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 17

TRANSCRIPT OF PROCEEDINGS

March 25, 2008 - Pages 1 through 232

BEFORE THE HONORABLE MARK RINDNER
Superior Court Judge

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

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PROCEEDINGS

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

A couple things before we get started. I'm told that one of the jurors is running a little bit late, but he's on his way, so we'll be able to get started today.

I've gone over Lilly and Company's counterdesignations for trial and objections to the Plaintiff's, State of Alaska, trial deposition and exhibit counterdesignation. Lilly asked that three cuts be added to ensure completeness. The cut that starts at 228 colon 17 and ends at 229 colon 6 should be added for completeness to the State's designations. The other two don't need to be. They can be played as rebuttal testimony, if Lilly wants to. Lilly made one objection to the State's counterdesignations and that objection is overruled.

Lilly has provided me -- I'm sorry -- I left it on the bench.

Or I left it in my chambers, but I think I remember it. There were four other witnesses that Lilly indicated they want to designate.

There was Curtiss and I find -- and State had lodged orally a overall relevance objection to all of these and then I think followed up some with some written and Lilly filed a response this morning. As to Curtiss and Campana, I find that their testimony is relevant, but as to Campana, if Lilly goes into -- plays his deposition with the portion where there's some talking about -- this is going to be a gross generalization because I don't remember the right words, but, basically, safety analysis that might have been done, the door will be open to the Eski deposition.

So the portions of the Eski deposition that have so far been excluded by me. So Lilly can make that determination as they want to as to what they're going to do with Mr. Campana.

I have not yet gone over the specific objections to the counterdesignations to Curtiss and Campana that Lilly filed this

morning, and I'll try to do that soon.
As to Mr. Gilbertson and --
MR. ALLEN: Ms. Jackson.
THE COURT: -- Ms. Jackson. I do not see the relevance of those depositions for commissioners or ex-commissioners to say they didn't know about the lawsuit or the lawsuit being filed when they're really not the decisionmakers for the lawsuit being filed. I believe will only confuse the jury and would be more prejudicial than probative than for them to say that we didn't know anything about these things.
And so, I will -- I find that the excerpts that at least have been provided to me are not -- are not relevant, or to the extent there might be some marginal relevance would confuse the jury and are more prejudicial than probative.
So I need to still look at the specific objections and counterdesignations and objections to Curtiss and Campana.
Those are my rulings as to those things.
I hope today to give everybody a

packet of half of the jury instructions. These are what I hope will be the noncontroversial jury instructions.
They're the sort of boilerplate that goes beforehand in talking to the jury about what evidence is and how to view witness' testimony and exhibits. They also go to the end as to how the jury should proceed with their deliberations when they do their deliberations, that ten of them have to agree to the verdict. It leaves out what I consider the guts of the instructions except for the definition of more likely true than not true.
As to the two main causes of action, the defect claim and the UTPA claim, I'm still playing a little bit with at least my proposals, and what I may end up giving to you is three more packets that will be what I call discussion packets, which may include things I'm thinking about doing or maybe want to see combined so that we'll have a little discussion and objections and I can get your positions on various things and then try to finalize that.
So what I hope to do sometime today -- and my secretary's sort of making them

look prettier -- is giving you a packet of what I hope will be noncontroversial portions of the jury instructions.
And then I may give you three other packets: One as to instructions regarding the defect claim; one as to instructions regarding the UTPA claim; and then something to talk about, a special verdict form. I've looked at both of your special verdict forms, and I'm sort of uncomfortable with both of your forms. I'm not sure -- I do believe we need to go into the kind of specificity that the State has provided as to the UTPA claims.
But I'm not sure why we need to go into that specificity year by year on the defect claim. If the product's defective, it's defective, and then we're into Phase 2 of the trial where we'll have causation having to be proved in front of a second jury and those things. And I don't know why it makes a difference, but I'm willing to hear that -- that's more the approach that Lilly took as to that cause of action.
I'm not comfortable with Lilly's approach as to the UTPA claim, because I think if

we don't know what the violations actually are, it's very difficult to have a second portion of the trial whether it's in front of me or in front of a jury or whether both of those things are applicable, not having to go back through all this evidence all over again, and I'm going to try to avoid that as much as possible.
And so I may just give you back those -- I'm just highlighting that now to discuss, but that's anyway, how I'm proceeding with the jury instructions. Sort of leaning that maybe we'll try to go late on Wednesday to do some discussion of jury instructions, but we'll talk about that some more.
Anything else before we -- while we wait for the jury?
MR. LEHNER: Yes, Your Honor, a couple things. One, I think certainly with respect to our jury instructions and the UTPA claim, the thrust of what we were indicating was that it's hard for us to put anything down until we really know specifically what the violations are. And I think if that's going to be the subject of the discussion that would be a prudent place to begin.

THE COURT: That will be certainly be that. The State has given me an instruction that lists each and every way that they believe the UTPA was violated and --

MR. LEHNER: But essentially it's just sort of a recitation of the UTPA statute put into sort of jury instructions --

THE COURT: No, they have another instruction that's about three or four pages that lists weight gain, hyperglycemia, hyperlipidemia. There's four things and as for each thing, they say how they claim the UTPA was violated, and then as to each thing they have something in there as to what they need to prove or what they say they need to prove.

But I think it pretty clearly spells out how they say the UTPA was violated and then the jury -- the special verdict form that they do seems to track that with each of those ways being identified and each of the years being under each of those things. I think that's what the State does. Whether that's the right approach or -- I'm trying to think about.

MR. LEHNER: And if I could ask for just brief reconsideration on your decision with

respect to Karleen Jackson and Joel Gilbertson, and there may be a distinction there.

THE COURT: Sure.

MR. LEHNER: Ms. Jackson is the current head of the Department that is charged with the responsibility for safeguarding the well-being of the citizens of this state, particularly with matters that are being discussed here and Medicaid payments.

And I think it is absolutely pertinent to the jury's understanding of the case what her knowledge was about the allegations that were made, when she learned about them, how she learned about them. She is the person, the buck stops with her presumably about these matters.

It goes to motive of the State. And we know that, as you've indicated, motive is an issue in this case and it ought to be a motive for the State. Mr. Gilbertson, albeit was the prior commissioner before the lawsuit was brought, we believe he has pertinent testimony, but certainly with respect to the current commissioner at the time the lawsuit was brought, her state of understanding of what the State knew or didn't know, I think would be very relevant to

the jury's understanding of why the State may have decided to --

THE COURT: Why if she's not the person to authorize a lawsuit or to make those decisions -- I mean, that's the implication of these questions, which is why I find it to be confusing and prejudicial, more prejudicial than probative because I mean, are we going to put on the attorney generals who made the decisions to authorize the lawsuit and let them talk about what they understood?

MR. LEHNER: It doesn't go to authorization; it really goes to knowledge. She is the person who is charged with sort of overseeing and thinking about what's in the best interest of the people here in the state. And even if she decided to say, I disagree or I agree, I don't think that's the relevant issue. The fact that she wasn't even consulted is the relevant issue. It's not whether or not she's authorized to initiate the lawsuit.

THE COURT: That implies that she should be consulted and that's where I'm kind of losing your argument.

MR. LEHNER: Well, I don't know but

I think it's relevant whether she was or not. Whether she should be isn't really an issue that we're raising. Here is somebody that the State has entrusted --

THE COURT: The President of the United States wasn't consulted either but -- and I use that as kind of a silly example to try to make a point.

MR. LEHNER: A number of people weren't consulted, but she is the person who is delegated responsibility as to oversee the welfare of the citizens with respect to the very matters that are here. So you would think -- one would think that she might have an opinion, a view. She might be consulted. She might not have been consulted.

The jury would be entitled to know that, given that that's her statutory titular responsibility to oversee the health and welfare, particularly with respect to these matters. It's not sort of a general, you know, the governor, too, is charged with the health and responsibility of the citizens, but specifically with regard to the matters that we're talking about here, that's her job. And the fact that

she knew nothing about this, I think, really goes to and certainly the jury can infer whatever it wants to infer from that, but it goes to the question of motive. And we think that's particularly relevant, given the fact that she held the job at the time this lawsuit was brought and she's still in that position.

THE COURT: Mr. Suggs.

MR. SUGGS: Your Honor, I don't even know what to say about this. This has nothing to do with Lilly's duty to warn physicians, nothing to do with whether the warnings' read, it has nothing to do with whether they violated the UTPA.

MR. ALLEN: And you've made your ruling.

THE COURT: I'm going to stick to my prior ruling and to the extent that you're orally asking me to reconsider that, I'll deny that request.

Anything else before we -- well, actually, I do.

Can you give me a sense of where we are so I can give the jury a little better sense of what is going to be happening and what next

week may look like? And that we -- Monday is a Court holiday, and -- with the one-day delay, I'm just trying to get a sense of where we are.

MR. LEHNER: Your Honor, of course, depending on many things, but we believe and I can tell you where we sort of are right now. Dr. Baker is going to continue his testimony today. I assume he's going to be cross-examined -- unless the State is going to waive its cross-examination. I would be loathe to predict how long that will take.

Our next live witness will be -- and then we have some videotapes to play. We have about -- I'm trying to think, we have today about -- a total of about 90 -- maybe a little bit less than two hours of videotape to play.

And then our next witness would be David Noesges, and again, unless the State waives its cross-examination --

MR. SUGGS: Doubtful.

MR. LEHNER: Doubtful. He'll be on. And then we would have to play the remainder of the videos, which is probably less than an hour video. Then we would be able to rest our case depending on any other circumstances that

may arise but we --

THE COURT: So we have Dr. Baker and David Noesges are live witnesses, and the rest is maybe a half day's worth of video.

MR. LEHNER: Yeah, probably three hours of video in total. Three to three and a half -- Dr. Cavazzoni, probably three and a half hours of video.

THE COURT: Depending on the cross --

MR. ALLEN: Based on that, I think we can -- based on that we can conclude on Thursday. If we get started today, that's --

MR. LEHNER: That would be my -- I suspect we can conclude on Thursday as well.

THE COURT: Okay.

MR. LEHNER: And then I don't know whether the State -- and the State may decide that they may put on a rebuttal case --

MR. ALLEN: I just have about two weeks of rebuttal, Your Honor.

MR. LEHNER: Call me when it's over, and I'll come back.

MR. ALLEN: Your Honor, our proposal for rebuttal is currently less than 30

minutes, so --

THE COURT: Okay. I appreciate the heads up.

We'll then see if we've got our full jury there and as soon as we do, we'll get started.

We'll be off record.

(Off record.)

(Jury in.)

THE COURT: Please be seated.

We are back on the record in State versus Eli Lilly. All members of the jury are present. Good morning, ladies and gentlemen.

Ms. Mitchell, I hope you're feeling better.

MS. MITCHELL: Thank you.

THE COURT: Are we ready to resume with the testimony of Dr. Baker?

MR. KANTRA: Yes, we are, Your Honor.

THE COURT: Dr. Baker, if you could come forward, please.

THE WITNESS: Thank you, Your Honor.

(Dr. Baker previously sworn.)

THE COURT: And, Dr. Baker, you took an oath in this case on Friday. Do you understand that you're still under the requirements of that oath as you testify today?

THE WITNESS: Yes, Your Honor.

THE COURT: Thank you. Please be seated.

Please proceed.

DIRECT EXAMINATION, continued

Q. (BY MR. KANTRA) Good morning, Dr. Baker.

A. Hello, Mr. Kantra.

Q. On Friday you had described for the jury several different studies in which you used the phrase treatment-emergent diabetes. Can you tell the jury what the phrase treatment-emergent means?

A. Yes. That's a term that we use in safety to indicate that whatever it is that's observed is observed during the course of the study, so that means it wasn't evident when the study started and it's observed during the course of the study. Doesn't tell you why it was observed, but it just tells you that that's when we saw it.

Q. So does the fact that an adverse event occurs while someone is treated with the medication mean that the medication actually caused that adverse event?

A. No, not necessarily. That's what we look at from -- for other reasons. So for example, last week when we talked about treatment-emergent diabetes, it just means that the diagnosis or abnormal blood tests weren't there when the patient went into the study. But during the course of the study it was observed, but we test the question of what caused it by other ways. So for example, we would look at what happened with placebo and remember, in that treatment-emergent diabetes study the number of treatment-emergent cases were not different on placebo than olanzapine and you certainly wouldn't think that or I don't think that anybody would conclude that placebo had caused that to emerge.

Q. Does the fact that diabetes is a common disorder in the population affect the assessment of causation with respect to diabetes as well?

A. Well, right. That -- things happen, you know, to all of us in the course of life, whether

we're on treatment or not. It happens over the course of time and when things are common, then you's expect some of those happening over time regardless of other things that are going on.

Q. When we left off on Friday, we were talking about the classwide labeling change in regards to diabetes. And I wonder if we could bring up again EL2135. And if you recall, when we were speaking on Friday, you were describing this letter.

Do you recall, again, this letter in which the FDA requested that the members of the manufacturers of atypical antipsychotics add a diabetes warning to their labeling?

A. Yes.

Q. Okay. And if we can look at the second paragraph of this letter here. It begins by saying that after reviewing the available data pertaining to the use of atypical antipsychotic medications and diabetes mellitus adverse events, we have concluded that the product labeling for all atypical antipsychotics should be updated to include information about these events.

I want to take you back to the beginning and ask you: When they refer to the

available data, what is your understanding of the data that would have been available to FDA in making this determination?

MR. SUGGS: Objection; foundation, Your Honor.

THE COURT: Overruled.

Q. (BY MR. KANTRA) You can answer.

A. Yes, a few things. First, we knew that they had asked for information from all manufacturers. We had gone over that on Friday, all those data submissions that we had sent in response to their letter requesting lists of all the atypical antipsychotic manufacturers early in 2000. So I believe that they would have looked at that information from all of them.

And then, in addition, we knew that they told us they were looking at other things such as that study, the epidemiology study that was done across all the VA hospitals that was completed shortly before this letter.

Q. So in addition to the submissions you described on Friday, there would have been submissions similarly from the four other manufacturers of atypical antipsychotics at that time?

A. I assume --
MR. SUGGS: Objection; speculation, Your Honor.
THE COURT: You're assuming. You don't really know what the other manufacturers submitted, do you?
THE WITNESS: That's right.
THE COURT: I'll sustain the objection.
Q. (BY MR. KANTRA) But the letter requested that information from the manufacturers? That's what the letter shows; is that right?
A. Yes.
Q. The letter shows, if you go to page 2, and if we look at paragraph 2 of that letter, in the first sentence it says that although we believe that the labeling changes accurately reflect the currently available information about antipsychotic use and diabetes mellitus, we acknowledge that additional labeling changes may be required as new information becomes available.
Was it surprising that the FDA was expressing that it might anticipate that additional labeling changes would be required?

A. No. That's the normal course of business in safety. We keep getting new information, we learn more when the drug is on the market and sometimes the new information leads to different conclusions and then new labeling change. So that wouldn't be a surprise at all.
Q. If we go down further to the sentence that follows here, the FDA identifies a couple of areas that they say require additional research. In particular they say that they include, but are not limited to: Identification of subpopulations at greatest risk for diabetes mellitus adverse events, exploration of the relative risk for diabetes mellitus adverse events among the different antipsychotics, and evaluation of the potential mechanisms of action.
And I want to take a moment just to ask you about those three areas that are identified there.
They refer, first, to subpopulations may be at greatest risk. And can you explain how Lilly understood that phrase?
A. Yes. That means within the overall population of people taking the drugs, and

looking at who has adverse events or who has diabetes in the course of treatment, trying to figure out whether there were groups that were more likely to do it.
This was the sort of thing that I had talked about in the TED analysis. So for people who have hyperglycemia or some elevation that's not diabetes at baseline, that would be a subgroup who are at greater risk than the subgroup that doesn't have that sort of thing at baseline. That would be our understanding.
Q. Okay. And the reference to exploration of the relative risks for diabetes among the different antipsychotics.
How did Lilly understand that?
A. That's referring to whether the rates differ from one to another, the sort of thing that you learn from head-to-head comparisons of one treatment versus another.
Q. And the reference to potential mechanisms of action at the end.
How did Lilly understand that?
A. That's looking for some explanation. If this is contributed to by the drugs, what -- what about it contributes? Why is it happening?

