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 12

TRANSCRIPT OF PROCEEDINGS

March 18, 2008 - Pages 1 through 215

BEFORE THE HONORABLE MARK RINDNER
Superior Court Judge

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

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PROCEEDINGS

THE COURT: We're on the record in State of Alaska versus Eli Lilly and Company. We are outside the presence of the jury. Counsel are all present. It's Case No. 3AN-06-5630.

I'd like to take up a number of issues, and you may have some issues, too.

One, I want to talk about what the jury's being asked to decide in this case and what they have to decide it. I want to talk about the motion to allow the testimony of the lobbying efforts of Lilly, and I'd also like to discuss -- I just received Plaintiff's objections and counterdesignations to Defendant's deposition designations as of March 18th, 2008. I assume that these counterdesignations are not designations that are going to be included in the defense playing of the exhibit because that's what Mr. Allen told me. So there are things that you'd want to play in the way of cross-examination.

So, now I need to get Lilly's objections to those. And I'm a little concerned that this is slowing down the whole process of getting these depositions played, which is what

I'm trying to avoid.

MR. LEHNER: Can I suggest a way to at least put this in line? We would like to start by playing Charles Beasley's deposition -- it's rather lengthy. So if you were to rule on the objections on page 3 of their memorandum that was submitted today, they've objected to -- they've objected to six or seven or eight parts of our deposition here.

MR. ALLEN: You know what -- is this our objections?

MR. LEHNER: These are your objections.

MR. ALLEN: I haven't reviewed them, Your Honor. I will go home tonight -- but I don't want to make objections -- I didn't do this, because I've been busy with other matters. Look at those for Beasley since somebody made them but I'll look at them tonight and I'll probably withdraw those objections.

THE COURT: I thought the idea was -- I thought what was going to happen today was that we're going to deal with these issues, and then bring the jury back. Then the State's going to finish with their deposition testimony,

and the State will rest and we'll deal with motions. And then Lilly is going to start, continue with its case, and wanted to continue with these deposition things -- so, that means I have to read it while your depositions are playing, which I probably can do. Because if we leave a light on back here, I'll just read it while --

MR. ALLEN: In order to accommodate the Court and to accommodate Eli Lilly, I am willing, without even looking at these objections -- if it would interfere with their ability to go forward and interferes with the Court's ability to do its work, I will withdraw the objections. If you have a chance to look at them and want to make some rulings, that's fine. But I'm not here to be obstreperous and I would be willing to withdraw them if the Court wanted me to to move forward.

THE COURT: I'm not -- like I said, if I know the order and stuff, I don't need to watch the State put on its video things as long as we can leave a light on so I can read, and I can be reading these objections while the State's playing its hour and 45 minutes or whatever it is

of videos. But I just want to have a process where I'm not going to have to hold up people playing -- doing on their case because I'm waiting for somebody to give me objections or you've given them to me and it's on an evening that I can't really work on them.

MR. ALLEN: And I don't want the Court to do that either. So I'm going to go home tonight, and I will look at all this. But if it does interfere with this Court's ability, and would slow the trial down, that's my problem, my fault. I say move forward and don't worry about it.

MR. LEHNER: Your Honor, since we're being so accommodating, I asked our people as well to look at their counterdesignations and to get our objections, if any, to you promptly. But I think we could go forward because I think we will not have time to play your counterdesignations today with Beasley and so then you don't need to look at those tonight but we did the same thing to make sure that we're --

MR. ALLEN: Nothing today -- you put them first. If they need to go forward and we haven't --

THE COURT: So what's possibly going to happen today is the most that we'll get through with the State is Mr. Beasley?

MR. LEHNER: That's correct.

MR. ALLEN: Eli Lilly.

MR. LEHNER: Eli Lilly 's Beasley.

THE COURT: I will bring that in when the jury comes in and just be prepared to go over some of these objections, and I may get to some of the others as well. We'll see.

MR. ALLEN: If you don't get to it, Judge, move forward and that's fine.

THE COURT: There may some others as well, but not too many.

MR. ALLEN: I can address the lobbying while I'm up here, if you'd like.

THE COURT: I don't care what order we take things in.

MR. ALLEN: It would be best since I'm here. How do you want to go about it, Your Honor?

THE COURT: Well, I've read people's memorandums. Do you want to briefly argue your positions? I don't care.

MR. ALLEN: Yeah, I guess their

memorandum, again, with due respect, I think it was somewhat misleading but they're doing their job to be persuasive. As the Court marked with the big red asterisks the other day, that they opened the door. You have to put this all in context, I think, and you have to look at the opening statement by Eli Lilly, Page 132, Line 3 all the way through 134 of the opening statement it talked about Alaska has no restrictions, no restraints. You will hear not just from Dr. Hopson, but the people who worked for the State they have not limited or restricted the use of Zyprexa in any way.

They then on the 12th of March, of course, Dr. Hopson's first day, they did talk about you have not placed a restriction one -- this is their words, restriction one on the atypical antipsychotic Zyprexa. Tell the jury what restrictions you have placed on Zyprexa. There is no restrictions on Zyprexa.

And then most importantly, I quite frankly, Your Honor, think they opened the door on the opening statement and then on the 12th. But if there's any question -- finally, on the 13th of March, at Page 62, Line 15, through Page

64, Line 8, for example, here's what they asked Dr. Hopson:

Now, Doctor, I think yesterday you told us that you are a member of the State of Alaska's P & T committee, correct?

He said, yes.

And they asked, What's the P & T committee?

Of course, he described it that the P & T committee's purpose is to go through the different classes of medications and come up with a preferred formulary list for Medicaid patients.

Ms. Gussack asked him, Are you the only psychiatrist that sits on the committee?

He says, No, there's another one. Her name is Curtiss Lacy [sic].

And then she goes on and says, And you've been sitting on this committee since 2004?

He says, yes.

And then she says, So it's fair to say that the pharmacy and therapeutics committee assesses efficacy and safety issues for medications that are being prescribed to Medicaid patients?

He says, yes.

Then she says: Now, the P & T committee can decide whether to restrict a medications that's being used for Medicaid patients?

He gives his answer.

Have you ever heard of the P & T committee to restrict the use of Zyprexa in any way?

And he says, No.

So they asked Dr. Hopson both personally at API and both through the State's P & T committee and in opening statement again and I didn't discuss it at length because -- but they said the people who work for the State of Alaska have not restricted this. And the answers, quite frankly, have been favorable for Eli Lilly, and the fact of the matter is that's exactly what the lobbying efforts were directed at, was the State P & T committee and the legislature to prevent these restrictions from being in place.

And if you want to look at the evidence in the most favorable light to Eli Lilly, which I take that you should not, you should look at it from our side. They said to

put no restrictions on any mental health care medications and they had an effort to stop that.

And so the inference, and in fact, not the inference, the argument, and not just an argument, but an affirmative statement's been made that you all aren't doing anything to stop us from selling it here in Alaska. And the facts of the matter is we have evidence that the reason, or a reason, and a significant reason that has not been done is through the efforts of Eli Lilly and their Alaska State Action Team to prevent the very restrictions that they say we haven't done. And I think that evidence should come in. That's all, I guess.

THE COURT: Ms. Gussack.

MS. GUSSACK: Thank you, Your Honor. Let me, if I might, take a few minutes to explain the factual predicate here that I think is so compelling as to why this evidence is not only remote and unconnected to any evidence that the Court -- that the State has put on, but also highly prejudicial and not probative of any issue before the Court.

The exhibits and testimony that the State seeks to introduce is evidence of lobbying

activity from the 2003/2004 time period in which Lilly, other pharmaceutical manufacturers, mental health advocacy groups, the Anchorage District Court Mental Health Court, the Anchorage Police Department and other entities all were interested in ensuring that both the legislature didn't do anything -- that the legislature was supportive of not having restrictions on mental health medicines across the board, all mental health medicines. Nothing specific to Zyprexa, all mental health medicines, and also urging the same kind of open access by the P & T committee.

There is no evidence of record in this matter that Dr. Hopson, API, was lobbied by Lilly with respect to mental health medicines or Zyprexa. Nor is there any evidence that the State was lobbied with respect to Zyprexa. The conduct of 2003/2004 is so remote in time as to not be probative of any issue here. And perhaps most importantly, and I want to show the Court this, because I think it is really --

THE COURT: Could you clarify that? What makes 2003 and 2004 remote? It's right in the middle of the efforts -- when was Prozac losing its --

MS. GUSSACK: 2000, Your Honor.
THE COURT: Okay. So isn't this all in the period of time Zyprexa is the big drug for Eli Lilly? The argument is and I realize it's argument at this point, that the motive here is to downplay any efforts to keep -- to have warnings on Zyprexa that would -- that would give some kind of additional warnings that might affect the sales of the drug. Why -- why, as long as it's in this period of time that actually we're talking about in this whole trial does it become -- why does this become remote?
MS. GUSSACK: I think when I say remote, Your Honor, I think it's remote in time in terms of having any effect on the determinations either by the P & T committee or by, for that matter, Dr. Hopson at API in terms of restrictions. There's no evidence that any activity limited in time in 2003 or 2004 had an impact as of the time that they brought the lawsuit, before the lawsuit --
THE COURT: Well, there is no evidence about that because I haven't allowed any evidence to come in. That's what we're talking about is whether or not there is some evidence or

inference or argument that relevantly could be made to a jury that that's exactly what happened.
MS. GUSSACK: Well, Your Honor, but most particularly since they claim that the questions elicited from Dr. Hopson opened the door. I think it's really important to recognize that the only questions that were put to Dr. Hopson were designed to cross-examine him on opinions that he offered during his direct as to his views about Zyprexa, and our ability to challenge why is your conduct inconsistent with the testimony that you're giving the Court here?
And that there was no basis -- we asked him personally, we didn't say did you on behalf of the State. We said, did you personally, sir --
THE COURT: I understand that. And if we had stopped -- if the questioning had gone -- and you don't put any restriction at API, we do not. Ms. Gussack -- if you wanted to in your role as medical director, could you, I could have. And then all of a sudden we're into the P & T committee.
MS. GUSSACK: Yes, Your Honor --

THE COURT: And the P & T committee, we explain what the P & T committee is. Okay, and is it fair to say that the pharmacy and therapeutics committee assesses efficacy and safety issues for medications that are being prescribed to Medicaid patients? Yes.
Okay. Now, the P & T committee can -- the committee can decide whether to restrict a medications that's being used for medications for Medicaid patients? And so, all of that's being explored and the suggestion clearly is that there's a committee in the State that can look at these things and hasn't looked at these things.
MS. GUSSACK: Correct, Your Honor. And the question put to Dr. Hopson was, not did the P & T committee consider Zyprexa and reject restrictions and impose restrictions; the question to Dr. Hopson was, have you, sir, personally shared your views within the context of the P & T committee about Zyprexa? And the answer was, no.
But let me take a minute longer. If you would bring up, Nick, Campana at 231, 232. Because the head of the pharmacy Medicaid program for the State who testified at deposition said

and explained: Sir, have you ever considered a preferred drug list for the P & T committee? And he said: Well, you know, we talked about it on -- this is as recently as his deposition in September of '07 reflecting back. He says, starting at Line 6 or 7, you know, we -- how often do you have a discussion? We had a discussion last May. We put a schedule together for this year.
Now what happened, we said to Mr. Campana, why did you not go ahead and review the antipsychotics? And he says: The psychiatrists on the committee, Dr. Curtiss and Dr. -- I'm sorry. Page 233 at Line 4, 5. No, we're not planning on it and the psychiatrist asked the question said, no, we don't want to do this.
Do you know who that psychiatrist was? Dr. Curtiss. And going to page 234, Dr. -- Mr. Campana said: Gee, there was political pressure on the P & T committee not to consider any preferred drug list for the antipsychotics. You know who that political pressure came from, Your Honor? Looking at page 234, Line 19. From psychiatrists. And which psychiatrists were

they? Going to page 235 at Lines 3 and 4, Alexander Von Hofften, the former president of the American Psychiatric Association and Dr. Hopson.

We had an absolutely legitimate right to ask Dr. Hopson: Have you personally urged the P & T committee one way or the another? Mr. Campana, the State's Medicaid pharmacy program director, saying the political pressure was not from Lilly, not from pharmaceutical companies, not from anything. The political pressure that he felt was from psychiatrists saying that they want all the medications to be available to them.

And, in fact, he goes on to say later on that psychiatrists are unique in that they want all medications available to them. There is no evidence, Your Honor, as to any -- any linkage between the proposed evidence that the State has with respect to lobbying activity in 2003/2004 and this P & T committee. They didn't elicit anything from Dr. Hopson with respect to his views about the P & T committee. We asked about his personal opinion.

THE COURT: What would you have had

them do? I guess that's the question, given my rulings? I mean, would they have been -- would you have seen it proper for them -- for question Dr. Hopson to say, were you lobbied in 2000 and did that affect the reason that you've never done this? That would seem to violate the ruling that I previously --

MS. GUSSACK: Your Honor, quite respectfully, I don't think the State has been shy or hesitant to press the boundaries of any of your rulings, and if they wanted to frame the issues to see if the door was open, they could have asked Dr. Hopson that question and have Your Honor give some guidance as to that.

Plainly, that was the time with Dr. Hopson on the stand to ask, what was the basis for the fact that he didn't personally urge that view or what were the consequences or what motivated him. But there is no evidence here that Dr. Hopson was lobbied, so what Dr. Hopson's views were with respect to the P & T committee are not affected by the Eski evidence, and the P & T committee, according to Mr. Campana's evidence -- deposition testimony, doesn't link up with whatever it is that they're proposing.

What they're proposing to do is to prejudice this environment with evidence of legitimate protected lobbying activity without any linkage to any of the issues before the Court.

THE COURT: Mr. Allen.

MR. ALLEN: Yes, Your Honor. First of all, Your Honor cited the correct testimony. And I very much respect Ms. Gussack, and so I don't like engaging in this, but the fact of the matter is the evidence hadn't come in concerning these matters. And the Eski exhibits and her testimony will show that part of their lobbying is to do the very thing that she discussed. I can give you, for example, copies of -- excuse me -- I've got a frog in my throat -- of exhibits. Those are just representative samples, Exhibits 3, 5, and 6.

One of the very things they do in their lobbying efforts, Your Honor, is to go to doctors and psychiatrists and prepare them letters -- those are the attachments, I think, on No. 3. If you look at Exhibit 3 -- I don't have it in front of me -- that they have PDFs of letters they prepare for doctors to send to the

relevant P & T committees and the legislature to prevent this very thing from happening.

She talked about the fact that the policemen and I think she said patients' alliances or medical groups were also involved. If you read the exhibit -- and I have more. That's what they do. Part of their lobbying efforts is to go to the police, which is called Partners in Crisis, as I recall and to NAMI -- I always screw this -- National Alliance of Mental Health -- if I screwed up the acronym, I get it backwards. They go to them and they enlist them in their lobbying campaign to influence the P & T committee.

So to come here and say we didn't do it, it was NAMI, it was the police, it was doctors, that's part of their plan on the Alaska State Action Team. You can look at Exhibit -- I think it's 5. They enlist Joey Eski, who we deposed, their sales rep and they ask her to go out and recruit doctors to prepare these letters, which they actually prepare for them and the doctors put their signature on it.

So Ms. Gussack's right in one respect. It was through doctors and it was

through partners in crisis and it was through patient alliances. That's what they do as part of their lobbying efforts.

And to suggest that they just asked Dr. Hopson's personal opinion. Again, I'll just read directly from the transcript.

Now, Doctor, I think yesterday you told us you told us you were a member of the State of Alaska's P & T committee, correct? Now the P & T committee can decide whether to restrict a medication. Your Honor, you're right, there's big red asterisks --

THE COURT: Let me ask a question that still bothers me considerably, because I wrote this. Tell me how these lobby questions relate to the warnings issues that are really what the guts of this case are about.

MR. ALLEN: They relate both to the warnings. It's the risk/benefit analysis, and, it's the -- remember, we have two causes of action, unfair and deceptive trade practices. The very clear --

THE COURT: If you're saying that lobbying is a violation of the UTPA, we've got some other issues to take up.

MR. ALLEN: I am not saying that.

THE COURT: So then, tell me how it relates to the warning. I mean, if -- as I understand it, and this is kind of edging into the second issue -- the violations that you're claiming are these --

MR. ALLEN: Your Honor --

THE COURT: -- labels, are the labels.

MR. ALLEN: Well, it's not just the labels, Your Honor. It's also, as Ms. Gussack said, and I have that if you'd like me to find it in her opening -- give me one second. I had it last night. I know I have it.

THE COURT: Let me ask you the question this way, Mr. Allen. You hit the home run and the jury finds for you on everything you want. What would they be finding were the violations for the UTPA?

MR. ALLEN: For the UTPA it would be the label. It would be the failure to warn through their marketing efforts on the --

THE COURT: So, is each marketing effort going to be a discrete violation subject to a penalty?

MR. ALLEN: Your Honor, to answer that, this is why I have these lawyers over here, Mr. Sniffen and Mr. Steele. And if they need to answer that, they will. That's the one issue in this case. I've been in charge of putting on evidence and all the legal matters; that's why they're here this morning. But under my theory of the case and my understanding of the law, I mean, the reason they clearly -- and the Court said it to Ms. Gussack when she was speaking.

What they imply through their defense is the drug is obviously safe and efficacious, it's obviously safe and efficacious because there's a means which the State can stop its prescription or limit the prescriptions of it in the state and that's the P & T committee who analyzes -- by the way, you know, what they analyze, as she said, they looked at the safety and efficacy of the drug.

THE COURT: I saw the testimony.

MR. ALLEN: We're looking at the risk/benefit. They're saying if the P & T committee felt that the warnings were inadequate or that they failed to give proper safety information and that the risk and the benefit

were out of whack, they could have put a restriction on the drug, and they did not. And I'm saying to this Court that that is an improper analysis of what the actual facts are in this case.

That the State P & T committee and that the Medicaid department, who I represent in this case, on behalf of -- which Mr. Sniffen asked me to represent, did not have full information on the risk of this drug.

And had they had the information that's being developed in this courtroom -- again, you have to look at the evidence I think in this regard in the light most favorable to our side. Had they had that evidence concerning the elevated blood glucose, had they had the evidence concerning the diabetes, had they had the evidence concerning, for example, the restrictions placed upon the drug in Japan, had they had the evidence from the internal HGFU study that the glucose elevations were probably causally related, had they had the evidence from 1999, November, where they went through an entire -- I can't remember the exhibit number, but they looked at clinical studies,

observational reports, epidemiology, animal studies, they looked at comparisons to Risperdal and they looked at Dr. Casey's analysis, and they concluded that there was a reasonable association, that was their words, a reasonable association with their product and hyperglycemia. Had they had all that evidence, the P & T would have acted.

Their implication is that you've got a P & T committee here in Alaska who evaluates safety and efficacy, and they have not acted. I say they didn't act for two reasons. No. 1, they didn't have all the evidence before them. Equally importantly, they were engaged in efforts -- this is what happened, Your Honor, this is what really happened. They were engaged in efforts to keep them from reviewing the drug at all. So don't even look at it. It's called a carveout, and you're going to hear the testimony. There's a mental health carveout, so you don't even look at -- you don't even sit down and evaluate them. I'm sitting here, Your Honor --

THE COURT: But that didn't happen, right?

MR. ALLEN: Yes, it did happen.

THE COURT: There was a carveout?

MR. ALLEN: Yes.

THE COURT: I thought there wasn't a carveout.

MR. ALLEN: Here's what happens. Mr. Campana will testify about it if he has to. They didn't do a full review of all of the -- they do a different type of review, and -- and Mr. Campana will testify, I think he has testified -- I didn't go back and look, but Mr. Steele's with me. He'll testify that one of the reasons they didn't get this opportunity was they were lobbied.

I'm sitting here arguing about something that it was stated on opening statement. It was said on March 12th; it was said on the 13th. The Court, with due respect to the Court, the Court was listening, the Court heard it, the Court made red asterisks. The Court has ruled.

Now they come back in and keep on arguing against me. It is clear what they have done and to not allow me to rebut this is wrong. I didn't have this as part of my affirmative case in chief. This is rebuttal of their arguments

and their evidence now. You were correct in your ruling yesterday.

THE COURT: This is what I'm grappling with, Mr. Allen. There is rebuttal and there's rebuttal. The question I'm trying to figure out is whether the proper kind of rebuttal would be some testimony that it wasn't carved out and what the P & T committee does, or if it was carved out, what the P & T committee is limited to. This lobbying effort wasn't Lilly about Zyprexa. It was all the drug companies about everything and it's a much broader kind of --

MR. ALLEN: No. You know, Your Honor, I think that's kind -- that's ironic, really, with all due respect to the Court. If we make our efforts larger and if we make it with more drug companies, and if we make it regarding all mental health drugs, the bigger and broader we make it, the less admissible it becomes. I don't understand that.

And by the way, far and away, they're, No. 1 -- and to say for all mental health drugs, with all due respect. There are only $4.8 billion blockbuster mental health drug in this state, which 70 percent is paid by

Medicaid is Zyprexa. So to sit there and say well, we're really talking about other mental health drugs is ignoring the facts.

