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 13

TRANSCRIPT OF PROCEEDINGS

March 19, 2008 - Pages 1 through 242

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: Please be seated.

We're on the record in State of Alaska versus Eli Lilly and Company, 3AN-06-5630 Civil. Counsel are present; we're outside the presence of the jury. Good morning to everyone.

We have a few things to take up before we bring the jury back. Just so that I can get some things out of the way, Eli Lilly filed objections to the State's counterdesignations for the Wojcieszek deposition. Those are overruled.

Eli Lilly filed counterdesignations to the State's designations of the deposition of Joey Eski. Those are overruled as well. I think we just got something for Lechleiter, and oh, Toleffson. Lilly objected to the State's counterdesignations for Gary Toleffson, and those are overruled. The ones for Lechleiter were just filed this morning and I haven't had a chance to review them.

There's a stipulation concerning the Physicians' Desk Reference, and I assume I will read that stipulation to the jury.

MR. ALLEN: Your Honor, we hadn't

signed it and --

MR. LEHNER: We had given it to them on Thursday or Friday of last week --

THE COURT: Oh, okay. This is a proposed stipulation; it's not a stipulation yet.

MR. LEHNER: We had provided them this draft Thursday or Friday of last week and hadn't heard anything back so we just went ahead and filed it today just so it has record on the record. So we were waiting to hear from them some.

MR. ALLEN: My comments would be if they will provide me the evidence to support this stipulation, I'll look at it. And we don't have this within our knowledge, and I don't feel comfortable stipulating to things that I do not know, including the fact that when it has to be supplemented. I don't know these things. If I signed it, it would be incorrect. We offered to put in the PDRs. I have no problem with them putting in the supplements to the PDRs. That's not a problem but I can't in good conscious stipulate to something when I don't know the facts.

THE COURT: You can find out the

facts pretty quickly, can't you?
MR. ALLEN: No, sir, I can't. I don't have any dealings with the Physicians' Desk Reference and the publishing company that does it. If they would provide me the evidence that supports these facts, I would sign it, but I don't have that evidence.
MR. LEHNER: If he looks in the PDR --
MR. ALLEN: I don't think it's -- they're acting like I'm being unreasonable, Your Honor. If they show me the evidence that supports it, I'll do it.
THE COURT: If you have something, why don't you show him.
MR. ALLEN: I'm a very reasonable man, but I'm not going to sign something I don't know is right.
THE COURT: The State has filed a motion to exclude the testimony of Dr. David Kahn on Daubert. To the extent it's a Daubert motion, it's more than just a little untimely; it's major untimely and it's denied on that basis.
To the extent there are issues about excluding a survey or dealing with

relevance, I'll listen to the testimony and take up objections as I hear the testimony, just as I have with the State's witnesses. Dr. Kahn's going to be limited to matters that were in -- and time frames that were in the scope of his report and his deposition.
MR. ALLEN: Your Honor, in that regard, last night I received their opposition to the motion to strike, which the Court's ruled on. I understand the Court's ruling and we'll move forward in accordance with that, but they stated in their response at page 3, Dr. Kahn's testimony is relevant and they had some bullet points.
And the second bullet point at page 3 said Dr. Kahn and the other physicians with whom he consulted and supervised were monitoring patients in the '90s for weight, lipids and blood glucose. This is relevant to show that doctors were monitoring blood glucose changes in their patients well before the 2003 label change.
MR. ALLEN: I have a copy -- Dr. Kahn's report. Did I give it to you? It didn't take me long -- I have a copy of Dr. Kahn's report, which I'll hand up to the Bench. Dr. Kahn, as you see, I think it's on

page 2 -- I can get my copy out, Your Honor.
Do you have another copy -- Dr. Kahn on page 2 of his report will now list A through E opinions. None of his opinions -- and those are a summary of his opinions -- you can read his entire report -- concerns either blood glucose levels, blood glucose monitoring, monitoring for weight lipids and blood glucose. So in anticipation of this testimony and as you've done with the State's witnesses, we need to object now and to prevent Dr. Kahn from going into matters that are not contained within his report.
If those matters were within the report, I'm fairly good with the English language. I'd like the other side to point out where that is.
MR. BRENNER: Your Honor, please. Stated in his report or attached are one of the things that he relied on. One of them is the consensus. He was interrogated about that in his deposition. That guideline talked about monitoring, talks about it in his report -- he was interrogated about those attachments and the guidelines. It's within his report.

MR. ALLEN: Your Honor, I don't think that's responsive to the question you asked. Show me in his report or in the guidelines -- where he discusses the monitoring of weight, lipids and glucose.
MR. BRENNER: Your Honor, I'd be happy to do it now, but it's in the guidelines.
THE COURT: Again, do the guidelines say -- I mean, your opposition to the motion to exclude say Dr. Kahn and other physicians with whom he consulted and supervised were monitoring patients for weight, lipids and glucose. So do the guidelines say that he was doing this in the '90s and was monitoring -- or is there just guidelines for people to be doing that and this a real practice -- that's the difference. That there may be guidelines is different than him saying we were actually all doing this in the '90s and I've consulted other doctors and that sort of stuff, and whether there's notice, that's where we're getting.
MR. BRENNER: The guidelines which collected the data in 1998 and published in 1999 reflect the real world practices of doctors throughout the United States. They reflect

monitoring that was ongoing. They reflect concerns about weight in connection with Zyprexa explicitly stated. Dr. Kahn collected these data and help promulgate the guidelines. His practice conforms with that.

MR. ALLEN: Well, he's yet to show you anything in Dr. Kahn's report -- ask him to show you a sentence in his report that addresses that issue or anything within the guidelines that discusses blood glucose monitoring or lipid monitoring. There's nothing.

THE COURT: Where -- other than a reference to a guideline -- you have his deposition and can you cite me to where he was extensively questioned about this in the deposition?

MR. BRENNER: About the guidelines themselves?

THE COURT: Well, is he going to testify that there's these guidelines, or is he going to testify about this is what we did and how doctors work, not just that there were guidelines. You're telling me that he's going to testify that these were being followed. Where does his report tell me that that's one of the

opinions that he's going to offer or was he questioned? Or is this just an article that's been attached to his deposition that --

MR. BRENNER: Your Honor, it was a major subject of the purpose of his being offered as an expert.

THE COURT: If that's the case, it will be in his deposition, I assume.

MR. ALLEN: Or his report or the guidelines.

MR. BRENNER: Depending on what counsel chose to ask him at the deposition.

THE COURT: But if it was a major purpose of his being offered, I'd expect something that was pretty specific and clear besides just a document attached as a information and materials considered. I would expect him to question him and expect him to testify on the information and materials considered as it relates to the things in the report, not as it doesn't relate to the things in his report.

MR. BRENNER: In his deposition, various guidelines, it was a major subject of his area of expertise. It is really a large reason why he was offered as an expert. Guidelines were

discussed at pages 54, 58, 60, 69 to 76, 81, 141 to 154, 161. With respect to the guidelines themselves -- bear with me just a moment -- item 38, which was the survey data which then translates into a guideline, talks about the routine screening that should be done is recommended for schizophrenic patients. Item 5 is blood chemistry screening, SMAC. That includes blood glucose screening and lipids for that matter. He's prepared to describe those --

THE COURT: Could somebody hand me the deposition testimony? Let me ask you, Mr. Allen.

MR. ALLEN: Yes, sir.

THE COURT: You claim -- Dr. Kahn claims expertise in psychopharmacology only to the extent that he claims expertise in how doctors make treatment decisions, how doctors make treatment decisions, what sources of information they use, and how they -- this claim is made as a clinician rather than a researcher. It's based on surveys, and then you go on to say it is clear that outside of his own clinical experience, Dr. Kahn's involvement with the expert consensus guidelines.

Why -- that suggests to me that you kind of understood that this might be part of his area of testimony.

MR. ALLEN: With due respect for the Court, that's absolutely incorrect.

THE COURT: That may be.

MR. ALLEN: Yes, sir. If you look at his opinions in the case, Your Honor, let me give you his opinions. Again, they haven't answered your question because there's a report prepared in this case and you can read it, and there's not a mention of any of this. Let me --

THE COURT: In looking at notice, it's not just the report that I focus on. It's the deposition, because if the report was a little vague but you went into all these areas or it's pretty clear that this was a subject, then you're on notice.

MR. ALLEN: You know what, sir, I would totally agree. I would not argue with the Court one iota on your comment. But they've yet to show you. Let me give you his opinions and this is what his opinions are, and then you can -- then he expounds on those opinions and has nothing to do with lipid and blood glucose

monitoring.
He said, treatment decisions for mental health patients are based on many sources of information and the unique circumstances of each patient. Then that opinion is discussed on page 5 of his report, and we're going to talk about that in a minute with regard to their call notes. Then he says Rosenheck's, that's an author's -- CATIE cost-effectiveness study does not provide a basis for the generalized statement that Seroquel and perphenazine are equally effective to olanzapine. That's opinion No. 2, nothing about blood and glucose.
No. 3, Primary care physicians need to be able to recognize and treat mental health diseases including bipolar disorder. You can read the opinions under there. Nothing about blood and lipid monitoring.
No. 4, Off-label use of mental health drugs, including off-label uses of olanzapine, is often clinically appropriate. You can read to your heart's content. Not a word, nary a thing.
No. 5, physicians base treatment decision on a risk/benefit analysis and cost.

That's his last opinion. And I -- I guess if it would be anywhere, it would be under that.
THE COURT: Let me ask you what this statement means. This is in his report on page 3.
MR. ALLEN: Yes, sir.
THE COURT: And I'm going to read a few sentences before I get to the one that I'm asking about. The ECPG, that's the expert consensus practice guidelines --
MR. ALLEN: Where are you?
THE COURT: I'm on the second paragraph after where it says, expert consensus practice guideline. It says, Rigor and consistency in consensus-based clinical treatment recommendations for study of mental health disorders, they were developed in the following manner. This is the sentence. First, the small group of experts in the relevant disorder developed a preliminary treatment algorithm based on currently available treatment guidelines and a thorough review of the scientific literature. What's that about?
MR. ALLEN: Nothing to do with blood glucose and lipids.

THE COURT: What does he mean by available treatment guidelines? Then we've got a document --
MR. ALLEN: Yes, sir, we do, and I'm going to find it for you right now. Here's the ongoing monitoring. It's called the maintenance phase; it's on Page 16. If anybody -- do you have an extra copy of his well-established article in the field of surveys? If you do, I can show it to the Court and we can end this debate.
MR. BRENNER: I'll be happy to hand it to the Court --
MR. ALLEN: All right, Your Honor. Guideline No. 6, this is the only place I could even a smidgen, a smidgen of a thing talking about monitoring. It's on Page 16, Guideline 6, the maintenance phase. Initially, we look down and there's a word at the bottom. It's called ongoing monitoring, Your Honor. And this is monitoring of patients that have schizophrenia only. This is a schizophrenia article.
Routinely evaluate for and properly respond to prodromal signs of relapse. Nothing to do with blood monitoring. Monitor for and

manage emerging side effects of each visit. You can go to 14, which is his reference used and you can come to the reference, nothing about blood glucose and lipid monitoring. Monitor for tardive dyskinesia. Zippo about blood and glucose monitoring.
Now the last one -- don't be confused. Plasma, that is blood, monitoring is occasionally useful when noncompliance with treatment is suspected. What they're saying there, Your Honor, is we're going to monitor the blood to make sure the patient is taking the medication. Nothing to do with blood glucose. Nothing to do with lipids and then it goes where pharmacokinetic actions are a concern. In other words, when there's some adverse reaction to the drug. There is no blood glucose lipid monitoring mentioned in this report or in these guidelines.
MR. BRENNER: Look at page 56, Your Honor, if you would.
MR. ALLEN: By the way, is this the psycho -- is the NAMI psychoanalysis guidelines? Which one is it?
MR. BRENNER: The Expert Consensus Guidelines Treatment of Schizophrenia, 1999.

MR. ALLEN: Complete blood count.
MR. BRENNER: Item 38, which talks about the recommended monitoring, blood chemistry screen, SMAC, lipid profile. And if we look at Item 39, creating the consensus of experts following these patients for comorbid conditions, diabetes is listed. At his deposition at page 117, commencing at line 3, Dr. Kahn was asked: The second heading, importance of individual patient characteristics to treatment decisions I take it we somewhat discussed that earlier, that is that the physician needs to observe and monitor how an individual patient reacts to medication. Your Honor, I can't control what gets asked by Plaintiff --
THE COURT: I know, but you can control what they were on notice so that they reasonably would ask --
MR. BRENNER: Sure. And this was the centerpiece of his expertise. There are devoted to the guidelines. The adversary system, and the adversaries will review the materials.
THE COURT: I'm on page 56. Looking at Table 38 again, and you mentioned something about diabetes --

MR. BRENNER: Item 39, same page, Your Honor.
MR. ALLEN: Your Honor, this is asking him to rate the appropriateness of having the psychiatric treatment team routinely monitor for the following comorbid conditions. It has a note of diabetes down there. It's the second line --
MR. BRENNER: It's not the second line. We're going to have the address line --
MR. ALLEN: I won't even argue with you. Let's say it is whatever he says it is. Your Honor, this whole consensus guidelines has all kinds of things that are not included within his report. You know what, you can disagree, but with all due respect I'd like to finish. He has a report outlining his opinions. If his opinions were read this, then I guess I would have been on notice. His opinions in his report don't reflect everything in these guidelines, and I'm supposed to pick this out. I guess he could come in here and talk about tuberculin skin testing, because it's on here too or he could have talked about mammography in women, but that's not in his report.

And so, I mean, you know, Your Honor, I'm telling this Court the truth. They know I'm telling the Court the truth. But you have to make whatever ruling you feel comfortable. His report doesn't say anything about it. It's not here. This is trial by ambush, but you know, whatever the Court's ruling is, I'll accept it. I think this is wrong. There's nothing about lipid monitoring. We now found a reference to diabetes in a survey that is not included in his report. I'm telling the Court the truth. The Court can make its ruling. I'll take it like a man.
MR. BRENNER: Your Honor, if you look at the Dr. Gueriguian's report, he referenced perhaps 100 -- did he reference each in his report? No. Your Honor, so they put us on notice. Those are the rules of the game.
THE COURT: I'm going to let him at least start to take it up. You can cross-examine him. I have no doubt you will effectively do that.
MR. ALLEN: Well, I don't know, Your Honor, sometimes I just don't know what I'm -- I'm just going to see how it all goes. I

hope we get to talk about Page 56. Can I go on to tuberculosis?
THE COURT: If you think it's relevant.
MR. ALLEN: Okay. I think I might.
THE COURT: If you think the jury might find it meaningful, and I don't have objections as to relevance.
MR. ALLEN: All right. I understand how the game is being played. And, Your Honor, I accept your ruling and I'll be happy to move forward.
THE COURT: I don't know -- we've got -- as I understand it, the remaining issues, at least, to take up deal with admission of evidence. And I think primarily we're going to have an issue about the call notes. And then once evidence -- I ruled on what documents are coming in, then the State's going to rest and I'll take up applications from the Defendants.
MR. ALLEN: Yes, Your Honor. I suggest -- I hope we start -- I have -- Mary Beth, can you come here now? We have -- and gave these last night to the other side.
Let me provide you, Your Honor,

with a -- we gave them a list --
THE COURT: Can we get in the documents that aren't going to be controversial?
MR. ALLEN: Yes. That's what I'm going to do. That's what I'm going to do.
THE COURT: And there was one that was hanging from last night. I forget which one.
MR. FIBICH: Eski document, I believe, Your Honor.
THE COURT: Eski 9, which has a different --
MR. ALLEN: Yes, sir, as a matter of fact it's going to be --
MR. LEHNER: It's included in this list here, Your Honor.
MR. ALLEN: Mary Beth tells me it's AK10097. Let's go ahead and move for the admission of that now.
THE COURT: Any objection to that? That is what it was, 10097.
MR. ALLEN: It's LillyUSA Sales Good Promotional Practice Definition of a Sales Call and call notes Eli Lilly and Company 02001.
MR. LEHNER: Your Honor, we had objections with respect to the relevance of this

document.
THE COURT: Is that what your objection is, relevance?
MR. LEHNER: Yes.
THE COURT: That objection is overruled, and I'll admit 10097 with objections preserved.
MR. ALLEN: Thank you, Your Honor -- Mark, I have it. I will actually give it to the Court. I'll give a copy to the Court, because in a minute when we get the call notes issue, you're going to want to read that.
Now, let me try to do noncontroversial documents. And Your Honor, we're going to start on page 1, which is the PDRs. And I'm just going to verify with the Court and with Mr. Borneman that some of these things are admitted, because I think they're critical to my case. The Court has previously admitted 10008, the 1996 label.
THE COURT: It's been previously admitted. Then, it's already admitted.
MR. ALLEN: Have you confirmed this?
MS. RIVERS: Yes.

THE COURT: 10008 we have as previously admitted.
MR. ALLEN: Your Honor, the State of Alaska moves to admit AK10178, the 1997 label for Zyprexa.
MR. LEHNER: No objection, Your Honor.
THE COURT: 10178 is admitted.
MR. LEHNER: The only -- I mean, let me look at this one for a minute, Your Honor. What they're admitting here, if I show you --
THE COURT: PDRs -- do you have any objection to the PDRs through 2008? If you don't, I'll just --
MR. LEHNER: With the PDRs through 2008 with the 2004 supplement, which we have here to put in the book, we have no objection to admitting the PDR.
THE COURT: If you want to admit the supplement, you can admit the supplement. What's the number of the supplement?
MR. ALLEN: I understand what the Court's trying to do but I think it would be more orderly if we got our exhibits in and they can admit the supplements. This can go on forever.

THE COURT: I don't care. Let's get the supplement in --
MR. LEHNER: I guess the reason I'm asking, it was unclear whether they wanted to admit the notebook as a PDR.
THE COURT: They seem to have given up on the effort to get together and admit the notebook, so they're admitting -- that's my understanding.
MR. ALLEN: That is correct, Your Honor.
MR. LEHNER: With respect to 10178, my objection is that this is an unreadable document. The photocopying makes it illegible and I'm not --
THE COURT: I'll admit it -- do you have any doubt that it's the 1997 label?
MR. LEHNER: No, no doubt.
THE COURT: Can we get a better copy of the 1997 label?
MR. ALLEN: Your Honor, they may be able to but --
THE COURT: If there is a better copy, we'll substitute it.
MR. ALLEN: On their exhibit list,

it's EL2954, just for the record.
THE COURT: I'll admit AK10179, 10180 -- 10181, 10182, 10183, 10166, which I think was previously admitted. It's admitted if it wasn't -- 10165, 10067. Both of those last two were previously admitted -- 10184, 10185, and 10168. I've admitted 10097 just a little while ago, so now we've got three more left before we get to the call notes.
MR. ALLEN: You know, you're right, Your Honor. Following this chart, I suggest after we get through Section 2, we go to Section 4 because I think that's going to be less, quote, controversial.
THE COURT: That will be fine, too.
MR. ALLEN: Your Honor, State of Alaska moves to admit AK1349.
THE COURT: Did you say -- what was the number?
MR. ALLEN: AK1349.
THE COURT: Okay.
MR. ALLEN: And, Your Honor, we believe you admitted it because at page --
THE COURT: Is 1349 admitted?
MR. ALLEN: There is some confusion

in the record. It's about human metabolism and it's a Lilly document from their files.
MR. LEHNER: No, Your Honor, I have no objection.
THE CLERK: Judge --
THE COURT: 1349 is admitted.
THE CLERK: It was one we had questions on.
THE COURT: 1349 is admitted.
MR. ALLEN: All right. Your Honor, the State of Alaska moves to admit AK4532, weight change strategy and tactics. These are ones that Mr. Borneman and Ms. Rivers and the defense had questions on, Your Honor. We believe it's admitted, but they wanted to discuss. It's a January, 2000 weight change strategy and tactics document from Eli Lilly's file. We move to admit AK4532.
MR. LEHNER: Your Honor, we have an objection. There was no foundation. I think you had indicated it was introduced with other witnesses. Bruce Kinon testified he did not recall seeing this document. If I recall, it had no Lilly marks on it. It was introduced from Lilly, but it was unclear --

THE COURT: Could I see the document?
MR. ALLEN: Your Honor, I guess, it's from their files, it's self-authenticating --
THE COURT: You said that three times at least. I went through the authentication portions of the evidence rules, and I don't find that as a basis.
MR. ALLEN: All right. It's an admission by party opponent which does not constitute hearsay, so an admission by party opponent is also admissible.
THE COURT: Just because it's in their files, it's an admission?
MR. ALLEN: Your Honor, this is a Lilly document, but I'm not going -- he also said at 245 of the transcript on March 14th that you'd admit it for at least purposes of notice.
THE COURT: If that is what I previously said, then I'm going to stick with it.
MR. ALLEN: Yes, sir. It's right here. Page 245, Line 16 through 17 of the March 14th transcript.
THE COURT: The last page certainly

has the Lilly logo or trademark is the right word, but it's -- it's on all the other Lilly documents.
MR. ALLEN: I just -- I mean, you've admitted it previously for notice. If they want to argue for the jury it's not their document, then so be it.
THE COURT: AK4532 is admitted --
MR. LEHNER: I think within the context of a number of documents that we're admitting for notice, I'm not sure if this was specifically referred to.
THE COURT: AK4532 is admitted. 8042 is next?
MR. ALLEN: Yes, sir, it's -- AK8042, we move to admit that. It's an e-mail concerning Zyprexa from Eli Lilly's files.
MR. LEHNER: I think that had been previously admitted for notice only, Your Honor. Page 3 --
THE COURT: Is that the issue? Page 3?
MR. ALLEN: Yeah --
THE COURT: You've got a note here, but see their Bates number. So what's that

about?
MR. ALLEN: Yes, sir. That's a handwritten note attached to the document doing calculations. It's Bates numbered in sequential order and it's dealing with that document.
Again, we move to admit it. If they want to argue it's -- whatever they want to argue, they can.
THE COURT: Mr. Lehner, what's the story with the Bates numbers?
MR. LEHNER: I'm not sure I understand your question, Your Honor.
THE COURT: My understanding is you have a concern about the third page. They said that this was sort of listed as a unified document when it was produced in your Bates number order.
MR. LEHNER: Clearly, that was produced sequentially, but I don't think there's any evidence tying this together.
MR. ALLEN: Just rip the back page off, Your Honor. Let's just move on.
THE COURT: We'll move on. The first two pages of AK8042 are admitted. The handwritten notes on page 3 are being withdrawn.