Q. And did Lilly, in fact, after the 2003 label change undertake further study and research of these three areas?
A. Sure.
Q. So why don't we talk a little bit about each one of these, then.
What did Lilly do to take a look at subpopulations in regards to this request at FDA?
A. We continued to do more work, more studies and then analyses within our studies looking at questions like who -- what would predict who would be at the most risk? So, again, submissions of whether say, one -- men are at more risk than women, or older more than younger. That sort of question.
Q. And these would have been in the context of Lilly's clinical trials, ongoing clinical trials?
A. Clinical trials and than also pooled analyses that would pool together more than one trial.
Q. And what about with respect to the request for additional evaluation of whether there were differences among the atypical antipsychotics with respect to risk of diabetes,

what did Lilly do to evaluate that?
A. We continued to do studies. There were a number of head-to-head comparisons between olanzapine and other treatments subsequent to this label change and also reviewed, of course, studies done outside of Lilly such as the CATIE study.
Q. What about with respect to mechanistic studies looking at potential ways if a drug caused something, it might do so?
A. We've continued to pursue clamp studies, looking for mechanistic direct effects. We have a clamp study that's going on now -- still going on, in patients with schizophrenia looking -- looking at this.
Q. Let's move from the 2003 label change to the 2007 label change. And I want to ask you, first, were you involved in discussions and evaluation of data relating to the 2007 labeling change that revised the diabetes warning?
A. Yes.
MR. KANTRA: Can we go ahead and bring up EL2958?
Q. (BY MR. KANTRA) And this was something we looked at on Friday, but just to -- just to

remind, if we go to the next-to-last page, and we look at the bottom there, does that reflect that this is the package insert from October of 2007?
A. Yes.
Q. And if we go to internal page 8 of that document, and we look down in the last half of that page where it begins with hyperglycemia.
And does that reflect the beginning of the revised warning on that?
A. That's right.
Q. Okay. Can you tell the jury what your role as a safety physician would have been with respect to this change in the labeling regarding hyperglycemia?
A. I was part of the group that met with the FDA to discuss it and then decided to accept the changes to our label.
Q. And with the benefit of four additional years of study, does this labeling state that Zyprexa causes diabetes?
A. No, it does not.
Q. Or hyperglycemia?
A. No.
Q. I want to direct your attention to the third sentence in that first paragraph, and the

sentence reads: Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood.
And I want to ask you: Was that sentence -- is that sentence the same as what appeared in the 2003 label?
A. Yes, it is.
Q. And I want to direct your attention to -- if we can go to internal page 29 for just a minute.
And there's a section that's entitled up at the top, Other adverse events observed during the clinical trial evaluation of olanzapine.
Are you familiar with that section of the labeling?
A. Yes.
Q. And if we go to the first sentence that follows that, does it identify the total number of patients that Lilly had data for at that point?
A. Yes.
Q. And that's about 8,661 patients?
A. Right.

Q. And is that larger than the original labeling when Zyprexa was approved back in 1996?
A. Yes.
Q. And if we look in the section on the endocrine -- if we go down below where it says digestive system, see there where it says diabetes is listed as being an infrequent disease?
A. It's listed as an infrequent adverse event during clinical trials.
Q. Okay. And is that the same as what appeared in the 1996 label --
A. Yes, it is.
Q. -- in terms of frequency?
And if we drop down further, do you see in the metabolic and nutritional disorders a reference to hyperglycemia?
A. Yes.
Q. And is -- that's also listed as having occurred infrequently during clinical trials?
A. Right.
Q. And is that the same as what appeared in the 1996 label?
A. Yes.
Q. And if we go up to the beginning of this

section in the section that begins with events or further categorized by body system. If we can highlight that for just a minute.

And that provides the definition of what an infrequent adverse event is; is that right?

A. Yes.

Q. And that would be events that are occurring in 1 to 100 and 1 to 1,000 patients, correct?

A. In that range, yes.

Q. Okay. Does the 2007 -- if we can go back to internal page 8 to the warning on hyperglycemia.

Does the 2007 labeling suggest that there is an increased risk of diabetes in patients treated with Zyprexa compared to other atypical antipsychotics?

A. No.

Q. Does it suggest that there is an increased risk of hyperglycemia with Zyprexa compared to other atypicals?

A. No.

Q. What does it say with respect to the risk of changes in blood sugar levels?

A. You can read it in this last sentence. It says: While relative risk estimates are inconsistent, the association between atypical antipsychotics and increases in glucose levels appears to fall on a continuum and olanzapine appears to have a greater association than some atypical antipsychotics.

Q. Okay. And can you tell the jury what -- how would you explain what a continuum is? What it means?

A. Continuum is a range.

Q. Okay. So what the -- what the labeling is saying, then, is that Zyprexa ranks higher than other atypical antipsychotics with respect to changes in blood glucose levels; is that correct?

A. Higher than some.

Q. Okay. And why isn't that the same thing as saying that Zyprexa has a greater risk of diabetes than some of the other atypical antipsychotics?

A. Because those are two different things. This is talking about average blood glucose levels. It doesn't tell you what proportion of those average glucose levels or for what

proportion of patients that would represent an abnormal change. Remember, diabetes is a disease; average glucose across studies is not a disease.

So the way that we look for the presence of that disease would be based on individual patients who actually have a diagnosis or who have increases that would put them into that range. And in the case of this analysis, that's what we looked for and that's where we don't find a difference from one treatment to another.

Q. Dr. Baker, you told us that you had participated in meeting with FDA with respect to this particular label change. And I want to ask you whether, in particular, did you participate in a meeting on September 17th with FDA about a proposed change to labeling in regards to hyperglycemia?

A. Yes.

Q. And during the course of that meeting, did Lilly present information to FDA from its clinical trials that compared Zyprexa to other atypical antipsychotics with respect to changes in blood sugar levels?

A. Yes, we did.

Q. And you're familiar with that data set that was presented?

A. Yes.

Q. Okay. Did you prepare a slide that would help you explain the kind of information that was presented to FDA in September of 2007?

A. I did.

Q. Can you bring up TD2131.

And why don't you explain what this presentation of data was at that September 17th meeting?

A. Yes. What we did for the FDA is that we looked at each of the individual comparisons that we had of Zyprexa versus another atypical antipsychotic, and we looked at it in a couple of different ways regarding this topic. So what you're looking at here is the average change from baseline to the end of treatment. So what you got before you were on medicine until after the treatment and how it looks for each of these different comparisons.

Q. And what does it show with respect to Zyprexa in comparison to two other atypical antipsychotics, Seroquel and Risperdal?

A. There was no difference. There was no difference among those three. So that's sort of the middle of the range.
Q. Okay. And then Clozaril and Geodon, how did Zyprexa compare to those two?
A. Well, at the bottom here is Geodon. That was the newest of these drugs, and you'll recall it's the one with the least weight gain among these. And what we found in terms of average glucose change is that there was more on Zyprexa than Geodon on average, and that was a moderate amount, about five milligrams per deciliter on average.
Q. Did this data provide any information as to whether or not patients actually developed diabetes more when they were on Zyprexa than on these other agents?
A. No. Again, these are average change. We looked at that question of who's developing diabetes in other ways.
Q. Okay. So why don't we go and look, then, at the next slide, which is going to be 2132.
And can you explain to the jury what data was presented in regards to rates of

potential cases of diabetes and how that looked?
A. Yes. This was what you have, and again, we looked at this based on the information we had from every one of the comparisons that we had of Zyprexa to other atypical antipsychotic drugs, and in most of the cases, we found no difference.
No difference between Zyprexa and Seroquel or between Zyprexa and Risperdal or between Zyprexa and Geodon. We did find a difference compared to clozapine with a greater number of patients developing potential treatment-emergent diabetes during clozapine treatment.
Q. And is the labeling in the diabetes warning -- if we can go back, Nick, to internal page 8 for a second and if we go down to the end of that first paragraph where it talks about increases in glucose levels. Is the language in the 2007 label regarding a continuum of risk consistent with the first analysis regarding average changes or the second analysis regarding potential rates of diabetes?
A. This is about the first analysis about average changes. It's about glucose levels.
Q. Let me ask you whether you're aware of

any data outside of Lilly that has been put together that evaluates the rates of diabetes on patients treated with Zyprexa compared to Geodon again, and ask you if you're aware of any of those kinds of studies?
A. Yes, there are some.
Q. Okay. Can you describe those?
A. Well, there's a couple of recent clinical studies, head-to-head studies that address that. One of them -- one of them is the CATIE study. I think we talked about that before. That was the National Institutes of Health study comparing the different atypical antipsychotics and schizophrenia. That one looked at the rate of diabetes through -- and they identified it through new introduction of treatment for diabetes. And that found that the rates -- the rates did not differ among the atypical antipsychotics in that study.
Q. Okay. And was that despite the presence of greater weight gain on Zyprexa than with the other agents?
A. Yes, that's right. And again, Geodon tended to be the lowest for weight gain, but that did not translate into differences in rates of

diabetes.
Q. And was there a second study that also addressed this as well?
A. Yes. There's -- there's a study that has just been released this year by Pfizer who makes Geodon. It's a very large observational study in which patients were randomized to treatment with either olanzapine or ziprasidone, and, in fact, it's now the biggest study we have. They looked at roughly -- I think it's over 9,000 patients on each drug for up to a year. And one of the things that they were looking at there was whether there's differences in ketoacidosis, diabetic ketoacidosis.
Q. And what is diabetic ketoacidosis?
A. That's one of the worst forms -- that's one of the worst forms or worst things that happens in the course of diabetes. It's very life-threatening and it was a very important question five or six years ago when Pfizer embarked on this study whether that was occurring at different rates from one atypical antipsychotic to another.
Q. Can we put 2958 back up again with the warning back up on page 8, and if we go to the

last paragraph on that page.
And, in particular, the one that begins with olanzapine monotherapy in adults. I want to ask you whether this labeling change in 2007 included fasting data from placebo-controlled trials?
A. It does.
Q. And when did that information become available to Lilly?
A. This is based on a number of placebo-controlled studies that were conducted between 2005 and 2007, the last two studies finishing in 2007 -- I should say the studies finished between 2005 and 2007, and then this analysis was done in 2007 once the studies were done.
Q. And then if we go up to the paragraph right above that, does that reflect that there were -- that there were data from the CATIE study that you've mentioned that were included in this 2007 label as well?
A. That's right.
Q. And what kind of information was provided from the CATIE study regarding changes in blood sugar levels?

A. This is showing the average change. This is a little different than some of the ways we've been looking at it, because it's looking at the average not from the beginning to the end, but it's looking starting at the beginning what's the highest -- they checked blood a number of times through it and they're looking for what is the highest change that you get at any point in the course of the study, and then it's averaging the two highest to give you this number.
Q. And separate from the average change data that was presented here, did the CATIE study actually provide information on whether or not patients developed diabetes during the course of that study?
A. Right. I had mentioned that earlier. They did look for the number of patients that started treatment for diabetes.
Q. And were there significant differences on that measure of whether they did or not?
A. No. That wasn't different, and the average changes weren't -- in glucose weren't different either.
Q. Can you tell the jury why Lilly made this labeling change in 2007?

A. Well, because the FDA had asked us for a change, and we met with them and discussed the change and put this in.
Q. And why would Lilly not have made a change earlier in its -- in its labeling to add this kind of information?
A. Well, because we'd been reviewing this information as it came in and looking at this in the context of all the information and the current labeling. Our medical and regulatory judgment was that the labeling had been okay.
Q. We heard a lot about the 2004 consensus statement that was sponsored by, among others, the American Diabetes Association.
Are you familiar with that consensus statement?
A. I am.
Q. And are the conclusions that can be drawn from the labeling change that we talked about consistent with the ADA consensus statement?
A. Well, some of them are and some of them -- some of them aren't.
Q. So why don't we begin by talking about how it is consistent, first.

A. Okay. Well, it's consistent in a couple of ways. The ADA consensus and the labeling both point to apparent higher rates of diabetes in patients with schizophrenia. And the ADA consensus and the labeling both talked about good medical practice in terms of screening patients, monitoring patients for diabetes during treatment. And I think that -- those are pretty consistent between the two of them.
Q. And how are they -- how are they inconsistent?
A. The main inconsistency is the ADA -- the ADA consensus says that there are differences or there is rank ordering in risk for diabetes, and that's not what the label says.
Q. Now, we've been discussing the science and the data for a little while now, and what Lilly did to analyze the data regarding Zyprexa and weight gain and diabetes and how Lilly communicated that to FDA.
What I want to do is move on now and talk about Lilly's communications with physicians regarding weight gain and diabetes.
I believe you told us at the beginning that you have frequently spoken with

physicians regarding various issues about Zyprexa, including weight gain and diabetes; is that right?
A. Yes. That was a part of my job for a number of years.
Q. And from the conversations that you've had with physicians, what is your understanding of the extent to which whether or not physicians primarily rely on information from pharmaceutical companies like Lilly in making decisions about what to prescribe and how to prescribe to their patients for treatment of schizophrenia?
MR. SUGGS: Objection, Your Honor; foundation.
THE COURT: The foundation is that this is based on his own experience --
MR. SUGGS: Speculation, Your Honor.
THE COURT: Again, to the extent that it's based on his own experience, that's not speculation. You can cross-examine.
Q. (BY MR. KANTRA) Go ahead.
A. Sorry, can you repeat that?
Q. Sure. Absolutely.
Based on your interactions with

other physicians, my question is: Is it your impression that they rely primarily on information from pharmaceutical companies like Lilly in reaching their conclusions about how to prescribe medications to their patients?
A. No. Physicians that I talked to would be very interested in what information we had or answers to their questions. That would be for sure. But they would, then, put it in the context of other information that they had and particularly, I think, in the context of their training and experience.
Q. In terms of information that Lilly provides to physicians, can you describe the ways in which Lilly provides information about Zyprexa and weight gain and diabetes to physicians?
A. There would be quite a few ways.
Q. Okay. Can you talk about a couple of those different ways that the company might do that?
A. Sure. Different doctors may look for different -- for information through different routes, and Lilly provides information through a lot of routes. There are some who prefer to get it from the scientific literature so we publish

our studies. We present them at meetings and it's available there.
There are others that will be interested in getting the information from the medical department, and we prepare medical letters across topics that are of interest to them to provide the information.
Some get it from the labeling, so information is available in the labeling.
Others like to hear from sales reps, so a lot of point of having sales reps and having materials that they have for promotion is for providing information for physicians.
There's others that prefer to talk to other physicians and Lilly typically -- and other companies typically engage speakers, doctors who are experts to talk about the information that's on the drug. And I'd say these days increasingly people like to do their own research. So we have a web site and if people are going onto the web to look for information that's one place that they could come and get medication information.
Q. I want to focus on one of the things that you mentioned there, and that is the medical

letters that the company provides to physicians.
Can you describe what a medical letter is?
A. Yeah. A medical letter is sort of like a research paper and it's something that is pulled together by our medical department to give background on what we know on whatever the topic is and Lilly's conclusions about that topic.
Q. And who -- who researches or writes these letters?
A. It's from the U.S. Medical Department and we have -- we call it a medical information department, health care professionals that work just on giving these answers and writing these letters, but the physicians also contribute and the physicians supervise and the letters are always ultimately the responsibility of the doctors.
Q. And is it in the ordinary course of Lilly's business to communicate scientific information to physicians about its products like Zyprexa to physicians through medical letters?
A. Yes.
Q. Are Lilly's medical letters prepared by people who have knowledge of the data that's

contained in those letters?
A. Sure.
Q. And while you were working specifically on Zyprexa, did you prepare medical letters?
A. Sometimes I did, yes.
Q. Did you supervise physicians who prepared medical letters on issues like weight gain and hyperglycemia and diabetes --
A. Yes.
Q. -- relating to Zyprexa?
A. Yes.
Q. Is it Lilly's ordinary practice to keep records of these medical letters?
A. Yes.
Q. And in keeping those medical records would it be Lilly's ordinary practice to keep historical or earlier versions as well as the current versions of those medical letters?
A. Yes. That's our policy.
Q. And I take it from your testimony that there were actually letters on weight gain and hyperglycemia that Lilly actually prepared for doctors?
A. Several of them, yes.
Q. Okay.