I mean, $4.8 billion selling annual sales, No. 4 selling drug in the world. That's the drug they're talking about. They're not worried about some other pill. And so the bigger and broader we make it, the more unified our efforts, the less admissible it becomes? I mean I actually think it speaks to the admissibility, not the inadmissibility.

And so I think the Court was right in its analysis. I think the Court was right in its rulings. I don't know what to say. I've been sitting here now since March the 4th listening to this, and I want to play 12 minutes of testimony that rebut it.

MS. GUSSACK: Your Honor, if I might.

THE COURT: Briefly.

MS. GUSSACK: Particularly in light of the suggestion. I find it really ironic, I would say, at least, that the State, charged with the health and well-being of its citizens would suggest that any -- any restraint on mental

health medications was some kind of manipulation by one company. Open access refers to the opportunity to have all mental health medications available to physicians prescribing in the State of Alaska. A policy and interest shared not just by Lilly, but by every pharmaceutical company who's making mental health medications as well as all of those who have an interest in mental health, and the patients at issue.

There's no question, if I might -- Your Honor's quite right. There was nothing done in 2003 or 2004 at the time of the lobbying activity that's referenced by Mr. Allen, and as you can see in No. 4, these are minutes of the P & T committee from October, 2004 in which they are reporting, Dr. Von Hofften, the psychiatrist, former Alaska Psychiatric Association president, comes in and presents to the P & T committee about the need to do metabolic monitoring for the atypicals. They had the information. They weren't stymied and they knew everything that they needed to know.

THE COURT: This is -- I understand the issues. I'm going to take it under advisement. There's no need that it be played in

before the State rests. If I'm going to allow it, it can just as easily be played before the trial is over. Part of what I'm concerned about it, I'll just front it for everybody is I don't want to have a mini-trial about lobbying and what this committee does and who was lobbying for what and the argument that we've just had for 35 minutes. I don't want argument back and forth. I mean Eski would just be the start I'm afraid.

MS. GUSSACK: Your Honor, you couldn't be more right because if this is introduced, we have a lot of information and witnesses that we would need to bring to the stand to explain what open access is, why those activities were appropriate, and the fact that none of it had anything to do with the decisions or actions of the P & T committee or Dr. Hopson.

And I think, most particularly, we should return to the question that you pose, Mr. Allen, which is it has nothing to do with the adequacy of the warning in this case. If they believe that the warning is inadequate in any way, it is irrelevant to what Lilly or others engaged in with respect to the P & T committee.

THE COURT: Again, to be fair about

this, if it was irrelevant, it was just as irrelevant when you asked the questions about the P & T committee and indicated that it looks at the safety and efficacy and can do those kinds of things and that's -- it was when those -- when the words safety and efficacy of the P & T committee looking at it, that's when I wrote my note, which is where --

MS. GUSSACK: I appreciate that, Your Honor -- plainly the State has injected motive in this case plainly over our objection and our right to counter that with the expectation that the State's motive could be examined and explored is --

THE COURT: I understand that, too.

MS. GUSSACK: Thank you, sir.

THE COURT: It's -- what I'm grappling with is the fairness of the trial in light of the evidence and the defenses and the ability to rebut the evidence and the defenses and how remote some of these things get to do that as well as are we going to have a mini-trial on lobbying, which I --

MR. ALLEN: You will --

THE COURT: -- I'm reluctant to

see.

MR. ALLEN: You will not, Your Honor. And by the way, it's a unique argument to make. We can talk about it on opening; we can talk about it on the 12th; we can talk about it on the 13th, but keep your evidence out because of mini-trial. I promising and that's what my point is. Twelve minutes of evidence and I will never say another word about it, but I'm entitled to rebut it for 12 minutes.

THE COURT: Well, I understand that you want to rebut it for 12 minutes, but I also foresee what may well need to happen than -- the same arguments I've had today and the evidence that's suggested to me about what was done or what wasn't done, I'm worried about going off onto a big side issue. And I haven't ruled yet. I want to think about this some more and see how some evidence develops. I'm not going to allow it before you rest. I'm not prepared to rule.

MR. ALLEN: Due process and fundamental fairness, it's a unique argument. We can open the door, but we're going to shut it down. Once we open it, it's going to take you some time to rebut it. That's not my problem;

that's what they did. I'm telling the Court, when it considers the mini-trial, I have 12 minutes of evidence. Now, if they choose to go for longer, I should not be burdened in my due process and the State's due process from fundamental fairness rights, burdened because they say they're going to go longer. That's an issue.

THE COURT: It's not a question of going longer. It's a question of do I interject that kind of side issue, what I see as a side issue that will sort of confuse the jury and won't advance, and due process and fairness goes both ways.

MR. ALLEN: I don't know if the jury is very confused right now. What they've heard only is the State has put no restrictions, the P & T put no restrictions, the doctors put no restrictions. That means it's safe and efficacious. I don't think they're confused. I think they have evidence on a one-way street going both ways and I'm asking to drive my car in the opposite direction for 12 minutes. Thank you, Your Honor.

THE COURT: I'm going to take this

under advisement and -- before it's -- I certainly will let you know before the State gets into its rebuttal case whether I'm going to allow that. We'll see.

MR. ALLEN: I plead and beg with the Court.

THE COURT: Let's talk about what the jury's going to decide here. And I will front my big issue. I do not want to leave this case at the end of the day -- I mean, if Lilly prevails on this first part of this case, this case is over. But if the State prevails on this first part of this case, I want to be sure that Jury No. 2, or whoever the tryer of fact is, No. 2 doesn't have to hear all the evidence again to render their verdict.

So my question is a very direct one is: How do you see this jury deciding this case, Mr. Sniffen? What are they going to be asked to decide from the State's point?

MR. SNIFFEN: Thank you, Your Honor. Ed Sniffen, for the record, from the Attorney General's office. I hope this issue is a much easier one than the last one because I think we have an agreement with Lilly on this.

That is, the jury will decide whether or not the evidence supports a finding that Lilly violated the Unfair Trade Practices Act and then issues relating to the amount of penalty, if any. And the number of violations would be issues reserved for --

THE COURT: Don't I have to have this jury tell me what those violations are? If you don't have that, you've got to put on all this stuff for labels again and why these labels violated the Act for Jury No. 2 to decide what those violations are.

At a minimum, I need to not have them just answer the question, did Lilly violate the UTPA, yes or no; I need to say how did they violate the UTPA. Was it -- and so I need to know what the State is contending. Is it the product labels that were each a violation of the UTPA? Was it going to doctors that was a violation of the UTPA? Was it something else that Lilly is contending the UTPA. I realize that I -- probably if I got that information -- we can wait for Jury No. 2 to decide or for me, if that's appropriate, which, again, I raise that question, to say how many violations were they.

If it's the label that's a violation.

Is it each time -- I mean, I haven't heard any testimony other than suggestions from the State that every time a prescription is written there's a label. But I don't know if that's true. There hasn't been any evidence of that. Is it each prescription? Is it each doctor who prescribes for one particular patient?

I understand I can wait for that if there's an agreement to wait for that, but I don't see how I can -- how we can avoid having this jury not tell us if they find that there's a violation, don't they have to tell us what constitutes that violation, because otherwise Jury No. 2 will have to do that. And I don't think Jury No. 2 can do that without hearing all the evidence pretty much in this testimony, because if all there is is a violation, they could be thinking that the lobbying was a violation. We won't have any idea what they thought the violation was. So that's my question. And just so that everybody knows, my goal is not to have -- I bifurcated this trial for reasons that I thought -- because I thought

it was appropriate to bifurcate it because it would advance the case and save time and it was proper to do that. But if I have to hear all of this evidence again, I just wasted everybody's time and you've wasted this jury's time.

MR. SNIFFEN: Certainly, Your Honor, and we understand that and appreciate the concerns. Fortunately, I don't think you need to burden the jury with those decisions because we believe it's the judge's responsibility to make those determinations under the statute. The jury will hear evidence, as they have and will continue to hear as Lilly puts on its case about what we believe the violation is. A special verdict form will instruct them how to answer that question. Did Lilly's failure to warn, in whatever year it was, constitute a violation of the Unfair Trade Practices Act?

And then in a separate proceeding, perhaps a smaller evidentiary proceeding before the Court, we will present our evidence as to why we think it's every prescription. Lilly will present its evidence on why they think it's perhaps one warning that perhaps should have gone into the PDR. That's for the Court to decide. I

think Lilly is in agreement with that so I don't want to argue too much about that but I'm happy if you need more information on that. Correct me if I'm wrong.

MS. GUSSACK: Your Honor, we spoke before court this morning. And I think the agreement we have, and I just want to be clear, is I think that the State and Lilly are agreed that the issue of the imposition of penalties is for the Court in a separate hearing to follow this jury's deliberations. And that that hearing requires some evidence that hasn't yet been developed and, in fact, may involve the database that has not yet been examined by Lilly.

What I hear Your Honor asking, though, is a different question than I think what we've discussed amongst counsel, which is what violations need to be decided. I think we were talking about a penalty hearing.

THE COURT: I have no doubt that I can -- if we knew, for example, that it was the labels that violated the UTPA or the labels from this period of time that violated the UTPA, and that was the only contention of what violated the UTPA, then I can figure out, well, how many of

these violations are there and what -- what -- because there's a range of what fine is and I'm pretty sure there's case law that talks about the factors I could look at in deciding -- or that would be analogous to deciding whether it's $1,000 or $25,000. And you all could give me some help with your positions on that, and that can be done. But if I don't know what the violation is, how can I -- who's going to decide what the actual violation of the UTPA is?

In other words, somebody in their briefing cited some case where a jury said there were 16 violations and that these things are the violations. And most UTPA cases it's clear exactly what the violations actually are, and I understand that the State at a minimum, I suppose, is saying that the product label is the violation. But don't I have to have the jury -- doesn't somebody have to decide that?

I mean -- because there's been other arguments made as to violations with the call notes and the advertising that a jury might think that those are the violations. And I'm going to get motions if the jury comes back in favor of the State, I'm sure, from Lilly that

says: The judgment notwithstanding the verdict, and I'd have to know what the actual violation is that I'm considering to rule on that, won't I?

MR. SNIFFEN: Yes, Your Honor. And that is something that we think the Court can take up at some other time, that the jury doesn't have to decide. The jury can decide, for example, whether or not the evidence we've put on here today satisfies one of the multiple tests under 45.50.471 and whether or not it constitutes a violation of the Unfair Trade Practices Act. Given that, if selling Zyprexa, if every Zyprexa pill was a car, it would be just like the result that we had in the Anchorage Nissan case, which is the case you referred involving the 15 violations or 16 violations, but we don't.

Lilly sells pills; they sell them through prescriptions. We can put on evidence in a separate evidentiary hearing about why it is that each prescription should be a violation. The jury doesn't need to do that.

THE COURT: Only if we know that the jury is deciding that the prescriptions are the violation. If the jury is deciding something else is the violation and we don't know that, how

can I have that second phase of trial? Unless you're suggesting that I can -- if the jury says they violated the UTPA, I can figure out which ones -- what the violation -- what document or what communication was the violation, and I'm not sure that I'm supposed to do that.

MR. SNIFFEN: It would be our position, Your Honor, that you are. If not for the failure to warn product liability issues in this case, we wouldn't even be before a jury. Or at least we would make an argument that actions under the Unfair Trade Practices Act at least brought by the Attorney General's Office aren't issues that are even appropriate for a jury.

THE COURT: I've raised that question, too. That's a separate issue that I'm not sure I've gotten a satisfactory answer about.

MR. SNIFFEN: Well, and I think the case law supports that. Under UTP cases across the country it's held widely. And I know there are some states that find statutory common-law causes of action have survived codification of these violations and UTPA acts. But for the most part, no, you don't get a jury trial on these issues. And courts across the country are

uniform in having the judges decide these UTPA issues.

If you look at our statute, 551(b), the statute that sets out the Court's equitable ability to issue the penalty, it says, the Court shall issue the penalty for each violation. And I understand the disconnect between the penalty and each violation, whether that should be something that the Court or jury should do. We believe it's something that flows from the equitable powers of the Court that you can do in a separate hearing. And we can present that evidence and you can decide that issue.

If we had a jury deciding, for example, these kinds of violation issues every time, enforcement of the Act would be extremely problematic, because there would be no consistency among decisions about how we assess penalties.

THE COURT: You've also got a UTPA action on your own, so even if I decide this part, a jury has got to decide that part. And to the extent that the State is alleging that it's been harmed by a UTPA violation, I understand the question of ascertainable losses for Phase 2 but

don't we still need to know from this jury what that violation is somehow, because otherwise, if we don't, and the jury in No. 2 has to decide that part of the UTPA claim, don't you have to present all your evidence all over again of what the -- what constitutes the violation?

MR. SNIFFEN: Well, it's our position, Your Honor, that once the jury makes its finding on whether or not the warning was or wasn't adequate, the number of violations will flow from that fairly logically, because there's no other way to really couch it.

THE COURT: The warning where? I suppose that's the question. The State has put on evidence that it's not just the warning on the product label. I mean, clearly, the product label has been talked about a lot. But there's also the warnings -- put on -- I've allowed them to put on a whole lot of evidence about these calls and marketing and going to doctors and what about that warning?

MR. SNIFFEN: Yes, Your Honor, I understand what you're saying. Those kinds of warnings, as you will, Lilly comes forward with the lack of information that we allege should

have been present in all of that kind of conduct.

THE COURT: Let me just ask this: Is the -- is the State asking -- is the State going to be asking for a finding that those constitute UTPA violations? I mean, at the end of the day, it's the same question I asked Mr. Allen earlier. If the State hits the home run and the jury gives them everything they want, what would be the violations that they're claiming of the UTPA? Is it just the product labels or is it something else?

MR. SNIFFEN: Well, we're going to ask the Court to decide that all of the conduct could potentially be a violation, and we take the position each prescription should be a violation because that's where all the warnings logically end up. They end up in a pill being sold to a consumer without all the information about the drug. There might have been violations when they made those representations to doctors as well. There may be violations whenever those representations were made to each patient. Those are legal issues that I think we can take up at another time.

THE COURT: I just want to warn

you: When you start talking like that, we're starting to get real into Phase 2 deposing all the patients and deposing all the doctors. Because if that's the position that the State takes, I don't see how Lilly can possibly fairly defend themselves against a claim that a warning and a communication to a doctor is a warning unless you know that the communication was actually made to the doctor. How could we ever count the numbers?

MR. SNIFFEN: Well, fortunately, our Consumer Protection Act doesn't require that we know how many people actually relied or were misled by any of this information. All we need to prove is that they engaged in commerce and acted in some way that could have the potential to mislead consumers about this product. And I don't know that it's going to be that complicated.

THE COURT: If I have to decide a penalty for each violation of the Act, which I do, that's what you're both telling me. Don't I need to know how many violations of the Act there were? In order to do that, don't I have to know what the violations were? And if a jury's going

to decide that question, doesn't it have to be this jury, because otherwise the next jury would have to hear all of this evidence all over again.

MR. SNIFFEN: Well, we do need to make those findings, Your Honor, but we believe it's a finding that the Court can make later and it's not something the jury needs to make. We can present evidence at some later time about exactly what would constitute a violation, and the Court can take that up at some later time. We don't believe that's appropriate for a jury in this phase of the trial and that's separate from the second phase of the trial where we're going to be looking at the State's actual damages and how much loss, ascertainable loss, have we suffered because of this conduct.

THE COURT: Well, to the extent this jury could come up with a verdict that says Lilly violated the UTPA, but I don't know what the behavior was that violated the UTPA, what are we going to do in Phase 2? I mean, you could have a verdict where this jury said, yes, Lilly violated the UTPA and they thought that the violation was the product label, but not the communications to the doctors, or it could be the

communications to the doctors and not the product label, or it could be both. But if I don't know, what do I do with that?

MR. SNIFFEN: I'm going to have Mr. Steele explain that. He seems to have a take on this.

MR. STEELE: I do.

THE COURT: I'm sorry if I'm chasing everybody down rabbit holes, but I don't think I am.

MR. STEELE: Let me see if I can clear it up, Your Honor and I'll take a shot at it.

Really there's three parts to figuring this out. If we take them one at a time, it becomes a lot clearer.

No. 1, there has to be a decision whether a practice is unfair or deceptive.

No. 2, you have to know -- and this No. 2 is Part A and Part B.

Part A is: What's the triggering event? Part B is: What is the number of triggering events? Okay.

No. 3 is what's the fine. All right --

THE COURT: When you say, just so I'm clear -- I don't have any problems following you so far -- but when you say was there a practice that -- I forget the words you used.

MR. STEELE: A practice that's unfair or deceptive is a generic way of saying --

THE COURT: When you say triggering event is triggering event a practice or is practice a different term? If it's a different term, don't you need to know what the practice is?

MR. STEELE: Yeah, you do. It is a different term. I'm going there. I'm right with you.

Here's how it works, I believe. If you look at the cases and you look at all of the cases, what you will see is the Court as a matter of law also decides what is the triggering event because it's a question of law. The way that the Court decides it is to look at what kind of commercial endeavor we're engaged in, all right? So let me go through it a piece at a time and I think it will become clearer. All right --

THE COURT: And let me just -- it would help me, Mr. Steele, if you answer your own

questions, so telling me what you think the triggering event is.

MR. STEELE: I will. So, the first question is whether a practice is unfair or deceptive. Well, you have to look at what is the nature of the commercial transaction that we are involved in? So, for example, let's say you're doing debt collection and the commercial practice that we're talking about is the sending out of letters to debtors saying, for example, we're going to sue you, when it's not true, we're not going to sue you.

THE COURT: That's O'Neill.

MR. STEELE: Okay. That's a form letter. It's the same. Just like a product label. Goes out to 500 debtors. The cases are quite clear that the judge decides the triggering event is the sending of the letter to the debtor. And if you do that 500 times and the letter is a lie, that's 500 violations. The triggering event -- it's decided by the Court as a matter of law. What is the unfair or deceptive practice is the lie that is contained in the form letter, okay?

So what the jury does is the jury

comes in and the jury says, here's the letter or as in this case, here's the label, among other things. And they look at it and they say: Were you lying when you wrote this letter? Here it's were you lying when you wrote this label? Were you lying when you went out and you told the doctors that Zyprexa either didn't cause or caused diabetes at comparable rates? Were you lying when you undersold the weight gain? Were you lying to doctors? Okay.

So the question in this case and the question we're going to ask the jury to address is: With respect to the sale and marketing of Zyprexa year by year by year, was Lilly guilty of unfair or deceptive practices with respect to how they sold and marketed Zyprexa? Okay?

THE COURT: Okay.

MR. STEELE: So you can do that. We have a special verdict form prepared that says, look, in 1996, unfair or deceptive with respect to how you sold and marketed Zyprexa? Okay.

THE COURT: Two questions or one question?

MR. STEELE: We've divided it into two, sale and marketing.

MR. FIBICH: By year.

MR. STEELE: By year. So it's every single year. All right?

Now, the next question -- they can answer that question so they'll tell the Court, yes, they were selling it in an unfair and deceptive way in 1996, 1997, 1998, 1999, 2000, yes or no, yes or no, yes or no, yes or no as to each year. Okay?

The question, then, for the Court in the second proceeding is: What is the triggering event? What we say is this, that it's very clear. The commercial transaction that we're talking about with respect to prescription drugs is paying for prescriptions. In other words, if the State is paying for prescriptions in an environment where Lilly has been selling and marketing its product in an unfair and deceptive way, that that is a triggering event. Why -- and really, when you look at these cases and you can look at all of them.

If you look at the commercial type of transaction that you're in, what it tells you

is what's a triggering event and it's always a decision by a judge. So if you look at it -- for example, if you look at the dunning letters to the -- to the people who owe money, okay, the triggering event is not the writing of a single form letter. The triggering event decided by the Court as a legal question is the sending out of the letter to 500 different people. It's always 500 different violations. It's never one form letter or one label. You have to decide.

THE COURT: I understand that, but it's not because people get this letter and get money.

MR. STEELE: It's because the letter gets sent out.

THE COURT: I understand all of this. The number -- I'm not concerned about. It clearly can be decided in the next phase. It's identifying what you're calling the triggering event, which also may be whether -- the way you've defined practices, I understand that.

But it's identifying the triggering event somehow from this jury, because this jury -- I don't know what this jury is going to do. It may decide that all of these things

were -- sales and marketing are violations of the UTPA, although I hope we can get a little more specificity with that, or they can decide that some things are or some things aren't. I want to know what they decide rather than leave it for Phase 2 to know, as you put it, what the triggering event is that becomes the violation. I don't like the term triggering event -- practice is actually a better way.

MR. STEELE: What event is the particular practice or -- but that is always a decision made by the Court. And what I'm saying is is that when you have a scheme like this where you're selling pharmaceuticals and the purpose is to sell prescriptions, the only thing that can ever be proved is that you were deceptive in the sale and the marketing. What we're saying is that there is a deficiency in terms of information in the environment in which this drug is sold.