MR. ALLEN: Thank you, Your Honor. I apologize.
Your Honor, I think we should go to Section 4 before we get to the call notes issues.
THE COURT: So do I.
MR. ALLEN: By the way, you have written there -- it's my internal document, description of these. All right.
AK7822, it's already been admitted. I wanted to confirm that though with Mr. Borneman.
THE CLERK: Number again?
THE COURT: AK7822.
THE CLERK: Judge, I've got that as admitted.
THE COURT: We've got that listed as admitted.
MR. ALLEN: Thank you, Your Honor, State of Alaska moves to admit AK439. It's a letter from the FDA to Eli Lilly concerning Zyprexa dated September 15th, 2003.
MR. LEHNER: No objection, Your Honor.
THE COURT: AK439 is admitted.
MR. ALLEN: State of Alaska moves

to admit -- what did you say?
MR. LEHNER: I said I think I have copies as we go through these.
MR. ALLEN: Okay. AK4871, it's an e-mail -- excuse me -- a letter from FDA to Eli Lilly dated December 16th, 2003.
MR. LEHNER: We have no objection to that, Your Honor.
THE COURT: AK4871 is admitted.
MR. ALLEN: State of Alaska moves to admit AK1926, Lilly's Zyprexa Primary Care Sales Force Resource Guide, Your Honor.
MR. LEHNER: Your Honor, we would object to that. There's been no testimony about that document. We would object also on -- give me one second here.
MR. ALLEN: Let me give the Court a copy of what we're talking about.
MR. LEHNER: On this 401 and 402 is not being relevant. No testimony of internal Lilly document, Primary Care Sales Force Resource Guide.
MR. ALLEN: So the Court can know the relevance of it because it's going to come up here in a moment. Let me just read from

Ms. Gussack's opening statement at Page 139 and 140; 139, line 19 through 23, But Lilly was sharing its information about weight gain and sharing its information with the FDA and it wasn't just relying on the label. Ms. Gussack goes on to say, Lilly trained its sales representatives who called on physicians to answer questions about weight gain and diabetes that doctors might raise.
Their training of the sales representatives concerning their statements to doctors is relevant. Ms. Gussack said so on opening statement.
MR. LEHNER: Your Honor, they've offered no testimony that would provide any context, relevance or background to this document, and I don't think there's any foundation for which the jury can consider this.
MR. ALLEN: Your Honor, I'm not being facetious. A party can write a note on a napkin in a restaurant and it's an admission by party opponent if it is made by statement -- a person in authority. This document is not only relevant; it's from their files and constitutes not even hearsay. And it's -- and it's relevant,

I guess, under the notice theory if for nothing else.
THE COURT: I will admit, over objection, AK1926.
MR. ALLEN: The State of Alaska moves to admit AK4361, Issues Management Planning, Diabetes, Final Draft.
MR. LEHNER: Your Honor, this had not previously appeared on their exhibit list. I object to the same grounds previously admitted -- previously discussed on relevance, marketing documents, and consistent with your prior order and what is in and what is out in this case.
THE COURT: Can I see 4361?
MR. ALLEN: Yes, Your Honor.
THE COURT: And was it on your prior witness list?
MR. ALLEN: It was used in the cross-examination of Inzucchi, I believe, when Dr. Inzucchi was giving his opinions concerning diabetes. It was used during the cross. As I recall it Mr. Suggs used it, but you didn't want us to display it. And, again, it constitutes an admission by party opponent and a hundred other reasons, but --

MR. LEHNER: On its face, while it says on the front cover Final Draft, from the text you can tell it is a draft as well, by the language in page 3.
MR. ALLEN: Drafts are admissible, Your Honor. Often drafts are the most relevant.
THE COURT: The fact that it has draft doesn't really bother me.
I will admit AK4361.
MR. ALLEN: Your Honor, I think you have the original there.
THE COURT: Sorry.
MR. ALLEN: Your Honor, the State moves to admit AK10035.
THE COURT: Let me ask you, I assume -- was this in -- Exhibit 2, Mr. Lechleiter's deposition?
MR. ALLEN: Yes, sir, Dr. Lechleiter and Ms. Torres both.
THE COURT: These, I assume, were portions of the depositions that you didn't feel was important enough to play for the jury.
MR. ALLEN: No, sir, I disagree with that completely. Matter of fact, I considered them very important and the Court had

struck those portions of the deposition prior to the time of our last Wednesday's hearing. This document is going to be relevant to Dr. Kahn, because what is in his report as opposed to blood monitoring and lipids is his opinion that primary care physicians need to be able to recognize and treat mental health diseases including bipolar disorder and off-label uses are appropriate.
He actually writes out a detailed sentence in his report concerning the use of these drugs, and let me read it to the Court -- here's what he says on page 7: Off-label use of mental health drugs including off-label use of olanzapine is often, often clinically appropriate. In addition to its approved indications olanzapine is used by clinicians to treat other conditions including anxiety, depression, behavioral disorders and Alzheimer's disease and other dementias.
He goes on to talk about on the next page of his report -- where is it? One of the conditions -- on the same page: One of the conditions that olanzapine is prescribed for off-label, including by myself, he says, is behavioral disturbances and dementia in the

elderly.
Now, this document goes directly to the issue of the safety of the use of this drug in dementia, which he has clearly --
MR. BRENNER: He's -- he's not going to be testifying --
THE COURT: Let him finish.
MR. BRENNER: I Beg your pardon. Thank you, Your Honor.
MR. ALLEN: He is testifying on these matters -- well, we'll see. But this document right here, Your Honor, specifically says that Eli Lilly on -- in November of 2000 -- Your Honor -- can I finish?
MR. LEHNER: Can I ask? Can we approach the bench, for a moment, Your Honor?
THE COURT: Sure. Although we don't have a jury here, so I'm not sure why.
(Bench discussion.)
MR. LEHNER: I'm going to tell you why. You weren't aware I don't think, Your Honor, of the article that appeared last week -- this is exactly what they're trying to do, is read this in front of the Court. You've already ruled that this document was not admissible, and

the context was --
MR. ALLEN: It's never been offered, Your Honor. For him to say this -- yesterday, do you remember during the deposition of Ms. Torres and I said, Your Honor, we need to hold one so we can talk about it. This is the one. So for him to say the things he says is just false. I'm here and I have to make a record and I shouldn't be prevented from making one. This is a public courtroom. I actually held off on this until today.
THE COURT: Again, this is a public courtroom and it's a public trial, and that's just --
MR. LEHNER: These sort of things are admitted and not admitted. This is really a transparent attempt to go right around having this document used in a public proceeding.
THE COURT: I'm going to over -- I'm going to sustain the objection to this exhibit, and I'm not going to admit this exhibit, at least not at this time.
MR. ALLEN: I need to make a record.
THE COURT: Your record is made

that you've offered this exhibit and that -- the record is made that I've overruled it.
MR. ALLEN: You know, Your Honor, I've been very patient.because I want it on the record. I resent Mr. Lehner's remarks about what I was attempting to do. I said yesterday on the record, I said, Your Honor, I need to hold off on this and this is the very document.
THE COURT: I would prefer both parties avoid casting aspersions as to the motives of other parties.
(End bench discussion.)
THE COURT: But 10035 is not admitted at this time. Again, as I've previously indicated on documents along these lines, we'll see where this goes.
MR. ALLEN: Yes, sir. Can I make this statement? Remember, it's on-label. We talked about this. It's impossible for them to market it off-label, because it would be against the law for them to do that.
THE COURT: I admire your efforts to turn a green light into a red light, but I think we both know that if I had left in the claim of off-label, this document would be

off-label.
MR. ALLEN: Yes, sir. It would be off-label, but it is impossible for them to have done it, because they didn't do anything wrong.
THE COURT: That may be, and I'm sure the federal government in the context of enforcing what I believe they have the ability to enforce, may be interested in that document, but for the purposes of this trial where the issues of off-label use are not at issue, I find that the document would be more prejudicial than probative and isn't really relevant at least at this point.
MR. ALLEN: I accept the Court's ruling, and I just want the Court to know that at least as the trial progresses, I don't even need to use the word off-label as much as other uses of the product. But I'll move on.
Your Honor, State of Alaska moves to admit AK7990. This was used by Dr. Gueriguian. It's an e-mail chain within the company, August 6th, 2002 concerning physician complaints concerning Eli Lilly's responses to their concerns about issues involving diabetes.
MR. LEHNER: Again, Your Honor, we

would object on the basis of 401, 402. No testimony about this document has been offered by any Lilly witness or anybody who had any direct knowledge.
THE COURT: Can I see 7990, please?
MR. ALLEN: Yes, sir. Can I have my copy?
Your Honor, this goes to physician complaints and putting Eli Lilly on notice as early as August of 2002 about physician concerns about diabetes. In fact, the doctor and his staff write a note that it is troublesome, frustrating and occasionally irritating to repeatedly hear the --
THE COURT: You don't have to read the exhibit. I can read it and I will -- objections are preserved. I admit 7990.
MR. ALLEN: Your Honor, the State of Alaska moves to admit AK2244, e-mail chain within the company at Eli Lilly. Okay.
THE COURT: Any objection to 22 --
MR. LEHNER: Again, Your Honor, 401, 402, and 403 is being confusing and a waste of time.
THE COURT: Can I see the document?

MR. LEHNER: E-mail chain. No testimony has been offered about this exhibit.
MR. ALLEN: Yes, sir. This discusses, among other things, epidemiologic studies, Your Honor, and diabetes, metaanalysis of data.
THE COURT: Am I correct that Ms. Cavazzoni is going to be a witness in this case?
MR. ALLEN: They've designated and her and they've used the documents.
MR. LEHNER: Yes. We're hoping that she's going to able to be here tomorrow.
THE COURT: So that means maybe yes and maybe no.
MR. LEHNER: Maybe yes and maybe no.
MR. FIBICH: That's called being coy.
MR. LEHNER: No, it's not being coy. It's being maybe yes or maybe no. Certainly if she's not going to be here live --
THE COURT: Do you have any problem in waiting to see if she shows up? If she shows up you can introduce it through her and if she doesn't show up I'll take it up again.

MR. ALLEN: You know, what, sir, I know -- and I just have to say for the record, I'll wait until she shows up one way or the other, but I still would think it's admissible. I'm going to do what the Court asks.
THE COURT: I'm just going to do that because I think it makes a better record.
MR. ALLEN: Yes, sir. Again -- State of Alaska moves to admit AK3223, which is an e-mail chain concerning the management of schizophrenia, within the company and the selection of atypical antipsychotics for the management of schizophrenia, which is going to be relevant here in about five minutes or so. Which it's relevant already, but it's 3223.
MR. LEHNER: Again, Your Honor, we would object on 401, 402, as well as 407 because it discusses subsequent remedial --
THE COURT: May I see --
MR. LEHNER: And I would just add, too, that there's been no testimony about this document either.
MR. ALLEN: Your Honor -- well, I'll let -- I'll just wait. The document, by the way, is dated January 14th, 2004, which is in the

midst of all these issues.
THE COURT: I will admit 3223.
MR. ALLEN: Thank you, Your Honor. State of Alaska moves to admit Exhibit 3872, a product positioning document from the files of Jack Jordan used in his deposition. If Your Honor recalls, positioning is actually a term of art. As Mr. Jordan said, a position is how we want our customers to think about our product. And this is a positioning document and it says Zyprexa is the agent of choice to help patients with debilitating mood, thought and behavioral disorders achieve the highest level of functioning.
MR. LEHNER: Your Honor, we have previously objected and our objection had been sustained on March 10th. This was not admitted, as I recall, at the time and I don't see anything that's happened subsequently to support the admission of this document.
MR. ALLEN: This was referred to in Mr. Jordan's deposition.
THE COURT: I'll sustain the objection to 3872.
MR. ALLEN: Your Honor, I'm going

to skip, I think -- what did I skip? 4046.
THE COURT: 4046 is your next one --
MR. ALLEN: I'm going to skip it for now, it's too thick.
Your Honor, AK -- State of Alaska moves to admit AK9578, Handling Weight, Hyperglycemia, Diabetes Algorithm.
MR. LEHNER: Your Honor, we have raised a 401, 402 objection that is consistent with your ruling about marketing.
MR. ALLEN: This is, again, a sales training piece. Training sales representatives how to answer questions about hyperglycemia, diabetes, and weight gain, which are -- I think is the heart of this case, I believe.
THE COURT: I will admit 9578.
MR. ALLEN: Thank you, Your Honor. You have my original. We're skipping 10097, Your Honor. You just admitted that earlier.
Your Honor, we -- State of Alaska -- well, this is going to be call notes, Your Honor, so -- so I'm going to skip 100 -- I'm going to come back to it in a second, 10099 and we'll come back to it in call notes. And we're

going to move to -- State of Alaska moves to admit 10090. Your Honor, this is a -- let's see what they say first. It was used in Mr. Noesges' deposition as Noesges Exhibit 2.

MR. LEHNER: Your Honor, this was not part of the deposition testimony that Mr. Noesges gave here. There is no foundation for this document, so we would object on 901. And it's -- it's not relevant in light of the testimony to date.

MR. ALLEN: Your Honor, just for one thing, as the Court's heard about restrictions and nonrestrictions, this document specifically says, and I'll bring it to the Court, but I think counsel would agree I'm reading correctly: A goal and objective of Eli Lilly is to ensure unrestricted availability of all Lilly products on all state formularies.

I mean, if I can't get in Ms. Eski's testimony at this juncture, at least I ought to be able to get a document that one of their goals is to ensure unrestricted availability of Lilly products.

THE COURT: When I rule on the formulary and questions for Ms. Eski, I'll rule

on this exhibit.

MR. ALLEN: Your Honor, I understand the Court's ruling. Let me just say for the record -- for the record, I understand the Court's ruling. I would argue, of course, that one is not even necessarily dependent on the other --

THE COURT: I understand that. I see the issue as being related.

MR. ALLEN: Your Honor, I'll take a ruling bad against me if I have to take it, but I just want to build a record.

All right. Your Honor, the State of Alaska moves to admit 10203 -- let me just say, I think these -- Your Honor, let's set these aside. These are also going to start relating to the issue -- I need to make a record actually before I close my evidence. So I'm sorry to take up the Court's time with this --

THE COURT: I'm sorry that I didn't tell the jury 10:00 o'clock instead of 9:00 o'clock. But that's done and everybody needs to make their records.

MR. ALLEN: I apologize, I didn't want to take up this time -- Your Honor, State of

Alaska moves to admit AK10203. It is an Eski exhibit concerning lobbying efforts that Eli Lilly engaged in with public relations firms and lobbyists to ensure access to their drugs here in Alaska. And I will concede it's an Eski exhibit.

THE COURT: Haven't we discussed Eski 7 in the context of a lot of things previously?

MR. LEHNER: Yes, Your Honor, and I think -- if you want to discuss it in the context of the prior document, this is something you've already dealt with.

MR. ALLEN: I'm just --

THE COURT: This -- I'm deferring on this exhibit as well until I make my ruling as to whether the door is open, and I'm going to allow the issue to become part of this case.

MR. ALLEN: Your Honor, I understand. I just need to make my record.

THE COURT: I understand.

MR. ALLEN: All right. Your Honor, the State of Alaska moves to admit on -- this should be an easy one -- 10204, which is the current label for Zyprexa.

MR. LEHNER: I need time to read it

on --

MR. ALLEN: You do --

MR. LEHNER: No, Your Honor --

THE COURT: 10204 is admitted.

MR. ALLEN: All right, Your Honor, before -- let's go to Section 5. You can overrule me and then we can go to the call notes.

THE COURT: Is this going to be just your being extra careful list of those portions of Eski, Bandick, Torres depositions that I sustained objections to?

MR. ALLEN: Yes, sir, it's my belt and suspenders method from a bad --

THE COURT: All right. 1089, 1091, 1090 can be filed for the purpose of establishing the record that Mr. Allen feels he needs to establish as to what portions I have not admitted of those depositions. I just -- Eski, Bandick and Torres, they're not admitted for any purpose. They're just part of the record so that it's clear to the -- it's crystal clear to the Supreme Court as to which portions of the deposition I have rejected.

MR. ALLEN: Thank you, Your Honor. And again, just from my experience, I'd offer

each of the witness' questions individually and the answers individually and as well as collectively. I assume you're overruling my offer.

THE COURT: You're offering them. I've previously sustained objections both to the groupings of those questions as a whole. To the extent you're offering them individually as for questions, I'll overrule -- I'll sustain those objections as well.

MR. ALLEN: Okay, Your Honor. Now we're going to move to the issue of call notes.

MR. LEHNER: Your Honor, particularly with respect to 10204, the 2007 label --

THE COURT: I thought it was in.

MR. LEHNER: I think we had done it previously that we had preserved our motion in limine objections about matters related to the 2007 label.

THE COURT: All exhibits that I have admitted have been admitted with the objections previously made to those exhibits being preserved.

MR. LEHNER: Thank you.

MR. ALLEN: Okay, Your Honor. Now we're going to go to the issue of call notes, which is Section 3 on page 2 of the paper I gave you to assist you.

I was served this morning, as I arrived -- where are my evidence rules -- with an objection to the call notes. Let me say I don't know exactly where to begin. I think -- the defense contends that these call notes are, A, irrelevant; B, hearsay; and C -- and if I misstate the argument, they'll tell me -- C, not probative of any issue in the case.

Let me begin, if I must. I think we should go back first to the start of the whole trial, and then we can go back to yesterday concerning violations. Ms. Gussack stated in opening concerning this case: Lilly was sharing its information with doctors about weight gain. In sharing its information with the FDA, and it wasn't just relying on the label. Lilly trained sales representatives who call on physicians to answer questions about weight gain and diabetes that doctors might raise. That's where we start.

Dr. Kahn, who is going to be Eli Lilly's next witness, gives a detailed opinion as

opposed to a passing reference to some survey. He talks about treatment decisions for mental health patients are based on many sources of information and the unique circumstances of each patient.

He states, their expert: Physicians' knowledge about treatment alternatives comes from numerous sources, the medical and scientific community. And he goes on: Other sources of information include: Information from drug manufacturers about their products and other products such as product labels, sales representative detailing, journal advertisements and responses to questions posed to the companies. The amount and nature of information communicated to a physician by a manufacturer will vary from physician to physician.

Clearly, Ms. Gussack -- clearly the Defendant's expert has recognized that when considering the conduct of a manufacturer concerning the information relayed to the prescribing community on a product, matters other than the label are clearly important. Now, those matters would include the detailing by a sales

rep. You heard Ms. Eski's testimony in this case, as well as Mr. Noesges. Ms. Eski, in fact, testified to this jury that she details doctors --

THE COURT: Let me stop you there, Mr. Allen. You don't have to spend a lot of time establishing the question of why you think these documents are relevant to the extent that the call notes contain something about the issues we're talking about in this case. In other words, if -- all the call note talks about is we're playing golf and we talked about somebody getting married and somebody really likes our product and stuff, I'm not sure why we need to give the jury these exhibits. But to the extent a call note has something that's --

MR. ALLEN: Right. And, Your Honor, you know what, I could make a contrary argument, but I'm not even going to try. And, you know, I'm going to shoot straight with the Court. I can make a contrary argument with that because I would call it influencing and let me just state this: You just admitted Eli Lilly 10097. That's their -- that's their call note detailing policy.

First, I'm going to paraphrase. If anybody thinks I'm misrepresenting anything, they can stand up. They said these call notes applied to all sales personnel throughout the United States. That's what Mr. Noesges said yesterday. In other words, it doesn't vary from state to state what they're supposed to do. Their policy says that these call notes shall appropriately document the sales call. Their policy says, and not that its necessary, that a call note is a business record documented within the call system, and that must accurately reflect all aspects of the sales call.

THE COURT: I understand that. I'm talking about -- let's get the jury evidence about this case, not about things in general.

MR. ALLEN: Your Honor, there's no problem with that. There's evidence in these call notes, which we'll see today, about weight gain and diabetes and hyperglycemia. And now, some of them, Your Honor, it's not -- it's just the real world. They talk about brought doctor waffles on Wednesday and also discussed issues of comparable rates. Brought doctor lunch. He seemed to really enjoy it. The cookies are good;

and we talk about diabetes. That is in the context of the call note. When they're talking about diabetes and chocolate chip cookies, I can't help that. So -- but the call notes, what I'm interested in, and the Court recognizes is comparable rates. Weight gain. There's no other way for me to prove it.

THE COURT: Okay. So that -- I understand the relevance thing. They've got objections based on hearsay -- maybe I should ask them to explain their objections. And do you have copies of these call notes for me?

MR. ALLEN: Yes, sir, I do. Let me get them for you. Let me get some.

Your Honor, I don't know how much you want --

THE COURT: I want to see -- I want to be able to look at the call notes you're asking me to admit, so that I can make sure I want to admit them or don't want to admit them.

MS. GUSSACK: Your Honor, if I might take a moment to characterize what I think is being proffered here, so you can look at them in the context, and particularly with Lilly's objections to them.

MR. ALLEN: Can I give you the call notes?

THE COURT: The context will become even clearer if I've got the documents.

MR. ALLEN: Yes, sir. So I'm going to give you copies.

MS. GUSSACK: Your Honor, while Mr. Allen is doing that, let me begin by offering various bases on which Lilly objects. One, Your Honor is quite right. We have hearsay objections to them. The fact of a call note, the fact that a sales representative called on a physician on a particular date is plainly a business record. It is the narrative text within the call note that Lilly identifies as not meeting any hearsay objection -- exception, I'm sorry, and particularly because it lacks the systematic, reliable requirements of the rule.

And both by Ms. Eski's testimony and Mr. Noesges' testimony, you can see that they don't rely on them for the content, the narrative content of the call note. You can't tell who said what to whom in these call notes. They use shorthand and it is not at all clear that it reflects a particular message. In fact, the

State elicited testimony from Dr. Hopson with respect to one of the call notes and he could not, in fact, respond to, saying that he had received or understood a message.

They questioned Ms. Eski about one or two -- I'm sorry -- three or four, maybe, of these call notes and she said, that is not what that call note means. It has a phrase in it, that's not what I said, that's not what I communicated to the physician. So the narrative content of the call note that they -- the State is offering them for is not the kind of quality evidence that would be recognized as an exception to the hearsay rule.

Furthermore, the policy that Mr. Allen has referred the Court to is a policy that was implemented in 2004 in large measure intended to ensure that these kinds of shorthand, loosely-phrased terms used in the call note would be eliminated and that the new policy that that policy refers to is -- requires a more systematic use of information in the call note, namely, there's a computer call note framework in which the -- all of the sales representatives have to use a consistent, systematic set of terms.

In addition, Your Honor, while Mr. Allen told the Court on March 5th, I'm not going to use all of Eski 8. I'm only going to use the call note of October 24th, 2001 where she referenced comparable rates. We'd object to the rest of the Eski call notes that weren't used at her deposition or proffered to the Court here as part of her testimony.

In addition, they seek to offer here some sampling of call notes, which they plainly have selected by using word searches. If you look at the call notes that Mr. Allen handed up, you'll see that in these call notes there's a term underlined in each of them, presumably their word searching.

So while Mr. Allen has said that what's critical for the State to offer is references to diabetes or comparable rate, I'm hard-pressed to understand why the State is offering call notes that reference "Martha" underlined in a number of call notes, "children" in a series of call notes, "Donna" and call notes that -- or type of patient, or "SSRI" referring to an antidepressant. And the handful of call notes that the State is proffering with respect

to comparable rates or diabetes is really quite limited.

Addressing Your Honor's questioning to Mr. Allen, it would be -- it is, I think, a manipulation of the system here. The Court has ruled that the communications with physicians by sales representatives about advertising and the matters that are regulated extensively by the federal government are exempt in this case.

This is an attempt to inject through the back door information about what the State believes is off-label and has characterized for -- in discovery for the better part of two years off -- their off-label allegations. And here they now seek on the pretense that these are communications with physicians about the warning call notes that they want to argue inferences adversely to Lilly.

In addition, many of these call notes bear no relationship to any of the issues in the case. And so I go back to the essential question that the Court has posed numerous times: What does this have to do with whether the warning is adequate? And in the vast majority of the call notes that are being proffered by the

State they have nothing to do with the adequacy of the warning.