A. Thank you.
MR. KANTRA: For the record, I'm showing Dr. Baker what have been marked as EL2990, 2991, 2993, 2996, 3003, 3004, 3008, and EL2994, 2995, 2987, 2988, 2944, 2973, 3014, 3015, and 3899.
I'll have Dr. Baker go through and read off the numbers that are in front of him. So when you're done taking a look through that.
Q. (BY MR. KANTRA) First, let me ask you: Are you familiar with these letters?
A. Yes, they look familiar.
Q. And these are -- what are these that you're looking at?
A. These are medical letters from our U.S. Medical Department related to issues with weight and related to glucose.
Q. Okay. And just so there's no confusion in the record, can you read through the letters that you have there in terms of -- there's a number on the bottom of each document.
A. Do you mean the one that's in this blue?
Q. Yeah.
A. EL2990, EL2991, EL2993. Looks like EL3003, EL3004. I'm sorry, this one's hard to

read. I think it's EL3008. EL2994, EL2995, EL2996, EL2987, EL2988, EL2973, EL3014, EL3015, EL3911, and the last one is EL3898A.
Q. Thank you.
The State has pointed out that these letters do not have a date or --
THE COURT: Mr. Kantra -- Mr. Kantra, just -- you reference two documents that I believe the witness didn't reference, and he referenced two documents that you didn't reference. Whether that matters, I don't know, but I'm just pointing that out.
MR. KANTRA: We'll go with what Dr. Baker identified and add in as we need to.
THE COURT: Okay.
THE WITNESS: There were two of them that were a little hard to read. I don't know if I misread them.
MR. KANTRA: We'll cover them.
THE WITNESS: Okay.
Q. (BY MR. KANTRA) Let me ask you again: The State has pointed out on earlier occasions that these letters do not have a date on them or a specific Lilly logo on them.
Do you see that?

A. Right.
Q. And can you explain why that is?
A. Yes. Because our -- our medical department would prepare a master copy of the research paper, medical letter, and then when it was sent to a physician, an individual physician, it would go out on Lilly's letterhead with the date that it was mailed to that particular doctor.
MR. KANTRA: And can we bring up EL3932?
And first of all, if we go to the end of this document, and go up a page or two before the references --
MR. SUGGS: Is this in evidence?
MR. KANTRA: This is EL3932.
MR. SUGGS: Your Honor, I don't know if this has been admitted into evidence. I thought our rule was it doesn't go up on the screen unless it's admitted.
THE COURT: That's the rule.
MR. KANTRA: I'm sorry. Take that down off the screen, then.
Q. (BY MR. KANTRA) I'll ask you to look at this letter.

A. Is this one that I have --
Q. Up on your monitor.
A. Okay.
Q. I can make it easy for you.
A. Thank you.
Q. Just let me know when you've had a chance to look through it.
A. I'm -- I scanned through it.
Q. Okay. Do you recognize this medical letter?
A. Yes. This is a medical letter regarding olanzapine and blood glucose changes.
Q. And was this a medical letter that you played a role in preparing?
A. Yes. And it's signed by me.
Q. And can we bring that, then, back up on the screen, then?
THE COURT: Are you moving to admit it?
MR. KANTRA: I'm sorry, I'll move that into evidence.
THE COURT: Any objection?
MR. SUGGS: No objection, Your Honor.
THE COURT: Okay. EL3932 is

admitted.
Q. (BY MR. KANTRA) And for the jury's benefit, if we can go back to the first page of that document. And at the top of it you see the Lilly logo in the right-hand corner?
A. Yes.
Q. And it's dated and addressed to an individual physician?
A. Yes.
Q. And if we go to the page right before, the reference is at the end of the medical letter. And one page further down.
And does that reflect your signature?
A. It does.
Q. Okay. Now, I want to ask you specifically about another medical letter, which is EL2994.
A. I think I have it.
Q. Okay. Good. Just in case you need it.
And if we can bring up EL2994.
MR. SUGGS: Is this admitted?
MR. KANTRA: I don't believe there was an objection to this.
MR. SUGGS: Your Honor, I don't

know if this is admitted or not.
THE COURT: Mark, is 2994 in?
MR. LEHNER: Your Honor, can we approach?
THE COURT: Sure.
THE CLERK: Judge, I'm not showing it.
(Bench discussion.)
MR. LEHNER: This was one that we used in the opening that was on the preadmit list to which there was no objection at the time, and they had been putting documents up like that.
MR. SUGGS: I was just asking.
THE COURT: He's just asking. We don't have it listed as being admitted, but you've laying the foundation for all of these sort of generic medical letters.
MR. LEHNER: Why don't you just move them all in.
MR. KANTRA: I can certainly do that.
(End of bench discussion.)
THE COURT: Do you want to get them all in, Mr. Kantra, and then we can put them on the screen so the jury gets to see them?

MR. KANTRA: That will make it easier.
Q. (BY MR. KANTRA) Dr. Baker, I've asked you about the medical letters regarding weight gain and hyperglycemia that I presented to you and the exhibit numbers that you've identified.
Those represent medical letters that you or a physician you supervised prepared regarding weight gain and hyperglycemia?
A. Yes.
MR. KANTRA: And, Your Honor, I move those into evidence at this time.
MR. SUGGS: No objection, Your Honor.
THE COURT: EL2990, 2991, 2993, 2996, 3003, 3004, 3008, 2994, 2995, 2987, 2988, 2973, 3015, 3899, 3911, and 3898A are admitted.
You, Mr. Kantra, referenced 2944 and 3014. And I don't know if Dr. Baker referenced those, so --
MR. KANTRA: That's correct. And if we go to those letters, we'll do those separately, Your Honor.
THE COURT: Okay.
Q. (BY MR. KANTRA) Okay. Let's look

specifically, then, at the letter that's identified as 2994, EL2994.
A. Okay.
Q. Do you have a copy of that there?
A. Yes, sir.
Q. And you recognize this document?
A. I do.
MR. KANTRA: For the record, this is a letter entitled Zyprexa Blood Glucose.
Q. (BY MR. KANTRA) Do you recall approximately when you prepared this letter?
A. Yes. This would have been from late 2000 or early 2001. It was in that time frame.
Q. And how do you know that?
A. Based on the literature review, the literature that's reviewed in here and the review of our spontaneous reports database, the timing of that would help me time the letter.
Q. Why don't we look at what's contained in the medical letter on this. On the first page we have a summary. Presumably that's an overview of the information that's in this letter?
A. Right.
Q. Why don't we go to internal page 3 of the document.

And if we look at the bottom, there's a section that begins Zyprexa Experience, and then there's a reference to Overall Integrated Clinical Trial Database.
A. Yes.
Q. Okay. Does that refer to the clinical trials of Zyprexa that helped to support the original approval by FDA back in 1996?
A. That's right.
Q. And if we go to page 4 of the document, and at the bottom, again, do you see something that says Post-Marketing Experience With Zyprexa?
A. Yes.
Q. And can you tell the jury what that refers to?
A. This is counting the number of spontaneous reports related to glucose or diabetes abnormalities that we'd gotten through -- through the spring of 2000 after about the first four and a half million patients had gotten it.
So, again, this is not information from our studies. These are reports that would have come into Lilly like if a doctor mentioned a problem to one of our sales reps or if somebody

calls our 800 number and tells us, hey, I've noticed something during treatment; that's a spontaneous report. This is a review of that information that had come into Lilly.
Q. And if we go to the top of the next page, and at the end of that first paragraph at the top.
Does this also include information about cases of positive dechallenge and positive rechallenge as well that Lilly provided to physicians?
A. Yes, it goes -- it's in the last sentence there.
Q. Let's go to page 5 of this medical letter.
Do you see the section that's entitled Head-to-Head Clinical Data?
A. I do.
Q. And does that reflect clinical trial analyses above and beyond what was submitted to FDA back in 1995 for approval by FDA for Zyprexa?
A. Yes, it does.
Q. And in particular, is this information from what you've previously described as the Allison analysis?

A. Yes, this is the analysis that Dr. Allison led from our head-to-head studies.
Q. Let's go to internal page 10 of the document, and I want to point you specifically to the section which is entitled Literature Summary.
And I want to ask you, first: How did Lilly go about identifying literature that would have been included in these kinds of medical letters that went to physicians?
A. Medical information department could do this for any medical letter. They use electronic databases. There's some libraries around the country that scan all of the medical literature and catalog it and electronically you can put in key words like olanzapine and diabetes and olanzapine and glucose and that would cull out any things that match those. And then we would look at those papers and include the ones that were most relevant to the question.
Q. Did Lilly include articles that were published by authors who suggested that there might be an association between Zyprexa and diabetes as well as those that did not?
A. Sure, both sides.
Q. Did Lilly include every single article

or presentation that was ever done on the issue Zyprexa and diabetes?
A. No.
Q. And why not?
A. Well, again, we'd look through those and we'd include the ones that are relevant for answering the question or background information that the doctors were looking for. If they wanted a comprehensive list, they could ask for a literature search, but that wasn't the purpose of the medical letter.
Q. If you look at the list of references that support this particular medical letter at the end of this document, how many references are listed there in support of this particular document?
A. This one includes 72.
Q. Does Lilly update things like the literature summary in letters like this and other parts of these medical letters as additional information becomes available?
A. Yes. Our usual practice is to review these letters at least annually and if there's important new information, to update it. If there's particularly new information, then we

might update more frequently.
Q. Last week the jury heard from Dr. Wirshing that he had published the first case report regarding Zyprexa and diabetes, and I want to ask you whether that case report is included in the list of these references here.
A. I think it is. It's -- sorry. It's No. -- it's No. 41. That's Donna Wirshing and Dr. Wirshing also contributed to this one.
Q. Let's go back to the Overview section. If we can go back to internal page 2 of the document, and in particular, if we can look at the conclusion there.
I wonder if you can read that to the jury.
A. Information available to date, from head-to-head randomized clinical trials, does not demonstrate a clinically important increase of risk of treatment-emergent glucose elevations with Zyprexa compared to other psychotropic medications. However -- however, available knowledge does support the prudence of attending to the general health of psychiatric patients, including glycemic control.
Q. And that was your conclusion at the time

that it was written?
A. Yes.
Q. And you believe that still to be true?
A. I do.
Q. Does Lilly attach its labeling to these medical letters when they're sent out?
A. Yes.
Q. And Lilly -- does Lilly have other medical letters on the topic of Zyprexa and diabetes as well?
A. Several.
Q. Okay. Let's take a look at them. First take a look at EL3015.
Do you recognize this medical letter?
A. I do.
Q. And for the -- for the record, what is the title of this letter?
A. Zyprexa Diabetes Mellitus, Natural History, Diagnosis and Management -- that's the letter, and then Executive Summary, I guess, is what's on this page.
Q. So is this was a letter that helped physicians screen, diagnose and manage diabetes?
A. Yeah, that's right. This particular

medical letter is just about the disease state of diabetes and screening and management. It's not -- it's not about the medicines, per se.
Q. And let's look at EL3911.
And do you recognize that medical letter?
A. I do.
Q. And what did that concern?
A. This was a letter for physicians describing the change in Zyprexa's Japan letter in 2002. This is a letter for U.S. physicians.
Q. Let's look at EL2973.
A. I have it.
Q. And do you recognize that?
A. Yes.
Q. And what is it?
A. This is a letter for U.S. physicians about the U.S. label change in 2003, the diabetes class -- or, sorry, the class warning that went into 2003.
Q. Lastly, can we look at EL3898A.
Do you recognize this letter?
A. Yes. I have it. I have it and I recognize it.
Q. Can you describe what this letter

addresses?
A. Yes. This one is providing an overview of information for doctors, expert advice on how to monitor patients who are on atypical antipsychotics. So it reviews a number of the different sets of recommendations that had come out on this from FDA or from Mt. Sinai or so forth, from the American Diabetes Association. That sort of thing.
Q. Thank you.
Why don't we turn now to the issue of how marketing messages for Zyprexa, in particular, as they regard diabetes and weight gain among other issues are actually developed. And I want to ask you whether you prepared a slide to help the jury understand how marketing messages are developed.
A. I did.
Q. Can we bring up TG123.
And using this slide, why don't we begin by having you explain what the roles of marketing and medical are with respect to the development of potential marketing messages?
A. Yes. There's a number of different stages to this but it all starts with our teams

doing brainstorming together regarding what are physicians' needs, how might our medicines meet those needs, what information would be useful to them, and then a lot of sort of back and forth ideas about what sort of things marketing may want to carry forward as it's developing materials for the sales force.
Q. Did you participate in this process yourself?
A. Sure.
Q. And are most of the ideas that are generated during this initial phase that you've labeled as brochure concepts, are most of those carried forward and actually put into pieces that are used with sales representatives?
A. Usually no.
Q. Why is that?
A. Because we want our teams to be creative, generate a lot of ideas, and then choose the best to move forward.
Q. Once an idea is identified for use in materials with physicians, how is that actually put into a brochure that might be available to a sales representative who does that?
A. The next step, once there's an idea that

they're choosing to pursue, is that marketing starts developing drafts or mockups or ideas and then medical talks with them along the way and, in particular, we may suggest scientific information or medical data to put into the brochure that would be shown to doctors.
Q. And if we look at the phase that's labeled as Brochure Content, are there draft brochures that never progress beyond that stage?
A. Often, yes.
Q. And if -- if a brochure does progress beyond that initial mockup stage, what has to happen before it actually goes into the hands of a sales representative?
A. So if there's one that they're thinking that they do want to use, then there's a formal process before it can go outside of the company and be shown to doctors. There has to be formal signoff. Three different groups sit down together, the medical group, representatives from our legal group and representatives from our regulatory group. All three have to sign off or else it can't be used.
Q. Can you describe what the role of medical would be in this review process?

A. Yeah. Really, two main things: One is to make sure that the scientific information is accurate, and also to make sure that the conclusions are in line with Lilly's medical conclusions on the topic.
Q. And did you represent medical in the process of reviewing materials in this MLR review process?
A. Sometimes it was me.
Q. Okay. And other times it would have been people who would have been under your supervision?
A. Well, at the point that I was supervising them, yes.
Q. Thank you. Can you describe what the role of regulatory and legal would have been in this review process?
A. Well, in general, legal would be making sure that whatever was being prepared was in accord with the law that bore on it. And regulatory would be making sure that it lined up with our label and with the FDA regulations.
Q. And if you or anyone else in the medical group disagreed with the content that was included in these materials, what would happen at

that stage of the review process?
A. Well, it couldn't go forward. It would either be rejected or it would go back -- sort of back up the chart for more work.
Q. And during the time that you were involved in the MLR review process, were more materials rejected or sent back or accepted?
A. It was more typical to be sent back to continue to hone them or improve them.
Q. And it was only after this approval process that sales representatives were provided with these materials to use with physicians?
A. Right. Only after all three groups had approved it.
Q. I want to ask you, first, about separate and apart from labeling and other communications that physicians -- or Lilly may have had with physicians about weight gain, were there specific programs that Lilly developed to help physicians manage weight gain in their patients?
A. Yes, there were a number.
Q. And I want to -- I want to focus you specifically on one program and ask you if you are familiar with something known as Solutions for Wellness?