Remember, with the UTPA and with respect to failure to warn, the focus is always entirely upon the conduct of the defendant. It doesn't matter what anybody else did or thought about it. Every UTPA violation and the failure

to warn, I can assure you, focuses solely on the conduct of the Defendant. What we're saying is that this drug is being sold in an environment where information is missing. Information is lied about --

THE COURT: I understand that. I'm just -- again, my concern is being sure that we know what this jury concludes actually violated the Act, because they can conclude some things did or some things didn't. I realize, just to foreshadow this, there's lots of arguments that I'm sure as to how many acts there are. One argument could be is that each act, just like when you send out the letters, there's 500 violations because it went to 500 consumers or there's 500 cars; it could be that you group it by physician. Physicians got labels; physicians got things. I mean, that's one argument. You could make your argument that it's each prescription.

I don't know what -- I mean, I have a feeling that the two of you are looking at the possibility of number of violations in very, very different ways.

MR. STEELE: A way that you could

do it, Your Honor, if you feel the need to do it is to characterize it into categories. You could say, were they unfair and deceptive with respect to their labeling? Were they unfair and deceptive with respect to their direct marketing to physicians? Were they unfair and deceptive --

THE COURT: That starts getting me to have a special verdict that gives me more information to do Phase 2 with either for a jury or otherwise. It also -- it may mean that certain actions the jury finds weren't unfair and deceptive.

MR. STEELE: You could characterize it broadly in terms of the categories we've talked about, which are the labeling, the PDR, the direct marketing to the physicians, the conduct of the drug reps, the information that Lilly put out publicly. You could arrange it in broad categories like that if you wanted to, and that would arguably provide you with an answer. We think it's every prescription because it's a prescription drug, and that's the essence of the commercial transaction. But if you wanted to do it the way that you suggest, a special verdict could be written in that way.

MR. BRENNER: Your Honor, could we just offer the Defendant's perspective on your question?

THE COURT: Please.

MR. BRENNER: We think the question to be put to the jury, however appropriately framed, consistent with the proofs and with Your Honor's pretrial rulings, were the labels, the warnings inadequate and if so, at what time? It does all boil down to that. That is fundamentally -- however it's correctly phrased in the jury instruction. That is the question, I believe, the jury needs to answer in this case.

Beyond that, I'm not sure that there are either proofs or that any other claim remains. I heard some talk, and it was in the context of a larger argument, about well, marketing efforts by sales representatives. Your Honor ruled out, if not all of those, certainly the great proportion of them under your exemption ruling with respect to the UTPA. I think that's not there. With respect to direct -- and I don't know what this means, exactly, but direct marketing efforts to physicians. Perhaps the State wants a jury

charge on that, but that's going to be subject to whether there were ever any proofs offered of that.

THE COURT: Well, there's certainly been proof, for example, of efforts by Lilly to neutralize the weight issue, to control -- I don't remember whether control is my word or somebody else's word -- but that there was all this evidence starting to show up of weight gain and hyperglycemia and other things. And that -- and there's been numerous documents introduced and even through Ms. Eski, there is certainly a fair inference that this was done in Alaska as well, I believe. That efforts were made to neutralize that, to suggest that all the drugs had this problem and were comparable. I mean, there's been all that evidence and I guess the question is: Is that a violation, too? I hear the State saying a big yes to that question.

MR. BRENNER: And we would disagree because we think it's encompassed in the adequacy of the warning, No. 1. And, No. 2, not to be unduly repetitive of what I just said, if you wanted to talk about Ms. Eski, the only sales rep under whom any evidence has been offered, we

would argue, Your Honor, any acts she allegedly committed were covered in the exempted and now dismissed portion of the claim. Your Honor can rule against us on that, but that will be our position.

THE COURT: No, I remember excluding portions of Ms. Eski's testimony that went to that and allowing portions of Ms. Eski's testimony that dealt with the marketing aspect.

MR. BRENNER: I can state my position -- Your Honor will rule. I want to at least be clear on our position.

THE COURT: Okay.

MR. BRENNER: Beyond that, if there are other acts, and the evidence that Your Honor has just alluded to, we think that all gets encompassed in the label. And we think those are not separate acts, but if Your Honor were to rule otherwise, I think there would be challenges, specific challenges, as to whether in fact there were proofs adequate to get to the jury as to whether any of that conduct occurred in Alaska. That would be a legal matter for the Court as we take up in every case, or virtually every case. My only purpose in rising, Judge, is to try to

answer directly your question, what do we think it is --

THE COURT: So you would have no objection to a special interrogatory, for example -- tell me what the question you think --

MR. BRENNER: The words are important. I don't mean to say these are the exact words. The concept as we see it is: The jury needs to determine -- put it positively or negatively. Was the labeling for Zyprexa adequate or inadequate? And because as we all know, the label has changed over time. There has to be some accounting for that however properly framed.

THE COURT: You would have no objection to the special interrogatories to the jury: Was the label and -- deceptive in each of the years done, as I understand the State wants to have done. It's the marketing portion that you would rather not have the jury --

MR. BRENNER: I think that's not subject to the evidence and Your Honor's other rulings, but if the ruling is to the contrary, you know, we'll move from there. That's how we see the issues. That's what we think the jury

should be asked to decide.

MR. SNIFFEN: Just to follow up, Your Honor. I don't necessarily disagree with what Mr. Brenner says, and I think his characterization of a special verdict form is mostly accurate, and we will be proposing one. I think the time to look at that is to look at the questions that we proposed, look at the questions they proposed. We'll figure out a way to do that.

I wanted to make one thing clear because I sensed a little confusion, perhaps, maybe it was just me, but when we were suggesting that there be a separate proceeding to determine the number of violations. We weren't suggesting that would be a second phase of the trial. There would be another proceeding in between that --

THE COURT: That I understand. You're suggesting it not happen in this case. Whether it happens in the second trial that will have to happen for other portions of the case or whether it could happen in a proceeding that might occur before then or -- I mean, I don't know when. Timing of -- let's get through Phase 1 and see whether we need Phase 2 before we

decide the timing of Phase 2.
MR. SNIFFEN: Sure and I know some of the questions that we'll propose on the special verdict form will include the sale of Zyprexa by year and the promotion of Zyprexa as well by year. We'll have to take that up in the jury instruction conference or a special verdict conference when we get to that point.
THE COURT: I understand that, but I raise the question now because I want to make sure that the jury is getting information that they need to decide what you're going to be asking them at the end of the day, because I'd hate to have a special verdict form that I decide, yes, we're going to use this and there's no proof on that.
MR. SNIFFEN: Our questions will relate to the evidence that's been put on in the case, Your Honor.
MR. STEELE: Just one point, Your Honor. I wanted to be very clear that the claim we're pursuing is not a failure to label case; it's a failure to warn case, and there is much more to it than the label.
THE COURT: Again, Mr. Steele,

you've got a failure to warn case, but you've also got a UTPA case.
MR. STEELE: It's a failure to warn under the UTPA.
THE COURT: It's the UTPA case that I'm concerned about is -- to take up your example, normally in these things you've got 500 letters, as you put it, or 15 car sales. And it's pretty easy to identify what the UTPA violation is. But here, we've had a lot of stuff -- it's not just the label -- I mean, if it was just the label, this would become very simple for me.
But I don't understand the State to be just arguing that it's just the label that's the UTPA violations. You're arguing for additional violations. And whether those are legally -- whether you have legally sufficient proof to do that or not, we can take up at a point. I'm just trying to understand and I want to be sure, but it sounds like everybody agrees that there will be a special verdict that can ask the jury those questions so we know what this jury -- not only that this jury thinks that the UTPA was violated, if that's what they think, but

that they can also tell us, at least in some ways, how it was violated. Because, again, I'm concerned that if we don't ask them the how-it-was-violated question, we've got to put on all the evidence to a second jury and I may have given that there are multiple theories that the State offers as to how it was violated and if we don't get that specifically done, I've got an ambiguous verdict.
MR. ALLEN: I'll say some evidence is fixing to come here in a minute, Your Honor. We haven't closed yet --
THE COURT: I understand that. I'm comfortable that we're moving along on the right track and that everybody understands the issues. Obviously, to the extent that people can start getting me special verdicts to look at as well as any other additional jury instructions, we can start handling these things in a way that we won't have to delay actual instruction of getting the case to the jury when it's ready to get to the jury.
Why don't we give the jury a few-minute warning and then we'll see if we can get them.

(Off record.)
(Break.)
(Jury in.)
THE COURT: Please be seated.
We're back on the record. All members of the jury are present.
Good morning, ladies and gentlemen. I apologize for the delay that we had. We will be continuing now with the State's case with their deposition-playing. Mr. Allen.
MR. ALLEN: Yes, sir, Your Honor.
Your Honor, we now call to the stand by oral videotaped deposition, Mr. David Noesges, former executive sales director for the western region for Eli Lilly, which includes Alaska, former U.S. marketing director. His deposition was taken on January the 11th of this year, and it lasts 12 minutes and 21 seconds.
Thank you, Your Honor.
VIDEOTAPED TESTIMONY OF DAVID NOESGES
Q. Would you state your full name for the record, please?
A. Yes, it's David Thomas Noesges.
Q. What is your occupation, sir?
A. I am employed by Eli Lilly and Company.

Q. And what's your job title?
A. I'm currently the national sales director for our U.S. diabetes unit.
Q. Okay. For the U.S. diabetes unit.
Have you previously had responsibility with respect to Zyprexa?
A. Yes, I have.
Q. And what were your job titles? When did you work on Zyprexa projects?
A. I first began working for Zyprexa in 1999 as the sales and marketing operations manager.
Q. Was that based here in Indianapolis?
A. Yes, it was.
Q. And did you have any other jobs with respect to Zyprexa after that?
A. Yes. Subsequent to that, in 2000 through 2001, I was the sales director for what was then our midwest area.
Q. Okay. And did you have any job responsibilities after 2001 with respect to Zyprexa?
A. Yes. From 2003 -- late 2003, November, I believe, of 2003, until October of 2004, I was the Zyprexa marketing director.

Q. Okay. And did you have any responsibilities for Zyprexa after 2004?
A. Yes. Then, from 2004 until the end of 2007, I was -- I was in a sales leadership role. First, as the national sales director for our neuroscience retail organization from 2004 until, basically, the end of 2005.
Q. Okay.
A. And then through -- from 2005 through 2007, I was our executive sales director for the west region of neuroscience.
Q. Would that include Alaska? West region?
A. Yes.
Q. The west region -- would you agree with me that sales of Zyprexa declined after 2004?
A. Yes.
Q. And do you recall that the company increased the price of Zyprexa after 2004?
A. Yes.
Q. And did the company do that after sales began to decline?
A. Yes.
Q. Is it fair to say that sales reps are expected to say particular things about Zyprexa and not say other things when they are selling the product?
A. Our sales representatives are required to follow our promotional guidelines and the promotional message that we establish for them.
Q. And that -- those promotional guidelines and the messages that you establish are for the product throughout the United States, and they're not particular for any given state or region, correct?
A. Yes, that's correct. We have one promotional message throughout the United States.
Q. I'm going to hand you what's been previously marked as Plaintiff's Exhibit 1941.
MR. SUGGS: For the record this is a document entitled "Zyprexa Frequent Areas of Concern" or "FAOC."
Q. (BY MR. SUGGS) I'll also represent to you, sir, that the database that has been provided to us by Lilly states that this document was generated on June 28th, 2002. And I'll also represent to you that Lilly has stated in answers to interrogatories in this case in Alaska that this document was in the knowledge management database and made available to sales representatives.

Have sales reps ever, to your knowledge, been instructed to go out and admit to physicians that Zyprexa can cause diabetes?
A. No. That has never been a specific verbatim for our sales representatives.
Q. Okay. And, in fact, they go on to say in this document -- the following sentence says: The incidence of diagnosed treatment-emergent diabetes with patients taking Zyprexa was comparable to those patients treated with Risperdal, Haldol and Depakote in every clinical study conducted by Lilly or by our competitors.
Did I read that correctly?
A. Yes, you did.
Q. The sales reps were told that if a doctor said he was concerned about diabetes, they should address that area of concern using that language that we've talked about here and after doing that, they should then check for agreement and get back to selling, correct?
A. Yes, that's correct.
Q. Now, you mentioned earlier that you knew a Dr. Charles Beasley, correct?
A. Yes.
Q. How did you know Dr. Charles Beasley?

A. He's worked as part of the Zyprexa -- Zyprexa molecule as a clinical research physician.
Q. Were you ever informed that in February of 2001, the same month this document was apparently dated, that Dr. Beasley wrote an e-mail in which he noted that Zyprexa had a statistically significant mean increase in random glucose as compared to Haldol?
A. No, sir, I haven't.
Q. I'm going to hand you next what's been previously marked as Plaintiff's Exhibit 1901. And the first paragraph in that section states, quote: Many physicians think there is a logical link between weight gain and diabetes. In market research, we see that many of them even use these two words interchangeably. We believe it is essential to weaken this link in order to neutralize the diabetes/hyperglycemia issue.
Do you see that language, sir?
A. Yes, sir, I do.
Q. If I could direct your attention to the summary at the bottom of page 3, it states: Eli Lilly has a proud history in innovative diabetes research. The relationship between Zyprexa and

diabetes, slash, hyperglycemia is a top priority for the company and has been studied extensively. The facts illustrate no difference in the incidence of treatment-emergent hyperglycemia and diabetes for patients on Zyprexa, haloperidol, risperidone, ziprasidone or divalproex. Neutralizing any concern from our customers will be essential to the future growth of Zyprexa in the marketplace.
Do you see that language, sir?
A. Yes, sir, I do.
Q. In November of 2003, you came back to the U.S. to head up U.S. marketing to take over from Jack Jordan, correct?
A. Yes.
Q. Okay. Before October of 2007, did Lilly ever instruct its sales force to tell physicians that Lilly believed that the rates of diabetes with Zyprexa were higher than with other drugs?
A. No, I don't believe that was ever a specific message that our reps were instructed to communicate to physicians.
Q. Between October of 2007 and the present, has Lilly ever instructed its sales force to tell physicians that the rate of diabetes with Zyprexa

is higher than with other drugs?
A. No.
Q. Okay. You were the executive sales director for Zyprexa in the western region?
A. I was the executive sales director for neuroscience, including responsibility for Zyprexa in the western region, yes.
Q. Okay. And under you, you had how many sales folks who were out selling Zyprexa?
A. I had approximately 700 sales representatives.
Q. Seven hundred sales representatives.
And they would call on, roughly, how many doctors?
A. Each of them calls on between 100 and probably 190 doctors.
Q. So we're talking thousands? Like 70,000 doctors? Am I doing my math right?
A. Yes, I think that's right.
Q. Okay. Which, for the record, is a copy of an October 5, 2007, Dear Healthcare Provider letter. And you have, I'm assuming, have seen this document before, sir; is that correct?
A. Yes, I have.
Q. And would you agree with me that this

letter to healthcare professionals informs them of a change in Lilly's label?
A. Yes. This is a letter to healthcare professionals informing them of a change in our label for Zyprexa and Symbyax.
Q. Okay. And the change in the label was to add additional language in the warning section regarding hyperglycemia, correct? That was one part of it?
A. These label updates included warnings for weight gain, hyperlipidemia, and updated information in the warning for hyperglycemia.
Q. Does Lilly still take the position that the -- that the rates of diabetes between the various antipsychotic drugs are comparable?
A. We no longer have a message that our sales representatives are presenting with regard to comparable rates, but it is, in fact, our position that the clinical data do not show a differential risk of diabetes with Zyprexa relative to the other antipsychotic agents.
Q. Well, suppose the doctor says, well, gee, Joe, you know, I remember when you were in my office in 2001 and 2002 and 2003 and you were talking about how there were comparable rates and

there were no consistent differences. I want you to tell me right now on the spot, you know, are you saying now that still that Zyprexa has comparable rates of diabetes? What would the sales rep do in that? Would he just say, I can't answer and walk out?

A. No, sir. What the doctor would be -- what the sales representative would be instructed to do is to politely indicate to the doctor, look, I would like to provide you all the medical information that we have available in the medical letter to answer that question.

Q. Mr. Noesges, I'm going to hand you what's been previously marked as Plaintiff's Exhibit 1962. The title on the first page is Hyperglycemia slash Diabetes Sell Sheet Implementation. And as we discussed previously, a sell sheet is a -- is a brochure that can be discussed with and shown to a physician, correct?

A. This is a promotional material that can be used promotionally by sales representatives with physicians.

Q. Okay. And this one on the second page -- or this document indicates on the second page that, Proper implementation is key. Our

goal and focus is on creating a market with Donna. The competition wins if we are distracted into talking about diabetes. So stand strong against their ploys and answer the AOC concisely and with confidence.

Did I read that correctly?

A. Yes.

Q. And the AOC that's being referred to is the diabetes area of concern, correct?

A. Yes, sir.

Q. Correct?

A. Yes.

Q. Okay. And on the following page, there's directions for handling the diabetes AOC, correct?

A. Yes.

Q. Below the heading it states: This is a highly competitive-driven issue. Therefore, we will not proactively address the diabetes concern, but rather only when it arises from an M.D.

Do you see that language, sir?

A. Yes, I do.

Q. And that was, indeed, the policy of Lilly at that time, in 2002, is it not?

A. That was the instructions that were being provided to sales representatives through this particular sell sheet implementation guide.

MR. ALLEN: Your Honor, that concludes our offer of the deposition testimony of Mr. Noesges, and we'd now like to offer exhibits to the jury, please, and to the Court.

Your Honor, we offer into evidence AK1901, Hyperglycemia/Diabetes Data on Demand Resource Guide, sir.

MR. LEHNER: Your Honor, consistent with your prior rulings, preserving all objections.

THE COURT: Preserving all prior objections, 1901 -- Alaska 1901 is admitted.

MR. ALLEN: Your Honor, we offer Comparable Rates of Diabetes and Hyperglycemia Among Psychotropics detail piece, Alaska 10092, Your Honor.

THE COURT: Subject to prior rulings, for which objections are preserved, 10092 -- Alaska 10092 is admitted.

MR. ALLEN: Your Honor, the State would offer Diabetes in Patients With Mental Illness detail piece, AK10093, Your Honor.

THE COURT: Subject to prior rulings, Alaska 10093 is admitted.

MR. ALLEN: Your Honor, we offer LillyUSA Sales Good Promotional Practice, Definition of a Sales Call and Call Notes, Alaska Exhibit 10097, Your Honor.

THE COURT: Alaska 10097 is admitted. All previous objections --

MR. LEHNER: Your Honor, this one I'm not sure was raised in this particular deposition, was it?

MR. ALLEN: It was not raised in the deposition, Your Honor. These are exhibits that are particular to the marketing and sales of Zyprexa through the sales force and he was the head of the sales force. I'm entitled to offer my exhibits.

THE COURT: You're entitled to offer them but there's got to be foundations and those kinds of things established --

MR. ALLEN: Your Honor, this was actually discussed with Ms. Eski, who was the sales representative working under Mr. Noesges in her deposition.

(Bench discussion.)

MR. ALLEN: This is exactly to what you were just raising when we went on the record.
THE COURT: That may -- the question is whether or not you've laid the foundation and stuff through some witness to come in.
MR. ALLEN: I'm not trying to be obstreperous for the Court. We don't always have to lay a foundation through a witness. These documents are admissions by party opponent. They have been produced; they're authenticated, they're not hearsay. You don't have to put them through a witness. You can put documents in at any time.
THE COURT: Let's take this up after --
MR. LEHNER: That's all I'm saying. If you have the ones --
THE COURT: I'll admit the ones that just came in through this witness and you can publish it. The one you want to put in without the witness, I want to look at --
MR. ALLEN: I've got call notes and everything.
THE COURT: To the extent you want

to put in a bunch of exhibits that haven't been discussed with a witness, you may have a basis for doing that. I just want to make a record and have an opportunity, because all the ones that you're putting in I've previously ruled on. This one I haven't looked at.
MR. ALLEN: If you want an example, that was Ms. Eski's deposition, and we did not put in -- we actually forgot when we closed, but she discussed this in her deposition.
MR. LEHNER: That may or may not --
THE COURT: If that's the case, there's not going to be a problem.
That's right. If I ruled on them -- just as long as I have both of you up here. The Beasley designations say July 26th, 2006, but I believe this is Volume 2. All of this stuff, which was on July 27th. So do either of you have a copy of that that I can be looking at while this is going on?
MR. ALLEN: Do you have it?
MR. LEHNER: I'll look, too. It starts at 567.
THE COURT: It all starts at 567. The deposition was continued from July 26th at

the end of the day to July 27th. So it's got to be in there.
We'll reserve on 10097.
(End bench discussion.)
MR. ALLEN: All right, Your Honor. I have another one. The State of Alaska would offer Alaska Exhibit 1970, which was discussed in the deposition. The Strategy Overview, Welcome to Zyprexa, Hyperglycemia Diabetes Data on Demand Resource Guide, Your Honor.
THE COURT: Subject to prior rulings with objections being reserved, AK1970 is admitted.
MR. ALLEN: Your Honor, the State also -- I think it's been admitted, but I would ask to be able to publish it to the jury. It was discussed in Mr. Noesges' deposition. AK1962 Hyperglycemia/Diabetes Sell Sheet Implementation Guide.
THE COURT: Is that 1962 already in, Mark? It's already in. Just let me ask you, Mr. Allen, has it previously been published to the jury?
MR. ALLEN: Your Honor, I have to be honest, eight days, with 11,000 exhibits, I do

not recall to be honest. I don't know.
MR. LEHNER: I think that was published to the jury, Your Honor, in connection with a prior deposition.
MR. ALLEN: I couldn't argue with him.
THE COURT: If it's been published once, I don't think we need to publish it twice.
MR. ALLEN: Well, I'll assume it has then, okay. Can I publish the -- other than 1962, can I publish --
THE COURT: You can publish AK1901, 10092, 10093 and 1970.
MR. ALLEN: Thank you, Your Honor.
THE COURT: 10162? No, I thought it was 1962 is the last one.
MR. ALLEN: It was 1962 that --
THE COURT: Was previously published. Okay. We're just trying to keep this straight.
MR. ALLEN: Can I proceed, Your Honor?
THE COURT: You may.
MR. ALLEN: Your Honor, the State of Alaska would call to the stand via oral

videotaped deposition, Mr. Michael Bandick, whose deposition was taken June 9th, 2006. He was director of marketplace management and brand manager for the primary care physician campaign. His deposition lasts 13 minutes and 55 seconds, Your Honor.