MR. ALLEN: Your Honor, like Joe Pesci said, in My Cousin Vinny, the opposite. Let me give you an example of the call notes in 10188. Joey Eski to Dr. Jean Bogan, Anchorage, Alaska in October of 2001: Went through full diabetes info. She agrees there are comparable rates across agents.

THE COURT: Let me make this easy, I think. I will admit the call notes. When there is a discussion of comparable rates, weight gain, hyper -- hyperglycemia, diabetes, those kind of things. If we're talking about use in adolescents, if we're talking about anything that appears to be off-label use, on-label use as you would now refer to it --

MR. ALLEN: It can't be off-label. They don't promote off-label, they say.

THE COURT: I understand your argument, but to the extent it's not relating to -- if you're going to use word searches, comparable would be a fine word search. Diabetes would be a fine word search, weight gain, those kinds of things that I think are the core of the

thing.

If we don't have that kind of information in there --

MR. ALLEN: I'll make your task easy, Your Honor, then.

THE COURT: So, that's --

MR. ALLEN: I'll make your task easy, Your Honor. As you see, which I have my descriptive for you only, so you could make it easier. I'd move to admit AK10186, comparable rates call notes and, in fact, it was the one call note used with Dr. Hopson --

THE COURT: Is that this one-pager?

MR. ALLEN: Yes, sir, 10186. I've used it with Dr. Hopson.

MS. GUSSACK: May I see it, Mr. Allen?

Subject to the argument --

THE COURT: 10186 will be admitted, but can you get me a copy without the word "comparable" underlined, because I doubt that that was underlined in the original?

MR. ALLEN: You know, what, Your Honor, my team says yes. I'm too ignorant about computers, to be honest with you -- yes,

sir, is the answer.
THE COURT: 10186, we'll substitute one without the -- we'll substitute one that looks like the original looks like.
MR. ALLEN: Yes, sir, I'm not -- didn't know that.
MS. GUSSACK: Just for the record, I don't believe 10186 was used with Dr. Hopson. It was used with Ms. Eski. Is that what you mean, Mr. Allen?
THE COURT: Well, it may have been used with Dr. Hopson because it was a call note of a visit that Ms. Eski had with Dr. Hopson. But I don't remember if that's the one that they asked him about or not.
MR. ALLEN: I'm telling everyone the truth as I know it. I pulled it out -- if I'm wrong -- I'll get you one without the underlining.
Your Honor, the State of Alaska moves to admit AK10188. Again, it is -- and we'll take out the underlining. A comparable rates series of call notes and we did a word search, as the underlining will show, to look for comparable rates.

THE COURT: 10188 does appear to discuss comparable rates and I'll admit 10188.
MS. GUSSACK: Subject to the objections, yes.
THE COURT: All of these, any documents I'm admitting here, all objections are preserved.
MR. ALLEN: Okay. And I will go back and get my staff to take out the underlining.
Your Honor, the State of Alaska moves to admit 10205. The word search was causation and this is causation of issues such as diabetes and hyperglycemia, such as you look on page 3 of this exhibit. Increase in appetite which may lead to obesity, but no causal relationship between Zyprexa and diabetes.
THE COURT: I see.
MS. GUSSACK: I think the cause pulls more weight gain here, and if we could --
THE COURT: Can we delete those causal things that don't have to do with diabetes, weight gain? There's one about muscle spasms, for example.
MR. ALLEN: I will take it --

anything dealing with hyperglycemia, diabetes, lipids, obesity, weight gain -- this is -- again, yes, Your Honor, I will take out --
THE COURT: I saw one with muscle spasms and the rest of them all do appear to be related. There's just that one --
MR. ALLEN: That's a call note. I will strike it. I see what you're talking about there. It's July 5th, 2000, Shelly Cramer to Dr. Susan Hunter Jones in Juneau concerning causation of muscle spasms. I'll take muscle spasms out of the case. Never thought it was in.
MS. GUSSACK: Appreciate that, Your Honor. I want to be sure that our objection includes the fact, particularly as indicated by that call note and others, that there's been no testimony offered by any of the percipient witnesses to these call notes in this proceeding, neither the physician receiving the message nor the sales representative providing the message. And that the State has said --
THE COURT: I think there was some general testimony by Ms. Eski about the call notes.
MS. GUSSACK: Her testimony, Your

Honor, was that the call notes bear no relationship to whom nor do they accurately reflect the message.
THE COURT: Well, that goes to the weight, I think. That itself may be relevant --
MS. GUSSACK: Understood, Your Honor. I want to make sure the Court is aware that repeatedly the State has acknowledged that the issue of call notes, their admission and the scope of them, are a Phase 2 issue. That we do not have here in this proceeding any of the percipient witnesses to these call notes and the issue that Lilly has raised repeatedly.
THE COURT: I don't think it is a Phase 2 issue. I think that it goes to -- and you talked about it in your opening and the question of Lilly's -- there has been more than a little testimony that Lilly, through the use of the people that were making these calls tried to -- I think one of the words used was neutralize the issue of weight gain or the association of Zyprexa or the comparable rates issue.
And a jury based on the testimony might well conclude that what Lilly was trying to

do was -- even though there may have been warnings and studies, that they were trying to minimize -- I think that was another word that was used.

And so I think all of this is very -- that whatever warnings that doctors might have been getting because I -- it's clear to me from the witness we just had that part of -- and what I hear about what the next witness will testify that part of Lilly's defense in this case is that doctors all knew about this. There was stuff in the literature and they were taking these precautions and the argument was being made.

And the relevance of it is that the doctors were -- it was being suggested to the doctors that they shouldn't worry about this. Even though there was stuff in the literature, it wasn't very good stuff, that's not really what the better information said or that it really didn't exist and to diminish their concerns that might have been raised from sources other than warnings.

MS. GUSSACK: I appreciate Your Honor's comments, but I want to clarify what

I believe is really prejudicial here. The documents that Your Honor has referred to are internal marketing documents. There has been no evidence offered in this courtroom that any of those messages or statements made in those internal documents were communicated to physicians by any sales representative in the State of Alaska contact. We have a total disconnect between information that was being presented about what was going on in a series of meetings.

THE COURT: Aren't these call notes exactly the evidence that you say there's no information on?

MS. GUSSACK: No, Your Honor. That these call notes do not reflect, either through the sales representative who has not testified here or a physician, that those messages were sent or received.

THE COURT: I think you can argue that and the Plaintiffs can argue and put together the documents they believe demonstrate something to the contrary, but I don't find that a basis to sustain --

MR. ALLEN: Your Honor, so the

State of Alaska moves to admit AK10205, subject to taking out the muscular abnormality. I don't think you've stated it's admitted.

THE COURT: Subject to that and removal of the underlining, 10205 is admitted.

MR. ALLEN: Your Honor, the State of Alaska moves to admit AK10192. This search, as you can tell, was weight gain. 10192, subject to taking out the underlining.

THE COURT: Subject to previous objections, I'll admit AK10192.

MR. ALLEN: Okay, Your Honor.

Next on the list, 10 -- 10200. The word search here was "diabetes."

THE COURT: 10200 is admitted with objections preserved and the underlining should be removed.

MR. ALLEN: Your Honor, the State of Alaska moves to admit 10187, which is Eski Exhibit No. 8 for her deposition. And the call notes discuss things as diabetes, comparable rates. Now, I will -- there is a few about children and weight gain, and I don't know how to handle that.

THE COURT: Just trying to find --

I'm not finding -- there's one without a number on it. What's the top --

MR. ALLEN: I'll bring it to the Court.

MR. LEHNER: 10197?

MR. ALLEN: No, 10187. These were actually used in Ms. Eski's deposition.

MS. GUSSACK: Your Honor, I believe that only six call notes were used in Ms. Eski's deposition. I don't -- and I have which six.

THE COURT: Well, again --

MR. ALLEN: I'm willing -- Your Honor, you know what, in order to avoid and so we can have this jury in, at least at this juncture, we can staple together the six that Ms. Gussack picks. I'll let them pick their own evidence. I'm just trying --

MS. GUSSACK: That will be easy. The call notes wouldn't come in --

THE COURT: If you did a search on diabetes, and some of these things talk about diabetes, won't they be in the exhibit that's not diabetes?

MR. ALLEN: Your Honor, not necessarily. I'm going to claim --

THE COURT: I'm asking your paralegal more than I'm asking you.
MS. RIVERS: I can't say for certain. I --
MR. ALLEN: I'm not trying to be obstreperous --
THE COURT: Again, I'll rule on the exhibit that I've got in front of me as an exhibit. If they want to pick six and I'll rule -- but as to Exhibit No. 8, what I would prefer you do is go back and make sure we're not doubling up. There are things in Eski 8 that would appear to be the kinds of call notes on issues that I'm excluding, and I want to make sure we're limiting our call notes to what I perceive this case is being about within the confines of my ruling.
MR. ALLEN: As you can tell, I'm skipping down this list and trying to do exactly as the Court ordered.
Let me see here. Your Honor, State of Alaska moves to introduce AK10196, which is tardive dyskinesia. Matter of fact, I think and if I can grab the report, but I'll bet the other side will concede, that one of the things

Dr. Kahn, their expert, is fixing to talk about, as soon as he gets on the stand, the benefits of Zyprexa outweigh the risks and one of the reasons they do is because there is no risk or a limited risk of tardive dyskinesia.
As the Court will recall in this trial, it's Exhibit 1196, the FDA in November of 1996 wrote Eli Lilly a letter saying they'd been engaged in false and misleading and deceptive trade practices by minimizing tardive dyskinesia. They are entitled to put on evidence that tardive dyskinesia is less than other drugs. I'm combating that issue.
You also know all the package inserts are in evidence. I'm paraphrasing the package insert warning on tardive dyskinesia but it says in there, the FDA has said there's no differentiation between these products concerning the risk of tardive dyskinesia.
So I move to admit AK10196.
MS. GUSSACK: Your Honor, I believe it was the State's expert that testified that the risk of tardive dyskinesia with the second-generation atypicals, including Zyprexa, was substantially less than the first generation.

But that really is to the side. I don't know what this has to do with the adequacy of the warning with respect to the issues that the State has identified here.
MR. ALLEN: Well, I do. It's a risk/benefit analysis. Let me read from the report of their expert, Dr. Kahn, if I can locate that for a second. He specifically talks about this.
MS. GUSSACK: Your Honor, I'm not really clear as to how -- in anticipation of evidence that has not been yet offered to the Court why these call notes are relevant as the State is concluding its case, before Lilly calls any witness on the subject.
MR. ALLEN: It's a risk/benefit -- you can't take a risk in isolation.
THE COURT: I understand what you're saying. For the time being I'm not going to admit AK10196. Either in cross-examination or rebuttal it may become admissible.
MR. ALLEN: Let me go ahead, Your Honor. The ones -- Mary Beth, do you have the ones that he's admitted? Do you have them written down?

THE COURT: The ones I've admitted are 10186, 10205, 10192 and then 10200.
MR. ALLEN: My esteemed colleague, Ms. Rivers, says you've also admitted 10188, comparable rates.
THE COURT: I did.
MR. ALLEN: Okay. Your Honor, I will save the Court time. I'm a little wary because of, you know, record, but I'll just take it as it comes. I will save the attempted admission or the call notes to a later date because you have a jury out there. I certainly appreciate the Court's attention to these matters. I apologize for taking your time here this morning on this matter.
THE COURT: There's no need to apologize. I believe in trials we need to make a record, and I think everybody is entitled to do it as clearly as they need to be in light of decisions that I've seen that people who don't make it clearly are punished for that.
MR. ALLEN: I want to apologize to the Court. I've met some judges that aren't so patient. Before we bring the jury in, can we get a little break?

THE COURT: I think -- is the State resting at this point?
MR. ALLEN: I think I am. Let me make sure.
THE COURT: Because there's going to be applications, I assume. And I'd rather deal with the applications --
MR. ALLEN: Can we take a break and come back in and rest?
THE COURT: Sure. Ten minutes?
MR. ALLEN: That will be nice.
THE COURT: And I'm going to give you back copies, extra copies.
MR. ALLEN: Yes, sir. I apologize.
THE COURT: That's okay.
MR. ALLEN: I know. I apologize. You are very patient and kind.
THE COURT: We'll be off record.
THE CLERK: Off record.
(Break.)
THE COURT: Please be seated.
Mr. Allen.
MR. ALLEN: Yes, sir, Your Honor. We are going to rest, but I have to offer one more exhibit. It's the August, 2001 United

States marketing plan for Zyprexa, AK4046. The State offers that exhibit, sir.
MR. LEHNER: Your Honor, consistent with your prior ruling on summary judgment, this we believe should be excluded, as well as it not being relevant. There's been no testimony about this document offered through any witness as well.
THE COURT: I'll defer on -- is this 4046?
MR. ALLEN: Yes, sir.
THE COURT: I'll defer on 4046. It can be -- Lilly witnesses can be questioned on this, and it can be admitted through them.
MR. ALLEN: Yes, Your Honor, with that, looking around at my counsel -- I ask two things, Your Honor.
First of all, the State rests. I know you're going to take up matters with the other side, and of course we'll respond. I would appreciate once -- if a determination is made that we're going to move forward, I'd like to be able to say "the State rests" in front of the jury.
THE COURT: That's fine.

MR. ALLEN: All right, Your Honor. The State rests. We appreciate your time.
THE COURT: Mr. Lehner.
MR. LEHNER: Yes, thank you, Your Honor.
Your Honor, Eli Lilly and Company, pursuant to Alaska Civil Rule Procedure No. 50, moves for judgment as a matter of law on the State's common-law failure to warn and Unfair Trade Practice Act claims. And I'm going to give to Mr. Borneman our motion -- our Rule 50 motion, if you please.
Let me, for the record, just briefly enumerate the grounds upon which we are seeking application under Rule 50. First, we believe that Lilly's entitled to judgment as a matter of law on the State's common-law failure to warn and UTP claims, because those claims based solely on the content of the Zyprexa FDA-approved label are preempted in their entirety by the Food, Drug and Cosmetic Act, and I'll return to that point in a minute.
Our second basis is that Lilly is entitled to judgment as a matter of law on the State's UTPCA claims. First, we believe that

this statute should not be applied to the sale of prescription medicine. Consistent with the interpretation of the federal -- the federal FTC Act, we believe -- which is inapplicable to prescription medicine, we believe that similarly the UTPCA should not apply. We also believe under this ground, Your Honor, that the conduct upon which this claim is based, and that is Lilly's alleged misrepresentation of Zyprexa in the product labeling, triggers the UTPA's exemption provision which bars this claim.
Our third ground, Your Honor, is that there is insufficient evidence of an inadequate warning, and I'll return to that in a minute.
Our fourth ground is that the State has failed to articulate a tenable theory for identification of the UTPC violations, and I think this is an issue that you raised yesterday, and I will address that briefly as well.
Our next ground is that the State may not seek UTPA civil penalties or restitution under that Act because it has not sought injunctive relief.
Our next ground is that the State's

damage claims are barred by remoteness and they should, therefore, be dismissed. That would go to this failure to warn claim.

And last, Your Honor, we believe that the State's strict liability claim is also barred by the economic loss doctrine which we set forth in our memorandum.

Let me briefly outline a couple of points that I think are pertinent here, Your Honor. It goes to the failure to warn claim, but I think it spills over into the UTPC claim as well.

I think the law is clear, as we've outlined previously, that in order to establish a failure to warn claim, the Plaintiffs must establish that the label failed to clearly indicate the scope of the risk, the danger posed by the -- or the danger posed by the product, that we failed to reasonably communicate the extent or seriousness of the harm, and that we failed to communicate those risks in a manner that was -- to allow a reasonably prudent person to understand the information that was being conveyed.

As I think the testimony before the

Court today has clearly indicated, the FDA has consistently monitored, regulated and, indeed, adjusted the warning to ensure that all these factors are met. That the warning, in fact, clearly indicates the scope of the risk, that the warning reasonably communicates the extent of that risk, and that that risk has been conveyed in a manner that would allow a reasonably prudent person to understand that risk. That testimony has been uncontroverted.

Everybody who has testified here has noted that weight gain -- people understand that weight gain has a number of risks associated with it, and they don't need to be informed about those associated risks through anything other than their basic medical education.

What the State is asking the jury to do, and what I think is improper and why this claim should be dismissed, is essentially to substitute its judgment in place of what the FDA has consistently done in regulating, monitoring, and as I said, as the testimony has established, adjusting the warning.

Secondly, because the Plaintiffs have failed to enumerate what the precise

elements of the label that are at issue here that are either false or misleading or inaccurate, I think their claim must fail as well. Did the label fail to claim information about weight gain? As of what date? Did the label fail to communicate information about hyperglycemia or diabetes? As of what date? As of what date did Lilly have information that they should have included in the label? That has been completely unclear. There's been no proof about that offered, Your Honor.

In fact, I think you heard Dr. Wirshing testify, having had access to all the material essentially that has been presented to this jury about anything that might be misleading or inaccurate; nonetheless, their own expert having testified that he is and having been accepted as an expert in labeling, and having testified that he reviewed all the labels with respect to Zyprexa, said clearly that they were neither inaccurate nor erroneous. That is his uncontroverted testimony.

Looking at this in the light most favorable to the Plaintiffs, that can only mean that there must be some evidence that's missing.

Perhaps he meant to exclude that, though. That was, I think, a most generous reading of his testimony. There is no evidence as to what the missing piece might be within the label that the jury would be able to say, had only that piece of information been in the label, then it would not be inaccurate or misleading. Was there some additional phrase? Was there some additional data that should have been in the label that would not have made it inaccurate or misleading in the words of their expert? There has been no testimony about that as well.

The testimony with respect to the adequacy of the warning was clearly supported by Dr. Gueriguian. Dr. Gueriguian was asked on page 181 of his testimony of March 11th -- he was shown a document, an FDA-review document by a Dr. Boehm and he was asked, had he ever seen this document before, and he said he didn't know. And he was asked to review it, and he looked at it. And I will read from the testimony.

He was handed the document by Mr. Brenner and Mr. Brenner said: Doctor, this is another review by Dr. Boehm of the FDA completed in 2005. Do you see that?

Answer: Yes, I do.
Question: Do you know if you reviewed this FDA review before forming your opinions here?
And he asked, would you hand me the document, please? And he was handed the document. And then he said, yes, I haven't seen this document, but I do agree with its conclusions -- having reviewed it on the witness stand -- which are very sensible and well supported.
Well supported, I assume he meant, in light of all the material that he had seen previously shown to him by the Defendants. In light of all the -- by the Plaintiffs, Your Honor. Well supported in light of all the allegations that the Plaintiffs have made about the inadequacy of the label.
What Dr. Boehm said in that report, and which Mr. Brenner went on to read, was that the FDA had no information, no data, no results of any tests that would change the position that they had previously taken. Now, the Plaintiffs have argued that, well, that report of Dr. Boehm may not have been accurate because Lilly had

withheld information from the FDA. I assume that must be their argument. But the information that was allegedly withheld from the FDA had been given to Dr. Gueriguian, so presumably he saw that information and yet he was still of the opinion that the FDA conclusion was well supported and he didn't disagree with it.
I think there's no evidence, Your Honor, that they have been able to advance that the label in any way has been -- is inadequate, that there's no specific piece of information that should have been included in the label, and I think their claim must be dismissed on that basis as well.
Finally, Your Honor, with respect to the allegations that go beyond the label and the claims that they make that somehow various communications constitute a violation of the UTPA, again, I think they've failed to establish what particular communications were made that were erroneous.
And I would particularly point to the communications that apparently they allege were erroneous and would be a basis for a UTPA claim violation that are documented in the 1996

FDA letter that you'd heard testimony about. This was a letter that the FDA sent to Lilly in 1996. Dr. Toleffson testified about it the other day. They've used it on cross-examination. Where the FDA said, we've heard various statements of Dr. Toleffson -- and I'll focus on those in particular -- where he made statements to investors about the therapeutic benefits of weight gain. And the FDA came back in 1996 and said, no, we don't think that that's appropriate. We think that's outside the label, and we think that that may be false and misleading in terms of what is communicated in the label.
Now, is it the State's claim that they are going to be able to take a statement by Dr. Toleffson made in 1996 for which there is no evidence that that statement was communicated to anybody here in Alaska, by the way. He made it in connection with a teleconference to investors. There was some vague testimony as to whether or not that conference was reported in the newspaper, but there's certainly no link that that communication was made to Alaska. Are they going to be able to ask this jury to say that that communication, that statement by

Dr. Toleffson, which the FDA has already commented upon was false and misleading under the UTPA and, therefore, should be the basis for a civil penalty? I think that would be contrary to the law.
And that is illustrative, I believe, of a number of the claims that they've made. There is no link; there's no tie-up to anything that happened here in Alaska. It's vague; it's remote. And I believe that they have failed in their proofs to establish a basis for moving forward on that claim because of the inability, as you raised yesterday, to articulate what precise communication was made that was -- would be a violation of the UTPA.
I would only, finally, conclude and I would use the analogy, really, that Mr. Steel made yesterday when he brought to your attention the case about the -- I guess it was a mortgage broker or somebody who wrote a letter, and in the letter there was apparently a line which he described was false or was a lie, and that was the basis for the violation. It was not the fact that there was some letter out there and they were engaged in some kind of activity. There was

a very precise, erroneous, misleading statement within that letter that formed the basis, as I understood it, for that claim.

There's been none of that proof here in this case, Your Honor, and I believe their claim should be dismissed on that basis.

THE COURT: Thank you, Mr. Lehner.

Do Plaintiffs feel --

MR. ALLEN: I don't know where to begin to respond, Your Honor.

Let's just start at the end concerning the '96 statement by Dr. Toleffson on the issue of weight gain. That statement was false, deceptive and misleading. And the evidence that is in the record -- and I do not, Your Honor, want to disclose strategy about what you're about to see here in a little while. The evidence in the record demonstrates beyond any doubt whatsoever that that false, deceptive and misleading statement was continued throughout the remaining course of this company's sales and detailing to doctors here in Alaska and throughout the country. I can prove it and it's in the record now. And I -- as you heard, I think -- you know, he said there's no linkage.

Mr. Noesges has testified, as has Ms. Eski, that they -- and as the exhibit you just admitted, I think it was 10067, if my memory serves -- that their sales practices are the same in New Hampshire as they are in Alaska. They didn't use the little words. They're the same across the country. They train these sales representatives; they have a policy of training; that their messages that they're trained on must be followed wherever they go. The sales representatives are not entitled to, I guess, ad lib or go off message.

So any material we have introduced, the label, the training materials, the detail pieces on comparable rates, all of that material -- and the call notes, representative call notes display the fact that -- that, in fact, all of these messages reached here into Alaska. In fact, to say so would ignore Mr. Bandick's testimony that messages, which is really -- it's a term of art. It's not just a word -- it's used differently. Messages are what a company wants to convey. And I asked him in his depo: Why do you convey messages? And I'm including and paraphrasing his answer, is because

we want to convey information about the product and we want our customer to feel a certain way. We have extensive messaging throughout the documents.

Mr. Jordan has testified in his deposition that -- and this is a term of art, product positioning is how we went our physicians to think.

THE COURT: Mr. Allen, in the interest of time, if you feel you need to make a record, make your record.

MR. ALLEN: Oh, I don't. Okay.