A. I am.
Q. And can we bring up EL3381.
You recognize this document?
THE COURT: Is this in?
MR. KANTRA: Actually, I'm sorry, I'm sorry. My apologies, Your Honor. Take that down, Nick.
Q. (BY MR. KANTRA) I want to ask you, first, can you take a look at this on your screen on EL3381?
A. Yes.
Q. Do you recognize that document?
A. Yes. This was one of the -- one of the brochures in the Solutions for Wellness program.
Q. Okay. And do you recall approximately when it was in use?
A. I -- approximately 2001, something like that.
Q. Okay. And you would have been familiar with this document --
A. Let me just clarify that. 2001, or it could have been 2002. I think both around that time frame.
Q. Okay. And you were familiar with this brochure through your participation in the MLR

review process and as a doctor within the U.S. affiliate at Lilly?
A. I think the latter. I don't think that this was one that -- that I personally reviewed in MLR, but it is one that I -- it's the sort of brochure that I saw in my role.
MR. KANTRA: Your Honor, we would move EL3381 into evidence.
MR. SUGGS: No objection, Your Honor.
THE COURT: EL3381 is admitted.
Q. (BY MR. KANTRA) And if we could bring that back up.
Was this document or was this brochure provided to sales representatives for their use with physicians?
A. I think that this is a brochure that actually went to patients.
Q. Okay. And is there information -- if we go to the last page of that document -- that would actually show the kinds of information that was being provided to patients in regards to how to manage their eating and their weight?
A. Yes. And again, to clarify your last question. You know, doctors would know that this

was available and then they'd have their patients sign up, and that's at the point that the patients would get it. But this is exactly what this is. This is information to be shared with patients to just try to give them suggestions around basics of weight management.
Q. So, physicians would have been aware of this program through sales representatives and they would have made it available to their patients?
A. That's how it worked, yes, and their patients regardless of whether they're taking Zyprexa or not.
Q. And was this program limited to physicians who prescribed Zyprexa to their patients?
A. No, this -- this could go to patients regardless of what medicine they were on. It was just a service from Lilly.
Q. Let's move from weight gain into diabetes and let me ask you the same question with respect to diabetes, separate and apart from labeling and other communications.
Were there communications and resources and programs that Lilly developed to

help physicians understand and evaluate the risk of diabetes in their patients?
A. There were.
Q. And can you describe the nature of those programs?
A. There were a number of different programs. Some of them were tools that we would provide, again, for our representatives to provide for physicians. So screening guidelines or tracking sheets that they could use on their individual patients.
Others were more educational programs, such as there were a number of these, but one in particular I would call this -- called psych/endo program. And Lilly would sponsor -- it sponsored a lecture tour when a psychiatrist and an endocrinologist would go out together and give lectures for physicians discussing the issue -- discussing how to manage the issue.
Lilly also hired diabetes nurse educators. These are nurses who are specialists in diabetes and they often work with patients who have diabetes but we hired them also to go to mental health centers or psychiatric clinics to talk, not just to the doctors but the staff more

broadly about diabetes, identifying diabetes, how to help people with diabetes, those kinds of programs.
Q. I want to focus specifically on something you had mentioned about written materials in something called a Diabetes Education Program. If we could bring up EL2814, not on the screen, but on Dr. Baker's.
And do you recognize this?
A. Yes. This -- this was one of those tools that was prepared for Lilly to give to the sales reps and then sales reps could leave this one with physicians who were treating patients with atypicals.
Q. And when were these materials available for use by sales representatives?
A. These also would have been in that time frame of around 2002 or a little earlier.
Q. Okay. And were you familiar with this educational program in your role at the U.S. affiliate as a psychiatrist?
A. I was.
MR. KANTRA: And Your Honor, we would move EL2184 into evidence.
MR. SUGGS: No objection,

Your Honor.
THE COURT: EL2184 is admitted.
Q. (BY MR. KANTRA) If we could go to internal page 4 of that document.
And can you tell -- can you describe the kind of information that is being provided there to physicians?
A. Yes. This has screening guidelines and what is listed on the top are risk factors for diabetes in the general populations. And then in the middle of the sheet where it says Criteria for Diagnosis of Diabetes, it talks about using blood glucose tests for -- for making the definition of the diagnosis, the patients with diabetes.
Q. If we go to page 6 of this document as well.
What does that provide to physicians?
A. These are screening recommendations that had been published specifically for what to do with people on atypical antipsychotics in terms of assessing them, monitoring them, following them up for diabetes.
Q. Okay. And I want to -- I want to look

now at some additional materials relating to diabetes, and if we can take that down and, again, bring up just on Dr. Baker's screen, EL3901.
I want to ask you, first, whether you recognize this document.
A. I do.
Q. And what is it?
A. This is one of those brochures that would have been approved by the MLR review for sales representatives to show to doctors.
Q. And would this have been approved through the MLR process?
A. Yes.
Q. And, again, what is the time frame in which this would have been used?
A. This one was from toward the end of 2000 or more likely I'd say early 2001.
Q. Okay. And are you familiar with this brochure as well through your work at the U.S. affiliate?
A. This looks like one that I approved.
MR. KANTRA: Your Honor, we would move 3901 into evidence.
MR. SUGGS: No objection,

Your Honor.
THE COURT: EL3901 is admitted.
Q. (BY MR. KANTRA) Let's take a look, first, at this first page of the document.
And I want to ask you, first, are you familiar with what has been called the comparable rates message?
A. I am, yes.
Q. Okay. And can you describe, briefly, what that is?
A. Yes. That was -- that was information for doctors in which we emphasized that diabetes was something that they would see commonly in their patient population, and that because in our research we were seeing that being observed or developing at similar or comparable rates across treatments, that they ought to approach patients with similar vigilance regardless of which of the atypicals they might prescribe.
Q. And before we go into looking at the data in this particular piece, let me ask you whether you helped to prepare a slide that might further elaborate for the jury what that message was?
A. I did.

Q. Can we bring up TG --
THE COURT: Before you do that, I just have a question.
You indicated that this document would have been prepared around 2001?
THE WITNESS: That looks like the time frame to me, yes.
THE COURT: Can you tell any way from the documents when -- do they continue to be used today? Did they become obsolete at some point? Do you know when they're obsolete?
THE WITNESS: I know that this one evolved and was replaced over time, so I'd be sure that this one is not still being used. And I think in that time frame we made a couple of changes. This one I could tell for sure because it's not referring to the warning, that it would be before 2003, and then from my memory, I know it was earlier in that time frame.
MR. KANTRA: Actually, we can go -- why don't we go to the last page of this document just for a second and we can look at -- that should provide us some information.
Q. (BY MR. KANTRA) If you look at the bottom of that page, and is there information

there that reflects when this material would have first been introduced?
A. Yeah. This -- it indicates -- it indicates 2001 where you've highlighted it.
Q. Why don't we take this down for a second and bring up TG2133.
And using this slide, Dr. Baker, can you help to further explain what the nature of the comparable rates message was that was included in these materials?
A. Yes. I had just described that message overall. And I wanted to make the point with this, again, that we were describing comparable rates based upon our clinical trial information. This is from the actual studies.
This isn't about spontaneous reports or epidemiological studies. It was about the clinical trials, and the rates that it's referring to are rates of presumed illness, diabetes or hyperglycemia. It's not average glucose change across the whole population. It's rates of individuals developing diabetes or hyperglycemia. And so the other point that I wanted to make on it is again, that based on the fact that those rates were comparable across

treatments, then the advice was to doctors that because there's high risk of diabetes in this patient population and the rates are comparable, monitor all patients on antipsychotics regardless of which one you choose.
Q. And why was it that Lilly focused this message around the clinical trial information that it had rather than the other information that you mentioned?
A. Because that was -- that's the best way scientifically or from a safety standpoint to actually compare rates from one agent to another.
Q. And if we can go back, then, to EL3901.
And I want to ask you, first, whether this is a brochure that represents Lilly's communication of the comparable rates message to physicians?
A. It is.
Q. And if we can look first at the graph on the left-hand side of this page, and what does this graph represent?
A. So this brochure looks at rates of diabetes or potential diabetes in a couple of different ways, and the way that you're looking at it here is these are actual diagnosed cases.

These are the research physician who is doing the study and this is the percentage of individuals who in the course of the study develop diabetes diagnosed by that doctor. And it's comparing in the longer-term comparison of olanzapine to haloperidol, the proportion of patients on the two drugs.

Q. When you say longer term, what's the time period over which patients were observed?

A. These were one-year studies and the average was 7 or 8 months.

Q. And were the rates of diabetes as identified there significantly different or not?

A. No. It indicates they're not significantly different.

Q. And if we look -- and those -- that information was drawn, it says at the top from three one-year pooled studies.

What does that mean?

A. It means that we took all of the longer-term Haldol, olanzapine studies and we pooled them together to get the most comprehensive answer that we could.

Q. Was Haldol one of the earlier first-generation antipsychotic medications?

A. It is. It was the most widely used of the older antipsychotic medicines.

Q. Let's look at the other graph that's on this piece, this brochure as well.

And does that look at a comparison with one of the atypical antipsychotics?

A. That's right. This is looking at risperidone and this is -- this is the information we had available at that time which was from a six-month head-to-head comparison of olanzapine versus risperidone for treatment of schizophrenia. And again, you're looking at the rates of diabetes that were diagnosed by the research physicians during the study, and you see it's about the same in the two groups.

Q. And, again, over what period of time were patients being evaluated here?

A. This was a six-month study, up to six months. The average exposure was shorter than that. I think it says here four to five months.

Q. But a longer-term study?

A. Yes, this was the longest that we had.

Q. Let's the turn now to the bottom of this first page of this brochure, and direct your attention to the section that is entitled:

Likelihood of Individual Random Glucose Elevations.

And I want to ask you, first, whether -- is this presenting data from what you've previously described as the Allison analysis?

A. Yes, that's it.

Q. And what does that Allison analysis show?

A. Well, this is the other way that we look for proportion of patients who might be developing diabetes. What we looked at before was the actual diagnosis. This one is looking based on changes in the blood glucose test from the beginning to anytime in the course of the study to see people who would have an increase that would move them into a category that looked like it might be hyperglycemia or it might be diabetes.

Q. And there were no significant differences among the agents that were being compared there?

A. No. Dr. Allison and the team looked at olanzapine versus risperidone and olanzapine versus haloperidol, also looked at placebo,

though it's not shown here, and looked at all of those at four different points. And across all those analyses, there were none that were significantly different from one treatment group to the other.

Q. If we look at the middle of this page, the section that's entitled Average Random Glucose Levels Across All Patients, is that additional information from the analysis that Dr. Allison conducted?

A. It is. This we provided for doctors' background. This was not rates information but this was average change, those analyses we talked about earlier.

Q. And what did that average change analysis show as compared to the analyses regarding rates of diabetes?

A. This is the one that found no difference between olanzapine and risperidone. It did find higher average change on olanzapine compared to haloperidol and it found lower average change on olanzapine as compared to clozapine.

Q. If there were average changes in glucose levels that were higher on Zyprexa than there were at least on some of the other medications,

how was it consistent with the comparable rates message?
A. It is because average change, again, is not indicating a disease. It's not telling you the proportion of patients for whom it's a meaningful change. It raises that question and then we identify that question through the other analyses that we just looked at, the treatment-emergent diagnosis and the treatment-emergent blood test changes in individual patients.
Q. Dr. Baker, was this brochure intended to minimize the risk of diabetes or hyperglycemia?
A. No, I'd say to the contrary. It's to emphasize to doctors that they're going to see this commonly in their patients.
Q. And can we go to internal page 4 of the document?
And look at the very top part of that. And what is the top part of that page telling physicians?
A. It says, Diabetes is common in the general adult population and it's more common in patients with psychiatric illness.
Q. And if we look in the third bullet

point, what information is that providing about patients who have serious psychiatric illness like schizophrenia or bipolar disorder?
A. It's saying that studies that compare or try to estimate the likelihood of diabetes to the general population find that it's higher in patients with schizophrenia or bipolar disorder.
Q. And is this information on this slide consistent with what's included in the class labeling for diabetes?
A. Yes. In that the class labeling also says these patients appear to be at higher risk than the regular population for diabetes.
Q. And I notice at the end of this third bullet point there's a reference to numbers 3 through 6.
What does that refer to?
A. That would be a citation to some of the -- some of the studies that supported this conclusion.
Q. And would there have been references within this brochure that physicians could review for themselves as well?
A. Yes.
Q. Can we go to internal page 3? And go to

the References section.
And if we look at 3 through 6, would those have been some of the references that would have supported Lilly's position?
A. Yes, those are some of them.
Q. Let's look at one other brochure, and again, this is going to be on Dr. Baker's screen initially. Bring up EL3429.
THE WITNESS: Can I look at the back page of this one also?
MR. KANTRA: Go to the last page of that, Nick.
Q. (BY MR. KANTRA) And I want to ask you, first, whether you recognize this document.
A. I do.
Q. And can you identify what it is?
A. This is another brochure that was prepared for sales reps to use with doctors.
Q. And what was the topic of this brochure?
A. This one is also talking about the same topic of diabetes and hyperglycemia.
Q. And do you know when this brochure would have first been used?
A. I was trying to read it on the back but it is a little too small for me. But I know this

one also would have -- this is more recent than the first one we saw, and this is before the 2003 label change, so I would say this is late '02 or earlier '03.
Q. Certainly before the labeling change happened?
A. That's for sure, yeah.
MR. KANTRA: Okay. Your Honor, we would move EL3429 into evidence.
MR. SUGGS: No objection, Your Honor.
THE COURT: EL3429 --
MR. KANTRA: 3429.
THE COURT: -- is admitted.
Q. (BY MR. KANTRA) Dr. Baker, is this another brochure -- before we do that, why don't we go to the last page of this document.
And if we look at the bottom -- blow that up. Does that give an identification of when that would have been in use?
A. It does. It says 2003.
Q. Okay. Let's go back to the first page of this document.
And if we look at the bottom half of that screen on the right-hand side, does that

provide, again, a reminder about the risk that this patient population is at for developing diabetes?
A. Yes. It said diabetes is common, and then this one picks up that your patients are at an even greater risk.
Q. And if we go to the bottom of this first page, what information is provided to doctors about where information is in the labeling in regards to diabetes-related adverse events?
A. This is what was in the adverse events section of the Zyprexa label.
Q. So this would direct physicians to where the information is in the labeling; is that right?
A. That's right.
Q. Let's take a look specifically at the information on page -- internal page 3 of the document.
And is this some of the information that supports the comparable rates message that would have been included in this particular brochure?
A. That's right.
Q. And if we look at the two graphs on the

left-hand side of this page, does that contain the data that was included in the previous brochure?
A. That's the same information we looked at a few minutes ago.
Q. So if we go to the right-hand side of the screen, what is the new information that's in that graph?
A. This brochure records the same sort of analysis, but done in a study in patients with bipolar mania. This one is comparing olanzapine to Divalproex, also known as Depakote, and that's the most widely used in treatment for mania.
Q. What does that show?
A. This one is also looking at diagnosed cases of diabetes that emerged or developed during the course of this study, 11-month study. And it found -- it looks -- that may look like it's a little higher on Divalproex, but it found comparability. There's no difference between those.
Q. Was this the longest-term data that was available at the time in regards to the comparison between Zyprexa and Divalproex in regards to the rates of diabetes?

A. It is.
MR. KANTRA: Your Honor, would this be a time to take the morning break?
THE COURT: How much longer do you have on direct?
MR. KANTRA: I would estimate approximately 30 to 45 minutes.
THE COURT: Yes, this would be a good time then. Ladies and gentlemen of the jury, we'll take our first morning break, and we'll be in recess for about 15 minutes.
(Jury out.)
(Break.)
(Jury in.)
THE COURT: Please be seated.
We're back on record, and all members of the jury are present.
Mr. Kantra.
MR. KANTRA: Your Honor, I just wanted to clarify one thing with you. I believe Dr. Baker had in front of him what is marked as EL3014 but I wasn't sure if that had been identified in the list of exhibits that you had read off.
THE COURT: He did have -- well, he

did have 3014, and I believe that was admitted.
MR. KANTRA: Admitted, okay.
THE CLERK: It was.
MR. KANTRA: Your Honor, at this time I would like to publish to the jury the medical letters and the brochures that we talked about this morning.
THE COURT: You may.
Q. (BY MR. KANTRA) Dr. Baker, I wanted to take you back to just one point that we had been discussing earlier. You had described a study that compared Zyprexa with Geodon and looked at the issue of diabetic ketoacidosis.
Do you recall that testimony?
A. Yes, that was from Pfizer's recently completed study comparing 9,000 patients on ziprasidone or Geodon versus 9,000 on olanzapine.
Q. And what -- what did it find with respect to the rates of diabetic ketoacidosis in regards to the two treatment groups?
A. There were few of them in either group and the number was identical over the course of the years to olanzapine and ziprasidone, identical.
Q. Dr. Baker, in your work on Zyprexa, and

your work as a safety physician now, is it your responsibility to review and be familiar with the labeling for other atypical antipsychotic medications?
A. Well, it has been over my time at Lilly, but I'd say no, not as part of my current --
Q. Current responsibility?
A. Yes.
Q. Are you familiar with the information in the packet inserts for current atypical antipsychotics as they existed after the class label change?
A. Yes.
Q. And as they exist today?
A. Yes.
Q. And can we take a look at those labels? And I'm going to show the witness what's been marked as --
THE COURT: Do you have a stack for your friends?
Q. (BY MR. KANTRA) If I could -- if I could direct your attention to -- take a look through those, and let me know when you've had a chance to look through them.
A. Okay.