VIDEOTAPED TESTIMONY OF MICHAEL BANDICK

MR. ALLEN: State your name for the Court and jury, please, sir.

THE WITNESS: My name is Michael Edwin Bandick.

Q. (BY MR. ALLEN) Mr. Bandick, my name is Scott Allen. I'm from Houston, Texas. I'm here to take your deposition today. Do you understand that?

A. I do.

Q. Do you understand the court reporter has sworn you in and you're under oath?

A. I do.

Q. When did you become employed by Eli Lilly?

A. May of 1991.

Q. And your title is described here under Denice Torres who was director of global marketing. There are four people who reported

directly to her; is that correct?

A. Yes, it is.

Q. And you were one of those four individuals?

A. Yes.

Q. And your title is listed, Mike Bandick, director, marketplace management; is that correct?

A. Yes, it is.

Q. Okay. I've also seen documents, Mr. Bandick, that indicated you were brand manager for Zyprexa for Lilly?

A. I did have that role previously.

Q. What year were you brand manager -- years?

A. 2000 -- part of 2000, part of 2001.

Q. When were you director of marketplace management for Zyprexa?

A. In the latter part of 2001 to the early part of 2004.

Q. You said as brand manager for 2000 to 2001, your answer was something like, I handled one segment of Zyprexa's market, right?

A. That's correct.

Q. What segment did you handle?

A. The primary care segment.

Q. That's the PCP segment?

A. It was also called PCP.

Q. Next question: Did you assist in writing documents that were prepared for the sales force to give to physicians about Zyprexa?

A. Sometimes.

Q. In your role and roles in the marketing of Zyprexa, why would you want to send audiences messages about Zyprexa?

A. As I indicated earlier, conveying a concept can be a very valuable piece of what we think those audiences would need to know. And I guess the difficulty I'm having in answering your question is the work that we did was always in the context of a particular situation, so without that context, it's hard for me to give you a very satisfactory answer.

Q. So you agree, you shouldn't withhold important information from doctors and patients about a drug product, and in this case, in particular, Zyprexa?

A. That's not what I said.

Q. Okay. Well, then, I'll ask you another question.

Do you agree you shouldn't withhold important information from doctors and patients about Zyprexa?

A. Without a specific reference to what you might mean by "important information," I'm not sure how to answer your question.

Q. One of the marketing roles of the Zyprexa sales force was to overcome obstacles presented by the doctors when they would ask questions about Zyprexa?

A. That's a phrase that is used in sales training as a way to help direct a sales representative in the context of a call.

Q. Part of the tool or channels of marketing for Zyprexa, was Lilly giving money to medical organizations?

A. There were medical associations that received that type of funding, yes.

Q. As part of the marketing activities for Zyprexa from Eli Lilly?

A. Yes.

Q. Tell the jury, please, those medical organizations or associations to whom money was given as part of the channel or tool in the marketing of Zyprexa.

A. The only two associations that come to mind are the American Psychiatric Association and the American Diabetes Association.
Q. How many millions of dollars was given to those organizations over the period of, let's say, 1995 to 2004 at the time you left?
A. I don't have any idea.
Q. It was millions, wasn't it?
A. I can't confirm that.
Q. Do you think it was in the millions?
A. I don't know.
Q. Mr. Bandick, I've handed you at the break what's marked as Bandick Exhibit No. 7.
Do you recognize this document?
A. Yes, I do.
Q. It is a document entitled the Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes. And it's published by the American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists and the North American Association for the Study of Obesity in 2004; is that correct?
A. It was published in Diabetes Care, and those four organizations are associated with it.

Q. By the way, did you attend this conference?
A. Yes, I did.
Q. Why were you selected to attend?
A. Many of the things that we -- we did involved a collaboration between marketing and medical.
Q. According to Table 2, which is directly in front of you, at a conference you attended, what second-generation antipsychotics carried the largest risk of weight gain and risk for diabetes according to Table 2?
A. According to this panel, clozapine and olanzapine, Clozaril and Zyprexa, had a higher relative risk for weight gain.
Q. And for diabetes?
A. And to answer the other part of your question, according to this table, they also identify clozapine and olanzapine as having a relatively higher risk for diabetes.
Q. Why don't you turn, now, sir, to page 598 in Bandick Exhibit No. 7, which is the Consensus Statement, and go to question No. 4.
Do you see that?
A. Yes.

Q. The question No. 4 reads: Given the above risks, how should patients be monitored for the development of significant weight gain, dyslipidemia and diabetes, and how should they be treated if diabetes develops, question mark.
Did I read that correctly?
A. Yes.
Q. The answer says: Given the serious health risks, patients taking SGAs should receive appropriate baseline screening and ongoing monitoring.
Did I read that correctly?
A. Yes.
Q. Do you agree with that?
A. Based on my conversations with Lilly clinicians, I believe that would be reasonable.
Q. And when did you form that belief?
A. I don't recall.
Q. What year?
A. Probably 2003.
Q. I've handed you what I've marked as Bandick Exhibit No. 9, which I'll represent to you is a 2005 PDR reference on Zyprexa.
Do you have that in front of you?
A. It appears that I do.

Q. Okay. Look at the precaution section, which begins on the fourth page of Bandick Exhibit No. 9.
Are you there with me?
A. I believe so.
Q. And there's a section in the precaution section entitled "Laboratory Tests," isn't there?
A. Yes, there is.
Q. My simple question was: In the precaution section of the label, is there any laboratory testing recommended for patients who take second-generation antipsychotics to have their fasting plasma glucose monitored?
A. Not under laboratory tests in the precaution section.
Q. Sir, let's go to the summary of the consensus statement, Exhibit No. 7, on page 600.
Do you see the summary, sir?
A. Yes, I do.
Q. Now, I'm going to skip down to the next paragraph. It says: These three adverse conditions are closely linked, and their prevalence appears to differ depending on the second-generation antipsychotics used. Clozapine and olanzapine are associated with the greatest

weight gain and the highest occurrence of diabetes and dyslipidemia.
Did I read that correctly?
A. That's what it says in this document.
Q. As the brand director of marketplace management for Zyprexa in the years you have indicated, do you agree with that statement?
A. Lilly disagrees with that statement.
Q. Do you have Exhibit No. 10 in front of you?
A. I do.
Q. You've seen this document before, have you not?
A. Yes, I have.
Q. When did you see this document?
A. I first saw this document when it was published in April, 2002.
Q. This document, it's dated April, 2002. It's Exhibit No. 10. Can you briefly describe for the jury what it is?
A. This is the English translation of a Dear Health Care Professional letter that was distributed to physicians in Japan following a label change for Zyprexa in Japan.
Q. What the Japanese government did is they

put a black-box warning on Zyprexa in Japan, didn't they?
A. It was comparable -- it was comparable to what in the U.S. we would call a black-box warning.
Q. And what they said -- and let me read a portion of this exhibit. It says: Emergency safety information regarding diabetic ketoacidosis and diabetic coma due to increased blood glucose during administration of an antipsychotic agent, Zyprexa tablets, olanzapine.
Since the marketing of this product in June, 2001, nine serious cases, parens, including two cases of death, closed parens, with hyperglycemia, diabetic ketoacidosis and diabetic coma have been reported for which causal relationship with this product cannot be denied, parens, estimated number of patients treated with this product, about 137,000 as of the end of December, 2001.
Did I read that correctly, sir?
A. Yes.
Q. Did Lilly change its label for Zyprexa in the United States consistent with what was required by Japan in April of 2002?

A. No, it did not.
Q. Did Lilly send doctors in the United States a Dear Doctor letter informing them about the equivalent of a black-box warning on the Japanese label in April, 2002?
A. I don't recall a Dear Health Care Professional letter being distributed on that topic.
Q. Have you ever informed the sales force of foreign regulatory actions concerning a black box on antipsychotics?
A. I don't recall an example.
Q. Well, let me see if I can refresh your recollection. I want to hand you what's been marked as Bandick Exhibit No. 11. Provide it to your counsel.
Can you tell the jury the date of this e-mail that you wrote?
A. October 18th, 2002.
Q. You sent this e-mail around the world, in essence?
A. That's true.
Q. And the subject is risperidone, which is Risperdal, cerebrovascular warning in Canada, right?

A. Yes.
Q. And it says, We would like to point out actual label changes such as the recent addition of a black-box warning pending to the Risperdal label in Canada.
A. In the context for that remark, the first part of the sentence is avoiding speculation on potential label changes because we thought that would be inappropriate. However, if there was an actual label change, that that would be something that would potentially be appropriate. And as you pointed out under 2 was to share selectively as appropriate. That does not represent a proactive, tell every customer you've got, if it came up, that would be something that could be cited as a fact.
Q. Do you think the actions concerning the equivalent of a black-box label change in Japan on Zyprexa? Do you see any inconsistency in your action concerning that action of Japan versus what you did concerning the Risperdal label in Canada?
A. I see them as very different situations.
Q. Do you see any inconsistency in what you did, sir, Mr. Bandick?

A. I can't evaluate the consistency or inconsistency. I see them as different situations.

MR. LEHNER: Your Honor --

MR. ALLEN: That concludes -- that concludes the State's offer of the testimony of Mr. Bandick, Your Honor.

MR. LEHNER: And I think Eli Lilly has some supplements to this that we'll play right now. Just a couple minutes, I believe.

THE COURT: Please.

CROSS-EXAMINATION

Q. (BY MR. ALLEN) So, in marketing the general summary of how you felt the brand compared to the other second-generation antipsychotics would accurately state that Zyprexa offers the best combination of efficacy, safety and ease of use; is that correct -- true?

A. It's a very broad statement. We wouldn't -- we wouldn't hold that position for every single patient. In comparing the major drugs out there, it's generally a reasonable statement. Again, not a verbatim that we would use in our promotion.

Q. Why don't you turn now, sir, to page 598

in Bandick Exhibit No. 7, which is the consensus statement, and go to question No. 4.

Do you see that?

A. Yes.

Q. The answer says: Given the serious health risks, patients taking SGAs should receive appropriate baseline screening and ongoing monitoring.

Did I read that correctly?

A. Yes.

Q. Well, did any letters go out from the medical affairs departments to your customers, be it hospitals, third-party payors, patients or doctors, informing them that Lilly believed as of 2003 that given the serious health risks, patients taking SGAs should receive appropriate baseline screening and ongoing monitoring?

A. There were materials that went out in the fall of 2003 with -- with those directions.

Q. What materials would those be?

A. Those materials were associated with a label change that occurred for all second-generation antipsychotics regarding association with hyperglycemia and appropriate screening and treatment of patients.

Q. Okay. Look at the precaution section which begins on the fourth page of Bandick Exhibit No. 9.

Are you there with me?

A. I believe so.

Q. And there's a section in the precaution section entitled Laboratory Tests, isn't there?

A. Yes, there is.

Q. Is there any recommendation in the precaution section of the label in 2005 suggesting that doctors or physicians monitor fasting plasma glucose?

A. No. There's language, however, that's in the warning section which is elevated, which would reflect even a greater level of awareness, that patients with an established diagnosis of diabetes mellitus who are started on an atypical antipsychotic should be monitored regularly for worsening of glucose control.

Q. This document, it's dated April 2002. It's Exhibit No. 10. Can you briefly describe for the jury what it is?

A. This is the English translation of a Dear Health Care Professional letter that was distributed to physicians in Japan following a

label change for Zyprexa in Japan.

Q. Did Lilly, in its marketing and/or sales department, inform its sales representatives that they needed to tell doctors and patients of the equivalent of a black-box warning being placed on Zyprexa in Japan?

A. Lilly did provide -- provide background information to the U.S. sales organization for use in discussions with physicians if the question arose. Lilly sales representatives were not in direct contact with patients. So, to answer your question, information was made available through the sales organization for physicians.

Q. Did you send out a document that says: While we do not want to speculate on potential label changes, ours or competitors, we would like to point out actual label changes such as the recent addition of the equivalent of the black-box warning in Japan to the Zyprexa label regarding diabetic ketoacidosis, coma and death. Did you say that? Did you send out anything like that?

A. We did not send out a document that said we would like to point out that an actual label

change occurred with the equivalent of a black box for Zyprexa in Japan. The reason for that was that we didn't believe that the data warranted that outcome.

Q. When a label change was made to your competition, Risperdal in Canada with a black box concerning CVAE, cerebrovascular events, you sent out a worldwide e-mail and said to the recipients, we'd like to share the black-box warning on the label.

I mean, can you answer that question. There wasn't an answer on the record to that one? What was the answer to that question?

A. We did not intend, nor did we communicate broadly to physicians about the Risperdal label change in Canada on CVAE. We informed members of sales and marketing in other markets of the change. We advised them to share the information selectively as appropriate, and similarly, we provided background information to the U.S. sales organization and to other affiliates on the label change in Japan and provided them with Lilly's view on why we felt the decision was inappropriate.

MR. LEHNER: That concludes those portions, Your Honor.

MR. ALLEN: Thank you -- excuse me. Thank you, Your Honor. I have some offers.

Your Honor, the State of Alaska offers AK2133, e-mail dated October the 18th, 2002 from Michael Bandick to the U.S. Sales Force Risperidone -- Subject, Risperidone, cerebrovascular warning in Canada.

MR. LEHNER: Consistent with your previous rulings.

THE COURT: AK2133 is admitted with all prior objections preserved.

MR. ALLEN: Your Honor, the State of Alaska offers AK10003, the 2005 PDR reference on Zyprexa.

MR. LEHNER: No objection.

THE COURT: AK10003 that hasn't been previously admitted is admitted. 10003.

MR. ALLEN: Your Honor, using belts and suspenders is why I'm doing this one. I believe this is admitted. The State of Alaska uses AK2368, the consensus statement. I'm certain that's in.

THE COURT: It should be if it

isn't. Hold on a second.

THE CLERK: That was one we had questions on yesterday. We're not sure if it's admitted.

THE COURT: 2368 is admitted.

MR. ALLEN: I think -- I wanted to make sure.

Your Honor, again, belts and suspenders but I think there's been some conversations. The State of Alaska offers Exhibit 320, which is the Japanese label change and Dear Doctor letter, Your Honor.

THE COURT: Subject to my --

THE CLERK: Admitted.

THE COURT: It's already admitted. AK320 is already admitted.

MR. ALLEN: Your Honor, State of Alaska, we offer AK1111, Issues Management Planning Diabetes.

THE CLERK: Admitted.

THE COURT: AK1111 has previously been admitted.

MR. ALLEN: I do not believe it's been published.

THE COURT: Let's do

admissions first and then we'll --

MR. ALLEN: Okay. I don't want to argue.

And, Your Honor, I have a bill to take up, but I think we'd prefer to move on, I think, to present the other depositions.

THE COURT: Okay.

MR. ALLEN: And I'd ask to publish to the jury AK2133, AK10003, and AK2368, the consensus statement. There was some question whether it was in. I can't imagine that it hasn't.

MR. LEHNER: Your Honor, before this is actually published to the jury, can we just have a brief conference?

THE COURT: You may.

(Bench discussion.)

MR. LEHNER: And whether publication to the jury -- actually, my understanding of the scientific treatises and that don't go back to the jury during their deliberation. They can be admitted into evidence. I don't know what the distinction --

THE COURT: The question is some of these things were being admitted for notice, to

the extent that they were admitted for notice, that Lilly was on notice, that can go back to the jury.

MR. ALLEN: We have found this in the files. These have been ruled upon and discussed.

THE COURT: I mean, to the extent you're just offering a publication that wasn't in the Lilly files and you're questioning an expert on it, I wouldn't let it go back to the jury. To the extent this comes from Lilly's files and to the extent Lilly was on notice of these issues, it's admitted.

(End bench discussion.)

THE COURT: 2133, 10003, and 2368 can be published to the jury.

MR. ALLEN: And, Your Honor, 320, Japanese --

THE COURT: Has that been published? I don't know either.

MR. ALLEN: I can't remember it being published.

THE COURT: You may publish it again, but could you try to keep track, Mr. Allen. I'm willing to have things published

once.

MR. ALLEN: Mary Beth tells me it has not been published.

THE COURT: The Japanese warning.

MR. ALLEN: The Japanese warning. Thank you, Your Honor. The State of Alaska -- can I proceed, Your Honor --

THE COURT: You may. Again, do either of the parties find Beasley, Volume 2?

MR. LEHNER: I think we asked for it, but it hasn't yet arrived, Your Honor.

THE COURT: Okay.

MR. ALLEN: May I proceed, Your Honor?

THE COURT: You may.

MR. ALLEN: Your Honor, the State of Alaska would call by oral videotaped deposition Dr. Gary Toleffson, product group president for neuroscience division of Eli Lilly, deposition taken November 6th, 2006. His deposition will last 20 minutes, Your Honor.

VIDEOTAPED TESTIMONY OF GARY DENNIS TOLEFFSON, M.D.

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

A. Gary Dennis Toleffson.

Q. And are you -- you were formerly employed as an executive at Eli Lilly, correct?

A. Correct.

Q. You are a medical doctor, correct?

A. Yes.

Q. And you also hold a Ph.D. in psychopharmacology; is that correct?

A. Yes.

Q. And I believe you went to undergraduate school, graduate school and medical school at the University of Minnesota; is that correct?

A. That's correct.

Q. And I believe you're board certified in psychiatry; is that correct?

A. Yes. I passed the American Board of Psychiatry and Neurology exams.

Q. And you left Eli Lilly in 2004; is that correct?

A. Yes, sir.

Q. What was the date that you left in 2004?

A. I believe it was April 1st.

Q. And what was your title when you left?

A. Lilly distinguished research fellow and vice president Lilly Research Laboratories.

Q. And at the time you left -- well, during

what period of time that you were at Lilly did you have any responsibilities for Zyprexa?

A. I assumed some responsibility for Zyprexa probably towards the end of '94 into the early part of '95, somewhere in that window.

Q. Okay. And then how long did you continue to have any responsibilities with Zyprexa?

A. Up through the late fall of 2000.

Q. Can you list and describe briefly the various positions that you held at Lilly after coming to the company in 1991?

A. From '91 to late '94, I was an executive director, clinical investigation, oversight for Prozac. In late '94, early '95, became the product team leader for Zyprexa. Continued in that role until probably the beginning of '99, at which time I became product group president for the neuroscience division and held that through, as we established earlier, the fall of 2000.

Q. Between 1994 and 1999, when you were the product team leader for Zyprexa -- well, what did that -- what did that role as product team leader involve?

A. I was overseeing the global clinical

development and global commercial planning for the molecule up to launch and then in the post-approval environment as well.
Q. And so you would have had medical people reporting to you?
A. Yes.
Q. And marketing people?
A. Yes.
Q. From your perspective, was there any particular person or group within your organization that was responsible for identifying any safety issues with respect to Zyprexa?
A. At what time frame?
Well, I think the issues -- it never resided in a single individual. It's a collective responsibility and obligation of the entire team. When I was leading the team, I would say it resided, as far as maybe point people, Dr. Beasley and the chief medical officer. That was Dr. Breier.
Q. Okay. And so it would be fair to say that you relied on both Dr. Beasley and Dr. Breier to keep you apprised of any potential safety issues with Zyprexa?
A. Yes.

