURT: I assume there will be other witnesses that 2007 is going to end up getting discussed. It's pretty hard for me to see how all the witnesses won't get cross-examined on that subject. So why don't we

arrange to get them the PDRs step by step and we'll deal with that.

Can we put up the verbatim page for one more minute?

MR. FIBICH: Sure. I'll go put it up.

Excuse me.

(End bench conference.)

THE COURT: Doctor, there are two questions. And just so that the jury knows, the second question is: What does the 2003 PDR warning label state for Zyprexa? Can you read it to us? What I've arranged to do, ladies and gentlemen, is as this trial progresses, we're going to get you all the PDRs over time so that you can see them all and actually have that. So rather than have the doctor take the time just to read the 2003 one, we'll get you the PDRs in the course of the trial.

The question, Doctor -- and that's why we put up Exhibit 1111 -- is: Do you agree with the statements of the verbatims -- which is why we put up the key verbatims page of that -- used by Lilly in Exhibit 1111? So could you go through each of the bullet points there and give

us -- let the jury know whether you agree with those statements and if you don't agree, I'll let you explain why not.

THE WITNESS: The comparable rates of diabetes and hyperglycemia among psychotropics, I don't agree with and the reason is simple and I've stated it earlier. The most you can say by being very -- as fair as can be expected, is that the issue is not settled. I also referred to a very well-done research that was published in 2008 that prove --

MR. BRENNER: Your Honor.

THE COURT: I don't want you talking about 2008.

THE WITNESS: Fine. So on that basis, I don't agree that the comparable rates should have been used in marketing because that's what it is all about.

Now, the weight gain and hyperglycemia, I totally disagree with the first subsection, which says that those who had an episode of hyperglycemia did not experience substantial weight gain in longer-term comparative studies. The issue is not, again, to categorize and work with the group. The issue is

that independently a certain fraction of the population have considerable significant weight gain and an internal Lilly document -- some of the expert scientists working for Lilly said some of them have shown more than 80-plus pounds of gain, and he added, It is ludicrous to say that there is no problem of weight gain here.

Independently, the same type of thing applies to the hyperglycemia. And this is very important because hyperglycemia, which is occurring very often relative to other drugs, and weight gain, which is certainly coming up very often and very severe in some cases, plus the -- dyslipidemias are in essence the definition of diabetes. So you can't ignore that.

Now, as to the -- even among those patients with substantial weight gain, over 96 percent had no glycemic abnormalities at all. Again, we call that a petition of principle, that is to say, we know that increased glycemia and diabetes occurs in only 1 percent or so of the population. What you have to say, what happens to those 1 percent, which is the question that we have to address for the public health, defense of public health.

Now, do you want me to continue, sir?

THE COURT: Could you just go through the other two factors?

THE WITNESS: Yes. Diabetes is common and more common in patients with schizophrenia and bipolar disorder. It really doesn't matter. The issue is not that. The issue is how many are getting to be diabetic or predisposing to diabetes in the people treated.

A number of factors affect risk for diabetes. Intrinsic factors, variable factors. Yes, but that's not the issue again. I'm not here to discuss the natural history of diabetes. We're here to answer the question: Does Zyprexa cause or is correlated with diabetes?

THE COURT: Thank you, Doctor. Any quick follow-ups? Was there another -- one more question?

MR. FIBICH: I thought we had another question up here, Judge.

VENIREPERSON: Oh, no, I'm fine.

THE COURT: Okay. Any quick follow-up, just on that?

MR. BRENNER: No, Your Honor.

MR. FIBICH: No, Your Honor.

THE COURT: Thank you very much, Doctor.

THE WITNESS: Thank you, sir.

THE COURT: Ladies and gentlemen of the jury, we've reached the end of our trial day. And, Counsel, I'm going to bring -- unless you tell me that that's going to create problems with the witnesses that are coming, I would propose that we bring the jury back and start with them at 9:30 in the morning. That will let us take up some of the issues that I was hoping we would get to, but I don't think we are going to get to.