Q. Do you recognize these as the labeling for Clozaril, Zyprexa, Seroquel, Risperdal, Geodon and Abilify for 2004, 2006 and the current labels?
A. I'm sorry. It is -- the labels are there for all those drugs, but I didn't check the dates on them. Do you want me to go back?
Q. If you can take a look and see.
A. I'm sorry.
THE COURT: Is there an exhibit number or numbers that the witness is looking at, for the record?
MR. KANTRA: Yes. These are on -- while he's looking through, EL3915, EL3916, EL3917 and those relate to Clozaril.
Then there is AK10165, which is EL3918, which are the 2004 and 2006 PDRs for Zyprexa.
There is EL3919, EL3920, and EL3921, which are the 2004, 2006 and the current labeling for Seroquel.
EL3922, EL3923, EL3924, which are 2004 PDR for Risperdal, 2006 PDR for Risperdal, and the current labeling for Risperdal.
Then there is EL3925, EL3926 and

EL3927, which is the Geodon 2004 PDR and the 2006 PDR, as well as the current labeling.
And lastly, there is EL3928, EL3929, and EL3930, which would be the Abilify 2004 PDR, the Abilify 2006 PDR, and the current labeling for Abilify.
THE COURT: And are you going to be offering all these into evidence?
MR. KANTRA: Yes.
THE COURT: Is there going to be any objection?
MR. SUGGS: Are they offered for notice or for the truth of the matter asserted?
MR. KANTRA: They're offered for the data that's contained in those labelings so they're being offered for the truth of the matters contained therein.
MR. SUGGS: I'd object it's hearsay, Your Honor. If it wants to come in for notice, I have no objection. There's been no foundation laid for these, and I don't think that Dr. Baker is capable of laying such a foundation.
MR. LEHNER: May we approach, Your Honor?
THE COURT: You may.

(Bench discussion.)
MR. LEHNER: Clearly this information would be within the hearsay exception on commercial publications. They already referred to the PDR. The PDR is -- tabulations, standards or other published compilations generally used by or relied upon by the public or persons in particular occupations. I think they laid the foundation for information from the PDR --
MR. SUGGS: Some of those are PDRs and some of them they're piling up.
MR. LEHNER: The PDRs, we can get the labelings later.
THE COURT: Which ones are the PDRs and which ones aren't?
MR. SUGGS: We have the 2008 PDR over here. There is an issue from the current one --
MR. LEHNER: Let's mark the PDR as the exhibit --
THE COURT: Are they all from the PDRs?
MR. LEHNER: We'll put these in as EL3909. Then we'll just move the PDR into

evidence, and I think they've already laid the foundation for the PDR. If they want to do that, we can do that.

THE COURT: Okay. So which ones am I going to admit right now?

MR. KANTRA: I can go back through the list. They're going to be the last on the list of each one that I referenced.

THE COURT: Are the two Zyprexa ones already in, EL3918 and AK1016?

MR. KANTRA: They're in.

MR. SUGGS: I also have an objection to the relevance. What's the relevance of the labels? What's the relevance of the Clozaril label?

MR. KANTRA: The relevance is to understand exactly what Dr. Baker knew in terms of the labeling and what he was aware of in terms of other information within the public domain.

MR. SUGGS: Sounds like notice, then, right?

MR. KANTRA: Among other things.

THE COURT: Well, no, you've indicated you want this in for the truth of the matter.

MR. KANTRA: These were being published and offered by the manufacturers of these medications.

MR. SUGGS: What's the relevance of the Risperdal label in 2004?

MR. KANTRA: Where the FDA described weight gain where it is in the label and the comparison to similar drugs.

THE COURT: I think there's enough relevance as to these other drugs. There's been all sorts of comparisons as to the side effects of Zyprexa compared to other drugs and what's in, and so I think what the labels said about those things aren't relevant. So, basically, I'm admitting all of these subject to the 2008 ones being substituted with the 2008 PDR.

MR. KANTRA: And we can do that -- we can do that now.

THE COURT: Okay.

MR. LEHNER: Did you want to enter this in evidence?

THE COURT: You can leave it here and you can copy it and substitute. I 'd prefer that.

(End of bench discussion.)

THE COURT: I will admit EL3915, 3916, 3917, 3919, 3920, 3921, 3922, 3923, 3924. Those are all EL.

3925, 3926, 3927, EL3928, 3929 and 3930, these -- the current versions of those labels that the witness has in front of him we're going to substitute the 2008 PDR versions for those ones that reflect current labels, and we'll take care of that after hours.

MR. KANTRA: And those are PDR current labels. The ones that are marked 3909, for the record.

THE COURT: That's correct.

Q. (BY MR. KANTRA) Dr. Baker, we've heard the State saying that Lilly hid information from an early HGAJ study about weight gain.

And before we get into that, I want to discuss with you the long-term weight information in Lilly's package insert. If we can bring up what's been marked as EL2954A.

And if you'd look at the -- if you'd look at the internal page 16 of that document -- actually, before we do that -- I'm sorry -- can we go back to the first page and at the bottom you see there's a reference to the

date of that package insert.

A. 1996.

Q. Okay. And if we go to internal page 16 of this document and, in particular, I want to direct your attention to the section on weight gain. And the last sentence of that second paragraph. What does that say in terms of what the average weight gain was during long-term therapy?

A. 5.4 kilograms.

Q. And what does that translate into in terms of pounds?

A. That would be about 12 pounds.

Q. And what studies provided the basis for that information in the labeling?

A. This -- this is the information -- the cumulative information from the three longer-term studies that went in the original Zyprexa submission.

Q. And is that consistent to put in information in your labeling with respect to the longer-term information from all the trials that are available at the time?

A. Well, sure. For longer-term or shorter-term information, we would want to put

into the labeling the best information that we could get from bringing together all of the information that we have about a given patient population. So that's what this would reflect.

Q. So from the three studies that you mentioned, would one of those studies have been the HGAJ study?

A. Yes.

Q. And approximately what was the time period over which patients were treated in this group of patients that made up this long-term weight gain information in the labeling?

A. The -- the studies went out to about two and a half years and to be in the long-term cohort this was everybody that had finished the acute phase, the first six weeks of treatment. So it's from six weeks to about two and a half years.

Q. And approximately how many patients would this have been?

A. This was -- give or take, it was about 800 patients.

Q. And why would Lilly rely upon three studies rather than one study in putting together the information that was included in the package

insert here?

A. Because the idea when we were making any of these safety decisions is to take all of the information we have and conclude what's going to be most representative, most helpful for the doctors with their patients.

Q. Let's take a look at the weight-gain information that's been presented by the State. And if you could bring up AK1586.

And, in particular, if we could go to internal page 8. If we look in the first paragraph, the next-to-last sentence.

Does that describe the subset of patients that the State relied upon for its 24-pound weight gain?

A. I don't know. It's --

Q. Let me ask you this: Does this document reflect -- let's go back to page 1 of the document.

And in one page -- and in the second paragraph, you see there's a reference to the fact that this is the presentation of safety results from HGAJ?

A. I do.

Q. Okay. And if we go from there over to

internal page 8, the second-to-last sentence reads: That patients who remained on olanzapine for 12 months gained an average of 24 pounds at the end of those 12 months.

What does that tell you about the patients that would have been included in that particular analysis of weight gain?

A. This would be a subgroup of the patients and a subgroup of the weight measurements from the study. This would be everybody who was there to be weighed at 12 months, and it would be the average for those patients at that particular time.

Q. And this would have been a smaller group of patients than what would have been included in the labeling for Zyprexa?

A. Right. These patients would have been included, but these would have been part of what's in the label as a larger group than what you have here.

Q. So those folks in that group would have been a part of the overall calculation of the average weight gain that's reflected in the labeling?

A. Yes. The average for these patients

when they completed their treatment would have been included in making that average that you see in our label. That they were part of that.

Q. Why wouldn't Lilly just have put information in its labeling in regards to the fact that patients in this analysis had gained 24 pounds at the end of 12 months?

MR. SUGGS: Objection; foundation; speculation. Can we approach, Your Honor?

THE COURT: You may.

(Bench discussion).

MR. SUGGS: This guy didn't join the company until 1999. How's he going to talk about what they did back in 1996?

MR. KANTRA: He's already testified earlier on.

MR. SUGGS: What did he review to answer this question? This is just speculation, Your Honor.

MR. KANTRA: He reviewed the NDA. He reviewed submissions to the NDA.

MR. SUGGS: Does the NDA talk about why they made the choices not to do this?

THE COURT: Again, lay a better foundation and then we'll take this up again.

And if I let it in, you can bring up all these points on cross-examination.

(End of bench discussion.)

Q. (BY MR. KANTRA) Dr. Baker, in your work at Eli Lilly and Company, is it -- are you responsible for understanding the registration trials that support the safety of the drug?

A. Yes, in general terms, and yes, for Zyprexa.

Q. And, in particular, in your role as a physician of the U.S. affiliate and also as a safety physician now, are you responsible for understanding the studies that supports the information in the labeling, particularly as it would relate to weight gain and hyperglycemia?

A. Yes, in general.

Q. Can you tell the jury why the company wouldn't have put this information into the labeling?

MR. SUGGS: Same objection, Your Honor.

THE COURT: Do you know -- you didn't join the company until when?

THE WITNESS: 1999, Your Honor.

THE COURT: Okay. And so you're

being asked why Lilly did something in 1996. Do you believe that your review of the materials you've discussed let you answer that question?

THE WITNESS: I could answer this based on knowing how we do safety and how we reach conclusions in general and that practice, and I've looked at what they've entered in. But I wouldn't have knowledge -- the knowledge I have is what our general practices are.

THE COURT: So then, understanding that you can -- based on what you understand the general practices are and then your knowledge of the literature and the other materials, you would be able to answer the question on that basis?

THE WITNESS: I think so, yes.

THE COURT: I'll let him answer it on that basis and you can cross-examine.

Q. (BY MR. KANTRA) So can you explain why it is based on your understanding generally of how Lilly handles long-term safety information, why they would have relied upon the three registration trials in their total rather than one subanalysis?

A. Yes, because the general approach, safety approach to our long-term information is

describing what events have been noticed but then in characterizing what happens on average. We look on average here across all of the patients that we have, and we would not choose one sliver that's not representative, that's higher than average anymore than we would choose another sliver at a different time point that's less than average. Our normal approach is to look at the change from beginning to end and report what we see across all the patients.

THE COURT: Dr. Baker, can you tell me why you do that? If you average people out, you take away the extremes. And if you're talking about safety, don't you want to know what the extremes are?

THE WITNESS: You do want to know what the adverse events are, what particular things would happen to a patient and we do want to capture those in labeling, you know, what happens to individual patients. Something like this of average weight gain is trying to -- is supplementing what you would say about what happens to individual patients to sort of characterize what happens on a general population level. This sort of average level would be

something that doctors could look at one label and compare to another label to get, you know, a sense of how this one --

THE COURT: Do you ever put in the range?

THE WITNESS: We sometimes do. In this particular case, there is now a range in there. Yes.

THE COURT: Okay.

Q. (BY MR. KANTRA) And, Dr. Baker, outside of a labeling context, were there other ways in which Lilly would have communicated with physicians about the amount of weight gain at 24 pounds or even greater than that with physicians?

A. Sure, several ways.

Q. And what would those have been?

A. Information on weight gain was in publications. Some of my colleagues published on this topic and had details at scientific meetings. We had breakdowns in information on this in the materials that sales reps had to share with doctors, and some of those medical letters that we had looked at earlier would be another source for more details on -- on weight gain.

Q. The State has also said that Lilly had other data that should have been included in the labeling as well. And I want to have you bring up what the Plaintiffs introduced as AK1605.

And looking at the title of this document, can you tell the jury what this is?

A. Yes. This -- this is one of many outlines of laboratory information that would come as a part of a study report. I think I mentioned on Friday that when we finish a clinical study, one of our research studies, that we summarize a report for our own review and to share with other regulators.

And in those reports, we look at all of the blood tests that are done and we look at them in different ways. We look at average change or individual changes above the threshold. And this -- this would be an example of those sorts of individual laboratory changes in the course of treatment. And this particular one is from the short-term, the six-week phase of the HGAJ study.

Q. And that's what the word "acute phase" means up there?

A. Right. This was from the first six

weeks of treatment. It was a year-long study; this was the first six weeks.

Q. So this wouldn't give you any information about how patients did during longer-term treatment with Zyprexa in this particular study?

A. No more than six weeks.

Q. If we go to internal page 11 of this document, and in particular, if we look at the section on Nonfasting Glucose and the High Nonfasting Glucose information.

And in this single analysis, was there a statistically significant difference in the Zyprexa group and the haloperidol group?

A. Yes.

Q. And why would that data not be included in the Zyprexa label?

MR. SUGGS: Objection; lack of foundation again, Your Honor.

THE COURT: Again, based on your knowledge of Lilly's practices and procedures in dealing with safety information, can you answer that question?

THE WITNESS: Yes. In this case, I would know how we approached this in general and

I know some of the other information that they were looking at in this case.

THE COURT: Okay. I'll overrule the objection.

Q. (BY MR. KANTRA) So why are those data not included in the Zyprexa label?

A. Well, again, first in terms of in general what would this be about, we'd look exactly at this list and other lists like this that would come from a study report in order to look for situations in which we're seeing something frequently or we're seeing a significant difference.

And the reason we look for that is that that's what gives us the signal that this is something that has to be looked at more closely as a potential issue with the treatment. And you look at it more closely by looking at that in the context of the other sources of information you have that would let you make a judgment, a medical, scientific judgment about what it means.

So in this particular case, the sort of information that would have been available at that time would have been this -- what this is looking at is based on the

laboratory tests with the predefined threshold, what's the highest or what's the lowest at any point in time, and how many patients in each group cross that threshold. In this case, crossing it for high.

They would -- they had available with this also, what's it look like once they finish the six weeks? They have available also what happens to patients across the whole study. This is just the initial weeks of the study. They would have available how many patients actually have diagnosis of diabetes, and that would be the sort of information that would be available from this study.

And then if you see in that a question like this that is going to say to you, hey, is Zyprexa causing a diabetes problem because we see in this particular number higher rates than haloperidol, you'd look at is it consistent across all those other things, which it isn't. You look at it is it consistent if you control this for how long they're on treatment, because how long you're on affects how likely you are to have blood tests and go across. That wouldn't be consistent.

And probably most importantly, you look at this not just based on one study, but across all the studies that you have available on this topic or compared to placebo. In this case they had the same analysis, you could look at the same question of olanzapine-treated patients versus placebo-treated patients which is, in any of our research, it's usually a key part of how we evaluate the safety of the medicine by comparing it to people who aren't on the medicine.

Q. And you told us on Friday that you had reviewed an FDA submission from July of 2000 that included the larger data sets regarding haloperidol and Zyprexa with respect to glucose levels; is that right?

A. I did, yes.

Q. And as well with respect to the placebo-controlled studies?

A. Yes.

Q. So can we bring up EL2043, and in particular, if we can go to internal page 74.

And if we look at Table 5.17, does this reflect an analysis, a larger analysis of trials that compared Zyprexa and haloperidol

during the acute phase?

A. Yes.

Q. And that's, again, with respect to high nonfasting glucose levels?

A. Right. This would be exactly the same analysis that you'd looked at, but in this case it's not just the HGAJ study, but it's HGAJ combined with the other studies that we have available comparing olanzapine and haloperidol.

Q. So in this bigger data set was there a statistically significant difference between the Zyprexa group and the haloperidol group?

A. No. As you see in this one, it's not significant.

Q. And how do you know that?

A. Because it says it on this line here, and the P value is above the threshold.

Q. And what's the threshold for the P value?

A. .05 and below would be considered statistically significant or potentially significant. And so this is a little more than twice that, which would make it nonsignificant.

Q. You've mentioned as well placebo-controlled studies. Can we turn to

internal page 71 and Table 5.12 in there?

And can you tell us what this represents as well?

A. This would be the same sort of analysis that we were looking at, but in this case instead of looking at the studies that compared olanzapine to haloperidol, this was bringing together all the studies that compared olanzapine to placebo in that submission.

Q. And what did it find there with respect to whether there was a statistically significant difference or not?

A. So again if you look at the top row, it's 1.2 percent on olanzapine versus 1.7 percent on placebo and it's not statistically significant. That's far above the .05.