Q. Okay. Back in 1995, before Lilly submitted its NDA to the FDA, you personally reviewed the -- the data from those studies, did you not?
A. What studies? May I clarify?
I would have reviewed at least summary reports of all the studies.
Q. Okay. And when was it that you first became aware that Zyprexa might be associated with hyperglycemia and diabetes?
A. I think that probably at the time of the submission there were cases of individuals that had hyperglycemia. And, in fact, in some of the longer-term data, there may have been individuals that had confirmation or new diagnosis of diabetes. So, in the sense of did anyone who was participating in a study have hyperglycemia or diabetes, it would have been during the assembly of the new drug application.
Q. Are you aware that Dr. Beasley has testified that you and he and others, would have reviewed computer analyses of data from the HGAJ study back in June of 1995?
A. We certainly would have reviewed analyses from all the studies --

Q. Okay.
A. -- and looked at them not only individually, but collectively.
Q. Okay. And so it is true, as Dr. Beasley said, that you and he both would have reviewed computer printouts of data from the HGAJ study back in 1995; is that correct?
A. Amongst others.
Q. Dr. Toleffson, do you recall that shortly after Zyprexa was launched in October of 1996 you were accused by the FDA of making false and misleading statements about the safety of Zyprexa?
A. I remember seeing a document that suggested that I may have perhaps overstated.
Q. Well, the FDA didn't just suggest that; they flat out said that you made false and misleading statements, didn't they?
A. I don't believe so, but I'd have to review the document.
Q. Let me show you what's been previously marked as Plaintiff's Exhibit 1169 -- in any event, this exhibit is a letter from Kenneth Feather, the senior adviser in the division of drug, marketing, and advertising communications

at FDA, to Charles Perry, Jr., director of pharmaceutical communications and compliance at Eli Lilly, and it's dated November 14, 1996.
Do you recall seeing this letter, sir?
A. Yes, I do.
Q. If I could direct your attention to the first page. In the first paragraph, the letter states: This concerns a number of labeling -- well, let me back up for a second.
If the date of this is November 14, 1996, that would have been just weeks after Zyprexa was launched here in the United States; isn't that correct?
A. I believe so.
Q. Okay. Directing your attention to the first paragraph, the letter states, quote: This concerns a number of labeling pieces for Zyprexa identified as a multi-page detail aid, OL0026, stack grams identified as OL0077 and OL0078, a letter to the California Department of Health Sciences assumed to be an example of similar letters to other states with an attached background, and a John Q. Public letter, all submitted as required with the form FDA 2253 and

also found during normal surveillance activities. This also concerns other promotional activities such as an interactive telephone conference held on or about October 2, 1996. The Division of Drug, Marketing, Advertising and Communications, DDMAC, considers these promotional labeling pieces and promotional activities to be false or misleading and in violation of the Federal Food, Drug and Cosmetic Act.

Do you see that language, sir?

A. I do.

Q. And did Mr. Perry advise you that the FDA had written to him in early November stating that the promotional labeling pieces and promotional activities relating to Zyprexa were false and misleading?

A. To my recall, Mr. Perry had mentioned to me the specific comment that was made by DDMAC on page 4 regarding an interactive teleconference I had with stock analysts on October 2nd, 1996. I don't recall mentioning the other pieces since that would be probably a U.S. affiliate related activity.

Q. Okay. Directing your attention to the following paragraph on page 1, the first part of

it states, quote: The promotional campaign, including the above-identified labeling pieces and others submitted with the form 253, is lacking appropriate balance, thereby creating a misleading message about Zyprexa. The promotional materials emphasize efficacy data, but do not provide sufficient balance relating to adverse events and cautionary information.

Do you see that language?

A. I do.

Q. And were you advised of that by Mr. Perry?

A. I don't recall that. Again, it would not have been my area of responsibility. So it would not have been necessarily expected that he would have said that to me.

Q. We were talking about the physician needs to consider both the benefits and the risks of a drug before he makes the decision as to whether or not he's going to use it in his patient, correct?

A. Correct.

Q. And here in this letter from the FDA, the FDA was saying the promotional materials emphasize efficacy data, but do not provide

sufficient balance relating to adverse events and cautionary information, correct?

A. That is what the sentence says.

Q. And when someone does a risk/benefit analysis, what they do is they balance the risks with the benefits, correct?

A. Correct.

Q. Okay. And what the FDA was saying here was that the information you were giving was not balanced, correct?

A. It would appear that there were some materials being used where that balance wasn't optimal.

Q. Okay. If I can direct your attention to the fourth page. On this page and the following page are some items that the FDA objected to that involved you in particular, correct?

A. Correct.

Q. Okay. And at the top of the page they note that there was an interactive teleconference held on or about October 2, 1996 by Dr. Gary D. Toleffson, vice president of Lilly Research Laboratories, correct?

A. Correct.

Q. And who were the other participants on

that teleconference?

A. This was a teleconference with a number of different investors or prospective investors in the company. These were not healthcare providers.

Q. And these teleconferences that you had with those investors were ultimately written about in various press articles, correct?

A. I do -- I do not know whether they were or were not. It wouldn't be a matter of routine to do that.

Q. They noted, the FDA noted that there were about six items that they characterized you as being misleading, correct?

A. Not all of them are ascribed to be misleading. Some of them in the eyes of DDMAC were.

Q. Well, at the top of the section on page 4 it says, quote: The interactive teleconference held on or about October 2, 1996 by Dr. Gary D. Toleffson, vice president of Lilly Research Laboratories is misleading in the following particulars, correct?

A. That's what it says.

Q. And then following that there is a

listing of six different items, correct?
A. That's correct.
Q. And I'm not going to go through all six of them. I'm not going to take the time to do that but there are a couple I'd like to discuss.
Item 1, it states, Dr. Toleffson states that therapeutic effects of Zyprexa are maintained over at least one year. The approve label effectiveness of the product was only established in short-term six-week studies, therefore, for any use over six weeks, the physician should periodically reevaluate the long-term effectiveness of Zyprexa. However, this cautionary information for the indication is never presented in the teleconference.
Did I read that correctly?
A. You did.
Q. And am I correct that the labeling that came out when the drug came on the market noted that the effectiveness of the product was only established in short-term six-week studies?
A. The approved labeling at the time of launch, that's correct.
Q. If I could direct your attention to item 6 -- pardon me -- item 5. In that portion of the

letter the FDA stated, quote: When asked a question about weight gain, Dr. Toleffson's response misleadingly turned an adverse event into a therapeutic benefit. He states, quote: So we went back and analyzed our data and saw that the vast majority of weight gain reported initially as an adverse event, in fact, was weight gain occurring in patients who had baseline before starting treatment, had been below their ideal body weight.
So we really look at this with the majority of patients as being part of a therapeutic recovery rather than an adverse event. And that data, I think, is fairly compelling because it was included in our labeling. Emphasis added.
Noting that the FDA has put in bold font some of that what I just read, correct?
A. Correct.
Q. Okay. And then they went on to say, quote: The information on weight gain was indeed included in the approved labeling but as an adverse event, not a therapeutic benefit. Since the product was approved at the time of this teleconference, Dr. Toleffson, knew or should

have known what information the approved labeling contained and in what section it appeared. His statements were, therefore, false and misleading.
Did I read that correct?
A. You read it correct.
Q. Would it be fair to say that Lilly wanted Zyprexa to be a blockbuster drug?
A. I don't think that anyone wants a blockbuster drug. I think one wants a drug that's going to benefit patients and address unmet medical needs. To what degree it does that, it may or may not be economically successful.
Q. Well, you wanted -- it was the strategic intent of Lilly to have Zyprexa be the largest-selling psychiatric drug in history; isn't that correct?
A. If the drug lived up to its potential in delivering benefits for patients, it had that possibility. So that was certainly an ambitious goal, but one that was achievable.
Q. In fact, it was your intent that Zyprexa would be the largest-selling psychiatric drug in history as early as 1997; is that correct?
A. We definitely tried to do clinical

studies to demonstrate where Zyprexa was beneficial in the treatment of psychosis, and it was then up to prescribers whether or not they wanted to use the drug and whether or not it became ultimately an economic success or not.
Q. Let me hand you what's been previously marked as Zyprexa MDL Plaintiff's Exhibit 6100.
For the record, this is a 64-page document. Appears to be a PowerPoint presentation. It has a -- title on the first page entitled Zyprexa Product Team, four-column summary. Then below it has the name Gary D. Toleffson, vice president Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, Indiana.
Do you recognize this document, sir?
A. I do.
Q. And what is it?
A. It's an annual strategic planning exercise that each and every product at Lilly went through.
Q. And to whom would this be presented?
A. It was presented to the head of the product group area. At that time it was an

individual named John Lechleiter.
Q. On page 37, there's a reference, year to date October, '97. And I was wondering if that would help you place this in time.
A. Yeah. It looks like it was probably around, as you said, '97/'98. And it's about the time, I think, that Dr. Lechleiter took over responsibility for the pharmaceutical product group. So I'm thinking that that's probably -- his staff is where this document was presented.
Q. Okay. And would he have been present at that meeting also?
A. Yes.
Q. Okay.
A. I would imagine.
Q. Getting back to Exhibit 6100. I believe you said you would have presented this at an annual meeting which would have been attended by Mr. Lechleiter and others, correct?
A. Correct.
Q. And what was the purpose of that annual meeting?
A. This was reviewing a proposed product strategy and summary for the upcoming business year.

Q. Okay. And if, indeed, this was prepared sometime in '97, and we're both assuming that it was; is that correct?
A. Give or take a year. I'm not sure.
Q. It would have been about a year or so after Zyprexa was on the market, correct?
A. It appears that way.
Q. Okay. The title on that page is Strategic Intent. Zyprexa will be the world's No. 1 neuroscience pharmaceutical in history, correct?
A. Yes.
Q. And was that a strategic intent that had been developed by you, or was it the consensus that that should be the strategic intent?
A. That was the strategic intent of the marketing group.
Q. Do you recall that by 2000 the price for Zyprexa was approximately $10 per 10-milligram pill?
A. I would have said more around $8, but ballpark.
Q. Did there come a time that you recall that Zyprexa did reach a price of $10 a pill?
A. I don't recall that. It's possible.

Q. You just don't know for sure one way or the other?
A. Depends on, you know, how many -- how many pills you're taking.
Q. What kind of discount you can get and so forth?
A. I mean, there are a lot of variables, but that's probably in the ballpark.
Q. Okay. You saw Zyprexa as a profound corporate opportunity, correct?
A. I saw it as a profound opportunity for patients and, in turn, a profound corporate opportunity as well.
Q. If I could direct your attention to the last physical page. There's a summary on that page; is that correct?
A. Correct.
Q. And several bullet points?
A. Uh-huh.
Q. And one of those bullet points is Zyprexa is a profound corporate opportunity, correct?
A. Correct.
Q. And this was your presentation to your superiors, correct?

A. That's correct.
Q. You said that -- earlier that you probably had some interaction with John Lechleiter about this issue with hyperglycemia and Zyprexa. Do you recall how often you would have such communications with him?
A. We met at least weekly. I would expect it was a topic that was discussed to some degree probably on a regular, recurring basis.
Q. Okay. Was there a regularly established meeting that you would have with Mr. Lechleiter?
A. Yes.
MR. ALLEN: Your Honor, that concludes the State's offer of the testimony of Dr. Gary Toleffson. And in accord with that, Your Honor, I've been informed by Ms. Rivers, Mary Beth, we offer AK1169, the November, 1996 letter from the FDA to Eli Lilly that was discussed in Dr. Toleffson's deposition.
MR. LEHNER: Your Honor, consistent with your prior rulings.
THE COURT: AK1169 is admitted with all prior objections preserved.
MR. ALLEN: We also -- the State of Alaska also offers, Your Honor, AK6100, the

Zyprexa Product Team four-column summary discussed in Dr. Toleffson's deposition.

THE COURT: Also subject to prior objections, AK6100 is admitted.

MR. ALLEN: We ask, Your Honor, to be allowed to publish these to the jury. And whatever the Court wants to do; it may be a good time to break.

THE COURT: That's fine. Why don't we have those documents published to the jury, and just remind me, what do you have left as far as --

MR. ALLEN: Your Honor, we have Denice Torres. Let me see. I can give you the exact time -- Ms. Denice Torres is 15 minutes and 57 seconds, and we have Dr. Allen Breier, the head of the product team, which is approximately 45 minutes. That would conclude our witnesses and then we'd have some issues to take up with the judge, introduction of documents, but after -- we've got approximately -- an hour.

THE COURT: Why don't we take a break at this point. We'll be in recess for about 15 minutes.

MR. ALLEN: Thank you, Your Honor.

THE CLERK: Off the record, Judge?

THE COURT: No, stay on the record. I need to just briefly talk to the attorneys.

(Jury out.)

THE COURT: Just briefly, I've gone over the counterdesignations that the State has made to Eli Lilly's designations. My understanding these counterdesignations will then be played after Eli Lilly was done playing the Toleffson designations in their case in chief.

MR. ALLEN: I think you are talking Breier.

THE COURT: No, I'm talking Toleffson.

MR. ALLEN: I'm sorry.

THE COURT: I haven't received Lilly's response to those, but I'll just preliminary say nothing jumps out to me as objectionable. Wojcieszek, the Plaintiff has objected three designations that Lilly has made and those are all overruled. And then the Plaintiff has offered counterdesignations and again I haven't gotten Lilly's response to the counterdesignations. Subject to receiving those, nothing jumps out at me.

Eski, I haven't had a chance to look at yet, and I'm waiting for Volume 2 of Beasley to take look at.

MR. LEHNER: It should be here. And I think, Your Honor, there's really no way we're going to get to that part of Beasley today, even if we started him. I don't think we're going to start him in light of --

THE COURT: We'll be coming back at about 11:20 or so, 12:20, we'll dismiss the jury and take up things. We'll see.

MR. ALLEN: I do have some --

THE COURT: There will also be some exhibits to get in. We'll see.

MR. ALLEN: I do have a bill to make on Bandick. I have documents to get admitted and so -- it's up to the Court, obviously.

THE COURT: We'll see where we -- if it's close to 1:30, we'll wait until tomorrow to deal with Dr. Beasley. But to the extent I can use this time to review those objections, I'd rather review the objections and deal with -- everybody can get it ready rather than waiting for tomorrow to get a ruling from me which won't

give --

MR. ALLEN: Yes, sir. I apologize to the Court and I do understand. I'm going to talk to Ms. Rivers, who is working her brains off. I'll get that over here.

THE COURT: We'll be in -- did you have something else, Mr. Lehner?

MR. LEHNER: No, that's it, Your Honor.

THE COURT: We'll be in recess, then.

THE CLERK: Off record.

(Break.)

(Jury in.)

THE COURT: Please be seated.

We are back on the record and all members of the jury are present. Mr. Allen.

MR. ALLEN: Thank you, Your Honor. Your Honor, at this time, we would call to the stand by oral videotaped deposition, Ms. Denice Torres, Executive Director for Global Marketing for Zyprexa whose deposition was taken in December of 2006.

Your Honor, there's also a technical problem with the tape that -- at the

time it did not record. So we will have to have myself read the questions and Ms. Rivers read the answers for a brief time period.

THE COURT: When that happens, there's an oath that we give to readers, so if Ms. Rivers would like to take the oath now.

MR. ALLEN: I bet she'd like to.

(Mary Beth Rivers sworn by the clerk.)

THE CLERK: State your name.

MS. RIVERS: Mary Beth Rivers.

THE CLERK: Spell your last name.

MS. RIVERS: R-i-v-e-r-s.

THE COURT: Ms. Rivers, I'll have you come up here just so we get a good recording.

MS. RIVERS: Yes, sir.

VIDEOTAPED TESTIMONY OF DENICE TORRES

Q. (BY MR. ALLEN) Good morning.
A. Good morning.
Q. How are you?
A. Good.
Q. Would you tell the jury your name, please?
A. Denice Torres.
Q. You're very familiar with the law as it

concerns marketing of drug products here in the United States, aren't you?
A. I am.
Q. Now, in preparing for the deposition, I looked at some documents to determine what your work history and background was, and I'm going to go over that in some more detail. But just for the record, for the jury, what was your title at the time you left Eli Lilly at the end of December of 2004?
A. Executive Director Global Marketing.
Q. Executive Director of Global Marketing for what product?
A. Zyprexa and then for a very short time period Symbyax.
Q. Symbyax is a combination product of Zyprexa and what else?
A. Prozac.
Q. And Prozac is also a Lilly product, right?
A. That's correct.
Q. You worked at Eli Lilly from 1990 through December of 2003; is that right?
A. That's correct.
Q. You're a lawyer?

A. Yes.
Q. And what products were you involved with prior to 2000 when you became involved with Zyprexa?
A. Evista, growth hormone. Prior to that, I was in charge of the market research group. I've been in managed care, new product planning, business development, I was a sales representative for two years.
Q. Okay. Prozac was -- at the time you were a sales representative, that was a No. 1 selling product for Eli Lilly, was it not?
A. Yes.
Q. It was a blockbuster product, was it not?
A. It was a blockbuster at the time.
Q. Well, we know Zyprexa was a multi-billion dollar blockbuster for Eli Lilly. We know that?
A. Zyprexa was a blockbuster and it was multi-billion, yes.
Q. By 2003, what was Zyprexa's sales worldwide?
A. I -- I don't remember for sure, but according to this document, it says -- it was

approaching $4 billion, globally.
Q. $4 billion, and what was -- wasn't Zyprexa by early 2003 not only a $4 billion worldwide sales drug, but one of the fastest growing drugs in terms of percentage sales in the world?
A. That's what it says here.
Q. I think in 2003, I -- global marketing for Eli Lilly -- wasn't by 2003 Zyprexa either the third or fourth largest selling drug product in the world?
A. Yes.
Q. So, it just goes without saying, Zyprexa was a very important financial product to Eli Lilly?
A. Yes.
Q. I handed you, prior to the start of the deposition -- I think you had it in front of you -- as Exhibit No. 1 a document entitled -- that we got from your files -- Restructuring of the Marketing Component of the Zyprexa Product Team. You've looked at that, have you not?
A. Yes, I have.
Q. Now, as I went through this document and described the members of this new restructured

global marketing team who had as one of its goals $6 billion in annual sales, right?
A. That was one of its goals, yes.
Q. You were in senior management at Eli Lilly in regard to Zyprexa?
A. In regard to Zyprexa, yes.
Q. What does the company -- or why did Eli Lilly have sales representatives?
A. One of the -- the one big reason is that in many therapeutic areas, you know, whether Prozac, or even Zyprexa, prescribers, physicians may not know about -- you know, they may not have learned as much in medical school about certain conditions, et cetera, because they can't be experts in everything. And so what sales representatives can do is help bring information about a therapeutic area, about treating customers -- treating patients or actual drug, bringing that information to those customers.
Q. The role of the sales representative is to give doctors truthful and accurate information about the risks and benefits of the product; is that true?
A. That's true.
Q. Do you recall being told -- any

presentations by Dr. Charles Beasley?
A. I was only in one meeting with Charles Beasley.
Q. Do you recall that meeting?
A. Only because he was swearing. Someone said that was his personality, but that's what I remember about him.
Q. Did Dr. Beasley ever tell you that Zyprexa was the worst offender in regard to weight gain in regard to second-generation antipsychotics other than clozapine?
A. No, I never had a one-on-one conversation with Charles Beasley.
Q. Did anybody tell you at Eli Lilly that Zyprexa's weight gain profile, the average weight gain profile was double that of Risperdal?
A. I don't believe so.
Q. Do you recall anybody from the medical or clinical department at Eli Lilly telling you that the animal model testing indicated that Zyprexa when administered on diet-restricted rats, that is -- in other words, food intake did not increase, that those animals still gained weight on Zyprexa? Were you ever told about that?