THE COURT: If you feel you need to convince me, you can sit down.

MR. ALLEN: Okay. Well, then, I don't need a record, and I could go on. Okay. Thank you, Your Honor.

THE COURT: I will -- in ruling on a motion for a directed verdict, the motion should be denied if it appears from the record that there is evidence from which fair-minded jurors can reach differing conclusions. That's the Mertz versus J.M. Covington Corporation case, 430 P2d 532, the Otis Elevator Company versus McLeany case, 406 P2d 7. And applying that

standard to the extent that the motion is based on insufficient evidence, I will deny the motion finding that there is sufficient evidence in the record from which fair-minded jurors could rule in favor of the Plaintiffs on their claims.

To the extent that the motion is based on arguments that previously were made and are being renewed as to preemption on the failure to warn claim and preemption and the exemption on the UTPA claims, I will rely on my previous decision on those issues. But I will add to it the following: When I made those decisions, I think it was clear from the record that I considered some of those issues to be, at least as a legal matter, a closed case. But having heard the evidence, at least in the State's case and recognizing that I've only heard it in the State's case, it is clear to me that the evidence establishes the wisdom of having such warning claims and UTPA claims under State law compliment FDA jurisdiction for many, many years.

The evidence, at least at this point, I believe, would establish to a jury that the FDA really isn't capable of policing this matter, that they are highly reliant on the drug

companies and the drug companies providing to them all information, and if they don't have the staff or the resources to fully do this without common-law claims, it is likely that -- at least based on the evidence that I've heard now, it is likely that many claims of -- and problems with warnings on drugs might well go unaddressed. And it is only based on the evidence heard so far through common-law claims that health issues such as the one that's being raised in this case can be -- might be properly raised.

And I, again, recognizing I've only heard half of a case, note that in -- in denying the motion for preemption and the exemption under the UTPA. The no civil penalties without injunctive relief, I will reject as a matter of law. While the civil penalties are tied to the ability of the State to get injunctive relief, the fact that the State has recognized in this case that changes have already been made and we've got a time limit that -- in terms of the allegations in this case that would make injunctive relief not necessary, I suppose, merely has saved time for the Court and the parties.

The State could have asked for injunctive relief and these penalties, and I could have denied injunctive relief even -- because of the timing and those kinds of things, and so I don't -- I believe that the State would have had a basis for seeking injunctive relief, at least during the time periods in question hadn't this lawsuit been brought, and I don't think the State is precluded from still seeking the civil penalties under that portion of the case.

To the extent it's argued remoteness or that the State really hasn't enunciated its theories as to what are the violations of the UTPA, I do not believe that the allegations contained are remote, and I believe that the State has certainly developed UTPA claims. Ultimately, we're going to have to resolve that through jury instructions and through a special verdict form in this case.

But I -- again, in applying the standard for a directed verdict, I don't find that those arguments merit dismissal of the case under Rule 50, and so I will deny the motion for Rule 50 relief.

Is Lilly ready to proceed with its defense?

MR. BRENNER: We are, Your Honor.

THE COURT: Then, why don't we go off record for two or three minutes, let the jury get ready to come in, and bring the jury in.

MR. ALLEN: Thank you, Your Honor.

THE CLERK: Please rise. Superior Court now stands in recess.

Off record.

(Break.)

(Jury in.)

THE COURT: We're back on the record. Parties are present; all members of the jury are present.

Good morning, ladies and gentlemen of the jury. And, again, I apologize for the delay. We've been spending some time admitting documents in the case. It's a necessary matter that we need to do, particularly as one party gets towards the end of their case, and it took a little longer than we expected.

MR. ALLEN: Your Honor, may I proceed?

THE COURT: Yes.

MR. ALLEN: The State rests, Your Honor.

THE COURT: Okay. Ladies and gentlemen, the State has rested at this point and concluded the presentation of the evidence in its case in chief. So at this point it's the Defendant's turn to begin presenting its evidence.

Mr. Brenner.

MR. BRENNER: Thank you, Your Honor. The -- Eli Lilly had previously called Dr. Inzucchi out of turn. We now call Dr. David Kahn.

THE COURT: Doctor, if you'd come forward, please, to the witness chair, we'll put you under oath.

(Oath administered.)

THE CLERK: For the record, will you please state your full name, spelling your last name for the record, please?

THE WITNESS: David Alan, A-l-a-n, Kahn, K-a-h-n.

THE CLERK: Thank you, sir.

THE COURT: Please be seated.

Mr. Brenner.

MR. BRENNER: Thank you, Your Honor.

DIRECT EXAMINATION

Q. (BY MR. BRENNER) Good morning, Doctor.
A. Good morning.
Q. I'll let you pour a glass of water there before I ask you a question.
Doctor, could you tell the jury what you do for a living?
A. Yes. I'm a psychiatrist.
Q. Where?
A. At Columbia University Medical Center in New York City.
Q. And could you describe in general terms the nature of your practice?
A. Yes. I diagnose and treat patients with mental illness. I am a hospital administrator and supervise a number of hospital inpatient units and clinic services. I'm vice chairman of the Department of Psychiatry at Columbia University, vice chairman for clinical affairs, and so I oversee the quality of care provided on those services and the education of many of the residents and faculty.
Q. Could you tell us briefly your medical

training starting with medical school?
A. I went to medical school at Columbia University, where I graduated in 1979. I completed that in the usual four years. I was then an intern in the Department of Medicine at Presbyterian Hospital and then a resident for three years in the Department of Psychiatry at Columbia University Presbyterian Hospital and the New York State Psychiatric Institute and was chief resident in that final year.
Q. Did you take any fellowships, Doctor?
A. Yes. I took an extramural NIMH-funded fellowship in treatment of severe depression.
Q. Are you board certified in psychiatry?
A. Yes, I am.
Q. And are you licensed to practice medicine anywhere?
A. Yes, in the states of New York and New Jersey.
Q. Doctor, do you -- I think you mentioned -- do you have a private practice?
A. Yes, I do.
Q. Can you give us an estimate, between your private practice and your hospital-based practice, how many patients do you typically see

over any period of time that's appropriate?
A. Yes. In my private practice, which I'll mention is just under the auspices of Columbia University; I practice as an employee of the university on the faculty. I follow approximately 250 patients in the hospital each year between the different units that I supervise. We admit approximately 1,000 patients per year.
Q. Among the patients you treat, do you treat patients with schizophrenia?
A. Yes.
Q. And with bipolar disorder?
A. Yes.
Q. Do you hold an academic rank, Doctor?
A. Yes.
Q. What is that?
A. I'm clinical professor of psychiatry.
Q. And could you tell us, briefly, what duties and responsibilities that rank entails?
A. Yes. It involves supervising and monitoring the quality of care provided by our faculty and by our residents, and assisting in the educational programs, and overseeing all of the clinical programs at the medical center in

the Department of Psychiatry.
Q. Okay. And you mentioned the New York State Psychiatric Institute.
Do you have an affiliation with that institution?
A. Yes, I do. Most members of our department are affiliated both with the New York State Psychiatric Institute and with the Columbia University Medical Center. These are across the street from each other. One is a large general hospital; the other is a State hospital.
Q. Do you treat patients with atypical antipsychotics, including Zyprexa?
A. Yes, I do.
Q. Doctor, have you ever published any medical literature?
A. Yes, I have.
Q. Have you done that in peer-reviewed journals?
A. Yes, I have.
Q. And approximately how many publications do you have to your credit?
A. Several dozen publications.
Q. Have you ever served as a reviewer for any medical journals?

A. Yes, I have.
Q. Approximately how many?
A. I've served for reviewers for four or five journals.
Q. In what subjects?
A. Bipolar disorder and delivery of health services.
Q. Do you serve any -- on any editorial boards?
A. Yes, I do.
Q. Which ones?
A. The Journal of Psychiatric Practice.
Q. And what does your work entail as serving on an editorial board?
A. Helping to determine the types of articles that the journal will seek to publish and helping to review articles for that journal. I also write a column for that journal, looking at case reports of unusual problems that have come to the attention of doctors around the country.
Q. Doctor, have you ever testified in court as an expert before today?
A. No.
Q. Are you being paid for your time today?

A. Yes, I am.
Q. At what rate?
A. $600 per hour.
MR. BRENNER: Your Honor, at this time we'd offer Dr. Kahn as an expert in psychiatry and psychopharmacology.
MR. ALLEN: No objection.
THE COURT: I will recognize Dr. Kahn as an expert in psychology and psychopharmacology.
MR. BRENNER: Thank you, Your Honor.
Q. (BY MR. BRENNER) Doctor, throughout the trial, the jury has heard something about schizophrenia and bipolar disorder.
I'd like to ask you some questions in a relatively brief way, but as comprehensive as you can make it, about those diseases starting with schizophrenia.
What is that disease?
A. Schizophrenia is a brain disease that has profound impacts on the ability of people to perceive reality, to think logically, and to behave in a normal fashion. It is a lifelong illness. It generally begins when individuals

are entering the prime of life, in their adolescence or early adult years.
There is no cure for it, and even with optimal management it frequently follows a progressive deteriorating course. It's a very tragic disease that has a tremendous impact on the individual and on that person's family.
It occurs in about 1 percent of the population of our country and, indeed, of all countries, both developed and undeveloped countries around the world. The cause is probably genetic due to various types of mutations that affect the chemistry and the structure and the physiology of the brain.
Q. Doctor, have we, with your assistance, put together a few slides that address the symptoms of schizophrenia and bipolar disorder?
A. Yes.
Q. And would those be helpful in explaining these concepts to the jury?
A. I believe so.
MR. BRENNER: Mike, could I have the first slide?
Q. (BY MR. BRENNER) Doctor, the first slide is one entitled Positive Symptoms. Could

you tell the jury what positive symptoms are in connection with schizophrenia?
A. Yes. Positive symptoms are among the most dramatic obvious symptoms of schizophrenia, particularly early in the course. These are things that the brain is producing that are highly visible. The two most prominent are delusions and hallucinations. Delusions are fixed false beliefs about the nature of reality. They can frequently be quite bizarre in the case of schizophrenia.
Hallucinations are perceptions, generally auditory, although they can be visual, or olfactory in terms of smell, or agustatory in terms of taste, or somatic in terms of physical perception. But most frequently hearing voices is the prime example of the types of hallucinations that people with schizophrenia have.
Disorganized speech is quite common in schizophrenia, incoherent, illogical speech, breaks in normal grammar, breaks in the usual logic or flow of how someone would try to communicate. And disorganized behavior, including very agitated or dangerous behavior can

also be a symptom of schizophrenia.
Q. Doctor, I know this recaps some of those items.
You've reviewed this film clip that's over on the right?
A. Yes.
Q. And could you tell the jury what -- we'll play it in a moment -- but who is this person and what does the clip depict?
A. This is a very tragic example of schizophrenia in an all too common form, although this was a very severe case that made the newspapers about ten years ago. This is a clip of Russell Weston. At the time that this was made, he was 41 years old. Six months prior to this tape he had shot and killed two police officers in the United States capital where he had attempted to barge into the Senate chambers.
He was acting under the influence of delusions that there was a conspiracy for cannibals to take over the United States, as well as for certain diseases to spread throughout the United States. He believed that only he could stop this from happening, and that there was a plot by the government to stop him from doing his

role, and that they were controlling his brain by means of a ruby satellite dish, as he refers to it, which was embedded somewhere in the capital.
He had been living as a hermit out in -- in Montana, as it turns out about 40 miles from the same place where the Unabomber had lived in Montana. And he'd fled from his family. Been in and out of hospitals. He'd been diagnosed with schizophrenia from the time that he was 20 years old.
His agitation and paranoia about the government had been building for a number of years. And at the time that this incident occurred, he went back to his parents' house, stole their pickup truck and his father's gun, drove all the way to Washington and then this tragedy ensued. He shot two guards. He was subsequently shot, nearly died and lost his life himself, recovered enough so that six months later when this tape was made, he was being evaluated for his competency to stand trial.
And this is an interview by a court-appointed psychiatrist who was evaluating him for that competency. The video was made available through the Washington Post.

MR. ALLEN: Your Honor, can we approach?
THE COURT: Sure.
(Bench discussion.)
MR. ALLEN: I think that was off line and I'm going to object, but a video being played concerning statements back and forth between a policeman and this gentleman are now irrelevant. And any probative value is far outweighed by the prejudicial effect.
MR. BRENNER: Well, he's a psychiatrist. Much the same way as pictures of diseased diabetic feet -- it's about a two-minute clip --
MR. ALLEN: This has conversations on it. That's the difference.
THE COURT: I'll overrule the objection.
(End of bench discussion.)
(Videotape played.)
A. Previously in the past I have found that Judge Sullivan was involved with black market racketeering and murder and cannibalism, also.
Q. And if that were true, how would that affect your trial in particular?

A. I am seeking to expose that conduct and to thwart them from continuing in that conduct. And, obviously, whenever I am in the position of doing that, they will -- they are going to try to stop me, in other words, hold me from stopping them from continuing their conduct. Some of the jurors will be part of the conspiracy also.
Q. Do you have some law background yourself?
A. Yes.
Q. Would you explain that?
A. In previous time to this case, I spent a great deal of time at Harvard University. First I went to school there, and then I became a law professor there at Harvard University, and then finally the dean of Harvard University, of the law part of the university and the medical university also.
Regardless of what the outcome of the trial is will be that I will inevitably regain control again of the ruby satellite system. And then instead of the cannibals controlling the -- we shall say the propaganda or informational content of the public airways and/or of documents, public documents, then I

control that.
Q. What would you do with it then?
A. I usually boil them in sour crude oil is usually what I do.
Q. Boil who in sour crude oil?
A. The cannibals in Washington, D.C. It amounts between 40 and 50,000 cannibals. I will put them in sour crude oil that's boiling hot, and whenever they get done, they're -- they turn out to be hard as rock.
Q. And what happens to them after that?
A. Well, they're usually deceased. Usually then I put a rope on them and I hang them up around Washington, D.C., and all the rest of the people who see these blackened corpses all over town know that cannibalism will not be tolerated.
Q. If theoretically a (inaudible) did recommend an insanity defense, would you go along with it?
A. No.
Q. Why not?
A. That is not advantageous to my position.
Q. First of all, do you perceive yourself as being (inaudible)?
A. No.

(End of videotape.)
Q. (BY MR. BRENNER) Doctor, briefly, what are the positive symptoms that you see in that clip?
A. He describes very bizarre and disturbing delusions, delusions which then directly led to this very agitated, violent behavior. He doesn't talk here about hallucinations. Those weren't evidenced in this particular tape. You could see that his speech was quite disorganized in the sense of idiosyncratic use of words, odd repetitions, strange ways of phrasing and pacing his speech.
Q. Doctor, what are negative symptoms in association with schizophrenia?
A. Negative symptoms are brain functions that seem to be missing, particularly over time as schizophrenia develops, although sometimes they can also be early warning signs that the illness is about to occur. These are losses of affect. The phrase used here is affect flattening. Affect refers to mood and emotion. Alogia refers to an absence of speech. Someone who would sit in a corner, not communicate, begin to shut themselves off from speaking with other

people.
Avolition, loss of volition, loss of voluntary functioning or loss of the ability to initiate activity. And anhedonia, which is loss of the capacity to experience pleasure. So, if you think of someone in a different stage of the illness or with perhaps a different personality than Mr. Weston shows in this tape, this would be aspects of the illness where someone literally sits curled up, away from people, locked in a room, incommunicative, with an absence of internal mental or emotional life or connection with other people.
Q. Doctor, this slide talks about cognitive symptoms.
What are those?
A. It's interesting that about a century ago when schizophrenia was first described in modern medicine, although it's been described in ancient medicine for thousands of years, the German psychiatrist who first described it gave it the name dementia precox or premature senility. People with schizophrenia don't look like they have senility in the way that we think of it, but they do have profound difficulty with

full intellectual functioning as the disease progresses.
There's difficulty with attention, with the ability to integrate memory into daily life, with decision-making and with abstract thinking. This can be picked up just in the course of seeing -- someone with severe schizophrenia, for example, might have trouble organizing a grocery list, going to the store, getting the items, coming home, cooking them, cleaning up, because that requires a fairly active mind, although it's something that we all take for granted.
Q. Doctor, this slide talks about comorbid conditions.
What does that phrase mean?
A. Comorbid conditions are other medical problems or other symptoms that are outside the strict range of schizophrenia that occur in the course of the illness.
Q. And what are some of those that you see in practice?
A. It's not uncommon for people with schizophrenia to develop independently a depressive illness, partly as a reaction to their

own tragic losses in their life, but also partly because of overlapping chemistry between depression and schizophrenia.

Substance abuse is a very common problem. Fifty percent or more of people with schizophrenia will experience episodes of substance abuse at some time in the course of their illness, which can include alcohol, marijuana, hallucinogens and other drugs. These don't cause the illness. They make the course of it worse, however.

Smoking of tobacco, very common in schizophrenia. If any of you ever had the opportunity to visit a friend or a loved one in a psychiatric hospital before smoking rules were established over the last five to six years, you may remember smoke-filled day rooms. Nicotine is a very powerful stimulant, and many people with mental illness, including schizophrenia, become addicted to it because of that.

Q. How about type 2 diabetes, Doctor? Is there a belief within your profession that that's associated with schizophrenics?

A. Yes. There --

MR. ALLEN: Your Honor, I object to

the form of the question about belief within your profession, as calls for speculation. He can give his opinion.

THE COURT: I'll sus -- could you rephrase the question?

MR. BRENNER: Sure, Your Honor.

Q. (BY MR. BRENNER) Doctor, do you have an understanding or opinion as to whether type 2 diabetes is associated with schizophrenia?

A. Yes. Many people with schizophrenia develop a number of medical conditions, including obesity, hypertension and type 2 diabetes in the course of their illness. They're at higher risk for these conditions, partly a result of lifestyle issues, and there is some evidence that they can also be in some way related to the course of the illness apart from treatment and lifestyle issues.

Suicidality is listed on here as well, and that is a complication of schizophrenia. That tragically occurs in up to 10 percent of individuals who are not able to get successful treatment for the illness. It's -- people who become suicidal in the course of schizophrenia are acutely aware of the kinds of

life losses that they have sustained.

Q. Doctor, are all schizophrenics obese or tend to be obese?

A. No. Some schizophrenics are thin, certainly at the beginning of the illness. Some schizophrenics, even as the illness progresses, remain thin, particularly if they've been unable to nourish themselves or care for themselves. If you've seen homeless people on the street, not all but many of whom have schizophrenia, you've seen them in an emaciated condition. They often come into our emergency rooms in profound states of self-neglect, often quite undernourished.

Q. Doctor, this portion of the slide talks about long-term deterioration.

What does that mean?

A. Well, if I were to make a graph for you of the level of functioning of someone with schizophrenia, it would show a series of steepwise declines in a broad number of areas of what we would consider normal and healthy and gratifying life functioning and being able to carry out roles. Schizophrenics have a very difficult time maintaining themselves in housing, often because of their poverty and also because

of their behavior.

They need supervision and care and often find it difficult to live independently. They have poor general health and hygiene, again, both because of poverty, but also because of lack of the ability to care for themselves or lack of appropriate concern or sensitivity to their own hygiene or health needs.

People with schizophrenia lose friendships, frequently never marry, frequently become estranged from their families or have at least difficult relationships, generally are unemployed. And, of course, sadly within our society often are stigmatized and socially outcast.

Q. Doctor, in your experience working with schizophrenics, is there an impact, a particular impact of the disease on their families?

A. It is a tragic experience for families. I had a colleague, a psychiatrist, who had a son who became schizophrenic. He wrote a great deal about this and described the experience as mourning for the death of the child who he knew when he and his wife and their other children became aware that this son had schizophrenia.

It's just a profound loss. The person as you know them disappears and is replaced by someone who can never experience the same kinds of relationships or emotions.

Q. Doctor, let's turn to bipolar disorder. First, what is it?

A. Bipolar disorder -- remember, I described schizophrenia as primarily a brain disorder affecting thinking. Bipolar disorder is another brain disorder primarily affecting mood. It tends to be episodic, although it can take chronic forms. It's episodic in the sense that patients have distinct mood episodes, typically of elevation and at other times of depression.

The elevated moods are called mania. Those are shown on the left-hand side of the slide. Those are characterized by a mood which can either be very euphoric or extremely angry and hostile, but to any observer would be considered high in some way, higher elevated. It can be accompanied by psychotic delusions and by hallucinations.

When you think of the types of classic delusions that we see in mania, this would be the textbook example of someone who

thinks that they're Napoleon or that they're Jesus Christ, but even in such -- in less bizarre forms, delusions that people have unusual powers or abilities or talents or gifts is not uncommon in manic psychosis.

Out-of-control behavior driven by these delusions or by inflated self-esteem is the rule that behavior can include a tremendous financial indiscretion. Spending lots of money that a person can't afford to spend. A very high sexual drive and tremendous sexual indiscretion can occur, and a wide range of behaviors that alienate other people and endanger the economic or emotional well-being of one's family or the physical safety of the person, him or herself.

Very high energy, decreased need for sleep. People with mania can get by on two or three hours of sleep a night for weeks or months at a time.

There is a related condition called a mixed state. I'll refer back to it again when we get to depression. But in a mixed state the person has all of these physical and energy symptoms of mania, but their mood is actually very depressed, miserable and unhappy. So mixed

states and mania are very closely related states.

Q. How about the depression side of the ledger?

A. The other side of the coin is depression. Manic episodes may go on for weeks or months at a time; depressive episodes can last for months or even years at a time. Depressive episodes are characterized by extreme sadness, loss of pleasure in everyday life, loss of interest in everyday activities.

There can also be psychotic delusions and hallucinations during depression. These typically have depressive themes. Themes of impoverishment, themes that one has an incurable illness. Themes that one is guilty of unspeakable crimes. Delusions that a person is completely worthless and that their life achievements have never amounted to anything.

Sleep is typically disturbed in depression. I described in mania that people don't need to sleep. In depression, people often can't sleep and are desperate to try to sleep. Sometimes they can sleep too much, 15 to 18 hours a day and just not even get out of bed. Tremendous self-neglect in depression. Again,

poor hygiene, failure to care for oneself, failure to sit down at the desk and pay the monthly bills. People get their phone service cut off. Their landlord calls them for the rent.

And suicide is an unfortunate sad outcome for many people with depression. Untreated, about 15 percent of people with bipolar illness kill themselves, typically in depressed states or in mixed states where their mood is depressed but their energy level is very high, and that often seems to facilitate the act of suicide.

Q. Are there cognitive symptoms associated with bipolar disorder?

A. Yes.

Q. What are they?

A. The cognitive symptoms are somewhat different in mania and depression. I mania there's a great deal of distractibility and something called flight of ideas. During depression, people describe their thoughts as being in molasses. They just can't think through anything. They can't focus, concentrate, even watch a television show or read a column in a magazine.

Poor focus is, again, common in both manic and depressed states in slightly different ways, as I've described. And poor judgment. Depressed patients will totally underestimate their potential, their capacity. They'll give up on things. Manic patients overestimate their potential and capacity and will make very bad, impulsive decisions.

Q. And are there comorbid conditions associated with bipolar disorder?

A. Yes, there are. Again, as we saw with schizophrenia, very high rates of substance abuse. People with bipolar disorder, especially in the manic phase, frequently try to medicate themselves with alcohol or during the depressed phase may use other drugs like cocaine and marijuana to try to bring themselves out of it. So rates of substance abuse in bipolar disorder, again, lifetime rates, are 50 to 75 percent.