Q. And based on these analyses of the data that would have been available at the time and your understanding of how Lilly makes determinations about putting safety information in labeling, why would Lilly not have put the original analysis that we looked at into its label?

A. Because I think that looking at that analysis in light of the other information that

is available concerning olanzapine and haloperidol and then particularly put in context of what we're seeing elsewhere, like these placebo-controlled studies, would not support that that was a real difference.

Q. And would that -- would the information that we looked at in the original, the 1605 document, have been submitted to FDA?

A. Yes, it appeared to me that was part of a study report and those go to FDA.

Q. Okay. And can we have EL3931? And, Nick, if we can bring that up just on Dr. Baker's screen.

I want to ask you if you recognize what this is?

A. This is a study -- sorry. This is a study report of the HGAJ study.

Q. And is it Lilly's ordinary practice to prepare study reports at the completion of all of its clinical trials that reflect its laboratory value data?

A. Yes.

Q. And you're familiar with this document as the study report for the HGAJ?

A. I've seen it, yes.

MR. KANTRA: Your Honor, we'd move EL3931 into evidence.
MR. SUGGS: No objection, Your Honor.
THE COURT: EL3931 is admitted.
Q. (BY MR. KANTRA) And if we go to internal page 3 of this document.
And about halfway down that table, you see where there's a reference to glucose NF?
A. Yes.
Q. And what does NF stand for?
A. Nonfasting.
Q. And so in this study report that went into FDA, this difference was identified to them; is that right?
A. Yes. This is the -- the same number we looked at -- the same results we looked at a couple of minutes ago, although in this case what you're seeing is a summary it's pulling out of the various laboratory tests within -- within that analysis all the ones that looked different between olanzapine and haloperidol.
MR. SUGGS: Excuse me. You said this was page 3?
MR. KANTRA: For our purposes,

internal page 3.
MR. SUGGS: So what's the page number in the exhibit?
MR. KANTRA: Page 147 of the document itself.
MR. SUGGS: Didn't think it was page 3.
MR. KANTRA: Thanks, Nick.
Q. (BY MR. KANTRA) The State has also told the jury that an internal analysis from February of 2000 was submitted to its global labeling committee showed that Zyprexa had -- excuse me -- a three and a half times greater risk of hyperglycemia as compared to placebo, but that Lilly submitted different information in May of 2007 when it made what's called a changes being effected label change for Zyprexa.
I want to first ask you: Are you familiar with the May of 2000 changes being effected label change that reported that the rate of hyperglycemia for patients treated with Zyprexa was 3.1 percent and for placebo it was 2.4 percent?
A. Yes.
Q. Do you have an understanding of why the

numbers in those two analyses differed?
A. My understanding is that the one that went to GPLC had -- had errors.
Q. And putting aside the numbers in the GPLC document for the moment, how do the numbers that were submitted to FDA in the May, 2000 changes being effected labeling change relate to results from other clinical trial analyses that Lilly did before and after the CBE label change?
A. Well, the numbers, of course, differ somewhat from one study in one analysis to another, but it's consistent -- the CBE change is consistent with our other olanzapine/placebo analyses in that they're not showing significant differences in rates of patients with hyperglycemia or diabetes, so the conclusion is the same. The specific numbers change from study to study.
Q. And that would include if we look before the NDA submission that Lilly made regarding Zyprexa?
A. Right.
Q. As well as the TED analysis and the Allison analyses that you've discussed?
A. Exactly.

Q. Let me ask you about another argument that the State has made, is that Lilly knew and admitted that internal documents that high blood glucose levels were probably related to Zyprexa.
Are you familiar with a study known as the HGFU study?
A. Yes, I was one of the authors on the publication from that study.
Q. And what kind of a study was that?
A. This was a study in patients who had bipolar mania, and the point of the study was to compare treatment with olanzapine to placebo when added to ongoing treatment for their mania.
Q. Did you review any of the data from this HGFU study when it first became available?
A. Yes.
Q. And if we can bring up what's been introduced previously as AK7802.
And can you tell the jury what kind of information is contained in this document?
A. This appears to be a summary of -- of -- this is a little bit like the data we were looking at before. This looks like it's a summary of the number of patients who in the course of treatment crossed a threshold on their

laboratory tests, and it -- I don't know for sure why it's culling out these particular ones, but it's culling out a number of different ones where they're seeing a difference between the olanzapine and placebo.

Q. I want to focus your attention on the line that says, Glucose nonfasting high near the bottom of the page?

A. Yes.

Q. And this is an analysis that shows that four patients in the olanzapine group developed high nonfasting glucose levels as opposed to none in the placebo group. And I want to ask you, first: Is that the type of information that would have led Lilly to conclude that Zyprexa caused nonfasting -- high nonfasting blood glucose elevations?

A. No. I don't recognize this particular analysis, but what it appears to be showing is four patients who had high nonfasting glucose on olanzapine, but if we got something like this, you know, the usual practice would be as I described it, you'd look at this particular finding, you'd try to understand what you're seeing there, but you'd very much look at it

across all the information that you have. And we have a lot -- a lot of information on this topic from studies in bipolar disorder, schizophrenia. So the short answer to your question, I guess is, no, I wouldn't make a conclusion just based on this one line.

Q. Would this -- would information about the rate of high nonfasting glucose levels from this study have been submitted to FDA in a clinical study report just as you described for the HGAJ study?

A. Yes, that would be the standard practice.

Q. And can we get EL3939? Again, just on his screen.

Do you recognize this document?

A. Yes, this is the study report from the HGFU study.

Q. And would you have been familiar with the data that would have been included in that study report?

A. Yes, I've reviewed the results.

MR. KANTRA: And, Your Honor, at this time we move EL3939 into evidence.

THE COURT: EL3939 is admitted.

MR. SUGGS: No objection.

THE COURT: Thank you.

Q. And if we go to internal page 2 of this document --

MR. SUGGS: Can you give me the real page number of this document?

MR. KANTRA: Page 334.

Q. (BY MR. KANTRA) And in particular, can we look at the section of this table at the top which is marked glucose nonfasting?

And if you see in particular the section that is marked high nonfasting glucose? Do you see how there's information there is presented in regards to the number of patients who developed high nonfasting glucose?

A. I do.

Q. And that number is actually higher than what was in that other document; isn't that right?

A. This describes -- it's described at the top as the same analysis, but this one in the study report says six patients; the other said four.

Q. And how would it be that there would be a difference like that between the two documents?

A. I don't know. I'm not sure really what the first document was. But this would be the study report, so this one would have been verified, validated by our statisticians to check the accuracy.

Q. And this -- this difference between the two groups was not statistically significant as indicated by the P value; is that right?

A. Right.

Q. Dr. Baker, I want to ask you whether you remember attending a meeting of something known as the North American Diabetes Advisory Board in October of 2000?

A. I do, yes.

Q. And can you tell the jury what the North American Diabetes Advisory Board is?

A. It's a group of experts in endocrinology, really prominent diabetologists that are independent. They're from outside Lilly, but they consult with Lilly on topics related to diabetes.

Q. And what was the purpose of this meeting in October of 2000 that you attended?

A. Well, we went to the -- to get their input, their perspective, their criticisms, their

advice about this question of Zyprexa, atypical antipsychotics and diabetes.
Q. And was this unusual for the company to be seeking feedback from outside advisers with respect to its data?
A. No, it's exactly what is common for us to do. We want to get the perspective of experts and the help of experts as we're thinking about our scientific information.
Q. Was the data that the company presented to these outside advisers in October of 2000 similar to the data that you had reviewed from the July 2000 submission to the FDA on glucose and Zyprexa?
A. I know that what was presented was information that was in that submission.
Q. Now, we've heard reference to some comments in that e-mail itself from advisers who allegedly suggested that there may be a diabetes problem with Zyprexa.
Did you hear that comment?
A. I don't remember hearing those words, but I certainly remember they had concerns and advice for us on that.
Q. So what kind of advice and feedback -- I

mean, based on what you heard at the meeting, what kind of advice and feedback were you hearing from the advisers?
A. The main thing that I took from it is that they -- they wanted us to not stop at the point where we were with our analyses, but to go forward with more analyses on our data sets, more study on the topic. There was advice to share, communicate the information that we had. There was advice to get outside people like themselves helping us, and in particular, there was advice that these were -- these were diabetologists.
There was advice that we talk to the psychiatrists and others who were prescribing Zyprexa about trying to help their patients to manage weight gain that they were getting in order to try to minimize health risks from weight gain.
Q. And why would it be that the company wouldn't tell physicians in October of 2000 that Zyprexa had a diabetes problem?
A. Well, because -- because that's not what our conclusion from -- from the data and from our studies were.
Q. If Zyprexa causes weight gain and weight

gain is a risk factor for diabetes, then why wouldn't the company conclude that Zyprexa caused diabetes?
A. Well, that sounds logical and certainly we were very aware of that question, but our conclusions -- our conclusions wouldn't be based on the theoretical chain. It would be based on looking at -- because we knew about that, looking at what we actually found in our studies and sharing with doctors what the actual results were, what we knew, not what we suspect.
Q. We also heard that at this meeting there was a recommendation that Lilly provide its data to an external independent review board for review.
Do you remember hearing comments like that?
A. Yes.
Q. And what did Lilly do in response to that?
A. We kept working on the question, but we kept working on it in concert with people who were independent from Lilly, and, in fact, we were fortunate enough out of this board with a couple of these diabetologists who hadn't been

looking at the issue of diabetes in schizophrenia or hadn't been familiar with Zyprexa actually worked with us going forward from that time to look at the data and to help us think about the studies that we did after that point.
Q. Were there members of the people who participated in that board meeting in October, the advisory board meeting, who actually helped Lilly with the analyses that were done afterwards?
A. Yes.
Q. And who were they?
A. Two that I recall; Dr. Holman, Rury Holman was a prominent endocrinologist from Great Britain and he worked with us on our research. And the second was Dr. John Buse from North Carolina who was also a prominent diabetologist and in fact is, the president of American Diabetes Association. He started working closely with us on this question as well.
Q. Was there anybody else who Lilly had been working with already in regards to analyzing the data on Zyprexa and diabetes and weight gain?
A. There were others. We mentioned Dr. David Allison, who's an obesity -- an obesity

expert at University of Alabama at Birmingham, and he was already working on it at this point.
Q. Did Lilly place any restrictions on the ability of these doctors to analyze the data that Lilly had on Zyprexa and hyperglycemia and weight gain?
A. No. I mean to the contrary we're looking to them, the experts, to guide us about what to look at and how to analyze it. No, we were looking for their leadership.
Q. And what analyses did they suggest that Lilly do?
A. Well, there were a number of them, but relevant to what we had looked at here and what we had shown them at that advisory board, they wanted us -- what we'd shown them already was thresholds and comparable rates of patients developing what looked like diabetes. They asked us to do more analyses of that to look also at hyperglycemia, so we looked at a couple of other thresholds.
They asked us to look not just at the proportion of patients or the rates of developing problems, but also to look at the average change across time, so those average

change analyses we've talked about earlier were exactly the sort of thing that were being recommended by this group.
Q. And Lilly completed those analyses as you've described them?
A. We did.
Q. And what did it do with those analyses?
A. We communicated the results. They were in one of the FDA submissions that you saw, but these were also exactly the analyses that we looked at in one of the medical letters earlier today for physicians. These were the analyses that went into those brochures that our representatives carried out for -- carried out to show to physicians. These were results that we put into slides that we gave to speakers, physicians who were speaking on behalf of Lilly.
Q. And were the results presented at scientific meetings as well?
A. A number of times, yes.
Q. We've also heard reference to the fact that in one of the e-mails that the State has relied upon that someone named Thomas Brodie indicated that members of this advisory board wanted Lilly to, quote, come clean.

I wanted to ask you first who was -- or who is Thomas Brodie?
A. He's a marketing professional and he works with the diabetes team at Lilly, LillyUSA.
Q. So I take it that he did not work on Zyprexa?
A. No, he did not.
Q. And he would not have been aware of the ways in which Lilly was sharing its data with both FDA and physicians?
A. No, I don't think Mr. Brodie had any knowledge up to the point that we're talking that day.
Q. Did you hear the comment about coming clean?
A. No, I didn't. I didn't hear that at the board, but I got an e-mail from Mr. Brodie that mentioned that phrase.
Q. And what was your understanding of what Mr. Brodie had meant --
MR. SUGGS: Objection, Your Honor; speculation. How is he going to know what Mr. Brodie said?
THE COURT: I'll sustain his objection.

MR. KANTRA: I'm asking for his understanding, when he read it --
THE COURT: Ask it that way.
Q. (BY MR. KANTRA) When you read the e-mail, how did you understand Mr. Brodie's reference to coming clean?
A. I -- I thought Mr. Brodie was referring to advice that we got from those advisers that we should communicate the information that we had, including communicate it with the FDA.
We had already sent it to the FDA, but when I was at the meeting, it seemed that they didn't understand that we had. And also the strong information that they were giving us to, you know, help doctors with this weight gain, talk to them about managing weight gain. That's how I took it.
Q. And in terms of how Lilly responded to these advisers, was this also part of what led to the development of things like Solutions for Wellness, and the diabetes education programs that you've developed that you've described?
A. Right, those were all tools to help -- to help patients. And these advisers the endocrinology experts were particularly

recommending that we talk to the physicians about behavioral things, the standard things that anybody can try for managing their weight.

Q. In your experience and based on your familiarity with the data regarding weight gain and potential ways to intervene and manage it, is weight gain manageable in all patients?

A. No. Sometimes it is; a lot of times it's not.

Q. Why does Lilly provide information on weight management programs?

A. Well, because we knew that doctors wanted that information to help their patients and we also knew -- we know from studies on this that -- that -- that attempts to control the weight help some and they certainly help more if you do try than if you don't try.

Q. You told us about the many conversations you've had with physicians particularly when you were working with the U.S. affiliate as a physician working on Zyprexa, and I want to ask you: From those conversations, did you have an awareness of the extent to which those physicians were aware of weight gain as an outcome with Zyprexa?

MR. SUGGS: Objection, Your Honor. Foundation; calls for speculation.

THE COURT: Could you repeat the question again, please.

Q. (BY MR. KANTRA) Based on your conversations with physicians that you've had, you said that you've described hundreds if not more than 1,000. I'm asking you based on those conversations, did you have an understanding of whether they were aware or not that weight gain was associated with Zyprexa?

MR. SUGGS: Same objection, Your Honor.

THE COURT: I'll allow him to testify to what he took from these conversations, understanding that it's what he took from these conversations.

A. Yes. I had many, many conversations over many, many years, and doctors were very focused on weight associated with Zyprexa. It was something that they could see, often had seen in their patients themselves, and they were very interested, especially in what we could recommend to them in doing about that. And, in fact, across all those conversations, many were focused

on this, and I don't think I've ever talked to a doctor using Zyprexa who was not aware that weight gain was a challenge for some of the patients on Zyprexa.

Q. (BY MR. KANTRA) Did you have an understanding, again, from your conversations with these physicians as to whether they understood that weight gain could be substantial in some patients?

A. Yes.

Q. And were you aware from these conversations that physicians understood that weight gain, particularly that leading to overweight and obesity, could be a risk factor for diabetes?

MR. SUGGS: Your Honor; leading.

THE COURT: No, I don't think it is. I'll overrule that.

A. Yes, that -- that's basic information that we learn in medical school and -- and doctors that I've talked to are all aware of that.

MR. KANTRA: Your Honor, could I have just a second to confer?

THE COURT: Sure.

(Discussion off the record.)

MR. KANTRA: Your Honor, at this time, we'll pass the witness.

THE COURT: Mr. Suggs.

MR. SUGGS: May I have just a moment to get my assistant up here?

THE COURT: Sure.

CROSS-EXAMINATION

Q. (BY MR. SUGGS) Good morning, Dr. Baker.

A. Hello, Mr. Suggs.

Q. You talked about the 2007 label change in your testimony, correct?

A. Yes.

Q. And that new label change has information in there, new information regarding hyperglycemia from when it existed before in 2003, correct?