MR. FIBICH: That will work fine with us, Your Honor.

THE COURT: Does that work for everybody?

MS. GUSSACK: That's fine, Your Honor.

THE COURT: Okay. Ladies and gentlemen of the jury, what I'll have you do -- we'll try to start our evidence at 9:30 in the morning because we're going to -- I know we're going to take up pretrial issues that I was hoping we would get to at the end of the trial

day, but I don't think we are given that we've gone -- so if you would all be here about 9:15, 9:20, and then hopefully we'll be able to get started right away at 9:30 in the morning.

Again, I would caution you: Please do not discuss this case with anyone or let anyone discuss it with you. Please try to keep an open mind until you've heard all of the evidence in this case. Have a nice afternoon.

(Jury out.)

THE COURT: If you've got any of the documents that were published, if you could leave them on that corner over there.

THE WITNESS: May I, Your Honor?

THE COURT: You may.

We're outside the presence of the jury. Please be seated.

Again, I'd like to take up in the morning the question of -- I suppose the interaction between off-label marketing and warnings and some of the other issues that were raised in the letters and the response to the letters --

Mr. Allen.

MR. ALLEN: Yes, Your Honor. And I

want to get something clear. I think that the phraseology and the semantics we're using -- excuse me -- I think the phraseology and the semantics we're using is leading to a misinterpretation. I'm not here talking about off-label promotion. What I'm asking the Court to do is not to worry about off-label promotion. I'm talking about the issue of the actual use of the drug in the population. Other uses. And on their opening statement they talked about 23 million people, and --

MR. LEHNER: Your Honor, are we going to argue this?

MR. ALLEN: No, no, hold on. Semantics, while we think about it. I'm not arguing anything about off-label promotion. That's all I want to say.

The other thing I'd like to say, Your Honor, is I know you have limited time. I gave you the Eski deposition. We have to play her Wednesday morning, and they haven't given the cuts, and I'd like the cuts and give them to you so you can rule, because we need to play it Wednesday morning.

THE COURT: And I would like that,

too, because while I may have some time tonight to work on the ones that I haven't worked on, Tuesday night will be more difficult.

MR. LEHNER: And we indicated yesterday that we would get them to you this afternoon so that you could work on them tonight.

THE COURT: Okay. So the next thing is Eski?

MR. ALLEN: Yes -- well, we are going to play Ms. Eski's deposition on Wednesday morning, but I knew that this is Monday, so --

THE COURT: Right. But, I mean, in terms of my order of trying to --

MR. ALLEN: Yes, sir.

THE COURT: What I'm trying to do is get out of your way, so that you can -- I can make my rulings and you can move on with your case presentation.

MR. ALLEN: And we'll need those rulings tomorrow. That's why you need -- sorry, that's all.

THE COURT: If you get me something today and it's just one deposition, I'll try to do it after hours tonight.

MR. LEHNER: We'll get them to you.

We will, Your Honor.

MR. ALLEN: And I apologize to Mr. Lehner if he thought I was trying to argue the motion. I apologize. But I'm not -- I want the Court to understand what my argument is not about. It's about other uses, not off-label promotion.

THE COURT: Okay. As long as I've got five minutes, what -- just give me a sense of scheduling and problems with scheduling, if there are some.

MR. ALLEN: I think we're fine, Your Honor. Tomorrow, we're starting at 9:30. We will probably play Dr. Charles Beasley in the morning, first thing. And we'll play -- we call Robin now. We'll probably play Robin after Charles, Dr. Beasley.

MR. LEHNER: Tomorrow?

MR. ALLEN: Tomorrow. Tomorrow's Tuesday.

THE COURT: Tell me her last name again and I'll phonetically do it, so I can --

MR. ALLEN: Well, now you've got me --

MR. FIBICH: Robin.

MR. SUGGS: Wojcieszek. It's got a J in there, but it sounds like a Y.

THE COURT: Okay.

MR. ALLEN: This is my tentative plan, Your Honor. I'm going to come close. We're going to play Beasley, Wojcieszek and probably Lechleiter tomorrow, and Tollefson. We probably have time for all the four of those. And Tollefson.