Smoking is common. Other medical problems; hypertension, stroke and heart disease, and, again, there appears to be an increased incidence of type 2 diabetes in individuals who have bipolar disorder.

Q. Do we know why that's so?

A. No.

Q. Doctor, about how many people does bipolar disorder afflict?

A. It's slightly more common than schizophrenia. Schizophrenia, I mentioned, afflicts about 1 percent of the population, and, by the way, is evenly distributed between men and women. In bipolar disorder, it occurs about three times as often in men as it does in women. And the total incidence in the United States and most developed and undeveloped countries is between 1 and 2 percent.

Q. Is there also long-term deterioration that's associated with bipolar disorder?

A. There can be. Sometimes the prognosis is much better than schizophrenia. Mood stabilizing drugs that have been available for decades, such as lithium and Depakote, as well as adjunctive use of antipsychotics, has been able to treat many people successfully. And the use of more recent atypical antipsychotics as mood stabilizers has also helped improve the course of this. So, overall about 30 to 40 percent of people with bipolar illness can have a relatively good response as long as they take medication.

They may continue to have relapses over the course of their life, but these can be controlled effectively with good medicine.

However, the majority of people with bipolar disorder do suffer from some form of chronic disability, from oncoming bouts of mania and depression, and may exhibit, of course, similar to schizophrenia with progressive problems with unemployment. Unlike schizophrenic patients who never get married, bipolar patients often have multiple failed marriages. They'll have difficulty maintaining housing, difficulty maintaining relationships, and over time, as they get older, often lead an increasingly sad and constricted life.

Q. Doctor, you started your medical training in the 1970s?

A. Yes.

Q. What -- what treatments were available at that time to deal with schizophrenia and bipolar disorder?

A. Well, the usual course for treating bipolar disorder was to give patients during acute manic episodes a mood stabilizer, and lithium was the only approved mood stabilizer at

that time. Every textbook taught us to treat patients simultaneously with a conventional antipsychotic, such as Haldol or Thorazine, which were also indicated for use in acute mania, particularly when psychotic delusions were present.

And for long-term treatment, we used lithium. Later Depakote became available, and other drugs, such as carbamazepine, were also used mood-stabilizing drugs. For treatment of schizophrenia, the only treatment that we had were the conventional or first-generation antipsychotics. In both conditions we also frequently had to use antidepressants, particularly in the depressed phase of bipolar disorder.

Q. Did you have an understanding from your training as to what treatments had been tried before the advent of first-generation or conventional antipsychotics?

A. Yes. There were no specific treatments that were targeted at what eventually came to be understood as the underlying pathology of schizophrenia, which was chemical. The earlier treatments were primarily forms of physical

sedation or restraint or efforts to try to just slow a patient down motorically. So ice baths, lobotomies, insulin coma. Sadly, these were essentially restrictive treatments that were used to control agitated or violent behavior with no specific effect on the course of the illness.

Q. The first-generation or typical antipsychotics, were they effective?

A. They were effective to a limited degree. There had been tremendous hopes when the first antipsychotics became available in the 1950s that they would produce a dramatic change in the course of schizophrenia as people in State hospitals began to receive these, and that's where most people with chronic schizophrenia lived. There was a move to deinstitutionalize people with schizophrenia, return them to the community, in the hopes that if they were able to take antipsychotic medication, they could function better.

Unfortunately, although they were helpful in treating the positive symptoms that I described before, especially delusions and hallucinations, they were not effective at treating the negative symptoms, and many of the

side effects that we'll get to later also would seem to make the negative symptoms either worse or more recalcitrant to treatment.

Q. And what were the side effects that you understood were associated with the first-generation antipsychotics?

A. There were a range of side effects. Weight gain and sedation were certainly serious side effects. They had a way of slowing down people's thinking. People taking first-generation antipsychotics often would describe the experience like there was a wet blanket over their head.

But the most serious side effects in terms of long-term safety of those drugs, you know, aside from general weight gain and consequences of being slowed down and sluggish, were neurological side effects called extrapyramidal side effects, and we'll describe those in a moment and --

Q. I'll tell you what, Doctor. I think we have a slide on that.

A. Good.

Q. Sorry.

A. So, these side effects included both

acute and long-term side effects. The first group here -- all of these can be lumped together in something that we call extrapyramidal side effects or EPS. That refers to an area of the brain called the pyramidal region that controls movement and muscle tone.

The acute side effects of a Parkinson-like syndrome and of akathisia were the most common ones that people would get within hours or days of beginning these drugs, particularly the high-potency antipsychotics, though we saw it with all of them.

Parkinsonism is a -- is a stiffness of the muscles accompanied by a tremor and can actually look a lot like negative symptoms as well. A person has difficulty getting up and moving around and their mind also feels very slowed down. If any of you, once again, had the experience of seeing loved ones or friends in a hospital who were taking these drugs or outside of a hospital, you would often notice immediately that these were people who were very stiff, tremulous, might have a shuffling gait. They really looked -- again, I hate to use a stereotype, but they looked like the stereotype

depiction many of us have in our minds of a mental patient. They just don't -- you don't look normal when you have these side effects.

Akathisia was also another neurologic side effect of extreme restless legs. People with akathisia had trouble sitting still in a chair. You can't sit through a movie. You have to get up and down from the table. Tremendous feeling of restlessness.

Now, these side effects were caused by blockage of a chemical in the brain called dopamine. Dopamine is present throughout the brain and has a number of functions, but for our purposes the two major areas of dopamine activity are in thought and mood on the one side and motor function on the other side.

The first-generation of antipsychotics were what we would call a very dirty drug or a shotgun drug. They blocked dopamine all over the brain. So the result was that it blocked dopamine in areas where it was thought to be involved in delusions and hallucinations. Too much dopamine was thought to account for these symptoms in the way, for example, you all know when people take cocaine

they can look like they're manic or look like they're schizophrenic. That's because cocaine stimulates the release of dopamine.

So there is a theory that schizophrenia was due to too much dopamine, so we got antipsychotics, they blocked dopamine in the brain, helped the symptoms, but they also blocked dopamine in the area involved in motor coordination. And this would produce Parkinsonism. You may have elderly relatives who have had Parkinson's disease. The treatment for that is giving a form of dopamine back to the person to restore the dopamine that's missing from their brain in Parkinson's disease. So you block dopamine with the drug, people get these Parkinson-like symptoms, they get the akathisia or restless leg type symptoms.

In very rare cases the muscle contractions of Parkinsonism, the stiffness would lead to very high fevers and breakdown of the muscle tissue. This produced a syndrome, called neuroleptic malignant syndrome. Now, virtually everyone who took antipsychotics -- or the vast majority of people would get Parkinsonism. Many would get akathisia. A very small number would

get neuroleptic malignant syndrome, but it was very dramatic and life-threatening when it happened.

We could treat these syndromes by giving certain kinds of drugs that would partially reverse them, and the drug that we gave most typically was a medicine called Cogentin. Now, remember, I described in Parkinson's disease we give people dopamine. We can't give dopamine in schizophrenia because it will make the delusions and the hallucinations worse. So we have to give something that works a little bit more indirectly. Cogentin was the drug that we would use, but Cogentin has its own side effects.

Cogentin causes blurry vision, dry mouth, constipation, confusion. Can cause disorientation, and some people actually abuse it because they can feel a little bit high or cloudy-headed when they take it in a way that they enjoy, so it had that potential problem as well.

So you have someone taking one drug. You have to give them another drug to counteract the side effect, and that drug has its own side effects. So it's just not a very pretty

picture, and it would often only be partially effective at alleviating the symptoms. And then, again, some people would go on to develop this life-threatening syndrome of neuroleptic malignant syndrome.

Q. What of the side effects you've listed here is long term?

A. Tardive dyskinesia and a related phenomenon called tardive dystonia. When someone is exposed to this type of dopamine blockade in their motor coordination area for very many years, over time the brain learns to adapt to that and develops a way of becoming more sensitive to the little tiny bits of dopamine that are left. That extra sensitivity to dopamine, we believe, causes -- instead of, you know, where we had the stiffness before when dopamine was blocked, now there is this sensitivity to little tiny bits of dopamine that are left and you get the opposite.

You get these big involuntary movements. Instead of being unable to move, parts of the body begin to twitch or move around uncontrollably. This is tardive dyskinesia or tardive dystonia. We see it in limbs. We see it

in the trunk of the body. We see it in the mouth and tongue. Sometimes it would reach the point where people couldn't swallow if they had severe tardive dyskinesia because the muscles of the throat would be affected.

Q. Doctor, do we have a film clip that depicts some of these long-term side effects?

A. Yes.

Q. And if we run that, could you just narrate to the jury what they're seeing?

A. Sure. This is tardive dystonia. The woman depicted here has a spasm of her back and her neck. She's in constant, writhing motion. This is -- this is almost a drug-induced form of something else you may have heard of called Huntington's chorea, which is caused by the same mechanism, but occurs naturally. This is another form of tardive dyskinesia. He's swinging his hands around. His neck is tightened back in a forward of tardive dystonia.

And we have two clips coming up at the end of tardive dyskinesia with movements of the face and the neck and the mouth, and you'll see a little bit of tongue thrusting in this gentleman as his tongue darts in and out of his

mouth. Imagine trying to eat a meal, hold a coffee cup, let alone go to work and perform a job or interview with an employer if this happens to you.

Now, these side effects typically happened in both patients with schizophrenia and bipolar disorder who took conventional first-generation antipsychotics over a period of time, and the risk went up with the years of exposure. The rates in schizophrenia were approximately 4 percent per year as patients were exposed to the medication. So that after 10 or 12 years of taking these drugs and, remember, this is a lifetime illness, the majority of patients would exhibit some signs of tardive dyskinesia.

In bipolar illness, for reasons that we don't understand, the rates were even higher. As much as 8 percent of patients per year taking chronic antipsychotic medication would be exposed to the risks of tardive -- would develop some form of tardive dyskinesia.

There's no treatment for tardive dyskinesia except taking the patient off the medication or lowering the dosage or trying a

different antipsychotic. Sometimes it will go away spontaneously over a period of years when a patient is off the medication, but then what do you do about their illness. Often it's irreversible and can persist for life even after the drug is stopped.

Q. Doctor, in the course of your practice as a psychiatrist, did there come on the market so-called second-generation or atypical antipsychotics?

A. Yes.

Q. Did they differ from the first-generation or typical antipsychotics?

A. Yes, they did.

Q. In what way?

A. Well, they differed in terms of their mechanism of action. The key feature that we would use in psychopharmacology to call a drug an atypical was selectivity of which dopamine receptors it blocked. Instead of blocking all the dopamine receptors in the brain, both the motor receptors and the thought or emotional receptors, the atypical antipsychotics were relatively selective for those receptors involved in thinking and emotion, and they spared the

dopamine receptors involved in motor control.

The result was that they were far less likely to produce extrapyramidal symptoms and far less likely to potentially exacerbate or overlap with making the negative symptoms worse. This was seen -- the effects of the atypical antipsychotics were very dramatic in far lower rates of these acute symptoms and far lower rates of long-term tardive symptoms. And this was really a very important part of what the revolution was about when these second-generation drugs came along.

Q. Doctor, are you saying that there were never or are never any movement disorders associated with the second generation?

A. No, there certainly are, but they occur at a far, far lower rate than they do with the first-generation drugs.

Q. And so in your experience did the advent of the second generations make a difference in terms of patient care?

A. Well, it was really quantumly forward in terms of the ability of people to take these drugs, feel physically comfortable and look physically normal with respect to their

neurological function.

Q. What was the first second-generation antipsychotic to come on the market in the U.S.?

A. Clozaril, or by its chemical name, clozapine.

Q. Did you prescribe that?

A. We prescribed it in very limited amounts because it had a very dangerous side effect. We had been aware of its use in Europe, and I was aware of researchers using it in the United States for a decade before it became available here.

But, unfortunately, about 1 percent of patients who take clozapine develop a fatal -- potentially fatal side effect in which the white blood cells that fight infection are wiped out in their bone marrow. We don't know why this happens, but it can kill people because suddenly you lose a very important part of your immunological defense.

But the drug was incredibly effective at more successful treatment of positive symptoms, more successful treatment of negative symptoms, and just the miraculous freedom from these neurological side effects. It

caused weight gain; it caused sedation. It wasn't an ideal drug, but for a number of people with treatment-resistant schizophrenia or people who had developed tardive dyskinesia, it was a Godsend by comparison with what the alternatives would have been for them, which would have been no treatment or continued treatment with the older drugs.

Q. Did any particular precautions have to be taken because of this risk of agranulocytosis?

A. Yes. Weekly blood tests had to be taken for six months -- well, when the drug was first released, they had to be taken weekly indefinitely. Over time we understood that the highest risk of this side effect was within the first six months, and after that blood tests could be taken every other week. But still for the lifetime of the patient, as long as they were taking the drug, it had to be dispensed by a special pharmacy. If someone was traveling or away, they might miss dosages if they didn't get their blood test done. It was quite a big production to put a patient on it, and many patients were not organized enough to follow the regimen. For those who were, it was incredible,

but, you know, for those who weren't, it was just very, very difficult and we didn't have an alternative.

Q. Doctor, did the second-generation antipsychotics, like Zyprexa, pose a similar risk of agranulocytosis?

A. No.

Q. Do patients on the newer atypical antipsychotics have to undergo that same level of blood monitoring as Clozaril patients did?

A. No weekly blood monitoring for the white blood cell drop.

Q. Was that a benefit?

A. It was a huge benefit. They could go to the pharmacy, fill the prescription, renew it. They didn't have to get the weekly blood tests. They didn't have the sword of Damocles hanging over their head that they might suddenly out of the blue develop this side effect.

One of the things about the agranulocytosis that I should emphasize is that it comes on with no warning. One day to the next you suddenly get a fever; you call your psychiatrist; you run to the emergency room; you get a blood test that shows you have the side

effect, and you have to come into the hospital and go on antibiotics and pray that your white blood cell count comes back up when you stop the drug. It came on very, very rapidly.

Q. Doctor, I'm going to hand you a document. I've previously given it to counsel. I'll provide the Court with a copy. It's been marked as EL3907.

I'd ask you, first, if you can identify that document.

A. Yes. This is the -- a publication. It was a supplement issue of the Journal of Clinical Psychiatry in 1999. And it's entitled The Expert Consensus Guideline Series, Treatment of Schizophrenia, 1999.

Q. And did you have a hand in developing that guideline?

A. Yes, I did.

Q. What was your role?

A. Well, I had been working for several years and continued to work between 1995 and 2000 with a group of other colleagues at other medical schools to develop a series of practice guidelines based on expert consensus, and this was one of the publications that came out of that

project.

Q. Tell the jury, what's a practice guideline?

A. Practice guidelines are used throughout medicine as a way to advise doctors about the best clinical practices and steps to take in treating a wide variety of diseases. There are practice guidelines for almost every major medical and psychiatric condition that you would think of. They're issued by groups of academicians or by professional organizations. They generally rely on reviews of literature, combined with expert consensus in those areas where the medical literature is not informative.

There are a lot of decisions we have to make in medicine where the literature doesn't provide total answers, head-to-head comparisons of drugs, what order you would give different medications, and how you would sequence the treatment, what you would do if the first one or two things you tried don't work. These are questions that generally aren't answered in rigorous clinical trials, and practice guidelines rely on expert consensus or opinion in order to advise clinicians on how to handle those

situations. They're not binding. They don't have regulatory authority, but they represent the best advice that professional groups can provide to their members.

Q. Are you familiar with how this particular guideline was developed?

A. Yes.

Q. In general -- let's not go into every detail, but, in general, describe what you and your colleagues did to develop these guidelines.

A. Sure. We did them in a number of different disorders, and in each case our process was similar. We had a steering committee that would assemble an editorial group of experts in the particular disorder, and I was on the steering committee that ran this project for several years -- for five years as I described.

We would get editors for a particular project. Those editors would then assemble a list of experts around the country in their field, typically 50 to 100 experts. They would develop a survey asking questions about various steps in the care of patients. What would you do in this situation? Here's a list of ten choices. Rank order them for us, please.

And they would send this survey out with anywhere from 100 to 200 questions, out to this group of experts, 50 to 100 experts. The surveys would take two to three hours to fill out. People would mail them back to us. We would generally get over 90 percent response rates.

And we then took those survey results, scored them, and took the data and derived guideline tables that gave detailed recommendations to practicing clinicians about what to do based on the assembled opinion of these experts. Kind of like when you go on Amazon or eBay and you look for the ratings of a product or of a sales person or a store. Each treatment would get a rank ordering about how good the experts thought it was in a particular situation that we would pose to them.

Q. Doctor, these guidelines are dated 1999, are they?

A. That's right.

Q. And over what period of time were the data collected that led to the creation of that guideline?

A. Each project took about a year, so this

one was no different.

Q. Based on your work on the guidelines, in your view, do they -- does that guideline reliably reflect the opinions of the experts in the field with whom you consulted?

A. Yes.

Q. Who funded this project?

A. A group of pharmaceutical companies.

Q. Did that include Eli Lilly and Company?

A. They were one of the sponsors.

Q. What kind of funding was provided?

A. The funding came to three medical schools that were running the project in the form of unrestricted educational grants. I was at Columbia, as I have been for my whole career. We had another colleague who was at Duke University, and a third colleague who at the beginning of the project was at UCLA and subsequently moved to Cornell University Medical School. So the three of us through our medical schools received the funding and that paid the costs of the project in these unrestricted educational grants.

Q. What does it mean when you say something is an unrestricted educational grant?

A. You go to one or more funding sources.

They can be foundations or pharmaceutical companies or anybody. You go to them and say, we have an idea for an educational project. Would you fund the cost for us? They say yes. They give you the money. There are no strings attached, and you do the work on your own and carry it on from there.

Q. Did Lilly or any other pharmaceutical company have anything to do with the preparation of the guideline?

A. No.

Q. Did they have any advanced notice of what your findings were going to be?

A. No.

Q. Did they have any role in editing, modifying it in any way?

A. No.

Q. And was this guideline published, Doctor?

A. Yes.

Q. In what journal?

A. It was published as a supplement, which means a special edition, to the Journal of Clinical Psychiatry and was circulated to thousands and thousands of psychiatrists.

Q. And do you have any information as to whether that guideline was actually used by practicing physicians in the field?
A. Yes. We know, first of all, that it was frequently cited in a number of other articles that would review for clinicians treatment recommendations. And it was particularly influential in the development of a whole project in the State of Texas called the Texas Medication Algorithm Project in which an entire state mental health system tried to implement practice guidelines and get its clinicians to follow well worked out practice guidelines and then research the effects that those had on the quality of care. So our guidelines were one of the bases for the Texas Medication Algorithm Project, which gave these step-by-step instructions to psychiatrists employed by the State of Texas.
MR. BRENNER: Your Honor, Lilly would move that exhibit in evidence. It's EL3907.
MR. ALLEN: It can be used with the witness, Your Honor. We object to it as hearsay. It's under the 803, 801 and 802.
THE COURT: I will admit EL3907.

The objection is preserved.
MR. BRENNER: Thank you, Your Honor.
Q. (BY MR. BRENNER) That's the cover page of the document, right?
A. That's right.
Q. Okay. Could I go to internal page 13, please?
Doctor, this is something called Strategies for Selecting Medications.
Is this one of the guidelines?
A. Yes. The final product were these tables organized into a series of guidelines that went through the basic steps in the care of patients.
Q. And guideline 1, what information did that convey to practicing psychiatrists?
A. Well, this would be a guideline for what do you do for initial treatment of an acute episode of schizophrenia. Patient comes into your office or comes into the hospital or comes into the emergency room. And we asked about a number of scenarios: If it was a first-episode patient with predominantly positive symptoms. If it was a first-episode patient who had both

prominent positive and negative symptoms. If it was a patient who has been taking a conventional antipsychotic and had a relapse, what would you do? And if it was a patient who was noncompliant with taking pills, what would you do?
So we asked them about a lot of choices for what they might take, and we at this point in the history of psychiatry were asking about classes of medication. We had a few of the new atypicals available. We had, of course, all the older drugs available. So we gave them the choice. Would you rank order? Would you give them an older drug, a newer drug, or would you give them an injection of a long-acting medication? Which were all from -- at that point was two of the older antipsychotics.
So you can see in these categories that the newer atypical antipsychotics, this excluded clozapine -- that was an older atypical antipsychotic -- that the newer drugs were far and away the treatment of choice. These bold italics mean that the majority of experts gave this particular choice their highest possible rating.
So, in each of these cases, the

newer atypicals, which at that time were Zyprexa, Risperdal and Seroquel were available, that these were the drugs that people were overwhelmingly recommending in acute treatment of schizophrenia in contrast with the older drugs.
MR. BRENNER: Can I have internal page 16, please.
Q. (BY MR. BRENNER) Could we pull up the -- what is this guideline 5 talking about, Doctor?
A. In this guideline, this only shows the top portion of it, but this went on for, I believe, a couple of pages about all kinds of side effects that can occur when patients take antipsychotic medication. And we asked the questions in sort of a twofold way. Which treatments are least likely to cause the side effect of concern, and which treatments might be most likely to cause the side effect of concern? And then assembled the tables on that basis.
Q. And with respect to weight gain, what was the consensus as to which drugs were most likely to be associated with weight gain?
A. Well, the consensus was that least likely to cause weight gain was ziprasidone,

which was just about to come on the market. Most of our survey respondents were researchers who had been using it in clinical trials, so they had experience with it before the general public, and risperidone or Risperdal. These were the least likely. And most likely, clozapine and olanzapine were deemed most likely to cause weight gain and drugs that you would avoid if you had a patient where you were particularly concerned about weight gain, as the title suggests.

Q. Were those survey and consensus results consistent with your experience?

A. Yes.

Q. Had you had experience in observing weight gain associated with Zyprexa in your patients?

A. Yes, I had.

Q. By 1998, 1999?

A. Well, I'd been using Zyprexa from the time that it came out. And from the time that it came out, we saw weigh gain with it and we were aware of this in a variety of ways, you know, as the drug was introduced. And this was par for the course.

MR. BRENNER: Can I have internal page 57, please? Blow up 38, item 38.

Q. (BY MR. BRENNER) Doctor, am I correct that this item reflects the actual survey results from the experts you had surveyed?

A. Yes. The guidelines consisted of two parts -- well, several parts. But parts of interest -- you've seen the sort of tables that we would show that would be the guideline itself, but we included all the survey questions and the raw data. Now, in the survey questions, we'd rank a bunch of things in alphabetical order and ask people to rate them on a scale going from 1 to 9. A rating in the range of 1, 2 or 3 would be given to choices that were not recommended or recommended only if everything else had failed.

An intermediate failing 4, 5 and 6, and a top or a first-line rating would be a 7, 8 or a 9. And then when we got all these results together, we calculated the averages. We calculated the amount of spread around that average, which is represented by the width of these bars which are called confidence intervals, and then we lined them up in rank order.

So, you can see on this slide

that -- on the right-hand side of the column is the average score, and this was the typical way that we presented raw data from every question that we asked.