A. Yes.

Q. And it also has a whole brand-new section in the warning section on weight gain, right?

A. That's right.

Q. It has a whole new section on hyperlipidemia, correct?

A. Yes.

Q. Just for the record, none of the other atypical antipsychotics have been required to issue such warnings regarding those matters, have they, sir?
A. No, except for the -- the warning that's existing on glucose for the atypicals.
Q. And that was the one that came in the 2003, correct?
A. Right.
Q. I was talking about with all of the changes that you folks had to make in 2007, just some months ago, none of the other atypical antipsychotic agents have been required to add that to their labeling, have they, sir?
A. Not that I know of, no.
Q. Okay. Now you also talked about the 2003 label change, and that was the first time that Lilly had in the warning section any language whatsoever about hyperglycemia or diabetes, correct?
A. I agree.
Q. Okay. And you testified under oath that after that change, you were particularly involved in communicating that label change to physicians; do you recall that testimony?

A. Yes.
MR. SUGGS: Your Honor, could I display on the screen that testimony from last Friday?
THE COURT: Sure.
MR. SUGGS: Can you pull that up, please?
THE COURT: Well -- yes.
MR. SUGGS: Okay.
Q. (BY MR. SUGGS) Mr. Kantra asked you:
Question: What involvement did you have in particular with respect to the September, 2003 labeling change?
Answer: I was part of the team at Lilly -- at Lilly that discussed it and made the decisions to accept the change, and then I particularly played a role as part of the U.S. medical group in communicating this as soon as it changed to physicians using Zyprexa.
And what were the ways --
Question: And what were the ways in which Lilly went about letting physicians know that there had been a change in the labeling as of 2003 about this diabetes warning?
Answer: Many different ways.

Question: Okay. And can you tell the jury some of those ways that Lilly communicated that information?
Sure. We changed the label so all the package inserts that they would get with the medicines or on our web site, the label was changed. We issued a press release so that it would be picked up in the news or in physicians' newsletters about this. We -- I took part myself actually in right away training our sales representatives and we instructed them to let all the doctors know that they're calling on know about it, to let them know the very next time that they spoke to any of the doctors that they're talking to.
We made slides and we provided it to people that were speaking -- physicians speaking on Lilly's behalf so that they could discuss it with physicians as well. We prepared a medical letter for doctors describing this and the background behind it. We made it available through the electronic forms that doctors would use, like the Hippocrates. Some people use it as an electronic database for adverse events and Lilly mailed to doctors in the United States

describing this label change.
Did I read that correctly?
A. You did.
Q. You were the architect behind that communication plan, weren't you?
A. No, I was involved.
Q. You said you were particularly involved. How particular? How central was your role in that, sir?
A. When I used -- I did quite a bit, but when I used that word particular, I meant particularly more involved in that than the other part in that sentence, which was discussing the acceptance to start with. It was referring back in that sentence. I was very involved in this.
Q. You were very involved in that. All of those communications, I'm assuming, went out within days or weeks after the September 11, 2003 request by the FDA to change your label; is that correct?
A. They started within days or weeks. I don't think they were all completed in that time.
Q. They would have been completed within what, a month or so after that?
A. I think our communication about this and

having discussions with doctors went on for quite a long time.
Q. Okay. In any event, there would have been quite a lot of communication from Lilly to physicians and other customers of Lilly within, what, three months or so of that? There would have been a fair amount of communication about that, correct?
A. I agree.
Q. Okay. And after you and others at Lilly went out and gave your spin about the change in the label, doctors complained that Lilly had minimized the importance of the label change and that Lilly had lost its scientific integrity?
MR. KANTRA: Objection, Your Honor.
THE COURT: Why don't you rephrase the question and take out the word spin.
Q. (BY MR. SUGGS) Okay. Sir, do you recall that after you went out and gave your message about the label change, that doctors complained that Lilly had minimized the importance of the label change and that Lilly lost its scientific integrity?
Do you remember that?
A. No, I don't remember that.

MR. SUGGS: Could you please pull up Exhibit AK2233.
And could you highlight Dr. Baker's name in the list of the CC's? About the third line from the bottom in the CC list.
There you go. And could you also blow up the date and who this e-mail is from? Chris, could you pull that second thing up there and show the date of the e-mail and who it's from? It's hid by the --
Q. (BY MR. SUGGS) Okay. This is a January 14, 2004 e-mail from Jerry Clewell. You know Mr. Clewell, don't you, sir?
A. I do.
Q. You did, in fact, receive a copy of this e-mail on or about the date indicated in January of 2004?
A. Looks that way.
Q. This would have been, what, October, November, December, January, February, about four months after the label change, correct?
A. Yes.
Q. If I could direct your attention -- by the way, in this e-mail -- who was Dr. -- Mr. Clewell? What was his job?

A. He was an outcomes liaison. He did -- he communicated with the insurance or the payors.
Q. You used the term payors. Can you tell us what payors means?
A. It's -- my understanding was that it's those insurance companies or Medicaid or those that buy the medicine.
Q. Okay. It would include insurance companies, but also include state Medicaid organizations, correct?
A. That was my understanding.
Q. Like the State of Alaska's Medicaid organization, correct?
A. I would think so.
Q. Okay. And there's also a term in here -- used in here, clinicians. That refers to doctors, doesn't it?
A. I don't see the reference in here, but, in general, clinician would be a health care professional. Somebody working with patients.
MR. SUGGS: Could you go to the second page, Chris, please?
And could you blow up that first paragraph at the top there, and highlight the text that starts off as a company -- can you make

that somehow bigger, Chris?
There you go. And could you highlight the last four lines of that e-mail starting off with as a company?
Q. (BY MR. SUGGS) This is Dr. -- Mr. Clewell saying: As a company, we all need to do a much better job of proactively listening to payors and other customers' concerns and proactively communicating information such as adverse effect label changes without a tone of minimizing their importance, e.g., weight gain, diabetes, CVA -- by the way, CVA stands for cerebrovascular accident; correct?
A. I agree.
Q. And in January of that month in 2004, you also had to add cerebrovascular accident to the warning section; correct?
A. It was in that time frame. I don't remember that January or December.
Q. Mr. Clewell goes on to mention: Payors and clinicians have clearly articulated that this is an area where Lilly has lost its scientific integrity and therefore exposed us to great skepticism and we need to communicate the positive benefits of our products.

You see that, sir?
A. Yes.
Q. After you got this e-mail from Mr. Clewell, you didn't write back and say, oh, gee, you're wrong, did you, sir?
A. Not that I recall.
Q. And about two weeks after this e-mail, Lilly got advance notice of the publication of the report of the consensus conference.
Do you recall that?
A. Yes, I recall that we got the report. I couldn't exactly date it for you, Mr. Suggs.
Q. But you do recall that you got advance notice of it; correct?
A. I do believe we heard about it in advance.
Q. And it was published in, I believe, February, was it not? February of 2004?
A. That sounds about right. I don't remember the exact day.
Q. And Lilly regarded the publication of the consensus report as a corporate level crisis requiring what was called a Zyprexa SWAT team to present Lilly's side of the story.
Do you recall that?

A. I don't -- I do remember it was an important thing for Lilly. I don't recall that as you've characterized it.
MR. SUGGS: Could you pull up AK3109, please, Chris? And could you blow up that first part about in the middle of the page, the e-mail from Hunter Heath.
Q. Who was Mr. Hunter Heath, or was that Dr. Hunter Heath?
A. Dr. Heath, he was the executive medical director for U.S. medical.
Q. Okay. And this is a January 27, 2004 e-mail from him to John Holcombe, Janet Tobian, some other folks, including yourself, correct?
A. Yes.
MR. SUGGS: Okay. And Scott -- I'm sorry, Chris, could you blow up the first six lines of the e-mail below that. Make it a little bigger.
Q. (BY MR. SUGGS) Doctor, he says: Dear All, if you're not aware at the time you read this, you will soon know that we have been asked by Mssrs. Lechleiter and Santini to gear up for a major assault on Zyprexa because of the ADA consensus statement copied below. This is

regarded as a potentially corporate level crisis. Specifically, the teams believe there will be a great need for physicians able to present Lilly's side of this story, to B2B and B2G clients. Let me stop right there.
B2B stands for business to business, does it not?
A. Yes.
Q. And that would be communications between the business of Lilly to the business of insurance companies, correct?
A. I think so.
Q. And the B2G stands for business to government, which is Lilly to State Medicaid outfits, correct?
A. I would think, among other things.
Q. Okay. And Dr. Heath goes on to say: I am therefore asking each of you to join an informal Zyprexa metabolic SWAT team requiring that you be trained by Tom Hardy and others on the slides to be used in presenting the case for Zyprexa.
Did I read that correctly?
A. You did.
Q. And you were part of that Zyprexa SWAT

team, were you not?
A. Not -- no, I don't think so.
Q. Well, what was said by Lilly -- by the way, the consensus statement essentially -- and the jury's heard a lot of testimony about this -- basically what the consensus statement said was that clozapine and olanzapine had the highest risks of weight gain, diabetes, and also hyperlipidemia, correct?
A. Yes.
Q. And Lilly disputed that -- those conclusions, correct?
A. One of them.
Q. Do you dispute that Zyprexa has a higher risk for diabetes, do you not?
A. That's right.
Q. Do you dispute that it has a higher risk for hyperlipidemia?
A. I -- we see higher lipid, increased triglycerides in particular than -- than most of the other atypicals.
Q. So you do admit to the increased risk of hyperlipidemia as compared to other drugs, and the increased risk of weight gain as compared to other drugs, but you dispute that there is a

higher risk for diabetes, correct?
A. Right, that's not what the -- our studies have shown.
Q. After the consensus statement, you disputed that and you're disputing that today in this courtroom, correct?
A. Yes.
Q. Okay. Now, who is Vicki Poole Hoffman?
A. Vicki Hoffman is a clinical research scientist. She's a doctor of pharmacy and she's worked with the U.S. medical group.
Q. And she was involved in getting out Lilly's message in response to the consensus statement, was she not?
A. I don't recall. It's possible.
Q. Do you recall a couple of months after Lilly had been disputing the consensus statement that she told you that Lilly's advisers were saying that your argument about comparable rates was making the company look foolish?
A. No.
Q. Can you hand me --
A. Thank you.
Q. Dr. Baker, I've handed you what we've had marked as Exhibit 3192. This is an e-mail

from Vicki Poole Hoffman to Thomas Hardy and a number of other individuals with a copy to you dated March 10, 2004.
Do you see that?
A. Yes, sir.
Q. And do you recall receiving that e-mail on or about that date?
A. Can I have a second to read it?
Q. Sure.
A. I'm sorry, Mr. Suggs, I don't remember it.
Q. Do you have any basis to dispute that you, in fact, received this e-mail on the date indicated?
A. No, it looks like I did.
Q. Okay.
MR. SUGGS: Your Honor, we'd move for the admission of Exhibit 3192.
MR. KANTRA: Your Honor, I don't think a foundation has been laid for this.
THE COURT: He doesn't dispute that he received it, and it was from one Lilly person to another.
MR. KANTRA: Okay.
THE COURT: I'll overrule the

objection. AK3192 may be admitted.
MR. SUGGS: Can you pull up Exhibit 3192, Chris? And blow up just the first couple of sentences in the e-mail.
Q. (BY MR. SUGGS) What was being discussed here in this e-mail was the preparation of an editorial for some journal called BHM.
Do you see that, sir, in the document that you have in your hand?
A. I do, yes.
Q. And what was BHM?
A. I'm sorry, I don't remember.
Q. Do you recall that it was a medical article -- or medical journal, rather?
A. That's what this looks like, but I don't recall the term.
Q. And Lilly was, in fact, preparing an editorial for inclusion -- for publication in that journal that was going to address the consensus statement, correct?
A. It looks like it would at least mentioned them.
Q. And Vicki Poole writes you back and says: I think you should delete most of the third paragraph and all of the fourth as they are

defensive and attempt to show that there is no differential risk of DM, diabetes mellitus, among atypicals in spite of the differences in weight gain. Our advisers have told us that this position is making us look foolish.
Do you see that language, sir?
A. I do.
Q. Who were the advisers that were telling Lilly that taking that position that there was no differential risk of diabetes in spite of the differences in weight gain was making you look foolish, sir?
A. I'm not sure whom she meant.
Q. But you're making that same argument here in this courtroom, aren't you, sir, that there's no differential risk of diabetes for Zyprexa despite the fact that you admit that there's more weight gain with the drug? You're still making that argument, correct?
A. Yes, that's what we found.
Q. Okay.
MR. SUGGS: Can you pull up Exhibit AK9281, please?
Q. (BY MR SUGGS) This is an e-mail that's in evidence. It's an e-mail dated February 6,

2004 from Dr. Alan Breier to U.S. medical.
MR. SUGGS: Chris, can you go to the Principles paragraph and blow up the last three sentences -- pardon me -- the last four lines in that paragraph, please?
Q. (BY MR. SUGGS) And Dr. Breier in that e-mail back in February of 2004 said, 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 -- is the word that's cut off there.
And, sir, that spinning of data that Dr. Breier refers to was something that you were involved in in connection with Zyprexa since you were with the company; isn't it, sir?
A. No.
Q. Well, let's talk about your background at the company. You came to Lilly in 1999,

correct?
A. Yes.
Q. You were trained as a psychiatrist?
A. Yes.
Q. You're not an endocrinologist?
A. Right.
Q. You're not a diabetologist?
A. Agree.
Q. You're not a specialist in diabetes?
A. No, except for this one narrow topic.
Q. Except for your on-the-job training at Lilly.
Prior to joining Lilly, you had no prior special training in diabetes, correct?
A. Right.
Q. You'd never conducted any research in the area before you came to Lilly?
A. No.
Q. Correct?
A. Correct.
Q. And before you came to Lilly you'd never had any publication in any peer-reviewed journals about diabetes, correct?
A. Correct.
Q. And yet despite your lack of prior

experience or expertise in the field, you were designated to be the No. 1 guy to drive the Zyprexa medical marketing strategy regarding blood glucose issues from the medical side; is that correct, sir.
A. Yes. No. 1 of the psychiatrists, the four psychiatrists that were working in our U.S. part of the company.
MR. SUGGS: Can you pull up Exhibit 8905, please, Chris. This is an e-mail from Dr. Paula Trzepacz, to another of the individuals, yourself included --
Q. (By MR. SUGGS) You are married to Dr. Trzepacz, are you not, sir?
A. I am, yes.
MR. SUGGS: If you could blow up, Chris in that second paragraph -- actually just blow up the whole paragraph.
Q. (BY MR. SUGGS) And about the middle of the paragraph it says: The primary person will be held accountable -- well, let me back up for a second.
In this e-mail, Dr. Trzepacz, your wife, appointed you to be the No. 1 guy to deal with glucose issues, correct?

A. Yes, No. 1 in the context of our group of psychiatrists.
Q. And she appointed Dr. Kinon to be the No. 1 guy in weight gain, correct?
A. I think that's right.
Q. She says in the middle of this paragraph: The primary person, which in connection with glucose would be you, will be held accountable to drive the medical marketing strategy from the medical side; is that correct?
A. Yes, you read that correctly.
Q. Now, by the time you got to Lilly in 1999 -- well, let me back up for a second.
So you were working hand in glove with the marketing folks to drive the medical marketing strategy from the medical side, correct?
A. I often worked with people from marketing, yes.
Q. And you were responsible for -- for creating many of the messages that went out to physicians about the issue of blood glucose changes, correct?
A. Well, yes, in the way that we talked about earlier, I would provide a lot of medical

input.
Q. You were involved in the creation of medical letters that went out?
A. Yes.
Q. On that issue?
A. Yes.
Q. You were involved in the creation of brochures that went out, correct?
A. Often.
Q. You were also involved in the training of sales reps on the issue of blood glucose?
A. Occasionally.
Q. And by the time you got to Lilly in 1999, Lilly had -- Zyprexa had been on the market for three years and the company had notice of literally hundreds of reports of elevated blood sugar in Zyprexa users; isn't that correct, sir?
A. Could you repeat the question for me, Mr. Suggs?
Q. Sure. By the time you got to Lilly in 1999, Zyprexa had been on the market for three years and the company was aware of literally hundreds of adverse event reports relating to increased blood sugars, correct?
A. I agree.