A. I don't remember that.
Q. As director of global marketing, were you ever told that there was statistically significant findings of elevated -- elevated blood glucose levels in the HGAJ study for individuals who took Zyprexa?
A. I don't remember the name of the study, so I wouldn't remember the specifics.
Q. So as director of global marketing, you were not told about any epidemiologic information or data supporting an association between second-generation antipsychotics, including Zyprexa, and diabetes?
A. I -- I'm sorry. I don't remember that.
Q. Thank you. Let's go to Exhibit No. 2, the Zyprexa Product Team, Answers That Matter. I'm going to skip to the page with the heading, The Chance to Make History. Do you see that? The Chance to Make History. All right. Are you there?
A. Yes.
Q. This next to last one, I'm skipping down to No. 3. It doesn't look like it says anything about science. It says, Zyprexa, the first team with the opportunity to set all industry

commercialization standard for the most successful pharma brand in history.
What does that mean?
A. The commercialization would be the product offering to the customer. So the -- in order to submit the -- or in order to be a standard for commercialization, you'd have to be outstanding in understanding your customers, understanding your customer needs and delivering value to those customers, and doing all those things right would be -- we would be incredibly successful financially, yes.
Q. Can you read that out loud for the jury, please?
A. The company's betting the farm on Zyprexa. The ability of Eli Lilly to remain independent and emerge as the fastest growing pharma company in a decade, depends solely on our ability to achieve world class commercialization of Zyprexa. If we succeed, Zyprexa will be the most successful pharmaceutical product ever, we will have made history.
Q. Straight Talk. What's at stake? The company's betting the farm on Zyprexa, the ability of Eli Lilly to remain independent, i.e.,

avoid a takeover and emerge as the fastest growing pharma company of the decade depends -- what's that word, solely?
A. That's what it says.
Q. You knew in marketing that what the label said on the product could affect the sales of the product, right?
A. Sure, could a label affect the sales? Yes.
Q. How long did you know that?
A. How long have I known the label --
Q. Could affect the sales.
A. Gosh, 15 years.
Q. Ever since you were at Eli Lilly?
A. Yeah.
Q. You personally wrote down in memoranda that label changes on Zyprexa could threaten Zyprexa's sales; is that right?
A. Yes.
Q. 2005 through 2007 --
MR. ALLEN: Is this it?
Okay. Your Honor, I think that was cut off. We were discussing the Zyprexa global brand plan written or she was responsible for for 2005 and 2007. Now I need to get my thing to

read.
THE COURT: And as you read it, could you just give us line and page citations for the record?
MR. ALLEN: Yes, sir, I will. Mary Beth, we're going to section -- actually 33 here, Page 241. Your Honor, I'm starting -- we're starting at 241, Line 19. Let me know when you're ready, Mary Beth. It's actually section 33. The tape is broken earlier than they thought. Mary Beth, you need to make sure to --
MS. RIVERS: All right.
MR. ALLEN: This first part will be 241 -- can I give it to you at the end --
THE COURT: Either way, as long as we have a clear record.
MR. ALLEN: I'll give it to you. Thank you very much, your Honor.
All right. Mary Beth, we'll start at section 33, okay?
MS. RIVERS: Okay.
Q. Question: And you were in charge of preparing this document sometime in 2004?
A. Yeah, it would have been 2004.
Q. But isn't it true that the marketing of

the product is supposed to be defined by the indications?
MS. RIVERS: Sorry, I have a different transcript, Mr. Allen.
MR. ALLEN: All right. Let me get it from the videographer. I apologize, Your Honor.
You with me, Mary Beth?
MS. RIVERS: I think so.
Q. But isn't it true that the marketing of the product is supposed to be defined by indications?
A. Sir, the word there is market and not marketing with atypicals. Basically, what this is saying is that, as we talked about earlier, you could have 30-something percent off-label down. That is still the atypical. The drug -- basket of uses for the drug. That all equates to the total number of sales. Nowhere does it say that this is -- that this plan is meant to capitalize on the sum total of what is used for the drug. All it is saying is that the market for -- excuse me -- atypicals, if you took the basket of them, by and large is defined by the total usage of those drugs.

Q. Under the warnings section of the 2003 PDR, is there a warning about weight gain, diabetes, diabetes associated with weight gain or hyperglycemia?
A. Not in the warnings section.
Q. In the 2003 PDR, in the warnings section or the contraindications section or the precautions section, or in any section of this PDR, is there a statement that doctors should monitor blood glucose levels on patients on Zyprexa?
A. No, I don't believe so.
Q. Didn't you at Eli Lilly know, if you truly warned about diabetes and hyperglycemia, it would affect your sales? Didn't you know that?
A. Did we know that if there was a warning for diabetes that that can impact sales? Is that the question?
Q. Yes, ma'am.
A. Sure. Yes.
Q. Can you remember or tell this jury when you knew that a warning about diabetes or hyperglycemia, when you knew that warning would impact sales in regard to Zyprexa? Can you tell us an approximate date or year?

A. I think, as I mentioned earlier I -- no, a date or year, absolutely not. I could have said that the first day I started work that, you know, again, something in the warning has a potential to impact sales.
Q. Ma'am, I'm going to hand you Exhibit 15, which is an e-mail you sent. Look at the very top. Is this e-mail from Denice Torres -- do you see Denice Torres sent this e-mail? That's you, right, ma'am?
A. Did I send the -- it looks like I forwarded an e-mail.
Q. Now, the subject line is Issues Update, and I want to read this, quote: I wanted to take this opportunity to -- to give you a brief update on the current state of affairs with regards to the issues facing Zyprexa focusing mainly on the diabetes, closed quotes.
Did I read that correctly?
A. You did, sir.
Q. What is this? Mr. Fiola is referring to quote, comparable rates, closed quotes.
What is comparable rates?
A. That was an aspect of communication with the physician.

Q. By the way, when you use, quote, comparable, closed quotes, what does comparable mean to you?
A. By and large, in the same category.
Q. That's the message you were giving doctors?
A. Comparable rates.
Q. Right. In fact, if you look at page 2, do you remember the tag line? I didn't come up with that myself. This is Mr. Fiola, who worked in marketing. He says, quote, on the commercial front, our tag line has been comparable rates, closed quotes, right? Quote, tagline, closed quotes; is that the word he uses?
A. It's an inappropriate use of the word, but it is the word he used.
Q. One thing leads to another --
A. Not necessarily.
MR. ALLEN: This is something, do you all want this in there?
Q. Hip --
A. No, a lot of people are obese, significantly overweight and do not have diabetes, so that's an incorrect mischaracterization of casual -- causal effect

with diabetes and weight.
MR. ALLEN: Your Honor, that concludes reading. I'll give you page and line. Are you ready -- let Mary Beth come back.
Thank you, Mary Beth.
Q. Ma'am, I'll hand you what's been marked as Exhibit No. 20. It was a neuro sales operation neuroscience retail action plan. This one came from Mr. Jordan's files. It says: The challenge, I need your leadership. The corporation needs your leadership at this time. Your leadership is needed in a massive way and in a way that you will look back on as a defining moment in your leadership careers, all of you. Going to the next page. The challenge, our business with Zyprexa, the heart and soul of this corporation, the engine room, the best little health product on this planet is faltering, slowing and the slowdown has been a sudden one.
Do you recall that occurring in 2003, ma'am?
A. The -- do I recall --
Q. Zyprexa sales suddenly began to slow and falter in 2003?
A. I don't recall the specifics of the

sale -- sales curve. There was a decline. I don't remember when they started or what the abruptness was.
Q. You actually prepared, as a marketing director, the Zyprexa global brand plan for 2004 and 2005, did you not, Exhibit 23?
A. Yes.
Q. And the category of worried patients will develop hyperglycemia and diabetes, that's Zyprexa; is that correct?
A. Yes.
Q. Worry patients will gain too much weight. That's Zyprexa; am I correct about that?
A. There's a high association and then you have other associations, yes.
Q. Another high association is worry they will develop hyperglycemia and diabetes, correct?
A. Yes.
MR. ALLEN: Your Honor, we also have the reading of the one section. I can do it.
THE COURT: Go ahead.
MR. ALLEN: This is Page 136, Line 6 through 15.
Question: Wasn't the majority of

the use of Zyprexa in the United States off-label?

Answer: There was a good portion. I don't -- I don't remember the exact numbers. I don't remember it being the majority.

Question: Can you give the jury your best estimate, please?

Answer: Maybe 30 to 40 percent.

That concludes our offer from Ms. Torres, Your Honor. I think the Defendants have something to offer and then we have some documents.

MR. LEHNER: Correct, Your Honor. We have a brief clip.

THE COURT: Please.

CROSS-EXAMINATION

Q. (BY MR. ALLEN) Let's go to Exhibit No. 2, the Zyprexa Product Team, Answers That Matter. I'm going to skip to the page with the heading The Chance to Make History.

Do you see that? The Chance to Make History.

All right? Are you there?

A. Yes.

Q. By the way, I think it would help to

tell the jury in direct language so they understand it, because when they look at your testimony, what is the Zyprexa product team?

A. When I joined the team, the product team were a group of individuals with different functions that were responsible basically for clinical studies. There was the medical portion of the team, a regulatory portion of the team, I believe reporting in to the product team leader, which was Alan Breier. So, medical, regulatory, marketing and the whole clinical study function.

Q. Does it appear that the company, being Eli Lilly, in order to make history and to commercialize Zyprexa, under the direction of Dr. Alan Breier was betting the farm on Zyprexa?

A. Was the company betting the farm on Zyprexa. I think I've answered that before. Short-term it was very successful, it was very important to the company. But betting the farm I don't think is accurate. It would mean that all resources were going to Zyprexa, and that was not the case.

Q. You knew in marketing that what the label said on the product could affect the sales of the product, right?

A. Sure. Could a label affect the sales? Yes.

Q. How long have you known that?

A. How long have I known the label --

Q. Could affect the sales.

A. Gosh, 15 years.

Q. Ever since you were at Eli Lilly?

A. Yeah.

Q. Is that just basic core concept knowledge in the marketing department at Eli Lilly?

A. Yes. Were potential label changes a threat?

Q. Yes, ma'am. You personally know that?

A. Yeah, could they be a threat? Sure, but the point is, you do the right thing.

Q. So, a warning about a medical condition would impact sales because doctors would be less likely to prescribe it, and patients would be less likely to take it with a warning, correct?

A. No. Sir, I don't think that's a fair characterization. Again, I think I referenced earlier that whether or not a physician prescribes and a patient takes a medication is based on so many factors; what the condition is,

whether or not there are alternate treatments, whether they've tried those alternate treatments, what the potential benefit is relative to the risk.

Q. You at Eli Lilly, you said you knew -- you said in one of your answers that Eli Lilly knew a warning about diabetes would affect sales. When did you learn that?

A. When did I learn that a warning about diabetes could impact sales? When did I learn that?

Q. Yes, ma'am.

A. Boy, it's something -- I don't think anyone had to tell me that. I mean, one could surmise a warning about anything could impact sales. You wouldn't even have to be an expert in the area to know. If you know anything about pharmaceuticals, a warning, information in the warning could impact sales just like information in efficacy would be a positive. It could be a positive impact.

Q. Now, the No. 1 goal was not to warn physicians about the potential of weight gain, hyperglycemia and diabetes, was it?

A. The No. 1 goal?

Q. Yes, ma'am. Was it to warn physicians about diabetes? Yes or no?
A. No.
Q. Was it to warn physicians about weight gain? Yes or no?
A. What goals are you referring to?
Q. The goal listed in this document.
A. The goal is referring to -- I mean, the overall goals from a global standpoint, and there's absolutely nothing wrong with this unless you try to twist it around. Goal No. 1, stop hyperglycemia/diabetes from becoming a top 10 attribute influencing prescribing. It obviously is a factor, hyperglycemia, to be considered or weight gain to be considered, but if -- I mean, the goal -- the goal is to have the prescribers consider the sum total of the benefits of the product and if things --
Q. Well, I don't see that listed. You just said the goal was to have the prescribers consider the sum total of the product. Tell me in this document where that is listed as a goal.
A. You asked me to -- to give my opinion about what this means, and I'm telling you. From becoming a top 10 attribute influencing

prescribing. There are a lot of things that influence prescribing. Sometimes they could be very negative things or they could be very positive things. And, again, going back to something I've said, you know, a handful of times now, what a prescriber will do is look at the sum total of an offering. If all they hear about are things like hyperglycemia and diabetes, will that impact prescribing? Absolutely. If they also hear, though, about positive things such as efficacy parameters, that is something we wanted to make sure was communicated to the physicians.
Q. Yes. This comparable rates, in regard to diabetes, remember, we're talking about the subject of diabetes. And what is this, quote, comparable rates, message to doctors? What is that?
A. If I remember correctly, it was that atypicals, in general, had comparable rates as it pertained to the incidence of diabetes, and that in accordance with good medical practice, prescribers should evaluate every patient for their risks and take appropriate actions as they deem appropriate.
Q. What caused the sales to decline, ma'am?

A. New competition and concerns about weight gain.
Q. What about concerns about diabetes?
A. Actually, I think it was more -- I think there were three things. The company launched our product for ADD, Strattera. So sales representatives were taking off to promote Strattera. And another reason was, I believe, competition. And, third, it was concerns about -- about weight.
MR. LEHNER: That concludes our offer, Your Honor.
MR. ALLEN: Okay. Your Honor, may I proceed?
THE COURT: You may.
MR. ALLEN: Your Honor, the State of Alaska offers Alaska 8564, the restructuring of the marketing component for the Zyprexa product team, Your Honor.
MR. LEHNER: That's fine, Your Honor.
THE COURT: Previous objections are preserved, AK8564 is admitted.
MR. ALLEN: Your Honor, the State of Alaska offers Alaska 10096, Lilly Sales Good

Promotional Practices.
MR. LEHNER: Same, Your Honor.
THE COURT: Previous objections are preserved. AK10096 is admitted.
MR. ALLEN: Your Honor, the State of Alaska offers AK9624, the Zyprexa Global Brand Plan, 2005-2007.
MR. LEHNER: Same.
THE COURT: Subject -- previous objections are preserved, AK9624 is admitted.
MR. ALLEN: Your Honor, the State of Alaska has already had admitted AK1145, but it has not been published. It was discussed in Ms. Torres' deposition. It's the e-mail from Anthony Fiola.
THE COURT: We'll take up publishing when we're done admitting.
MR. ALLEN: Okay. Yes, sir. I'm sorry. Your Honor, the State of Alaska offers AK9054, the e-mail from Denice Torres dated September 4, 2002, Issues Update.
MR. LEHNER: Same.
THE COURT: AK 9054 is admitted with prior objections preserved.
MR. ALLEN: Your Honor, the State

of Alaska offers AK3924, the PowerPoint presentation concerning the engine room of the company that was discussed in Ms. Torres' deposition, Your Honor.

MR. LEHNER: Same.

THE COURT: AK3924 is admitted with prior objections preserved.

MR. ALLEN: And, Your Honor, the State of Alaska offers AK946, the Zyprexa Global Brand Plan, 2004-2005.

THE COURT: AK946 is also admitted with prior objections preserved.

MR. ALLEN: Your Honor, I have another exhibit. It was discussed, but I think we probably best take it up pursuant to other rulings at another time.

With your permission, Your Honor, I would ask to publish to the jury those exhibits you just admitted as well as Exhibit No. 1145, the e-mail from Mr. Fiola concerning top 10 attributes which was discussed in the deposition.

THE COURT: Exhibits AK 8564, 10096, 9624, 1145, 9054, 3924, and 946 all can be published.

MR. ALLEN: And you want me to hold

off on 1145?

THE COURT: No. 1145, I said, could be published as well.

MR. ALLEN: The official exhibit is over there. Can we publish the one without it, or do we want to find the official?

MR. LEHNER: That's fine --

THE COURT: You can publish the nonofficial, as long as we get back for eventual submission to the jury the official.

MR. ALLEN: Your Honor, pending issues that we need to take up with the Court and technical matters on evidence, State of Alaska calls as its last witness Dr. Alan Breier, vice president and chief medical officer of Eli Lilly, head of the Zyprexa product team. We're going to take a minute to get set up. Mr. Suggs is going to get documents ready. His deposition lasts a little under 45 minutes, Your Honor. We've got to get the screen set up.

THE COURT: Ladies and gentlemen of the jury, what I suspect will happen, after this deposition is over, I'll let you go for the day. We'll have some legal matters to take up at the end of the day.

Mr. Lehner, subject to my rulings on matters following presentation of testimony, what is Lilly's plan for tomorrow?

MR. LEHNER: We would be prepared to call a witness, Your Honor.

THE COURT: So there will be some depositions tomorrow and live witnesses as well?

MR. LEHNER: I think we'll start with live witnesses and then do depositions.

Can we approach, Your Honor while Mr. Allen is there?

(Bench discussion.)

MR. LEHNER: We -- I think we have about 17 or 18 minutes of Breier that we would intend to play following -- and not in our case. We could play it first thing tomorrow.

THE COURT: No, no. I want to get Breier -- let's get the Breier thing finished. We can finish up all of Breier and deal -- and send the jury home, and we can do admission of exhibits and stuff and other exhibits, things, and then we'll take up any applications.

(End of bench discussion.)

MR. ALLEN: Do you need me?

MR. SUGGS: No, thanks.

MR. ALLEN: All right, Your Honor, I think we have everybody ready for Dr. Alan Breier. Thank you, Your Honor.

VIDEOTAPED TESTIMONY OF ALAN BREIER, M.D.

Q. (MR. SUGGS) Good morning, would you state your full name for the record, please?

A. Alan Breier.

Q. And you are currently vice president and the chief medical officer at Eli Lilly; is that correct?

A. That's correct.

Q. And you assumed that position in August of 2003?

A. Yes.

Q. And before joining Lilly, did you have any particular training or expertise in the diagnosis and treatment of diabetes other than what is generally provided in medical school?

A. I did not.

Q. Okay. Am I correct that you had not conducted any research regarding diabetes before joining Lilly?

A. No, I did not.

Q. And you had not published any scientific articles regarding diabetes before joining Lilly;

is that correct?
A. That is correct.
Q. And am I correct that you became head of the Zyprexa product team in 1998?
A. Actually, I believe in 1999.
Q. 1999. As team leader of the Zyprexa product team, between 1999 and 2002 were you responsible for both the medical and marketing aspects of the Zyprexa product team?
A. Yes, I was.
Q. Sir, isn't it a concern that when you have medical and marketing people working closely together, the medical people can get sucked into a spinning mentality to gain a competitive marketing advantage for their drug that their company is promoting?
A. No.
Q. And do you recognize this e-mail, sir?
A. I see that, yes. I did write this. I am familiar with this.
Q. Okay. I was confused when I saw this as to who this went to. It's addressed to -- in the e-mail to U.S. underscore, medical, underscore, medical U.S. Who was that, or what group was that?

A. At a minimum it would be medical personnel in the U.S. Quite frankly, I'm not sure if this would have gone outside of the U.S. or not, based on just that header.
Q. And this would have been written by you some, what, six months or so after you'd taken over the position of chief medical officer?
A. That's correct.
Q. Okay. And I assume you gave careful thought to the language that's in this e-mail before you sent it out around to those hundreds of people; is that correct?
A. Yes.
Q. Okay. And in the middle of the first paragraph -- pardon me -- middle of the first page, there's a paragraph that has a bold entitled Principles.
Do you see that?
A. I do.
Q. And in that paragraph you stated, quote: Making medicine for people facing illness is a much different and higher calling than making consumer products for other markets. We do not sell soap. It therefore requires a different and higher code for conducting our business.

Do you see that language, sir?
A. I do.
Q. And I assume that no one ever came back and contradicted you about that; is that correct?
A. No.
Q. Okay. And if I can direct your attention to about the third line from the bottom, you state, quote: We are particularly challenged when it comes to presenting our data in a completely objective, unbiased manner because of our passion for our molecules and the belief that spinning data is sometimes necessary to gain a competitive advantage. If we do not abandon the spinning mentality, we will not restore confidence in our medical research and rebuild the public trust our industry has compromised.
Did I read that correctly?
A. You did.
Q. And the competitive advantage that you were referring to there would be a competitive advantage in the marketplace; is that correct?
A. Yes.
Q. Okay. And you clearly said that if we do not abandon the spinning mentality, we will

not restore confidence in our medical research and rebuild the public trust our industry has compromised, correct?
A. That's correct.
Q. When you talk about restoring confidence, you don't use that term "restore confidence" unless that confidence has already been compromised, correct?
A. That's correct.
Q. And when you talk about rebuilding the public trust, you don't use that phrase, "rebuilding" something, unless that public trust has already been broken, correct?
A. I would agree with that.
Q. Were you aware, sir, back when you were head of the Zyprexa product team, that FDA regulations require that the labeling shall be revised to include a warning as soon as there's reasonable evidence of an association of a serious hazard with a drug and that a causal relationship need not have been proved?
A. Let me just understand. So, are you describing criteria that would be used in order to determine where information would go on the label?

Q. No, sir -- well, in part. I'll represent to you, sir, that the FDA regulations do state that -- and require that the labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug. A causal relationship need not have been proved.

I'll represent to you that's what the regulation states.

My question to you is: Were you aware of that when you were head of the Zyprexa product team?

A. Yes.

Q. Okay. With respect to labeling decisions within the Zyprexa product team, and whether a labeling change should be taken to the global product labeling committee for review, where did the buck stop in the Zyprexa product team for that type of decision?

A. On the Zyprexa product team the buck would stop with me. That determination, again, would be predicated on a cross-functional group of scientists, content experts, working on the data, and determining on the strength of the data we would then make a decision whether to go to

GPLC.

Q. Okay. When did Lilly regard olanzapine-associated weight gain and possible hyperglycemia as a major threat to the long-term success of Zyprexa? Did it start -- did that perception start with your writing of this memo in November of 1999, or did it begin at some earlier point?

A. If you would accept my characterization of -- of excessive weight gain, my answer to your question would be Day One.

Q. Sir, did you tell physicians at any time that an analysis of clinical trial data from Lilly's own studies showed that the incidence of treatment-emergent hyperglycemia was three and a half times higher than in the placebo group? Yes or no?

A. We did not.

Q. And was Dr. Casey a consultant to Lilly back in 1999 and 2000?

A. Yes.

Q. When Dr. Casey came to Lilly and gave that presentation in which he said that 18 percent of people with normal blood levels had diabetic blood levels after using the drug for

four months or more, was that -- did that come as a surprise to you at that point, or were you aware of his findings before he came to give the seminar?

A. I don't recall if he and I talked about the data before he came or not.

Q. And would you have expected the majority of people from the Zyprexa product team to be there?

A. I, again, don't recall who was in attendance. Typically when we have a seminar of an outside speaker, we advertise it fairly broadly within the company. It's an open-door policy, so those interested in this particular area were invited.

Q. If I could direct your attention next to Plaintiff's Exhibit 1453. The subject of this e-mail is the meeting with endocrinologic consultants, and it goes on to state, quote: Robert, clearly this group of endocrinologists who spoke up, and I would rate those who did speak up as the leaders of the pack, are very concerned with the approach Lilly is taking towards the issue that Zyprexa leads to diabetes. I can only hope that you and all of the team who

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

Do you see that language, sir?