Q. And what was -- this is a ranking by how important each of these screening tools --

A. So let me describe the question. This is the actual text of the question we sent to the experts on the survey. The question we asked them was: Please rate the appropriateness of including each of the following tests as part of the annual routine screening for patients in maintenance treatment for chronic schizophrenia.

Q. And what was the most highly-rated test recommended?

A. In a sense, the most important test to perform was weight monitoring. As you can see, 96 percent of the experts rated it a first-line treatment. I don't have a pointer, but you can see on the top line under first-line, 96 percent gave it a first line; 55 percent rated it a 9 as their treatment of choice. In the way that we've graphically displayed the results, there's an asterisk in that first box because that's the indication that the majority of experts rated it

a 9. And you can see that that box is relatively narrow, indicating that there was a very high level of agreement among the experts that this was very important. This was mom and apple pie; you've got to monitor the weight of patients taking antipsychotics, particularly maintenance treatment with chronic schizophrenia.

THE COURT: Doctor, you keep on using the term "experts." What was the criteria for making somebody an expert?

THE WITNESS: Sure. That was our term of art in terms of the guidelines, but we called on people who we believed were experts. The criteria are stated in the guideline for this project. The experts for the psychopharmacology section were individuals who had high reputations as researchers in schizophrenia, specifically members of the American Psychiatric Association Task Force that worked on the DSM-IV and DSM-III sections to define the diagnostic criteria, members of the American Psychiatric Association Task Force to develop practice guidelines for schizophrenia, members of the PORT, a federally-funded effort to develop practice guidelines in schizophrenia.

So they were recognized research experts around the country in the field. We called them experts in the text of the guideline, so I'm just referring to them in that way.

Q. (BY MR. BRENNER) Doctor, the fifth item says blood chemistry screen, EGSMAC.

What does that refer to?

A. An SMAC -- I've actually never known what the initials stood for, but it's a general chemistry screen. When you go to your doctor and they draw laboratory tests, they can get 21 tests or so tests out of the tube of blood that measure all kinds of things, including your liver function tests, your cholesterol and triglycerides, kidney tests, blood glucose, minerals like sodium and potassium and calcium and so forth. It's a broad-based screening test that includes the basic blood chemistries.

MR. ALLEN: What page are we on here?

THE COURT: I think we're on the same Table 38. Am I correct, Doctor?

THE WITNESS: Yes.

MR. ALLEN: What page?

MR. BRENNER: I believe it's 56. I

don't have it right in front of me.

MR. ALLEN: Okay. I apologize. Thank you. I got it, Your Honor.

A. So it's a very inclusive blood chemistry panel, part of everyone's annual checkup.

Q. (BY MR. BRENNER) I'm not sure if you said this. Would it include blood glucose levels?

A. Yes, it would include a blood glucose level. And typically when you go to your internist each year for your annual checkup, you know, you'll see them either before or after they tell you, go get your fasting bloods. Guarantee the SMA screen is part of that.

Q. By 1998/1999 were you performing that kind of blood chemistry testing or monitoring on your schizophrenic patients?

A. Well, I've been performing it on my schizophrenic patients from the time that I was treating patients with schizophrenia. It's part of good standard medical care and certainly in these years we were, you know, as we always had recommended that patients with schizophrenia be regularly monitored for a variety of problems.

MR. BRENNER: Mike, could we bring

up the bottom part of that page, Item 39.

Q. (BY MR. BRENNER) Doctor, briefly, what is Item 39, or what data does it reflect?

A. Now, in contrast to 38, question 38, which was about what tests would you do, this one was -- read: Given real world limitations, rate the appropriateness of having the psychiatric treatment team routinely monitor the following comorbid medical conditions and risk factors.

Now, what we meant by real world limitations was that people with schizophrenia can be difficult to corral into following your advice when it comes to, you know, getting sent around to do different kinds of medical tests, so what can you do. And what are your priorities going to be in terms of medical conditions that you're going to be watching them for like a hawk.

And No. 1 on the list was obesity; 82 percent of the experts said this would be a first-line priority to monitor for, and it was their top-ranked priority in terms of the range of medical conditions that we asked about.

Q. And I also see that diabetes is reflected there.

What did your data reveal about

monitoring for diabetes?

A. That, again, the majority of experts recommended that diabetes be on the radar screen.

Q. Was that consistent with your own practice circa 1998/1999?

A. Yes, it was.

Q. Doctor, is it fair to conclude from these results that in the period 1998/1999 it was recognized that doctors treating schizophrenic patients should monitor them for weight?

MR. ALLEN: Your Honor, objection. Calls for speculation. Goes beyond this man's opinion. Now calling for hearsay testimony of witnesses not present.

THE COURT: Can you rephrase the question to reflect the use of the term experts?

MR. BRENNER: I will, Your Honor.

Q. (BY MR. BRENNER) Doctor, is it fair to conclude from these results that in the period 1998/1999, at least experts in the field treating schizophrenics understood that they needed to be monitored for weight?

A. Yes.

MR. ALLEN: Objec -- well, of course, we have the answer. I'll accept it and

we'll move on.
MR. BRENNER: If there's going to be an objection, I have a similar question, Your Honor.
MR. ALLEN: You know what, I'll withdraw my objection.
MR. BRENNER: Thank you, Your Honor.
Q. (BY MR. BRENNER) Doctor, is it fair to conclude from these results that in the period 1998/1999 experts in the field treating schizophrenics understood that they needed to be monitored or screened in terms of their blood glucose levels?
MR. ALLEN: Your Honor, I hate to object to every question on the same grounds. Can I have a running objection to this?
THE COURT: Well, I'm not sure what the --
MR. ALLEN: He's calling for conjecture and speculation; giving hearsay testimony about people who are not present for me to cross-examine. He can give what he has to say.
THE COURT: I'll overrule the

objection, and to the extent you have that objection to some other questions, just say same objection and I'll make the same ruling.
MR. ALLEN: Okay.
THE COURT: I don't --
MR. ALLEN: I don't like to interrupt.
THE COURT: I can't give you a running objection, because I think it's too specific of a question and answer.
MR. ALLEN: Yes, sir. I didn't want to interrupt. I apologize.
Q. (BY MR. BRENNER) Do you need the question again, Doctor?
A. No. Among the psychiatrists who we surveyed, the -- who were experts in the field of schizophrenia, there was clearly a majority opinion that obesity and diabetes were very key things to be screening for.
MR. BRENNER: Can I have internal page 74, please, Mike? It's the top part.
Q. (BY MR. BRENNER) Doctor, was there a portion of the 1999 guidelines that addressed advice to be given or recommended to be given to patients and their families?

A. Yes.
MR. BRENNER: Could we have internal page 77? The top left part, yeah, that would be great.
Q. (BY MR. BRENNER) Was there a recommendation as to advice and precautions to be given to patients regarding weight gain?
A. Yes. All of our guidelines contained a section in the back that was meant to be a handout that could be photocopied, or we distributed it independently as well that could be given to patients and families as an educational booklet and it contained all kind of resources for them and advice. So there was always a section on drug side effects. And you can see this middle paragraph. We advised patients and families that weight gain can be a problem with all the antipsychotics, but it is more common with the atypical antipsychotics than the conventional antipsychotics. Diet and exercise can help.
MR. ALLEN: Your Honor, I don't see it on page 77.
MR. BRENNER: Because the internal page is different. It means it's 76 probably.

MR. ALLEN: Okay. That's why I keep getting lost.
MR. BRENNER: Sorry. It is 76.
MR. ALLEN: 76?
MR. BRENNER: Yeah.
Q. (BY MR. BRENNER) Doctor, for how long have you been prescribing Zyprexa?
A. Since the time it came on the market.
Q. When you first started prescribing Zyprexa in 1996, were you aware of a risk of weight gain associated with that drug?
A. Yes, I was.
Q. And how were you aware of that?
A. I was aware of it through two primary means before I even prescribed it. One, a number of my colleagues work in research and clinical trials, and those who had experience with olanzapine or Zyprexa described it in very, you know, nice terms that they --
MR. ALLEN: Your Honor, objection to what his colleague described it as. That's an out-of-court statement; object to hearsay.
MR. BRENNER: Your Honor, I'd offer --
THE COURT: Well, an expert can

rely on hearsay in the rendering of his opinions.
MR. ALLEN: But he has -- he's going to testify to hearsay, which I've never heard and can't cross-examine without testifying he relied upon hearsay. All I'm just reading is his answer. He said, a guy told me one time, and I can't object timely.
THE COURT: I'll overrule the objection.
MR. ALLEN: Okay.
Q. (BY MR. BRENNER) Go ahead and finish your answer, Doctor.
A. Sure. Well, my colleagues who had been involved in clinical trials described Zyprexa as being as effective as clozapine for symptoms, but without the white blood cell problems. But similar to clozapine had a liability toward weight gain, and told us as we introduced it into clinical use in our medical center to watch for that. And the package label, among the adverse side effects, stated very clearly that weight gain occurred both in short-term and long-term use.
MR. ALLEN: I need to object and move to strike on hearsay grounds, Your Honor,

and also object as nonresponsive.
MR. BRENNER: Talking about the package insert, Your Honor.
THE COURT: I'll overrule the objection.
Q. (BY MR. BRENNER) Doctor, as a practicing psychiatrist in 1996, were there risks you associated with weight gain?
A. Yes.
Q. What were they?
A. Weight gain is a health problem that has a lot of associated risks, ranging from arthritis, low back pain, gastric reflux, sleep apnea, hypertension, heart attacks, hyperglycemia, hyperlipidemia, diabetes. Whole range of health problems associated with weight gain.
Q. How did you come to that knowledge?
A. Learned it in medical school.
Q. What, if anything, did you do with respect to those risks that you understood were associated with weight gain?
A. Well, we all make New Year's resolutions to try to lose some weight. I mean, we tell our patients to do that. It's just part of medicine.

Again, it's another mom and apple pie thing. When patients gain weight, we try to watch that and monitor for side effects from the weight gain that might be related to it and try to help people to take steps to mitigate that.
Q. From 1996 onward, Doctor, did you do anything to monitor patients you had on atypical antipsychotics?
A. Yes.
Q. What did you do?
MR. ALLEN: Can we approach?
THE COURT: You may.
(Bench discussion.)
MR. ALLEN: This is nowhere in a report and there's not a basis for his opinion. Now he's going to talk about how he monitored his patients. You can look at that report until you're blue in the face and it's not in there.
THE COURT: Where is it in his report?
MR. ALLEN: It's not.
MR. BRENNER: Your Honor, I recall the Court's observation about making speaking objections. I'd appreciate it if we --
THE COURT: Yeah, okay. I'd

prefer -- I mean, if you want to say objection, relevance or if you what to say those kinds of things, that's fine. And if I need more, I'll ask you.
MR. ALLEN: It's hearsay. This is beyond the scope of his report completely --
THE COURT: Where is it in his report?
MR. BRENNER: Can I just get my papers, Your Honor?
THE COURT: Sure.
MR. BRENNER: Your Honor, he was offered by us as an expert in psychiatry and the ways in which he uses these drugs and the information he had. And in his deposition he was actually asked a bit, not extensively, but a bit about monitoring practices. I think it's fairly within the context of his report. Can I point you to a sentence where he used the phrase? No, I can't.
MR. ALLEN: You can't because it wasn't part of his opinions in the report. There's not a single -- or a smidgen and I didn't take any deposition -- I can show you the deposition. I'll certainly didn't take it. This

is MDL. It goes way beyond his report. You can't -- as he said, you can't find a sentence, not a word.
MR. BRENNER: I understand, but he chose not to take his deposition. Other attorneys did.
THE COURT: Well, that's neither here nor there. The question is -- it's a question of notice. And the question is: Does his report suggest that he was going to testify about monitoring of his patients? That's my question.
MR. BRENNER: Your Honor, I cannot point you to that sentence in the report.
THE COURT: All right. Then, find a different question.
(End of bench discussion.)
MR. BRENNER: Sorry. May we approach, Your Honor, so I avoid another objection?
THE COURT: Sure.
(Bench discussion.)
MR. BRENNER: Your Honor, I would have proposed to ask him about whether he was aware of the 2003 and 2007 label changes and

whether that impacted his conduct in any way. I don't know if that falls within Your Honor's ruling.
MR. ALLEN: Is it in the report --
MR. BRENNER: It does talk about the labeling. It does talk about a source of information and he was interrogated about the labeling.
THE COURT: Was he interrogated about the 2007 label, or was this --
MR. BRENNER: It couldn't have been the 2007 label.
THE COURT: Well, then, just like Plaintiff's expert, if his deposition was taken and his report doesn't talk about 2007, I won't let you talk about the 2007 labeling.
MR. ALLEN: And he didn't talk about 2003 or any labeling. He says labeling is a source of information. He can go that far. I have no problem.
MR. BRENNER: He was asked a question in the deposition about labeling.
MR. ALLEN: He's not offered as an labeling expert.
THE COURT: I'm going to exclude

that evidence too. I don't find that his report allows it.
(End of bench discussion.)
Q. (BY MR. BRENNER) Doctor, in the course of your practice, have you ever had any patients develop hyperglycemia while on any atypical antipsychotic?
A. Yes.
MR. ALLEN: Your Honor, can we approach?
THE COURT: You may.
(Bench discussion.)
MR. ALLEN: This is all beyond his report. Judge, you're actually looking at their motion as opposed to his report. That's not his report. This is on -- his practice, page 2, a summary of his opinions. There's nothing about any of these issues, and then he expounds on the opinions. You can look until you're blue in the face, it's not in there.
THE COURT: What's the question you were going to ask?
MR. BRENNER: I'm going to ask him whether he in treating patients with atypical antipsychotics has had any develop hyperglycemia,

and then I would ask him about diabetes.
MR. ALLEN: Whether it's happened -- I'll let him. What he does about it -- you know, it's not in his report, and I don't know where he's going.
MR. BRENNER: I'm going to ask him, has it happened and how often.
MR. ALLEN: Well, no, that's not in his report. How often is not in his report.
MR. BRENNER: His report addresses patient characteristics.
THE COURT: I'll allow -- I'll allow that line of questioning.
MR. ALLEN: What's that, Your Honor?
THE COURT: Whether or not -- whether or not in the course of his treatment or in the course of treatment, in general, schizophrenia patients develop hyperglycemia. Is that the question?
MR. ALLEN: He can't testify as to rates. There's no way --
MR. BRENNER: His experience.
THE COURT: That's right. I'll let you ask about, does it happen. I don't think he

should testify as to rates.
MR. BRENNER: I just want to ask his experience. Is that acceptable?
MR. ALLEN: It's beyond his report, Your Honor. I can't really prepare. There's nothing on this. The patient characteristics is how you -- the risk/benefit about whether to give them the drug. Mr. Brenner is now just misrepresenting. It's nowhere in his report. You can't find it. You can read all day and ask him to show you a line.
MR. BRENNER: I don't mean to misrepresent anything, Your Honor. It's broad and it covers a lot of different topics.
MR. ALLEN: It didn't cover this one.
MR. BRENNER: I think it does. It's a very narrow question.
THE COURT: I'll allow the question.
MR. ALLEN: But not on rates?
THE COURT: He can testify about his experience as to -- but only his experience.
MR. ALLEN: He's can't say -- well, I'm going to be back on my feet, Your Honor,

because I'm going to have to say it calls for conjecture and speculation and hearsay and it's beyond his report.
THE COURT: Well, his rates won't call for conjecture and speculation and hearsay.
MR. ALLEN: Well, he talks about experts and things --
MR. BRENNER: That's not the question.
MR. ALLEN: We're walking a fine line here. Thank you.
(End of bench discussion.)
Q. (BY MR. BRENNER) Doctor, have -- in the course of your practice, have you had patients develop hyperglycemia while on atypical antipsychotics, including Zyprexa?
A. Yes, I have.
Q. Can you give us a sense of how often that's happened in your practice?
A. You know, this is hard to quantify and say it happens -- you know, I'm going to include in my practice, of course, the patients whose care I supervise in the hospital, because I round on the patients and I'm aware of their complications and developments and their

treatments, so that gives me the --
MR. ALLEN: Your Honor, can we approach?
THE COURT: Sure.
(Bench discussion.)
MR. ALLEN: I apologize.
There he goes. He's going to include patients he rounds on. It's not in his report. Now he's going on patients besides his. I can't even cross-examine him. There's nothing I can do. There's nothing in here. He can say what he knows about his patients. This man's been giving a survey all day long.
MR. BRENNER: I'll limit the question, Your Honor.
THE COURT: Limit the question.
(End of bench discussion.)
Q. (BY MR. BRENNER) Doctor, with respect to patients you personally have treated --
A. Yes.
Q. -- not necessarily those you've consulted on or overseen. With respect to patients you personally have treated, have any of them developed hyperglycemia while on an atypical antipsychotic, including Zyprexa?

A. Yes.
Q. Has that happened frequently, infrequently?
A. I can count them on less than the fingers of one hand.
Q. With respect to patients you yourself have treated with atypical antipsychotics, including Zyprexa, have any of them developed diabetes?
A. Yes. One has.
Q. What medication was that person on?
A. That patient was taking Seroquel. Had a prior history of taking Clozaril.
Q. Doctor, could you tell us where practicing physicians get their information about drugs they prescribe?
A. Yes, a number of different sources. First and foremost, I think, physicians rely on peer-reviewed medical literature to learn about medications in terms of their effectiveness and their potential side effects. They read about clinical trials, and they read review articles that try to summarize clinical trials and metaanalyses and so forth.
Doctors learn at medical

conferences that are sponsored by academic groups or by professional organizations. Doctors learn from each other. Ask colleagues questions all the time. Call up a friend and say, you know, have you had experience with this, or what would you do in that situation? Get consultation from each other. We learn from our own experience with patients based on what we've seen, and we also learn from materials supplied by manufacturers, and we learn from product labels.

Q. You mentioned product labels. You're not a regulatory expert or an FDA expert or anything like that, are you?

A. No, I'm not.

Q. Do you use product labels, or package inserts as they're called, in your practice?

A. Yes, I do.

Q. In connection with your work with residents or with other physicians, do you ever give them instruction or advice as to how -- the best way to use a package insert?

A. Yes, I do.

MR. ALLEN: Objection. May I approach?

THE COURT: You may.

(Bench discussion.)

MR. ALLEN: None of this is in his report, how he instructs people. I mean, it's putting me in an awkward position to have to stand up and object every time. This is not in his report.

MR. BRENNER: Your Honor, (inaudible) his position on the information on prescription drugs and he was examined on that.

THE COURT: Yeah, I think his sources of information clearly is -- how would physicians do it, and that his experience and what he does, particularly in the context of the specific questions he's asked or his involvement, would -- clearly you'd have been on notice of that.

MR. ALLEN: Your Honor, wait a minute. What he tells people that he trains? How am I on notice of that? How am I on notice of what he tells people he trains in his residency program? I mean, where?

MR. BRENNER: With respect, Mr. Allen is suggesting you have to script out the entire expert's testimony. Clearly this was front and center in his report.

THE COURT: No. 1 is physician sources of information about prescription drugs. I mean, clearly that's the first point that he identifies as he's talking about, and that his personal experience would not be part of that, and what --

MR. ALLEN: He's talking about his experience, not his teaching. But here's my point, Your Honor. I assure you, I'm a man who doesn't like to stand up every 15 minutes, every second. I like to sit down. This man is trying to get inadmissible hearsay throughout his entire testimony, and I need to -- I don't know what else to do. I mean, this witness --

THE COURT: Again, what he's doing, does himself is not even hearsay, let alone inadmissible hearsay. He's an expert and is entitled to rely on hearsay for his opinions anyway, and I think you're on notice of this line of questioning.

MR. ALLEN: Okay.

(End of discussion.)

THE COURT: Let's take a break. About 15 minutes at this point.

MR. BRENNER: That's fine.

Actually, I am near the end, but that's fine. If the jurors want a break, absolutely.

THE COURT: The jurors need a break and let's give them a break.

MR. BRENNER: Very good, Your Honor.

THE COURT: We'll be in recess for about 15 minutes.

THE CLERK: Please rise. Superior Court now stands in recess. Off record.

(Jury out.)

(Break.)

(Jury in.)

THE COURT: Mr. Brenner.

MR. BRENNER: Thank you, Your Honor.

THE COURT: We're back on the record. All members of the jury are present.

Q. (BY MR. BRENNER) Doctor, could you tell us, how do you use a packet insert for a prescription drug you're going to prescribe?

A. A package insert is a kind of basic skeleton that gives you an outline of some key things that are helpful to know about using a drug when it comes out or over the course of your

experience with a medication if you have to look something up. It is helpful for getting a rough idea of dosages that are used.

Of course, in real life you sometimes have to give more or give less, but it gives you an outline for how to begin dosing it. It gives you a picture of the pills. If you're looking at the PDR, for example, in the front you get a photograph.

You get a sense of common drug interactions. The package insert is very helpful for that, what other medications a patient might be taking and what other medication they might be taking and how it might affect their metabolism. Again, it gives you lists of adverse events.

Q. In your experience, do package inserts change over time?

A. Package inserts do change over time.

Q. When you talk, meet with your residents, do you point that fact out to them?

A. Yes, I do.

Q. In your practice, how do you become aware of changes to package inserts?

A. There are a couple of different ways. The manufacturers will send out letters and I

read my mail. The letters are often marked very prominently on the envelope, Prescribing Information or something of that nature in big, you know, red, bold letters. Can't miss it.

And you read those and you find out about significant new changes in the inserts or the labeling. There are trade publications in psychiatry as in every other area. These are magazine or newspaper-type publications that come out every month or so, and they carry the news and standard press releases that you may read about in the lay press.

Q. Do you use the Internet at all?

A. Yes, I do.

Q. Are there resources available on the Internet regarding current or updated package inserts for medicines?

A. Yes. You can go to the companies' web sites and there's a number of proprietary places like WebMD or, you know, sources like that where you can get the equivalent of the package insert.

Q. Doctor, we've heard in this trial about Physicians' Desk Reference or PDR. You're familiar with that.

A. Yes.

Q. Are there any limitations you find with respect to the use of the PDR?

A. The PDR is not always up to date. You know, it arrives each year. It's a commercial publication. It's a compilation of package inserts and photographs in the front, as I mentioned. It arrives every year like a big early Christmas present around Thanksgiving time. I'm not sure when it's assembled in the course of a year, but, you know, it -- updates come, they're a little bit cumbersome to put into it, but from the time you get it, it's kind of static from whenever the information went in until the next one arrives the following year. So you get the 2008 PDR it will contain information from before 2008.

Q. Do you ever point out your perception of that limitation to the residents with whom you interact?

MR. ALLEN: Objection. Can we approach?

THE COURT: Sure.

(Bench discussion.)

MR. ALLEN: It's not in his report. I let it go on just because I got tired of

objecting. But what he's pointing out about package inserts, how he uses them. There's nothing in there.

THE COURT: To the extent he talks about sources of information, that was a topic that you were on notice on. And to the extent that what he does and those sources of information that he describes are going to be discussed, you're on notice of that. And so I will overrule the objection.

MR. ALLEN: He starts talking about what he says -- what he says.

(End of bench discussion.)

Q (BY MR. BRENNER) I'm not sure. Did you get to answer that question, Doctor?

A. Yes.

Q. Are there -- are you familiar with something called medical letters?

A. Yes.

Q. What are they?

A. These are communications sometimes called white papers, medical letters, put together by pharmaceutical companies that describe particular issues with medication. Sometimes I've called a manufacturer to get their

advice on what happens with a patient who's having what may be an unusual side effect, something I haven't heard about before.