MS. GUSSACK: Mr. Allen has cut down Dr. Breier, I understand, but I don't know that we've received those revised designations. Have we?

MR. ALLEN: No, but I'm not playing him tomorrow. But I'm getting -- you know what I'm doing, Ms. Gussack? Right now they're trying to print you out a new one for Dr. Breier.

MS. GUSSACK: Terrific. Okay.

MR. ALLEN: Here. They've appeared.

MR. SUGGS: This is hers and the judge's?

A SPEAKER: This is the Court's.

MR. ALLEN: So, now, I think you have every deposition that we're going to play.

THE COURT: So --
MR. ALLEN: That's Dr. Breier.
THE COURT: Breier, I have not -- this is Breier and Eski revised deposition cuts. So this is what I will -- I'll be getting a -- the objection and the other objections or requests from Lilly as to Eski. Am I going to get Breier, too?
MR. LEHNER: Probably won't get Breier this afternoon, since we're just getting the revised for Breier right now, but then we'll get you those tomorrow if we can.
MR. ALLEN: Your Honor, one thing. So the record's clear when they read the record, that is not a revised Eski cut. That's the exact Eski cut I gave them yesterday. And so to go on your scheduling, we're fine. We got through tomorrow. I think I have -- what did I say? -- Beasley, Wojcieszek, probably Tollefson and Lechleiter. And then we're going to move into Eski on Wednesday, and we don't know who else after that. We're going to give them 24 hours' notice. But we have the next day taken up.
THE COURT: Okay. And in terms of where we're going, there had been some mention

over the weekend that there was a witness that the defense might call on Thursday and that because of that the Plaintiffs would probably be resting on Monday. Are we still there or --
MR. LEHNER: She's not available now on Thursday as it turns out, and I had let them know yesterday afternoon.
So, I guess I'd like to know when you all think you may be finished and we would be required to put on our first witness. If you have any idea, that would be very helpful.
MR. ALLEN: We'll work on it.
THE COURT: You're not going to be calling any witnesses in the middle of their case, it looks like?
MR. LEHNER: Well, the only one that I mentioned then was that there was a doctor who's coming on Monday from the East Coast who would be here on the 17th. But if they're done on Friday as we thought you might be, then that shouldn't be a problem.
MR. ALLEN: We'll let you know as soon as we can, Your Honor. We had worked around their schedule for their Thursday witness, and -- the whole trial, before it started, so it's kind

of thrown us off a little bit. But we'll let you know as soon as we can.
THE COURT: Okay. I'd just like to periodically update the jury as to how we're doing and when the Plaintiffs might be resting, and let them know as things are moving along that things are moving along and --
MR. ALLEN: Things are moving along.
MR. LEHNER: When they would be resting would be helpful so that we could begin to plan when we need to --
THE COURT: Again, they're not resting before Friday. So by -- we'll revisit this question towards the end of the week.
MR. ALLEN: They've thrown us -- they threw us off when they changed their mind, so we're going to have to work on it.
MR. FIBICH: Your Honor, there's one other issue. Some of us thought that you said you may not hold court on Monday, the 17th?
THE COURT: I don't think I said -- well, I might have said that at some point downwind because I do -- today's a Monday. Normally, I would be doing settlement conferences

for other judges on Monday. But I moved my morning settlement conference for this Monday, and I believe I've moved it for next Monday as well. So we -- unless I tell you differently tomorrow, we're going on both Mondays -- well, we went today and we'll go next Monday as well.
Then, I'll see the parties somewhere between 8:15 and 8:30 tomorrow, and we'll take up some of these other legal issues. And I will try to get -- I'll wait to get the defense response to the Eski cuts and then I'll try to work tonight on Eski.
MR. ALLEN: Thank you, Your Honor.
THE COURT: We'll be off record.
(Off record.)

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 testimony and proceedings taken at that time; and that I am not a party to, nor do I have any interest in, the outcome of the action herein contained.

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

_____

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