A. I do.

Q. And you were informed of that language, were you not?

A. I was informed of the -- of the meeting.

Q. It appears that Robert Baker took that e-mail from Thomas Brodie and he forwarded it on to you and Charles Beasley with copies to those other folks; isn't that correct?

A. That appears to be the case.

Q. Sir, my question is: When you got this information in this e-mail that this group of endocrinologists was telling you that Lilly needed to come clean on this and that he hoped that those who attended the meeting are gaining the ear of senior leadership in articulating this finding, did that cause you any concern?

A. The come clean comment to me is -- I

have no idea what that person was thinking about.
Q. Sure. Can I direct your attention to page 2? This is an e-mail in the same chain from Dr. Beasley to you with copies to Robert Baker, Paul Berg, Scott Clark, John Holcombe, Roland Powell, Alvin Rampey and Roy Tamura, correct?
A. Yes.
Q. And in his second paragraph he says, quote: These guys were really concerned about the weight gain, not only because of the diabetes risk, but all the other potential health risks.
Do you see that language?
A. Yes.
Q. And what other potential health risks are there as a function of weight gain?
A. Well, one would first have to qualify weight gain as excessive weight or obesity as opposed to mere weight gain. If we're talking about obesity, then there are other health risks, cardiac, et cetera.
Q. Let's go on to Dr. Beasley's e-mail. He says: They initially thought it might simply be a response to improvement in schizophrenia with a few outliers, a rather naive view, but they ain't shrinks. When they understood that this is seen

in nonpsychotic normals and animals on fixed diets, less concern with animals, and that olanzapine is the worst offender other than clozapine, they advocated a different marketing strategy than we are taking.
Do you see that language?
A. I do.
Q. And did you inform Dr. Toleffson of that?
A. Again, we had frequent and ongoing discussions about this topic.
Q. So you believe you would have told Dr. Toleffson about that?
A. Yes.
Q. If I can direct your attention back to Dr. Beasley's e-mail. Three lines up from the bottom he says: There does not seem much to say about scientific analyses of weight gain. We know it's a weighty problem. When you translate 1 to 2 percent gain of 40-plus kilos into the absolute number based on 5 million patients, the number is 50 to 100,000. 100,000 people putting on 90 pounds of weight is a lot.
Were you aware of that type of calculation before Dr. Beasley mentioned it in

this e-mail to you?
A. I knew the distribution of weight gain. I knew it had been talked about, the tails of a bell-shaped curve.
Q. The last paragraph of Dr. Beasley's e-mail states, quote: With regard to the marketing side of this issue of impaired glucose tolerance slash diabetes, the message was clear, don't get too aggressive about denial. Blaming it on schizophrenia or claiming no worse than other agents until we are sure of the facts and sure that we can convince regulators and academicians. WL with Rezulin was the example. Sounds exactly like what Dan Casey was saying.
Do you see that reference?
A. Yes.
Q. Okay. In November of 2001, Denice Torres reported to you and the Zyprexa product team, correct?
A. Yes.
Q. Okay. If I could direct your attention, first, to Exhibit 1110, the one on weight gain. And, in particular, the second page, there are several headings there. The first one is Issue, and the second one is Our Position. And under

Issue, the first bullet point states: Weight gain remains the No. 1 liability of Zyprexa and is leading to many of the new issues surrounding the drug, diabetes, lipids, et cetera.
Do you see that?
A. Yes.
Q. And were you aware in November of 2001 that weight gain remained the No. 1 liability of Zyprexa?
A. I wouldn't necessarily use those terms, but that was a significant -- a side effect for some patients, and it was an area of substantial focus.
Q. If I can direct your attention to the second page -- or, I mean, the following page on page 3, there's a section there about Marketplace Feedback and some bulleted items.
And in the middle is a quote stating, quote: It is laughable when Lilly comes in and tries to talk about weight gain.
Do you see that?
A. I do.
Q. Were you informed that the market research was that doctors were saying it was laughable when Lilly comes in and tries to talk

about weight gain?
A. This sounds like the quotation of -- of one individual. It was not my impression that that was generally held. We, again, were quite -- quite active in our transmission of data on the particular topic. My general sense was that people were impressed with what we were doing.
Q. If I can get you to direct your attention to page 4. There's a heading towards the bottom saying -- it says, What We Don't Know.
The last bullet point in that section states, quote: Knowing that weight loss programs only work approximately 5 percent of the time in normal volunteers, does Lilly want to provide a program where if it doesn't work, it may be looked at as another laughable attempt?
Do you see that language, sir?
A. Uh-huh.
Q. Sir, if weight gain -- if weight loss programs only work approximately 5 percent of the normal time in volunteers, how can weight gain for most patients be managed?
A. I -- I'm not prepared to accept this 5 percent. I don't know who authored this

document. I don't know what their resource was or their knowledge base. I'm familiar with the studies that we conducted on interventions and, again, would state that for some patients interventions were quite helpful and for other patients they were not.
Q. If I can direct your attention to Exhibit 1111. This is one that has the title Diabetes. In particular, if I can direct your attention to page 4, there's a heading at the bottom that says, What We Don't Know.
And the second point there of what we don't know was, quote: How to effectively deal with the weight gain associated with Zyprexa, end quote.
Do you see that?
A. I'm reading the page. I see that.
Q. Sir, if you didn't know how to effectively deal with the weight again associated with Zyprexa, then it would be a falsehood to tell doctors that for most patients weight gain is manageable; isn't that correct?
A. I'm going to have to raise the same concern about this document that I raised with the weight gain document. I don't know who

authored this. I don't know what the source of the information was. I don't know, for example, is this an early draft? Was it one person's opinion? Was it -- or what it was. I will, again, indicate that we had a number of different interventions for weight gain. For some patients they were helpful; for other patients they were not.
Q. Those two statements are mutually incompatible, correct?
A. I mentioned earlier today that I did not know and cannot confirm that Lilly was telling doctors that weight gain could be managed for most patients.
Q. Are you going to deny to the jury that Lilly told doctors that weight gain was manageable for most patients? Wasn't that, in fact, a central part of your marketing pitch in 2000, 2001, 2002, 2003?
A. And, again, I'll say that I -- I don't know that that was the case. I can speak, again, to the data. I've already reiterated that. There were a number of different studies that were -- that were conducted to look at interventions, and some of them were effective

and some of them weren't.
Q. If I can direct your attention to the second page of Exhibit 1111. Dropping down to the next heading there regarding Our Position, it states, quote: Diabetes slash hyperglycemia may occur in patients taking antipsychotics and/or mood stabilizers, including Zyprexa, at comparable rates with the possible exception of clozapine.
Do you see that, sir?
A. Yes.
Q. And you -- you were aware and, in fact, endorsed that as Lilly's position, correct?
A. This is an accurate statement of the data.
Q. And you endorsed that position, correct?
A. Yes.
Q. Okay. And then below that, at the very bottom of the first page, is the rationale for the position. And it states, quote: Showing that diabetes is a common occurrence for all antipsychotics and not just Zyprexa will help reduce the perception that diabetes is linked specifically to Zyprexa and, in turn, will help to eliminate this risk from the risk/benefit

equation.
Do you see that, sir?
A. I do.
Q. And were you informed that at least the marketing department viewed that as a rationale for the position?
A. I am, again, going to say that this is a -- an isolated point. I don't know where it came from. There's elements of this statement that are not something that I would agree with and are not consistent with my view of the data.
Q. If I could direct your attention to page 4 of this exhibit. There's a heading there entitled What We Know.
The first bullet point says: Olanzapine does cause modest elevations of mean random glucose.
Do you see that language?
A. Uh-huh.
Q. And physicians were never told that, were they, sir?
A. Again, I -- this is -- this is misleading. It's not accurate and I can't -- I can't support it.
Q. And you would agree with me, sir, that

treating physicians were never warned by Lilly that, quote, olanzapine does cause modest elevations of mean random glucose, correct?
A. There -- there is no data to support a cause-and-effect relationship.
Q. Sir, again, that's not responsive to my question. I need a direct answer to my question.
Lilly never told prescribing physicians that, quote, olanzapine does cause modest elevations of mean random glucose?
Whether you think that's true or not, the fact of the matter is Lilly never told doctors that, correct?
A. Our marketing message followed the scientific understanding of the data.
Q. Lilly never told treating doctors that olanzapine does cause modest elevations of mean random glucose; true or not?
A. Correct.
Q. If you go to the third bullet point, it states, quote: Glucose elevation partially accounted for by weight gain.
Do you see that language?
A. I see it.
Q. Physicians were never advised of that,

were they, sir, by Lilly?
A. It's not supported by the data. Again, we -- we've looked at that very carefully. So, I -- I -- we talked about this earlier today, and I -- those data are not supported.
Q. Well, sir, isn't it true that Dr. Beasley wrote you a memo in February of 2001 in which he specifically said: These increases -- pardon me -- these changes are accounted for, in part, but not entirely weight increase.
Do you recall that?
A. I'll have to look at it.
Q. Do you recall receiving this e-mail from Dr. Beasley back in February of 2001?
A. I do.
Q. And in this e-mail Dr. Beasley wrote, starting in the third sentence, quote: Our continuous analyses show that olanzapine does result in statistically significant mean increases in random glucoses relative to placebo and haloperidol. No significant difference relative to risperidone but power is small. Clozapine is associated with a larger, olanzapine versus haloperidol, and significant increase

compared to haloperidol. These increases are occurring as early as Week 1. May not represent a true deterioration in glycemic metabolism, but simply an increase in food intake since these are random and not fasting glucoses. These changes are accounted for, in part, but not entirely by weight increase.
Do you see that language, sir?
A. Yes.
Q. If I can direct your attention to page 6. There's a table there entitled Desired Evolution.
Are you familiar with that?
A. I've not seen this before, no.
Q. It lists as an action step drive in the minds of our customers that risk of developing diabetes is no different on Zyprexa than with other agents.
You were certainly aware of that?
A. I was -- well, I was aware of the data that indicated that there were comparable rates among -- on the atypical antipsychotic drugs.
Q. And the desired outcome for that action step was to, quote: Lower the percentage of customers that directly linked Zyprexa with

diabetes, end quote.
Do you see that, sir?
A. Yes.
Q. Sir, at least the language that's stated in this document indicates that whoever wrote this, their desire was to get doctors so they didn't even think about diabetes with Zyprexa and, in fact, took it out of the risk/benefit calculation; is that correct?
A. No, that's completely inconsistent with our approach. We were very clear about the data. We were clear that there was a higher rate of diabetes in schizophrenic and bipolar patients. We had medical letters, slide sets, publications.
What I'm trying to address in this point is what is most critical is that prescribers have an accurate understanding of the information and through multiple different approaches, we strove to achieve that.
Q. Sir, you just denied that it was the approach of Lilly to have physicians take diabetes out of the risk/benefit calculation. Can I direct your attention to page 2 of this document? Can you see at the bottom of that page there's a Rationale For Position?

A. Uh-huh.
Q. Can you read that aloud for the jury, please?
A. Showing that diabetes is a common occurrence for all antipsychotics and not just Zyprexa will help reduce the perception that diabetes is linked specifically to Zyprexa and, in turn, will help to eliminate this risk from the risk/benefit equation.
Q. Dr. Breier, do you recall that in April of 2002 the Japanese regulatory authority required Lilly to drastically change their warnings and issue an emergency safety information letter to Japanese physicians warning about the risk of diabetes with Zyprexa?
A. In April of 2002 there were label changes to the Japanese label for Zyprexa that included a warning and a letter to doctors.
Q. And, sir, do you recognize this as a translation of an emergency safety information letter that Lilly issued to Japanese physicians in April of 2002?
A. Yes.
Q. Okay. And in the actual letter, am I correct that the border that appears to be black

on this black-and-white copy is, in fact, red?
A. In Japan. Yes, that is their -- their practice.
Q. Okay. And the heading at the top of the letter says Important in the upper left-hand corner, and then in big bold letters right at the top says: Emergency safety information, correct?
A. Yes.
Q. This was definitely designed to get the attention of physicians in Japan, correct?
A. Yes. That's the purpose of a communication to prescribers.
Q. And, in fact, it did definitely get the attention of physicians in Japan, correct?
A. Physicians in Japan were aware of this -- of this warning and the data.
Q. And Zyprexa sales went dramatically down after physicians in Japan received this label; isn't that correct?
A. I don't recall the sales trends after this was issued.
Q. Sir, don't you recall writing a memo about those sales trends? To Mr. Lechleiter?
A. Sitting here today, I don't recall that.
Q. Okay. We'll go over that in some more

detail later.
Let's talk about this -- this Dear Doctor letter that went out to -- or this emergency safety information letter that went out. This was done at the order of the Japanese regulatory authorities by Lilly, correct?
A. Yes.
Q. It's fair to say that the situation with respect to the Zyprexa label in April, 2002 was as follows, then. In European labeling there was discussion that diabetes and hyperglycemia in the special precautions and special warnings section of the labeling and such discussion had been there since July of 1999; is that correct?
A. The European label does not have a separate warnings and a separate precautions. It's all-inclusive, so there's warnings and precautions. And you're correct that in 1999 there was information put into that section.
Q. Okay. And then we also had the warnings in Japan that we've just discussed, correct?
A. That's correct.
Q. But in the U.S. there was no language in either the warnings or the precautions section about diabetes or hyperglycemia; isn't that

correct? In April, 2002.
A. At that time, that is correct.
Q. Okay. First of all, do you recall, sir, that there was a policy committee meeting which was given a Zyprexa safety overview in April of 2002?
A. Prior to looking at this -- this document, I don't recall that specific date.
Q. And was Sidney Taurel, the chief executive officer, was he usually present at these policy committee meetings?
A. Yes.
Q. And was John Lechleiter usually present at those policy committee meetings also?
A. Yes.
Q. Okay. And at these policy meetings, was it the usual practice to give a presentation regarding the safety of Zyprexa when Zyprexa was discussed?
A. The topics would vary, so it would depend on -- on the particular theme that the policy committee was either interested in or we felt was important to present to them.
Q. Okay. And who would give the presentation to the policy committee regarding

Zyprexa?
A. The format of that meeting was a relatively brief preread and then --
Q. Can I interrupt you for a second?
What do you mean by preread?
A. A short text of the topic at hand.
Q. With that background in mind, if I can direct your attention to Exhibit 4051. And does this appear to be a preread that you referred to?
A. It appears to be.
Q. Okay. And who would have prepared this Zyprexa safety overview?
A. I don't have a recollection of who prepared this particular document. Given the nature of the document, I'm going -- going to venture that it was likely physicians that worked on Zyprexa, scientists that worked on Zyprexa, Zyprexa product team. Perhaps other scientists as well.
Q. Okay. Who were the likely candidates for having a hand in that?
A. At this time, myself, Patrizia Cavazzoni, Charles Beasley would have been the people who likely could have worked on this.
Q. Okay. And I'm presuming since this --

the members of the policy committee were all upper-level executives, correct?
A. Yes.
Q. I'm assuming that in the preparation of these types of prereads, that you would take care to make sure that things were stated accurately, correct?
A. We strive to do that.
Q. If I can direct your attention to the second page. In the Introduction section, in the second-to-last sentence it states: A side effect that is associated with Zyprexa is the weight gain and the sequelae of weight dean.
And what is the -- the word "sequelae" is a medical term, is it not?
A. It is used in medicine.
Q. And when it's used in medicine, it means the results of or the effects of something, correct?
A. I would say may be associated with.
Q. If I can direct your attention to the section on Clinical Data. There's a section there for weight gain that says: Five atypical antipsychotic agents are associated with more weight gain than most traditional neuroleptic

agents in the following order. Most to least: Clozaril greater than Zyprexa, greater than Seroquel, greater than Risperdal.
And then below that it says: Zyprexa weight gain is roughly twice that of Risperdal; is that correct?
A. You've read that correctly.
Q. And was that conclusion on the basis of studies that had been conducted by Lilly, or was that an analysis of other data?
A. This would represent a combination of the available data at the time, so that would include Lilly data, but it would also include other sources of data.
Q. If I could direct your attention to the next section in this document that pertains to diabetes, and there are a number of bullet points below that heading. And, in particular, I direct your attention to the third bullet point.
You see where I'm indicating, sir?
A. Yes.
Q. Okay. And the first sentence there states, quote: Results of two Lilly epidemiological studies. Analysis of advanced PCS and GPRD databases indicate that the risk of

DM is increased in patients treated with antipsychotics, including Zyprexa.

And the DM that's referred to there is diabetes mellitus, correct?

A. That is correct.

Q. Okay. So Lilly had conducted two epidemiological studies which showed that the risk of diabetes is increased in patients treated with antipsychotics, including Zyprexa, correct?

A. You've read that sentence correctly.

Q. Who is Bert VandenBergh?

A. Bert VandenBergh is an executive at Eli Lilly and Company.

Q. What was his position back in July of 2002?

A. He was president of neuroscience and my boss.

Q. Okay. And do you recall traveling to Japan for four days in June of 2002 with Mr. VandenBergh?

A. I do.

Q. And when you came back, you wrote a memo -- you and Mr. VandenBergh wrote a memo to Dr. Lechleiter and Gerhard Mayr and -- with a copy to Mr. Mescarenhas; is that correct?

A. I'm not recalling that specif -- a specific message. When we returned from visiting Japan, we communicated notes about our trip, but I can't say that I'm recalling the specific e-mail to the people that you mentioned.

Q. And did you, in fact, prepare this memorandum with Mr. VandenBergh on July 1, 2002?

A. I'm not recalling the -- the preparation of this specific message. I see both of our names at the bottom, so I'm assuming that we -- we both worked together on this communication.

Q. Okay. And I'm assuming that you and your boss, when you prepared this memorandum for Dr. Lechleiter and Mr. Mayr, would have taken care to be accurate in your reporting on -- on your trip to Japan, correct?

A. We would strive to be accurate.

Q. It appears that you went to Japan with Mr. VandenBergh from June 23 to June 27, 2002, correct?

A. That's correct.

Q. And in the first paragraph of your memo you state in the second sentence, quote: It is clear that the impact of the label change in Japan has been very profound. We concluded that

we have lost substantial ground and trust in our relationships with the MHLW.

And am I correct that MHLW are the initials for the Japanese regulatory authority?

A. You are correct.

Q. Okay. And your memo continues on to state, quote: Market research shows we have also lost quite a bit of credibility with prescribers and opinion leaders. Basically they felt left in the dark with what they perceived as the late sharing of safety information. As a result, there has been a 75 percent drop in new patients who are being put on the drug and a continuing fairly high dropout rate.

Did I read that correctly?

A. You've correctly read -- read the words in the e-mail.

Q. And I'm assuming that that market research was conducted by Lilly, correct?

A. That would also be my -- my assumption.

Q. Now, if I can direct your attention to the last page, about four lines up from the bottom of that last paragraph there. There is language that states, quote: There appears to be a decrease of hyperglycemic AEs since the label

changes.

Am I correct that AEs refers to adverse events?

A. You are correct.

Q. Okay. So by -- if the label change went into effect at the beginning of April of 2002, only April, May, June -- three months would have expired between the time of the label change and the time you wrote this memo, correct?

A. May, June. Two months, something like that.

Q. Okay. And my question was: Even in the short span of time between when the Japanese label change was made and the date of your writing of this memo, it appeared that there was a decrease in the number of hyperglycemic adverse events, correct?