A patient that is trying to get pregnant, for example, taking a medication, I want to know what experience they've had. They'll put together a document and send it out to me and that's an example of a medical letter.

Q. Doctor, are you familiar enough with package inserts that you recognize there are different sections within the insert?

A. Yes.

Q. There's a section typically called warnings and precautions and adverse events?

A. Yes.

Q. When you review a package insert for a medicine you're going to prescribe, do you restrict your review of a package insert to any particular section?

A. No.

Q. Why not?

A. Well, to be honest, not being -- I mean, I don't know quite what the regulatory significance is of the different sections, but they can be a little bit baffling to a practicing

physician. A lot of the things that we want to know about the most are at the end of the label under adverse reactions. They're often fairly common things that can happen to a lot of our patients.

There are -- I certainly, you know, will look through the warnings and precaution sections. Those appear to my eye to often contain, you know, things that can be very significant for a patient, but some of them are so rare that you might never see it.

Q. Can you give us an example of that?

A. Yeah. The package inserts for all of the second-generation antipsychotics in the warnings section talks about neuroleptic malignant syndrome that we talked about before. Most psychiatrists will go through their professional career and never see a case of it.

Q. Doctor, in your experience, can data about a drug be statistically significant yet not clinically significant?

A. Yes.

Q. Can you give us an example of that?

A. Sure. One of the medications shown up here, Geodon or ziprasidone --

MR. ALLEN: Your --

THE COURT: Objection?

MR. ALLEN: I don't know how to --

THE COURT: Yeah. This one, I'd like you to come forward on.

(Bench discussion.)

MR. ALLEN: Is that a medically significant --

THE COURT: Yeah, where is that in the report?

MR. BRENNER: It's a lead-in to the package insert, Your Honor. I can tell you exactly what the question is going to be that on Geodon there's a warning for an event called QTc interval that he says no one ever sees. It's to further exemplify this issue of how you use the package insert.

MR. ALLEN: That's not in the report. On Geodon? I --

THE COURT: I don't quite know -- Go to that question.

MR. ALLEN: I'm going to object to that. There's nothing in his report, interpretation of Geodon labels or anything to do with this. It wasn't in his report.

THE COURT: Again, the question is if you're on notice of general topics and that these kinds of things -- and to the extent this is used as an example as a general thing. That's what I understand it's being used for.

MR. ALLEN: He needs to skip the question about medical significance.

THE COURT: I've asked you to do that.

MR. BRENNER: I'll not ask that question.

(End of bench discussion.)

Q. (BY MR. BRENNER) Doctor, you're familiar with the second-generation antipsychotic, Geodon?

A. Yes.

Q. Are you generally familiar with information that appears in the warnings section of that?

A. Yes.

Q. And is there a warning there for something called QTc interval?

A. Yes.

Q. What is that?

A. QTc interval is something that's

measured on an electrocardiogram and it measures the length of time it takes the electrical signal in the heart to cross through a certain portion of the heart.
Q. What's the risk? What's the medical concern?
A. Well, there was some concern in the original clinical trials with Geodon that the length of the QTc interval was statistically increased in those patients compared with other patients who were not taking Geodon, and in cardiology if the QTc interval increases too far, there can be fatal cardiac arrhythmias as a result. So the package insert contained a warning that patients taking Geodon should be watched for this particular complication which could lead potentially to a fatal arrhythmia.
Q. This was in the warning section?
A. This was in the warning section.
Q. Have you ever seen that side effect or event?
A. Well, not only have I never seen it, but study after study from the time that Geodon was released has failed to replicate that original finding.

MR. ALLEN: Your Honor, studies on Geodon?
THE COURT: We're going to exclude that. Ladies and gentlemen, I'll ask you to disregard that last statement.
Q. (BY MR. BRENNER) Have you ever seen that event in your practice?
A. No, I haven't.
Q. Doctor, you've talked about information you get as a prescribing physician from pharmaceutical manufacturers.
In your practice is it your expectation that a pharmaceutical manufacturer is going to provide you with every piece of data or every analysis it has run on a drug?
A. No.
Q. Why not?
A. Well, first of all, there's far too much of it for me to possibly assimilate. Second of all, I know from working in a research institution that a great deal of the data that's produced in the course of running studies is preliminary, may never be replicated, has to be analyzed, has to be put in context, has to be compared with other samples and other studies.

So I'm naturally interested in data that's been well validated, that appears to be true, because it's been replicated in some way and that's really passed muster in some process of careful peer review.
Q. Doctor, in your practice today, is Zyprexa treated, used as a first-line atypical antipsychotic?
A. Yes, it is.
MR. BRENNER: Thank you, Doctor.
Nothing further at this time, Your Honor.
THE COURT: Mr. Allen.
CROSS-EXAMINATION
Q. (BY MR. ALLEN) Dr. Kahn, Scott Allen. How are you?
A. Good morning. I'm fine, thank you.
Q. You and I have never met, sir, have we?
A. No.
MR. ALLEN: Give me one second, Your Honor.
Q. (BY MR. ALLEN) Doctor, you just got through discussing Geodon. I'm going to have to use this ELMO. Is it on?
THE COURT: It is.

Q (BY MR. ALLEN) You just got through discussing Geodon?
A. Yes.
Q. Exhibit 19 is in evidence in this case, and I think you discussed Geodon in relation to what your views of Geodon were concerning QTc prolongation?
A. Answered a question about whether I had ever seen that particular side effect.
Q. Yes, sir. And you also stated, did you not, that -- and we're going to get into it in more detail -- that doctor sources of information include detail personnel from the drug companies, right?
A. No, I didn't say that.
Q. Is it in your report?
A. Yes, it is.
MR. BRENNER: Objection, Your Honor. The report is hearsay. The report was done long before the trial. There are many issues addressed in the report that are no longer germane either.
THE COURT: Well, this one would seem to be germane, so I'll allow the question.
Q. (BY MR. ALLEN) Doctor, your opinion in

your report is very clear concerning sources of information doctors rely upon in making decisions, correct?
A. Yes.
Q. And one of the specific things you said in your report concerning sources of information doctors rely upon is the detail people that come from the drug companies, right?
A. Could I have my memory refreshed?
Q. Oh, certainly.
Your qualifications of Dr. Kahn -- you remember this report, don't you?
A. Yes, I do.
Q. In fact, I think you testified in your deposition that this report was written entirely by you, but that Pepper Hamilton Law Firm typed it up and formatted it for you, right?
A. Yes.
Q. And you testified that you had all the information you ever needed to prepare this report, correct?
A. Yes.
Q. You, in fact, testified in your deposition that you asked for information from Pepper Hamilton that might even be remotely

relevant. You wanted it all, correct?
A. Yes.
Q. Why did you want something that might be even be remotely relevant?
A Just to be thorough.
Q Yes, sir. So you had everything you needed. You said there was nothing else you needed to prepare this report, right?
A. That's right.
Q. You even testified in your report you had three volumes of marketing material from Eli Lilly, correct?
A. Correct.
Q. And by the way, you said you reviewed all of this material. Anything that might be remotely be relevant, including three volumes of marketing materials and prepared this report in 30 hours; is that right?
Isn't that what you said?
A. I don't recall the number of hours, but, yes, it was a lengthy process.
Q. Would it help refresh your recollection concerning the number of hours by looking in your deposition, sir?
A. Not necessary, sir.

Q. Well, do you agree with 30 hours?
A. More or less if that's -- yes.
Q. You do agree with it?
A. Yes.
Q. Okay. Now, 30 hours to review all information concerning remotely relevant and then you gave some opinions, did you not?
A. Yes.
Q. And you listened -- listed -- this is your expert report of Dr. David Kahn, right?
A. Yes.
Q. And you gave a summary of your opinions, did you not?
A. Yes.
MR. BRENNER: Your Honor, objection. Can we take that off and approach?
THE COURT: Sure.
(Bench discussion.)
MR. BRENNER: This is the problem we're going to have. The report, for example, dealt with off-label. Of course, the report was done long before the trial.
THE COURT: And if the report deals with information that is irrelevant or that I've excluded, like off-label, I'm not going to allow

you to talk to him about it. But if the report -- so you've got to be careful when you put it up that you don't put up stuff that's not going to come in, because if you put up a big -- in other words, you guys are able to narrow down with all your technological stuff --
MR. ALLEN: I've got it.
THE COURT: That's what needs to be done.
(End bench discussion.)
Q. (BY MR. ALLEN) By the way, do you want to change any opinion you rendered in this report?
A. No.
Q. You stick by every one of them?
A. Yes.
Q. Okay. Opinion No. 1 -- or A, treatment decisions for mental health patients are based on many sources of information and the unique circumstance of each patient.
Did you say that?
A. Yes.
Q. Do you agree with that?
A. Yes.
Q. And so it's -- and these many sources

you went on to describe in your report, did you not?
A. Yes.
Q. And you described it right here, physicians' sources of information about prescription drugs, right?
A. You're looking at No. 1 is just going in and out of my screen a little bit.
Q. Yes, sir, I'm sorry. I have to focus -- let me get you a copy of your report.
THE COURT: Mr. Allen, you can use mine.
MR. ALLEN: Here, I'll give him one.
THE WITNESS: Which page, sir?
MR. ALLEN: Page 5 of your report.
THE WITNESS: Okay.
Q. (BY MR. ALLEN) You list the physicians' sources of information?
A. Yes.
Q. Okay. You talked about medical literature, continuing medical education, professional meetings, guidelines and algorithms and exchanges between colleagues, correct?
A. Yes.

Q. Right. Now, sir, we're going to talk about those in a minute, but would you agree with me that Eli Lilly is involved in all those areas of communication also?
A. I don't know how much they're involved in.
Q. Well, just for the record, medical literature, Eli Lilly is involved in that, are they not?
A. Sir, I don't know how much they're involved in medical literature.
Q. Yes, sir, I'm not asking about quantity. I'm asking: You know for a fact that Eli Lilly helps and crafts part of the medical literature, correct?
A. I'm not aware of their role in the medical literature.
Q. You've never read an article written by Eli Lilly employees and sponsored by Eli Lilly?
A. Oh, yes, I've read articles written by Eli Lilly employees.
Q. Right. So, in fact, the medical literature is influenced in part by Eli Lilly.
A. A portion of it.
Q. Continuing medical education?

A. Yes.
Q. In fact, that's influenced by Eli Lilly?
A. I don't know if it is.
Q. Have you read any call notes in this Alaska case?
A. No.
Q. Have you ever heard of a PsychLink, sir?
A. No.
Q. Okay, so you've read no call notes in this case and you're not able to testify about PsychLink and sales representatives questioning to Alaska doctors and giving continuing medical education courses?
A. No, I'm not.
Q. Okay. Professional meetings. We heard from Mr. Bandick that millions of dollars were given to the American Diabetes Association, the American Psychiatric Association during the time he was there.
Did you know that?
A. I know that pharmaceutical companies support the professional meetings.
Q. Yes, and every time there's a American Psychiatric Association meeting Eli Lilly has a booth set up, do they not?

A. An advertising booth.
Q. Well, we'll get down to advertisements. You testified that in fact doctors rely on advertisements, true?
A. I don't see the word rely.
Q. Let's see. Physicians' sources of information. Physicians' knowledge about treatment alternatives comes from numerous sources.
A. Yes.
Q. Okay. Physicians' knowledge, okay?
A. Yes.
Q. And, in fact, you told us right here in your report advertisements from drug companies are part of a physicians' knowledge about the drug, true?
A. Let's see. It says a source -- other sources include information. Doesn't say it's relied on.
Q. Okay. Well, you use knowledge, all right.
Let's go back to professional meetings. The fact of the matter is, Eli Lilly has a big booth set up with executives and sales representatives at every one of the American

Psychiatric Association meetings you attend, true?
A. Yes.
Q. Guidelines and algorithms, that's what you were here talking about today, right?
A. That's right.
Q. That was funded by Eli Lilly in part, was it?
A. In part, the project we did was.
Q. Yes. Exchanges between colleagues. Have you ever heard of key opinion leaders and thought leaders that Eli Lilly hires?
A. I've heard the expression key opinion leaders and thought leaders. I know nothing about the ones who they hire.
Q. Okay. But you do know that Eli Lilly hires physicians to go talk to other physicians about their product?
A. I'm not aware of that.
Q. Are you aware that in fact Eli Lilly prepares slide shows and PowerPoint presentations?
A. I'm not familiar with what Eli Lilly does.
Q. Okay. We'll get to that in a minute.

And then you go on to say, the physicians' experience using the drug will also be significantly determinative of his -- I guess it's his or her future use.
A. His or her. Uh-huh.
Q. Other sources, we're talking about sources about prescription drugs, right?
A. Yes.
Q. Other sources include information from drug manufacturers about their products and other products, such as product labels -- you briefly discussed that, correct?
A. Yes.
Q. Sales representative detailing. That's another source of information, is it not?
A. Yes.
Q. Have you reviewed one single solitary note from here in Alaska from a sales rep?
A. No.
Q. Okay. Journal advertisements and responses to questions posed to the companies.
Did I read that correctly?
A. Yes.
Q. Now, did you know, in fact, that Eli Lilly has training manuals and guidelines

training their sales representatives how to answer questions?
A. No.
Q. Well, you did not review those in this case?
A. In this case in Alaska, no.
Q. How about in any case?
A. I saw train- -- actually, yes, in the earlier preparation of this, there was some training materials.
Q. Right. And so since physicians' knowledge comes from detail persons and responses to their questions, we have to see how -- how these sales reps were trained to answer questions, right?
A. I don't know, sir.
Q. You don't know. If somebody's knowledge depends upon how they answered questions, you have to see what they were told, do you not?
A. I didn't say it depends upon it, sir.
Q. What did you mean when you said the knowledge? What did you mean?
A. Well, I also wrote in the opinion, different physicians are differentially receptive to information provided by pharmaceutical

companies. It's one source of information and doctors evaluate and sift and sort.
Q. Yes, sir. You go on to say the amount of and nature of the information communicated to a physician by a manufacturer will vary from physician to physician. Right?
A. Yes.
Q. So what you're saying each doctor, he or she may get different information?
A. The amount and nature of information will vary from physician to physician.
Q. You know, though, do you not, that Eli Lilly has a policy put in place to prevent that from happening?
Did you not know that?
A. No.
Q. This Alaska Exhibit 1097, LillyUSA Sales Good Promotional Practice. And it describes its policy. It says it is the policy of LillyUSA that all sales personnel appropriately -- let me get down here -- document sales calls with healthcare professionals in the call tracking system.
Do you see that?
A. I see it there, yes, sir.

Q. And it gets down to talk about definitions. It says a call note is a business record documented within a call system that accurately reflects all aspects of a sales call.
Do you see that?
A. Yes, I do.
Q. And we were told -- have you seen the testimony of David Noesges in this case?
A. No, I have not.
Q. Do you know who Mr. Noesges is?
A. No.
Q. Mr. Noesges was, in fact, a supervisor of sales representatives in the Western region of the United States, including Alaska.
Did you know that?
A. No.
Q. Did you know he testified that sales representatives are trained on their messages and how they're to detail the products and it's the same throughout the United States?
A. No.
Q. Would that be important to you in trying to determine what doctors were told by Eli Lilly?
A. No.
Q. So it would not be important to you to

know what Eli Lilly told their sales representatives to tell doctors?
MR. BRENNER: Objection, Your Honor. The witness was never asked to give an opinion on that subject.
THE COURT: I'll overrule that objection. Whether he was asked to do it, it's proper cross-examination.
Q (BY MR. ALLEN) If you're trying -- or let me rephrase it.
If you're trying to figure out what doctors were told about their product, wouldn't you want to know what Eli Lilly told their sales reps to say?
A. I don't know how that would relate to what doctors were told.
Q. Well, assuming that the sales reps did as they were told, would that help you?
A. I don't know anything about the sales aspect of the pharmaceutical industry, sir. I don't think I can answer the question.
Q. Sir, I'm sorry. I thought you said under physicians' sources of information that that would include sales representative detailing.

A. Yes, that's true, but I don't know how the companies work internally. I don't have expertise in that.
Q. So, therefore, you couldn't testify to what a physician knew or didn't know from a sales representative; is that what you're telling us?
A. That's right.
Q. And you said doctors' information is dependent upon responses to questions posed to the companies --
A. That's not what I said, sir.
Q. Sir, I'm sorry. You said physicians' sources of information and their knowledge about treatment alternatives comes from numerous sources and one of them is answers -- responses to questions posed by the companies, true?
A. That's right.
Q. And, therefore, do you know what the responses to the doctors in Alaska's questions were when they met with the sales representatives in the company?
A. No.
Q. So therefore, you can't testify as to what doctors in Alaska knew or didn't know, can you, sir?

A. That's -- this is not my area of expertise.
Q. Right. And so my question is: You can't tell this jury, and you're not attempting to tell this jury, what doctors in Alaska were told by the company; is that true?
A. That's true.
Q. You're not attempting to tell this jury what doctors in Alaska knew about the drug; is that correct?
A. Correct.
Q. You're not attempting to tell this jury the content of the information doctors were informed about; is that true?
A. The content -- I don't know what -- what they were told.
Q. Right. So you don't know what physicians in Alaska knew or didn't know; is that correct?
A. That's correct.
Q. Okay. So, it is accurate to tell this jury that Dr. Kahn came from New York City and Dr. Kahn cannot tell this jury anything about what this company told doctors in Alaska or what doctors were informed by Eli Lilly about Zyprexa;

is that true?
A. Yes.
Q. Thank you, sir. Now, you talked about Geodon, and I wasn't going to ask you this originally, but it was right before they passed you to me. This is Exhibit No. 19. Okay?
It's an implementation guide, and Ms. Eski test- -- do you know who Ms. Eski is?
A. No.
Q. Have you reviewed her testimony?
A. No.
Q. She's a sales representative for Zyprexa in Alaska. She testified that implementation guides were used to train her before she went to talk to doctors.
You didn't know that?
A. No.
Q. Okay. And, in fact, they trained sales representatives to talk to doctors about Geodon.
Did you know that?
A. No.
Q. And did you know that regarding QTc, which you were talking about, the brand team is working on an audio conference that -- conference that frames the issue of cardiovascular risk, and

were preparing a one-page sell sheet with Pfizer's own data that proves that all atypicals are not created equal, and that there is a cardiovascular risk with Geodon.
Did you know that?
A. No.
Q. So, regardless of your, quote, personal experience with Geodon, you did not know that Eli Lilly trained its sales representatives to tell doctors there was a problem with QTc?
You didn't know that?
A. No.
Q. Why do you think Eli Lilly would train their sales representatives to tell doctors that their competitive product has a cardiovascular risk?
A. I have no opinion on that.
Q. Isn't the reason they'd do that is because they were trying to create risk around the other product and sell more Zyprexa?
A. Sir, I have no opinion on that.
Q. Okay. Now, we'll start -- Doctor, I'm going to start with what I prepared last night, okay?
I noted on your report there's no

letterhead. It's just a white piece of paper.
Do you see that?
A. Yes.
Q. And, of course, you're here today expressing your opinions, correct?
A. Correct.
Q. You're not here as a spokesperson for anybody, are you?
A. That's correct.
Q. You're not here as an official representative of the Alaska Psychiatric Association?
A. Nope.
Q. You're not here as an official spokesperson for Columbia Hospital?
A. No.
Q. You're not here as an official spokesperson for any medical organization, hospital or anybody; is that right?
A. That's right.
Q. What you're here is giving your opinions that you gave about what you think.
A. Yes.
Q. That happens all the time in medicine, doesn't it? Somebody has one opinion and

somebody has another opinion?
A. Yes.
Q. The fact that you have your opinion doesn't make you right, does it?
A. Not necessarily.
Q. And, in fact, somebody else could have another opinion, and their opinion could be valid, could it not?
A. Or the other way around.
Q. Or the other way around. Right?
A. Yes.
Q. In fact, two people can have two different opinions and they can both be right; isn't that true?
A. I imagine there are times that could happen, sure.
Q. Really, what somebody does in reaching an opinion is to look at information; isn't that right?
A. It's one way to reach an opinion.
Q. What's the other way? I'm trying to think of the other way.
A. Okay.
Q. Is there any other way to reach an opinion without looking at information?

A. Without looking at the -- I see what you mean.
Q. I know, sir. I apologize. I'm sincerely apologizing.
But I asked you if there's any other way to reach an opinion without information.
A. Informed opinion would rely on information.
Q. What do you mean by informed opinion --
A. Sir, I understand what you mean and I agree with you.
Q. Yes, sir, and I've changed my question.
What do you mean by informed opinion would require information?
A. Sir, an opinion would be based on information available to the person who was holding it.
Q. Yes, sir, I'm back to your answer.
What do you mean by informed opinion would require information?
A. An opinion related to information.
Q. Yes, sir. What's an informed opinion?
A. An opinion related to information.
Q. And in order to have a valid informed

opinion you need the information; correct?
A. Yes.
Q. And without the information you can't form an informed opinion; correct?
A. Without valid information.
Q. Who makes the judgment if something is valid or not? You? Or don't you like to get the information, weigh it for yourself so you can make that determination?
A. There are certain kinds of information where I don't have the expertise to weigh its validity.
Q. Well, who makes the decision as to whether you have the expertise or not? Shouldn't you get the information and then look at it and then use your judgment in order to assist your patients?
A. Not necessarily.
Q. Okay. But we agree on one thing, in order to have a valid opinion -- excuse me -- we agree on another thing: In order to have an informed opinion, you need information. We agree on that?
A. Valid information.
Q. Yes, sir. Like information from a

clinical trial?
A. That may or may not be valid.
Q. We were told by Dr. Inzucchi that clinical trials are the gold standard.
Do you agree with that?
A. Good clinical trials, well-conducted clinical trials.
Q. Well, like the largest clinical trial ever conducted -- do you know what the largest clinical trial for Zyprexa was?
A. No.
Q. Did you not know it was the HGAJ study?
A. No.
Q. So you would expect if it was the largest clinical trial done on Zyprexa, it would be a good clinical trial if it was done by Eli Lilly, wouldn't you?
A. I don't have an opinion as what would make it a good clinical trial, sir?
Q. Other pieces of information, how about Eli Lilly hiring experts to give them opinion concerning statistical evidence? That would be something you'd want to know about, right?
A. Sir, it might not be. I really can't offer an opinion on what, you know, the answer to

that question would be good information or not.
Q. Well, okay, sir. But we're just agreeing, so I guess you and I will have to stop and cross our paths.
You need in order to make an informed decision, you need information, valid information?
A. You need valid, accurate, true information.
Q. All right, sir. You've already testified, you were paid $600 an hour at the time of your deposition you said -- I never met you before, right?
A. That's correct.
Q. I didn't take your deposition?
A. That's correct.
Q. All right. And your deposition, I think, was taken a year ago. Is that about right?
A. About that.
Q. You had spent 30 hours, $18,000. Have you been -- spent any more time?
A. Yes.
Q. How much more time?
A. Hard to say. The equivalent of a few

days. I haven't added it up.
Q. Sixteen more hours?
A. Could be.
Q. The only way I know is to ask you, sir. I did see you here -- you were here for Dr. Inzucchi's testimony on Monday in the back of the courtroom with Mr. Brenner; isn't that right?
A. Yes, I was.
Q. So you have about another 16 hours or so?
A. Yes.
Q. Okay. Now, it was Ms. Gussack that hired you to testify in this case; isn't that right?
A. That's right.
Q. Now, you testified in your deposition, page 27 and 30. Let's see -- if you'd like me to show it to you, I will -- that you were asked to provide an opinion and you did provide an opinion concerning, quote, how doctors make treatment decisions, what sources of information they use, and how they individualize those decisions to the care of patients?
A. Yes.
Q. So, these sources of information we

listed that you saw, which included drug company package inserts, drug company detailing, the answers to questions that doctors pose to the drug company, the doctors' answers to questions when they go to medical meetings and have Lilly there, are sources of information that doctors use, in your words, to make treatment decisions, right?
A. They're sources that are available to them.
Q. They're available sources?
A. I can't tell you what every doctor uses in each case, but those are sources of information that exist.
Q. And would you suspect, Doctor, that doctors would use that information?
A. It's a broad question.
Q. No, it's very narrow.
Do you expect that doctors would use the sources of information they get from they drug company?
A. I don't know when they would use it. It would depend.
Q. I didn't ask you when they would and they wouldn't. I guess by your answer you're

admitting they would use it?
A. Sometimes they might.
Q. Yes, sir. Would you agree that sometimes they will?
A. Sometimes they will; sometimes they won't.
Q. And if sometimes they will use what they get from a drug company in order to determine how doctors make treatment decisions, we must know, to give a fair and impartial judgment -- you want to give a fair and impartial judgment, do you not?
A. Give what a fair and impartial judgment?
Q. Your opinions in this case.
A. Yes.
Q. To be fair and impartial in order to understand how doctors make treatment decisions, we have to know what those sources of information they get say to them, right?
A. Yes.
Q. Thank you. Now, you said in your report that doctors make their treatment decisions based on a risk/benefit analysis?
A. Yes.
Q. Now, would you agree you need a fair and

balanced presentation of both the risks and the benefits?
A. With good, accurate, well-verified information.
Q. So the answer to my question is yes, Mr. Allen, doctors need a fair and balanced presentation of both the benefits and the risks?
A. Yes.
Q. Okay. You don't want to -- for example, a drug company should not understate the risks, should they?
A. No.
Q. And they should not overstate the benefits, should they?
A. No.
Q. And, in fact, if there is a risk with a product, it would be wrong for a drug company or anybody else to try to minimize that risk, true?
A. True.
Q. It would be wrong for a drug company or anybody else to try to neutralize that risk, true?
A. True.
Q. It would be wrong for a drug company to have as its design concerning the risk to

eliminate that risk from the risk/benefit equation, true?
A. True.
Q. Isn't it true, when you looked at the material in this case, you found written, documented evidence that this drug company did try to neutralize the risk?
You saw that, didn't you?
A. No.
Q. They didn't give you that information, "they" being Eli Lilly's lawyers?
A. I don't know about information designed to neutralize risks.
Q. Didn't you see the information, the plan of the drug company, Eli Lilly in this case -- well, let me ask you this -- before I ask that. You've already testified to us it would be wrong to try to neutralize risks, right?
A. A known risk.
Q. You've testified for us that it would be wrong to try to minimize risk, correct?
A. Yes.
Q. And you've testified it would be wrong to try to eliminate the risk from the risk/benefit equation, true?

A. A true known risk, yes.
Q. Eliminate, it would be wrong?
A. Yes.
Q. And to do that would be unfair, wouldn't it?
A. Yes.
Q. It would be deceptive, wouldn't it?
A. If it was a true risk, yes.
Q. It would be false?
A. If it were a true risk.
Q. Right. And by the way, is the drug company supposed to suppress or withhold information?
A. I don't know what drug companies are supposed to do, sir.
Q. Assuming this -- I'm going to take Dr. Kahn, okay? If you were trying to make a decision and you were looking to me as a source of information, would you want me to withhold or suppress information from you?
A. Accurate, valid, complete information that was true, I wouldn't want you to withhold that.
Q. Now, how would you know whether or not I was withholding accurate, valid, true information

if I didn't give it to you?
You'd have to depend upon me to be honest, wouldn't you?
A. Yes.
Q. So, really, before one can make a determination as to whether or not you're withholding information from me, you have to give me the information so I can see it, right?
A. No.
Q. Well, how can you make a calculus or determination about whether information is valid or worthwhile information unless you see it?
A. There's -- I'm not qualified to judge all types of information.
Q. Well, of course, I didn't expect you to, sir. Nor am I. But before you can make a decision as to whether or not you are qualified to judge the validity or correctness or worthiness of the information, you need to see it first, right?
A. Sir, even seeing it, I still would not be in a position to judge it. I can't give you an opinion on your question.
Q. Well, I thought you said that -- and it was in your -- we're going to talk about your

survey in a minute.
By the way, that blood testing you said in your survey?
A. Yes.
Q. Just so the record's clear, that was an annual blood test that's part of a routine physical that everybody does, right?
A. Yes.
Q. It wasn't any specific blood test for glucose, was it?
A. Glucose is included in the general chemistry panel of am SMA screen.
Q. Yes, sir, I understood that but the blood test you referenced in the 1999 survey, was an annual blood test done if anybody in this courtroom went to a doctor, correct?
A. Yes.
Q. It wasn't particularized toward any second-generation antipsychotic, was it?
A. The question asked about patients and maintenance treatment for schizophrenia.
Q. Yes, sir. And I'm not trying to quibble with you, but you said -- in this question 38.
A. Yes.
Q. Blood chemistry screen, e.g., SMAC;

right?
A. Correct.
Q. That was an annual routine screening for patients, right?
A. Can you read the rest of it?
Q. Yes, sir, I'll read whatever -- sir, I'll read whatever you'd like me to read. Is there another part you'd like me to read?
A. Yes, for patients in maintenance treatment for schizophrenia.
Q. Yes, sir, it has to be for schizophrenia because this whole article deals with schizophrenia, right?
A. That's correct.
Q. Okay, back to my question. And if at any time you think I'm misrepresenting anything, I want you to infer and read in anything you'd like, all right?
A. Okay.
Q. I lost question 38. Here it is.
This was an annual routine screening, right?
A. Yes.
Q. And this was blood chemistry screening, SMAC, correct?

A. Correct.
Q. And that's the type of blood screening that any of us would get if we went and had an annual physical, right?
A. That's right.
Q. Okay. Tell us what that SMAC is.
A. SMAC is a broad-based chemistry screen.
Q. What's it stand for?
A. I told you I don't know what the acronym means.
Q. What's it measure?
A. It usually measures anywhere in my experience from 17 to 21 or so common chemical measures, generally including electrolytes, liver function tests, kidney tests, glucose, usually lipids, triglycerides, et cetera.
Q. Right. It's a standard test, right?
A. That's right.
Q. Overstating the benefits, that would be wrong also, wouldn't it?
A. Yes.
Q. And, in fact, have you seen Exhibit 1169 in this case?
A. I'm not aware of it by number, sir.
Q. This was a letter sent by the FDA in

November of '96 to Eli Lilly concerning their marketing of Zyprexa.
Have you ever seen this letter in the material you've reviewed?
A. No.
Q. One of the things that they told Eli Lilly when they were engaged in false and misleading conduct was that their campaign, included -- was lacking in appropriate balance, thereby creating a misleading message about Zyprexa.
Do you see that?
A. Yes, that's what it says.
Q. And you certainly believe and agree with the FDA that when a drug company discusses a product with a doctor, he or she should be given fair and balanced information?
A. Yes.
Q. It should not overstate the risk -- I'm sorry -- should not overstate the benefits, right?
A. Yes.
Q. Should not overstate the risks, correct?
A. Correct.
Q. And one of the things they specifically

told Eli Lilly, and I guess you would agree with this, you were talking about mechanism of action a minute ago. Do you recall that, on Zyprexa?
A. Yes.
Q. Of course, you don't know what the mechanism of action is, do you, sir?
A. Not precisely, sir.
Q. In fact --
MR. ALLEN: Your Honor, I'll have to step into the alcove. That's where the blowup is. I apologize.
THE COURT: Okay.
Q. (BY MR. ALLEN) Neither you nor any other doctor in the country could tell us what the mechanism of action with Zyprexa is, could you, sir?
A. There are strong theories.
Q. Yes, sir. I'm not asking about a theory. We need to hear facts in this courtroom.
And the fact of the matter is the mechanism of action for Zyprexa is unknown, is it not?
A. That's what it says where you're reading it.
Q. Well, where am I reading from?

A. I don't know what that is.
Q. I'll represent to you that it's a blowup of the PDR on Zyprexa.
A. Oh, yes. I see the notation on the upper right-hand corner.
Q. Yes, as a matter of fact, this is a '98 PDR. The same words are used in the 2007 and 2008, is it not?
A. Yes.
Q. So, just for the record, when you were telling this jury about how Zyprexa worked, you were talking about a theory, right?
A. That's right.
Q. Not a fact?
A. That's right.
Q. And, in fact, when Eli Lilly tried to describe how Zyprexa worked, the FDA told them not to do that.
Did you know that?
A. No.
Q. Let me just read on page 3 of Exhibit 1196, sent to Eli Lilly back in 1996, that's 12 years ago. On page 19, the presentation of Zyprexa's pharmacologic profile is misleading. The labeling states that the mechanism of action

is unknown and provides proposed theories of the drug's activities.
That's what you've just told us, right?
A. Yes.
Q. And then they go on to say something very important: It should be emphasized that the pharmacologic action of Zyprexa to alleviate psychotic symptoms is unknown, right?
A. That's what it says.
Q. So, if you were trying to tell this jury anything regarding the pharmacologic activity of Zyprexa, vis-a-vis any other second-generation or first-generation antipsychotic, that was a theory, correct?
A. That's a theory.
Q. Yes, sir. Now, tardive dyskinesia, in fact -- the facts, as opposed to theory, is that tardive dyskinesia -- remember those movies you put up there, or slide shows?
A. Yes.
Q. The fact of the matter is tardive dyskinesia occurs in Zyprexa patients, right?
A. It can.
Q. It does, doesn't it?

A. Yes.
Q. In fact, Joey Eski, who's testified under oath in this case as a representative for Eli Lilly, said that tardive dyskinesia since the day -- and I'm paraphrasing -- since the day she started working on Zyprexa was a known side effect and risk of Zyprexa.
A. Yes.
Q. Okay. Just so the jury's clear, those photos and pictures that you showed up there, that's happened to Zyprexa patients, right?
A. I don't know if that precise picture has happened, but, yes, patients on Zyprexa have gotten tardive dyskinesia.
Q. Right. So those patients -- so let me see, concerning mechanism of action of all those products behind you?
A. Yes.
Q. You've seen that? Are only theories, right, the theories, mechanism of action?
A. Yes.
Q. Concerning the risks, they all carry the risk of tardive dyskinesia, right?
A. Yes, they do.
Q. Okay. So the risk of tardive dyskinesia

it says whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown, right?
A. I see that it says that.
Q. You're not disagreeing with that?
A. I would disagree with that based on my own experience.
Q. Yes, sir. That was back to my original question. I asked you that. You were here talking about your personal opinion, right?
A. Yes.
Q. What the FDA is doing right here is accumulating all of the body of evidence and putting it in this package insert, true?
A. I don't know how things get into the package insert, sir.
Q. Well, would you suspect that it's more than one doctor's opinion?
A. I don't know how it's put together. I don't have an opinion.
Q. I think you said this is another source of information for doctors?
A. That's right.
Q. And under the warnings, at least the FDA has said that all of the second-generation

antipsychotics carry this risk, right?
A. Yes, the FDA that said that.
Q. Okay. We have products -- oh, Ms. Eski testified, by the way, there's nothing in this package insert that makes Zyprexa more superior on efficacy than any other second-generation.
Did you know that?
A. I don't have any comment on her testimony.
Q. Yes, sir. Is there anything in the package insert approved by the FDA that would say Zyprexa is more efficacious that any other second-generation antipsychotic?
A. I don't know.
Q. Have you reviewed the package insert?
A. Yes.
Q. Is there anything within the package insert that would support the fact at all that Zyprexa is more efficacious than any other second-generation antipsychotic?
A. Not to my recollection.
Q. All right. You don't have anything saying it's superior; you have the same risk of tardive dyskinesia, right?
A. In the package insert.

Q. In the package insert, right.
A. Yes.
Q. And you have a theory about how it works?
A. That's correct.
Q. But we know as a fact that Zyprexa carries an additional risk that the other products do not carry, right?
A. I'm not sure what you're asking.
Q. Well, we know -- you've seen the consensus statement, have you not?
A. Sir, tell me what you're referring to.
Q. Let me ask you -- I'll just ask you and then you can tell us.
Are you familiar with any consensus panel or other scientific publication indicating that Zyprexa has a greater risk concerning a very serious side effect than the other second-generation antipsychotics?
A. Yes, I'm aware of that consensus panel.
Q. What greater risk does Zyprexa carry over and above the other second-generation antipsychotics?
A. Well, according to the consensus panel, there's a differential risk of weight gain.

Q. And diabetes?
A. According to the consensus panel.
Q. Okay. So, if we take the package insert, they all carry the risk of tardive dyskinesia, there's no superiority of efficacy between them, but we know from the consensus panel that Zyprexa carries a greater risk of weight gain and diabetes, right?
A. Well, we don't know it. The consensus panel states it.
Q. All right, sir. But that would be certainly information you would like to know as a doctor, right?
A. There's -- the consensus panel information is one source of information I'd like to know.
Q. Why would you want to know that?
A. It's a source of information. It's not the only source of information.
Q. Well, one of the reasons you would like to know that, I think you said it in your report, which I probably -- right there -- is because for patients -- is it ultimately your decision to take -- whether a patient takes this drug?
A. It is my recommendation to a patient.

Q. Yeah. Ultimately, whose decision is it?
A. It's a collaborative decision between the patient and the physician.
Q. Yes, sir. And what if the patient says, I don't want to take the drug; you give it to him anyway?
A. Under certain circumstances that can be done.
Q. You know this patient that you put up here on the board. What was his name?
A. His name was Russell Weston.
Q. Was that your patient?
A. No.
Q. Where did you get that video?
A. That was obtained through the Washington Post.
Q. Newspaper?
A. Yes.
Q. Okay. Did you treat that patient?
A. No.
Q. Do you have any personal experience with that patient?
A. No.
Q. Now, for the record, that was a schizophrenic patient?

A. That's my understanding.
Q. How do you know? Did you diagnose him?
A. No, that's the way the -- the patient was described in the materials that were released by the government to the press.
Q. Okay. So you never looked at that patient's medical records?
A. That's correct.
Q. You never diagnosed that patient?
A. That's correct.
Q. Okay. Now, are all schizophrenic patients like -- I apologize -- his name again?
A. Mr. Weston.
Q. Are all schizophrenic patients like Mr. Weston?
A. No.
Q. Mr. Weston was a severe case, right?
A. Yes, he had severe schizophrenia.
Q. A lot of schizophrenics, they have jobs, they have careers, they have families, do they not?
A. Not a lot.
Q. There are some?
A. Yes.
Q. Just so the jury's clear here,

Mr. Weston was an extreme example; right?
A. Yes.
Q. You're not here to represent or imply to this jury that Mr. Weston is representative of all schizophrenics?
A. Well, the symptoms that we were demonstrating as positive symptoms are representative of what positive symptoms may be like.
Q. What positive symptoms may be like, correct?
A. Yes.
Q. So, really, Mr. Weston is one patient?
A. Yes.
Q. You told us Mr. Weston is not like all schizophrenic patients?
A. He has severe schizophrenia.
Q. So therefor he's not like --
A. He's like some, not others.
Q. Like you said in your report, treatment decisions have to be individualized?
A. That's right.
Q. You have to look at not only the patient but the risk of the product?
A. Yes.

Q. You also made it clear he's a schizophrenic patient; he's not a bipolar patient, right?
A. According to the description that was given in the publicly available materials.
Q. From the Washington Post?
A. Yes.
Q. He's not a bipolar patient?
A. Not as far as I can tell.
Q. Now, it's true, is it not, Zyprexa is not indicated for bipolar depression, is it?
A. Not for bipolar depression.
Q. Right.
A. Not for acute treatment of bipolar depression.
Q. And tell the jury what that means. It's not indicated for that.
A. There are several phases of bipolar illness; there's acute mania and mixed states and there's long-term preventive treatment of recurrent episodes of bipolar illness.
Q. Okay. It's not indicated for bipolar depression?
A. For acute bipolar depression.
Q. It's not indicated?

A. That's right.
Q. It is indicated for schizophrenia and bipolar mania.
A. Yes.
Q. Anything else?
A. Yes. Mixed states.
Q. Mixed states. Anything else?
A. Yes. Preventive treatment, long-term treatment of bipolar illness and in combination with other mood stabilizers and it's indicated for agitation in bipolar illness and schizophrenia.
Q. Agitation in bipolar illness and schizophrenia?
A. Yes.
Q. It's not indicated for agitation in the elderly, is it?
A. No.
MR. BRENNER: Objection, Your Honor. Maybe we can approach on this?
(Bench discussion.)
MR. ALLEN: Risk/benefit.
THE COURT: To the extent that he's asking what it's not indicated in a general sense, I'll allow it. If we start -- but I don't

want questions about what Lilly may have tried to do.
MR. ALLEN: I'm not.
(End of bench discussion.)
Q. (BY MR. ALLEN) Back to my question. It's not indicated for agitation in the elderly, is it?
A. It's not indicated for agitation in elderly patients with dementia specifically. There may be elderly patients with these other illnesses who have agitation.
Q. That would be schizophrenia and bipolar disease?
A. Yes, it's indicated in those circumstances regardless of the age of the patient.
Q. I'm not asking you that question. It's not indicated for agitation in an elderly patient with dementia, is it?
A. No.
Q. It's not indicated for agitation of a patient with Alzheimer's?
A. No, it isn't.
Q. It's not indicated for a patient that has depression, ordinary depression; is it?

A. For acute treatment of that depression but if it's part of a preventive regimen in long-term treatment of bipolar illness, it might be preventing both mania and depression. That's conceivable. But not for acute treatment of a depressive episode.
Q. So is the answer to my question, it's not indicated for depression?
A. Well, you have to specify. It's not indicated for acute treatment of major depressive episodes.
Q. It's not indicated for children of any kind, is it?
A. For children? You know, I'd have to look at the label to see the precise age cutoff, sir. I don't want to quibble over the words so I'm not sure where the age cutoff is.
Q. It's not indicated for attention deficit disorder, is it?
A. No.
Q. It's not indicated for -- what do they call it? ADD --
A. ADHD is attention deficit hyperactivity disorder.
Q. It's not indicated for that, is it?

A. No, it isn't.
Q. It's not indicated for anxiety, is it?
A. Anxiety is not a specific diagnosis.
Q. Is it indicated for anxiety unrelated to schizophrenia or bipolar mania?
A. No.
Q. It's not indicated for irritability, is it?
A. Unrelated to schizophrenia or bipolar illness, no.
Q. It's not a mood stabilizer, is it?
A. Well, you're asking about things that are diagnoses and not formal terms. Anxiety, irritability are not diagnoses. Mood stabilizer is not a formal term with an agreed-upon definition.
Q. In fact, you said -- I think in your deposition, here it is -- I've got to find it. Here it is. Here it is. That's not it.
MR. ALLEN: Tommy, do you have my deposition? I apologize.
MR. FIBICH: His deposition?
MR. ALLEN: Yes, sir.
There it is, sir.
THE COURT: Let me ask you, we're

getting at 1:30, and I have a feeling you've got more than a little bit left.
MR. ALLEN: Your Honor --
THE COURT: And I have some jurors who have appointments that I want to get them to.
MR. ALLEN: You're right. Yes, sir. I guess I have a little more. Whatever you want me to do.
THE COURT: Why don't we recess for the day.
MR. ALLEN: Yes, thank you.
THE COURT: Ladies and gentlemen of the jury, we've come to the end of our trial day, and I'm going to let you go for the day. We'll start up, hopefully, at 8:30 tomorrow morning.
Before you go, again, I'll remind 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. Please do not read any newspaper articles, look at the Internet or listen to any TV or radio or other forms of communication that are about the subject matter of this case. I'll see you tomorrow at 8:30.
(Jury out.)

THE COURT: Please be seated.
We're outside the presence of the jury.
Anything we need to take up before we break?
MR. LEHNER: One brief matter, Your Honor.
If we could get some guidance. This relates to designating deposition testimony of Mr. Campana who works at the Department of Health and Social Services and heads the Medicaid branch there and is sort of the executive director of the P & T committee. This really goes to the question of what you might believe is the sort of the swinging of the door. We would intend to ask Mr. Campana about what the P & T committee is, what it does, how it functions, but we would not ask him questions and designate questions about what it actually has done.
THE COURT: If you start asking him questions about the P & T committee, the door is swinging.
MR. LEHNER: Purely it's -- we may be swinging. I guess I'm asking is how far is it going to be swinging open.
THE COURT: I would have to hear

the questions. Pretty hard to give you guidance about that.
MR. LEHNER: The questions would be very specific. What does it do, what is its function. He can describe those activities. We would not ask him what has it done, what action has it taken or what action it has not taken.
MR. ALLEN: They wouldn't need to because they already have testimony on it. So they're just trying to bolster the testimony they already have.
THE COURT: This is what I'm going to say. I'm trying to keep out as much as possible P & T testimony and what goes on in the P & T committee and Safety and efficacy and review of drugs, and there's a question whether the door's open and there's a question in my mind as to the general relevance to that.
If you think it's relevant to talk more about the P & T committee, that will answer the question in my mind about relevance and that's going to be opening the door. I'm trying to keep -- I have been ruling to keep that out so far in the case as much as possible, and the question is: Have the Defendants interjected it

sufficiently to open the door and make it probative for the Defendants to ask their questions and play their deposition about that.
MR. ALLEN: I'll bet he can leave, Your Honor.
THE COURT: I want to ask him a question after it's all over about whether he knows somebody I know. If you don't mind.
MR. ALLEN: I'm sorry.
MR. LEHNER: All right. Your Honor. I think I understand --
THE COURT: I think you can pick it up for that. I would hope that we can get started relatively close. I really don't like to keep the juries sitting. If you tell me you think there's a bunch of stuff to take up, I'll tell them to come in later so they can have their own lives instead of sitting in the jury room.
MR. ALLEN: I totally agree. I didn't know it would take so long to introduce exhibits.
THE COURT: Just for my own edification, tomorrow once we finish up with the doctor is --
MR. LEHNER: Tomorrow we intend to

call Dr. Baker tomorrow as a witness. Depending on how long he goes, we may run some videos, but our next live witness will be Dr. Baker, and our intention is to have him here tomorrow to testify.
MR. ALLEN: And I'm going to try to narrow this down.
THE COURT: Are we still looking -- I realize that today probably didn't get as much done as the parties would have hoped. Are we still hoping Monday?
MR. LEHNER: I think we can still hope for Monday. Slip in an hour or two on Tuesday.
THE COURT: Okay. If there's nothing else, then, we'll be off record.
MR. ALLEN: Thank you.
(Trial adjourned at 1:35 p.m.)

REPORTER'S CERTIFICATE

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

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

IN WITNESS WHEREOF, I have hereunto subscribed my hand and affixed my seal this 19th day of March, 2008.

_____

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