A. You -- you've reflected that sentence accurately.

Q. Okay. And after stating that to Mr. Lechleiter, you then went on to say: Again, we will make every effort through promotional efforts and physician-to-physician and medical communications to ensure that we promote the use of the drug within the label, which would by

design -- pardon me -- which would by design dramatically reduce the number of events.
Did I read that correctly?
A. You did.
Q. And the events that are being referred to there were also adverse events, correct?
A. Yes.
Q. Okay. And on the marketing side, as you've indicated, there was a global marketing team and that was headed up by Denice Torres, correct?
A. When I began as product team leader in 1999, Roland Powell was the medical director for two years. Denice Torres then assumed the position when Roland Powell rotated into a new position.
Q. She testified to me under oath that it was common knowledge that a warning on a drug product could affect sales.
Were you aware of that?
A. I don't recall discussing that with her having that, knowing of that view.
Q. Didn't you have actual evidence, empirical evidence by the summer of 2002, you, that a warning about diabetes and blood

monitoring would for certain have a very profound effect on the sales of Zyprexa?
A. Again, I'm going to answer no.
Q. Okay. I hand you what I've marked as Breier Exhibit No. 6. One for your counsel. This is the summary of the Japan trip that you took over to Japan from June 23rd to 27th with Dr. Lechleiter. And you told us at least one of the reasons you went to Japan was to assess how the affiliate was doing in Japan after the label change, right?
A. That's correct. We wanted to assess the implementation of the guidelines.
Q. Yes, sir. And if you look at Paragraph 1, and I will read it into evidence, so it will be easier than making you read it: It is clear that the impact of the label change in Japan has been very profound. We conclude we have lost substantial ground and trust in our relationship with the MHLW.
That's the Japanese equivalent of the FDA, correct? Sir?
A. Yes.
Q. Market research shows we have also lost quite a bit of credibility with prescribers and

opinion leaders, basically, because they felt left in the dark with what they perceived as the late sharing of safety information, period. As a result, there has been a 75 percent drop in new patients who are being put on the drug and a continuing fairly high dropout rate, period. That's going to lead to a significant performance impact probably over and above the 10 percent assumed on the sales line in the short term, although we think we will be able to stem the tide and turn this around.
Did I read that correctly?
A. Yes.
MR. ALLEN: Is that it, David?
Your Honor, that concludes the State's offer from the deposition of Dr. Breier. I think the opponents have some and then we may have some documents, Your Honor.
MR. LEHNER: That's correct, Your Honor. We have some additional segments.
THE COURT: Please.
CROSS-EXAMINATION
Q. Okay. I'm going to be asking a lot of questions about your activities regarding Zyprexa, but before I do that, I'd like to find

out more about your background.
Am I correct that you received a bachelor of arts degree from the University of Toledo in Ohio in 1975?
A. That's correct.
Q. And you received a doctor of medicine degree in 1980 from the University of Cincinnati School of Medicine?
A. Correct.
Q. And then you were a resident in psychiatry from 1980 to 1984 at Yale University School of Medicine; is that correct?
A. Yes.
Q. And I know that you completed your residency in 1984, and that before you joined Lilly in 1997, you were at the University of Maryland and at the National Institute of Mental Health, sometimes referred to as NIMH, but I'm unclear as to what you were doing in that 13-year time period.
Could you sort of flesh that out?
A. Sure. When I left residency training at Yale, I joined the intramural program of NIMH. That was primarily for further research training, and I focused at that time on primarily

schizophrenia research. After completing a three-year research fellowship, I then assumed a position at the University of Maryland in the Department of Psychiatry and was an associate research professor there.

After completing that position, I returned to the NIMH in a more senior position, and I was there, I believe, for about four years, and then joined Eli Lilly and Company in 1997.

Q. Were you aware, sir, back when you were head of the Zyprexa product team, that FDA regulations require that the labeling shall be revised to include a warning as soon as there's reasonable evidence of an association of a serious hazard with a drug and that a causal relationship need not have been proved?

My question to you: Were you aware of that when you were head of the Zyprexa product team?

A. Yes.

Q. And in the context of that FDA regulation requirement, what did the term "association" mean to you when you were head of the Zyprexa product team?

A. Well, there's a number of different

types of association. There's a temporal association; there's a causal association. If we're talking about association that relates to labeling, one must consider things like the consistency of the data, the strength of the data, the quality of the data. So all of those factors are taken into account when determining information that should go into the label and then where in the label it belongs.

Q. Okay. You may have been responsive to this, but I'm not sure, so I want to probe this further.

A. Okay.

Q. In the context of that FDA regulation that I just talked about where the FDA does require the labeling shall be revised to include a warning as soon as there is, and the FDA regulations terms phrase, reasonable evidence of an association of a serious hazard. That's what the regulation says.

What did "association" mean to you in that context?

A. Are we specifically talking about a warning? Is that what your question is?

Q. Yes.

A. Again, that would be -- a few of the things that would be very, very important would be the strength of the association, the quality of the data, the consistency of the data. If there is a causal relationship, that would be important. The type of event we're talking about in terms of its gravity and seriousness. So, again, multiple factors are considered when determining where one proposed to put something in the label.

Q. Okay. Would you agree, sir, that reasonable evidence of an association could include a statistically significant finding in a clinical study that an adverse reaction occurs more frequently with a particular drug as compared to placebo or some other control group? That that could constitute reasonable evidence of association?

A. You, again, would kind of need to look at the exact phenomenon you're talking about, and one would look for quality, consistency, validity of the signal. It's a little difficult to talk about this in the abstract. But typically one study and one finding, if there's other data available that perhaps is contrary to that one

study, would not suffice. So one would need to look at the totality of the information in order to make their ultimate decisions.

Q. But you would agree that statistically -- a finding of a statistically significant increased incidence of an adverse reaction in a clinical trial could constitute part of the evidence that would be assessed in making a determination as to whether there was reasonable evidence of an association, correct?

A. I can't -- I can't agree with that statement as you just articulated, because one would need to look at that particular clinical trial, the strength of the trial, the methodology, other data that might be available, mechanistic issues. In other words, what I'm trying to indicate is that labeling is a very serious business. One needs to consider all of the relevant information, methodology, other data, et cetera, before one can make an informed labeling decision.

Q. Would you agree, sir, that results of a controlled clinical trial is often regarded as the gold standard of scientific evidence?

A. I would not agree with that statement as

you articulated, because each clinical trial is subject to its own strengths and weaknesses. And there are some clinical trials that provide certain sorts of proof of evidence and other sort of clinical trials that don't. So, one would have to actually look at the clinical trial in question. We call it kind of looking under the hood, really understanding the methodology, the patient characteristics, all of those factors before one could make an informed decision on results from that trial.

Q. Let me ask the question this way: You remember how Harry Truman had a sign on his desk that said "the buck stops here"?

A. Yes.

Q. Okay. With respect to labeling decisions, within the Zyprexa product team and whether a labeling change should be taken to the global product labeling committee for review, where did the buck stop in the Zyprexa product team for that type of decision?

A. On the Zyprexa product team, the buck would stop with me. That determination, again, would be predicated on a cross-functional group of scientists, content experts working on the

data, and determining on the strength of the data we would then make a decision to go GPLC.

Q. And would it be fair to say that while you were president -- pardon me -- while you were team leader of the Zyprexa product team, that you would have been aware of any proposal made by the product team to the global product labeling committee with respect to a label change?

A. Definitely.

Q. It's your testimony that you assume that you were aware back in 1999 of this data from the HGAJ study showing a statistically significant increased incidence of high glucose, correct?

A. As I stated before, I'm presuming I did.

Q. And why is it that you are presuming that?

A. We're a very science-driven team. We looked at data a lot. We looked at signals. We had a process of continual iteration of data where a signal would pop up. We would reanalyze. We would look for better data. We would continually strive to understand what the studies were telling us. We did that with J, as well as other trials. So I'm -- again, I'm presuming that in the course of my activities, we probably

reviewed this, and then as I was indicating before, went on to try to determine is this real or not, and through careful analysis determined that we did not feel this was a signal.

Q. Okay. If I could direct your attention back to Exhibit 8262, your November, '99 e-mail?

A. Yes.

Q. And then later in your e-mail you refer to a meeting of this cross-functional team in a couple of weeks and state that the purpose of the meeting was for the executive steering committee to review the ongoing work, future study plans, and resource needs, and to provide guidance for the scope of future activities; is that correct?

A. You read it correctly.

Q. And did the members of that executive steering committee that are listed there, which is composed of yourself and a number of others, did they stay involved in this process?

A. Yes. We had been working with a number of them before this and had a number of activities -- scientific activities going on. The purpose of the steering committee was to update a broader group of what we were doing, get their input and their suggestions for future

directions. Because we had already had cross-functional interactions with some of the key people, we decided that we would continue on as we had before.

In other words, I would take responsibility for bringing in key people at appropriate times as opposed to, say, having a biweekly meeting or something like that with these people on a formal basis. So, the spirit of that was continued on, but not as a regular meeting of those key individuals. Although, I took, again, responsibility to keep them informed and to continue to get their input.

Q. For how long had weight gain and possible hyperglycemia been regarded by Lilly as a major threat to Zyprexa?

A. I'm going to have to answer it the same way I did before. We were very cognizant of weight gain from Day One. It was very well described at that time, and those characteristics of weight gain did not change.

Q. Did you regard weight gain as a major threat to Zyprexa from Day One?

A. We acknowledged that weight gain was, for some patients, particularly excessive weight

gain, was an undesirable attribute of the drug.
Q. That's not my question. You used -- in your e-mail you describe olanzapine-associated weight gain and possible hyperglycemia as a major threat to the success of Zyprexa.
My question is: For how long had you regarded that as a major threat?
A. And, again, I'm putting the word threat into context, explaining it as -- those individuals who gained weight to an excessive amount, was a clear side effect of the drug.
Q. Okay. But it's fair to say this was -- when you talk about -- when this is in the market research section of your e-mail, was that market research that was coming back and telling you that was the ordering of weight gain, or was it actual clinical scientific research?
So the first part was the market research telling you that olanzapine was viewed by physicians to have more associated weight gain than risperidone, Seroquel and traditional neuroleptics, and the fact was that that was true?
A. Correct. So those clinical observations that were captured in the market research was

compatible or consistent with the known literature.
Q. And then in your next bullet point you say: Blanket detailing will be damaging since many physicians do not see OWC as an issue.
Did I read that correctly?
A. You did.
Q. So when you're talking about blanket detailing here, what you're talking about -- that phrase would mean having sales representatives from Lilly go out and talk to all physicians about a particular issue, correct?
A. No. What -- what this phrase means is having a unidimensional message. In other words, as opposed to presenting all relevant data or important relevant data would be to have a single isolated message.
Q. And how was it determined that many physicians do not see olanzapine weight change as an issue? Do you know?
A. Well, again, this is market research. This isn't Lilly's opinion. This is the information coming into the company from prescribing physicians. What I interpret this to mean is to say that physicians that were in the

survey were -- some of them were saying, I'm interested in different information in a detail call. I'm not seeing weight gain as a problem in my patients, but I've got questions about other things. So don't give me a single-message detail, but -- but give me information that's important to me. And I think each physician has at various times different questions and different needs for data, and that's what I interpret this bullet point to be referring to.
Q. The phrase treatment-emergent hyperglycemia refers to hyperglycemia occurring during the context or after a person's been exposed to the drug in a clinical trial; is that correct?
A. I would characterize it as the data coming from a clinical trial.
Q. Well, then, what does the phrase "treatment-emergent" mean?
A. Treatment-emergent is a term that's used for an event that crosses a certain threshold. It doesn't refer to what the baseline was or the starting point.
Q. Well, doesn't the phrase treatment-emergent indicate that the situation

emerged during treatment?
A. Yes, but the reality of glucose, particularly random glucose, is there's a lot of up and down. It's very possible that someone could have a high level at one point, say, a baseline, a low level later, a high level later on. So there's quite a bit of fluctuation with glucose. So if you crossed a certain threshold at a certain point in time in a clinical trial, that would be considered a treatment-emergent event.
Q. And it's your testimony that your -- you have no recollection of this submission being made to the global product labeling committee?
A. During the 2000 time frame, I do not have a recollection of this analysis or this document.
Q. Your labeling never advised physicians of the proposal that was made here, correct? Yes or no?
A. We did not advise clinicians of this particular finding because additional analyses were conducted that were more valid and clinically meaningful than these analyses, and it was the correct analyses that we submitted to the

FDA and shared with clinicians.
Q. Okay. And it's fair to say that, also, isn't it, sir, that Lilly never advised prescribing physicians in the labeling of Dr. Casey's findings, did it, sir?
A. No, we didn't, because this gets to a very central point that we've been discussing today, and that gets to quality of data.
Q. Sir --
A. If I could just finish. These are 39 patients, a retrospective analysis in which there are no controls, no understanding of baseline factors, inadequate amount of data to really understand even a full temporal association. So, these are the very kinds of data that, while it's important to look at all the data and we were interested in looking at all the data, this is the type of study alone that one cannot draw very many conclusions.
Q. And the desired outcome for that action step was to, quote, lower the percentage of customers that directly linked Zyprexa with diabetes, end quote.
Do you see that, sir?
A. Yes.

Q. And were you informed that that was the desired outcome?
A. Again, I don't know the origin of this document. I don't know who constructed it. That would not be consistent with our approach to doing the science that we could do, the best science we could do, and then creating the marketing messages from that science.
Q. Okay. So, it's your testimony it would be inappropriate to have this as the desired outcome, to lower the percentage of customers that directly link Zyprexa with diabetes?
A. No. That's really not the point. It's what the data says.
Q. When you said that would not be consistent with our approach, if it's not consistent with your approach, then it would be inappropriate, correct?
A. Let me tell you what I -- what I do mean. When it says, lower the percentage of customers that directly link Zyprexa to diabetes, if there was a misunderstanding or a misperception about the data, then correcting that misperception would be appropriate. There's not a baseline here upon which to kind of further

interpret that statement. The goal would be to help prescribers have a realistic understanding of what the data said.
MR. LEHNER: That concludes, I think, this part of the presentation.
MR. ALLEN: Your Honor, I'm sure it's probably time to go. I have a document that we can publish tomorrow, that has not been published; it's been previously admitted. It's AK10017, which is the Japan trip summary but do you want to wait until tomorrow?
With that, Your Honor, subject to our discussions here this afternoon, and the technical matters, we call no more witnesses and once we get that cleared up, we'll rest.
THE COURT: Any reason why I shouldn't let the jury go right now and then we'll take the technical matters for a while today and I have another matter that starts at a quarter of -- or if I can finish up --
MR. ALLEN: It would be best for us to come back, because we could get everything in order.
THE COURT: Ladies and gentlemen of the jury, I'm going to let you go for today. We

have other matters to take up today. I'll let you go and we'll try to start back up at 9:00 o'clock tomorrow. And I'll just leave it at that.
Once again, before you leave, I will 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 or magazine articles or any -- listen to any TV or radio or do any Internet research about the subject matter of this litigation.
I'll see everybody tomorrow morning. Hopefully we'll get started around 9:00.
(Jury out.)
THE COURT: Please be seated. We're outside the presence of the jury. Just for the parties, while the depositions were being played I had a chance to look at the Eski and Beasley additional designations and stuff. The State had some objections to the Defendant's designations, and I'm overruling all of those objections. And Lilly had some objections to

three of the State's counterdesignations, and I'm overruling those as well.

I'm also overruling the State's objections to the Eski designations that Lilly has made. I've reviewed the counterdesignations of the State. Lilly hasn't given me its objections yet, but at least in my initial plans I don't see anything that jumps out at me, but if Lilly has something for either Eski or Wojcieszek, they'll need to get those to me. But I think that deals with all the subjects of what other additional things Lilly may have filed on the counterdesignations for Eski and for Wojcieszek. And I guess Toleffson, too. I think that catches me up on your designations.

We have 10097 hanging. It was Noesges 9 --

MR. ALLEN: Can I get -- yes, sir, I think we have --

THE COURT: That was the U.S. Sale Good Promotional Practice Definition of a Sales Call and Call Notes. That was an exhibit that you wanted to admit, Mr. Allen, even though it hadn't been discussed in the deposition. I think

you said it was self-authenticating and it came from the Lilly file and would be a business record.

MR. ALLEN: Yes, sir, I have numerous documents like that.

THE COURT: Maybe we should take them up first thing in the morning.

Am I correct as a procedural manner of what's logical to proceed, until I've admitted all the exhibits that the State has admitted, I probably should take up any applications that Lilly makes, because you're not going to rest until these exhibits are in so I guess what we're going to do, then, is take up -- why don't you show all of these, quote, unquote, numerous exhibits to your friends this afternoon, and we'll see if we can narrow down what's objected to.

And then I'll deal with all the admissibility issues, get exhibits in or not in, and then we'll take up applications on -- application from Lilly in the morning. And depending on what I rule, we'll either end the case or continue with Lilly's case.

MR. ALLEN: Yes, sir. We will get

those together. Mary Beth -- we're fixing to go back to the hotel. We'll get that done. We do have a fair amount. I'll tell you what they primarily deal with, Your Honor when I look at them. We're going to make sure every PDR is in evidence. We're also going to make sure we have the call notes, not just with Eski's, but were in the database which reflect that the activities which we have discussed throughout this trial occurred in Alaska. We have call notes, and we have PDRs, and I bet we have a few isolated documents. But that's the main -- I just want you to know, so you have a heads up of what's going to --

THE COURT: What I would like you to do is to go over them with opposing counsel so that because there may be a bunch of them. I hope that the number of the PDRs are going to be problematic. We'll get as many of them as agreed to as possible, so we can admit those and take up the ones that there's a fight over.

MR. ALLEN: That would be my goal, but -- that would be my goal.

MR. LEHNER: If they're complete and you just send us the document numbers, unless

you got them already here, it's fine.

MR. ALLEN: The main concern -- it's going to be the call notes from the call note database.

MR. LEHNER: We can do those.

MR. ALLEN: Thank you, Your Honor.

MR. FIBICH: Your Honor, on a scheduling matter, the lawyers for Lilly have been particularly coy about who they're going to call. To the extent that we may have rebuttal witnesses, can we get a general feeling within some reasonable time limitations when they think they're going to be through with their case?

THE COURT: Well, that's a reasonable question given --

MS. GUSSACK: Your Honor. Coy is not something I've been accused of very often so I'm going to mark this in my book.

MR. ALLEN: I would not accuse her of being coy.

MS. GUSSACK: As I explained to counsel for the State, we are currently engaged in an analysis of which witnesses we will be calling over what period of time. We've advised who we would be calling tomorrow, and we continue

to evaluate which witnesses we'll call by deposition and calling live --

THE COURT: Again, you know who they're calling tomorrow?

MR. ALLEN: That was coy, though, her answer right there.

THE COURT: You know who they're calling tomorrow.

MR. ALLEN: Dr. Kahn, as I understand it?

MS. GUSSACK: And Dr. Beasley by deposition. And we continue to provide notice to them as --

THE COURT: I'm not going to hold it to you, but can you give me your best shot as to how long you think your case is going to be -- I realize it's hard, because cross-examination goes longer. Everybody is experienced here. Are you hoping to rest on Friday? Are you hoping to rest on Tuesday?

MS. GUSSACK: Your Honor, I would say that we're hoping -- what we're hoping is probably not predictive of what we think is likely to happen, and it could well be Monday or Tuesday, but as we continue to evaluate that

we'll advise the Court and counsel.

THE COURT: They want to try to plan people coming -- they need to be rebuttals by planes or otherwise, and so they need to start planning on this. And I realize things are fluid, and, again, I'm not going to hold you to it, and to the extent you're giving me your best shot, nobody is wasting any time so I'm not going to hold them to it. They are -- it's a fair question.

MS. GUSSACK: Certainly, Your Honor. As soon as we know, we'll advise counsel and the Court.

THE COURT: But right now your best estimate is Monday, Tuesday, Friday? I mean, last week you told me you thought that we'd have -- Friday is what I got the sense of, was that you thought you were going to rest on, and I don't know if things have been slowed down. We've certainly had a few arguments and stuff, but I haven't heard two days worth of slowing down. And I realize that -- as the evidence comes in, you may change who you want to call and that sort of stuff, but last week your best shot was Friday. Is your best shot right now

Tuesday or Monday?

MR. LEHNER: No, I think it's probably going to be closer to Monday. That may depend a little bit in part on what you're talking about earlier. What is your preference in doing a conference to work on jury instructions? That's going to be, I think, an elaborate and fairly intricate dance here.

THE COURT: The question they've asked is actually a question for me because if I know -- I mean, I'll look at my calendar. I don't think I have afternoons open, which is generally my preference. If we need to get this done a little quicker, we'll take an evening or a good part of an evening, but at the end of the day what we'll end up doing, if we have to, is we'll send the jury home for a day and we'll spend the day working on jury instructions and take whatever time we need to do, and then you all can go back and practice your closings.

I mean, I am assuming that closings, if they don't take a full day between the both of you, not each, they're going to take close to a day. If I could have jury instructions ready to go and you could close and

then I could read jury instructions and they could start deliberating, that would be ideal. If need be, we'll close and I'll read the jury instructions the following day and then we'll start deliberating.

But I kind of have to get a sense of when the evidence is going to be in, and, once again, the sooner you can give me any additional jury instructions and give me -- for example, I don't know if people are going to want as jury instructions letting the jury know that there's an FDA regulation that says the following and you can consider this if you want to, and those kinds of things.

I don't think I've seen those in the packets I've been given, but that's kind of typical. At least if there was a car crash I'd be getting all sorts of things about what the statutes require and discussions of that. It's my -- certainly my hope that at least this weekend, if I've got your stuff, I can go through it and be able to give you on Monday -- Monday morning or even Sunday evening here's what I'm thinking of giving, and everybody will be given a full opportunity to make their record as to what

I didn't give that you think I should have given or what I am giving that you think I should be giving. Does that answer your question?

MR. LEHNER: No, no, that does. That's very helpful.

THE COURT: But, again, I have to have it from you to take it to start putting it together and redoing what I'm going to do. And I got more of a packet from Lilly, I think, than I did from the State, who seem to suggest, not inappropriately I think, that sometimes you need to see how the evidence is coming in, but now we're kind of there where I need it.

MR. ALLEN: Your Honor, we'll get it done. I hear the Court. And I'm going to get somebody that knows how to do it to charge -- to do us a charge and I'll just argue it.

THE COURT: If there's nothing else, then I'll see everybody normal time tomorrow, and then we'll take up these matters and hopefully be close to 9:00 o'clock.

MR. ALLEN: Thank you, Your Honor.

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

(Trial adjourned at 1:25 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 18th day of March, 2008.

_____

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