Q. Okay. And the company was well aware that for every case or adverse event that was reported, there was likely going to be many more that were not reported, correct?
A. Yes. We typically -- yes, we know that not all spontaneous -- not all adverse events are reported through spontaneous reports.
Q. And there's been testimony that the number of events that are actually reported is only 1 percent to at most 10 percent of those that actually occur?
A. There's general estimates like that.
Q. Okay. So, Lilly was well aware that those hundreds of reports that they had by 1999 were only the tip of the iceberg and that there could well be thousands, if not tens of thousands of reports of increased on -- pardon me -- either thousands or tens of thousands of actual cases of elevated blood sugar in Zyprexa users, correct?
A. We assumed that they would be a subgroup.
Q. Okay. And doctors had written to the company and specifically urged Lilly to investigate hyperglycemia and report on the findings rather than just sending out literature

saying that all antipsychotics increased the probability of hyperglycemia.
Do you recall that, sir?
A. Yes, I certainly recall that we got the advice to investigate the issue.
Q. Okay.
MR. SUGGS: Let me have Exhibit 7731. Have a copy for you too, Judge.
Q. (BY MR. SUGGS) Dr. Baker, I've handed you a copy of a letter dated November 17, 1999 from a Dr. Albert Morero, staff psychiatrist at the Ventura County Behavioral Health Department and it's addressed to John Hayes, M.D.
Who was Dr. Hayes back in 1999?
A. At that time, he was the medical director for the neuroscience group that I worked in U.S. medical. So he was my boss at that time.
Q. Was he your direct boss or your boss' boss?
A. He was my direct boss.
Q. Your direct boss, okay.
By the way, you came to the company in 1999, did you not?
A. Yes, in September of '99.
Q. And in this letter, Dr. Hayes is writing

about patients of his who had high blood sugars after taking Zyprexa, correct?
A. No, this is not from Dr. Hayes.
Q. If I said Dr. Hayes, I misspoke. This letter from Dr. Morero to Dr. Hayes is talking about cases of high blood sugar that Dr. Morero saw in his patients after they've been on Zyprexa; is that right?
A. It looks that way.
MR. SUGGS: Your Honor, I move everybody for admission of Exhibit 7731.
MR. KANTRA: If it's being offered for the truth of the matter, we would object.
MR. SUGGS: We're offering it for notice, Your Honor.
THE COURT: I'll offer it for the purpose of notice.
Ladies and gentlemen, it's being admitted to show that it was -- Lilly was on notice of the contents of the document, not necessarily for the truth of the contents of the document. What was the number again?
MR. SUGGS: It's 7731, Your Honor. AK7731.
THE COURT: And that's admitted on

that basis.
MR. SUGGS: Chris, can you pull up 7731, please. Can you blow up the first paragraph?
Q. Dr. Morero writes: This is to inform you that we have contacted our local drug representative for Zyprexa in our county as well as the regional supervisor to let them know that we have had eight patients out of possibly 35 patients on Zyprexa show up with high blood sugars. Two patients had to be hospitalized due to out of control diabetes and the other six, who were not diabetics prior to taking Zyprexa, ended up with blood sugars higher than 120 fasting.
Do you see that language, sir?
A. Yes.
Q. And that percentage, if you do the math on that, eight patients out of 35 works out to something less than, what, 25 percent of the patients that this physician had prescribed Zyprexa showed up with high blood sugars?
A. I agree, according to what he says here.
Q. Okay. Chris, if you could drop that down and blow up the last paragraph.
Dr. Morero says: I believe it is

Lilly's responsibility to look into this delicate matter in lieu of the many reports that are coming out showing the danger of Zyprexa with weight gain and hyperglycemia. I think that it would make sense for Lilly to investigate and report on these findings rather than turn the other way and send literature on how all antipsychotics increase the probability of hyperglycemia.
Do you see that language?
A. Yes.
Q. And, sir, in fact, by this point in time, in November of 1999, Lilly was, indeed, sending out literature saying that all antipsychotics increase the probability of hyperglycemia; isn't that true?
A. I believe -- I'm not sure. I believe by this time, though, there was -- we had literature showing high rates across patients.
Q. Chris, can you go to the second page? Blow up the second to last paragraph.
Dr. Morero says: Please take this situation into, did. I guess what we are asking is a report from Lilly in regards to Zyprexa and its potential for high blood sugar, regardless of

what the general antipsychotic statistics are. We certainly have never seen this with Haldol, Navane, Risperdal and others to this extent.
Do you see that language, sir?
A. Yes.
Q. Sir, in fact, at this point in time, this is November 17, 1999, on the very date that this was written there was a document, there was a report, a secret report inside Lilly that the company could have provided to Dr. Morero, wasn't there, sir?
A. I don't know.
Q. You're not aware of the report?
A. I'm not sure what you're referring to.
MR. SUGGS: Can you pull up Exhibit 4176, please? Can you blow up the date on the first page in the title.
Q. We've had testimony about this report that was written on November 17, 1999 by Dr. Kwong.
Do you know Dr. Kwong?
A. Yes, I knew him.
Q. Dr. Kwong was in what was called the pharmacovigilance department; is that correct?
A. Yes.

Q. Pharmacovigilance is a word I never heard until I got involved in this case.
Tell us what it means, sir.
A. That's part of our safety group. Pharmacovigilance is the group in particular that gets the spontaneous report that we've been talking about that get reported in to us or people that call into our 800 number, its pharmacovigilance that records the information, processes it and sends it into the FDA.
Q. The purpose of the pharmacovigilance department is to be vigilant about potential safety problems with your drugs, correct?
A. Right. We want to hear about these reports and evaluate them.
Q. They don't just look at the adverse events that are reported to the company. They look at the literature; they look at internal controlled trials; they look at animal studies; all of those things, don't they?
A. That's partly correct. As it is now, the pharmacovigilance companies looks at the spontaneous events and they look at the published literature and then certainly the broader safety group, the broader group looks at our internal

studies, our animal studies, brings it all together.
Q. The function of that, the reason why they do that is to see if there was a problem, if there's a safety problem, correct?
A. Yes.
Q. Can you go to the second page, please, Chris.
And Dr. Kwong was nice enough to prepare a summary for us at the beginning of the report. And could you blow up that first bulleted heading there, please?
He refers to registration trials. Those are the studies -- trials that were done for the NDA, correct?
A. Yes.
Q. Okay. And he reports that 1.7 percent of 2500 patients who received olanzapine experienced treatment-emergent hyperglycemia with nonfasting blood glucoses greater than 250 milligrams per deciliter.
Let me stop right there for a second.
The cutoff for a diagnosis of diabetes with a random blood glucose is 200,

right?
A. Yes. That would be part of the diagnosis.
Q. Okay. And here he's talking about that you had 1.7 percent of those in the clinical trials who had random blood glucoses greater than 250, correct?
A. It says that.
Q. And he goes on to say: Most studies were six to eight weeks in duration. Studies of longer duration are needed to determine the true incidence as the mean time of onset of hyperglycemia was 16 weeks based on spontaneous reports and weight gain plateau occurred after 38 weeks.
Do you see that language, sir?
A. Yes.
Q. And, in fact, later on in this report, Dr. Kwong concluded that if you looked at the longer studies, longer studies would show a higher percentage of that.
Do you recall that, sir?
A. No, I don't recall this report.
Q. Can you go to page 10, please, Chris?
The last paragraph, item 2, it

states: The incidence of treatment-emergent hyperglycemia among 2500 patients studied, initial registration of studies of Zyprexa was 1.7 percent where high nonfasting hyperglycemia was defined as blood glucose greater than 250 milligrams per deciliter. As these trials are mainly short-term studies, the actual incidence, had patients been exposed to olanzapine for longer period would be higher.
Do you see that language, sir?
A. Yes.
Q. Now, you testified about your experience and how you know about these clinical trials based on what your review was.
Why did Lilly have a cutoff of 250 instead of 200 or lower, sir?
A. I'm not sure why it was 250 for this report.
Q. You don't know why? 250 is definitely in excess of the 200 cutoff for the diagnosis of diabetes, correct?
A. Yes, 250 is greater than 200 -- and 200 is part -- it's one of the diagnostic --
Q. According to the cutoff that you used here, if you had patients who showed up at 200,

they wouldn't be included as having high blood glucose, would they, sir?
A. No, unless -- according to this, unless they were over 250.
Q. Okay. So according to your -- the cutoff that you folks were using in your clinical trials, you could have patients show up with a random blood glucose of 200, 210, 220, 230, 240 and the way you guys sliced the data, that was normal; isn't that right, sir?
A. Not necessarily, but it depends on which -- which cutoff. But if it's 250, it would have been below 250.
Q. Right.
MR. SUGGS: Can you go back to page 2, please? And blow up the second bulleted point there.
Q. (BY MR. SUGGS) It also refers to a retrospective study by Dr. Daniel Casey. The jury has heard some testimony about this study that was done by Dr. Casey. In fact, the jury's heard testimony that Daniel Casey came to Lilly in November of 1999 and gave a seminar on this review that he did.
Were you at that seminar, sir?

A. Not that I recall.
Q. Okay. Anyway, Dr. Kwong reports Dr. Daniel Casey, a Portland Veteran Health Science Center reviewed the charts of 136 patients who had taken olanzapine for four months or more. The average duration of treatment for these patients was 17 months. 50 percent of 136 patients experienced weight gain of 7 pounds or more after initiating olanzapine therapy. Seven of the 39 patients, 18 percent, who had normal blood glucose at baseline developed treatment-emergent hyperglycemia.
Do you see that language, sir?
A. Yes.
Q. Lilly never warned treating doctors about that, did it, sir?
A. Not -- not of Dr. Casey -- Dr. Casey's findings weren't in the label, no.
Q. You never included that in any of your brochures, did you, sir?
A. No. Not that I know of.
MR. SUGGS: Chris, can you go to page 11?
Q. (BY MR. SUGGS) The second-to-last paragraph under Fasting Glucose. There's further

reference to Dr. Casey, and it notes that 60 patients had fasting glucose levels before and after olanzapine therapy, 39 had normal fasting glucose levels. Of these 7, 18 percent had an increase in their fasting glucose levels. Mean fasting glucose levels was 100 before olanzapine, and 139 milligrams deciliters during olanzapine therapy. Based on the new diagnostic criteria of ADA, diabetes mellitus is said to be diagnosed if a patient's fasting blood glucose is greater than or equal to 126.
So, according to that, these folks didn't just have hyperglycemia. The 18 percent that's being referred to didn't just have hyperglycemia, they had hyperglycemia at a level that was diagnostic for diabetes; isn't that right, sir?
A. No, you couldn't conclude that from this.
Q. He says that the mean after olanzapine use was 139 milligrams per deciliter, correct?
A. Yes.
Q. Okay. And 139 is in excess of 126 fasting glucose cutoff that's diagnostic for diabetes, according to the American Diabetes

Association, correct?
A. I agree.
MR. SUGGS: If I can direct your attention, Chris, back to the second page, again. And if you blow up that section on the animal studies.
It says: Two of 10 rhesus monkeys developed fasting hyperglycemia after switching to calorie unrestricted diet and initiation of clozapine treatment. The average weight gain was 26 percent. The HbA1c of all monkeys became elevated above the upper limit of normal.
Do you see that language, sir?
A. Yes.
Q. Were you familiar with those animal studies?
A. No, I don't recall those -- those studies.
MR. SUGGS: Chris, if you could go back to page -- I believe it's 12. In the discussion section, if you could blow up the first three lines there.
Q. (BY MR. SUGGS) Dr. Kwong concludes by saying: Both postmarketing reports, retrospective study in patients in veteran

hospital in Oregon and animal studies suggest an association between obesity and treatment-emergent hyperglycemia in patients treated with atypical antipsychotics.
Do you see that language, sir?
A. Yes.
Q. And you could have sent this report out to Dr. Morero and others who were asking for that type of information, correct?
A. Report -- yes, I guess.
Q. Okay. Can you go to the very first page of the document, sir?
But the reason why you didn't -- can you blow up that box there -- was because Lilly regarded this as secret, right?
A. I see that. That is a stamp that goes on many of our documents. I can see it here.
Q. Doctors didn't deserve to know this information before they used your drug in their patients?
A. No, to the contrary. The information we would give to doctors is the overall conclusions that we would have from looking at our information.
Q. Dr. Morero on November 17 was asking for

a report about the safety of Zyprexa on this very day this report was ready and available, and you never sent that report out to him or any other doctor, did you, sir?
A. I'm not aware of this particular report having been sent out.
Q. No, instead what you did was you had your medical folks and your marketing folks, your regulatory folks, you got all together and you got your own messages out later on, put them in brochures and medical letters, right?
A. Sure. We summarized the information in our conclusions.
Q. And the marketing department was involved to make sure that nothing that went out was going to hurt the reputation of the sales of the drug, correct?
A. No.
Q. You didn't send out this report? Did the marketing folks ever even consider sending this report out?
A. Marketing would not have a role in our medical information.
Q. Did this report go through your MLR review that you talked about?

A. No.
Q. Who would -- who would have made the decision not to do that, sir?
A. The medical -- the medical group, the medical information group would respond to requests that we have for informations.
Q. Now, clearly, Dr. Morero was personally aware of the issue of hyperglycemia in November of 1999, because he was writing in to the company to tell the company he was seeing problems and he was asking for help, right?
A. We saw his report of what he's seen in his patients.
Q. But we've heard testimony from you and our Lilly witnesses that doctors -- they already knew about the issue of diabetes with Zyprexa even without the company having to warn them about it; isn't that right?
A. That's not accurate.
Q. Well, in fact, we know and Lilly knew that most doctors were not aware of the diabetes issue with Zyprexa even years after Dr. Morero's letter; isn't that right, sir?
A. No, no. It depends what you're referring to as a diabetes issue. I think

doctors were very aware of questions about weight and diabetes.
Q. I'm going to hand you what we've had previously marked as 3860 --
MR. SUGGS: Your Honor, this document has been discussed before, but I don't think it's ever been admitted -- do we have another copy?
Don't show it yet.
Do you have any objection to the admission of this?
Q. (BY MR. SUGGS) Dr. Baker, if I could direct your attention to -- by the way, the title of this is called Handle Weight Hyperglycemia slash Diabetes Issues, correct?
A. Correct.
Q. And it's on the document that has the Lilly logo, correct?
A. Yes.
Q. And Answers That Matter?
A. Yes.
Q. That's a catch phrase that your company uses, right?
A. It's a company motto.
Q. Company motto. Answers that matter.

It means that you're supposed to be telling doctors the truth, right?
A. Yes, among other things.
Q. Among other things?
A. It means also that Lilly hopes its medicines are providing answers for their patients' needs.
Q. Sir, if I could direct your attention to the bottom left side of each page starting with page 2 and continuing throughout the document, there is a little legend below the text that says: Company confidential, and then below that has copyright 2001, Eli Lilly and Company; is that correct?
A. Where do you see that, Mr. Suggs?
Q. I'll point it out to you.
MR. SUGGS: I do have another copy here, Judge.
Q. (BY MR. SUGGS) According to the language -- right there.
A. I see it here.
MR. SUGGS: Your Honor, we move for the admission of Exhibit 3860.
MR. LEHNER: Same objection as last week, Your Honor.

THE COURT: I will admit 3860.
MR. SUGGS: Chris, can you pull up page 5, please?
Q. (BY MR. SUGGS) You said that you thought most doctors were aware of the issue of diabetes. If you look at the last bullet point on page 5 -- let me know when you're there, sir.
It should be showing on your screen as well, sir.
A. I have it, Mr. Suggs.
Q. It says: Currently -- this is on a document with a 2001 copyright on it -- physicians are unaware of diabetes as an issue, but the competition will make it one. So when diabetes comes up, address it.
Do you see that language, sir?
A. I do.
Q. And by the way, who was it that would have prepared documents like this, handling weight, hyperglycemia slash diabetes issues? That would have been the medical marketing group, right?
A. I don't recognize this document but it does not look like anything that the medical group prepared.

Q. It looks like something the marketing prepared, right?
A. Possibly.
Q. Okay. If I can direct your attention to the previous page, page 4, at the very top, can you blow up the first sentence in that first bullet point, Chris. There you go -- oops -- starting with On Every Call and then the first bullet point.
It says: On every call, either in the safety section within the patient profile or the overall safety spread, say the following: Doctor, there is a potential for increased appetite, but it is manageable, unlike EPS or TD.
Do you see that, sir?
A. Yes.
Q. And sales reps were telling doctors that Zyprexa doesn't cause weight gain but an increased appetite.
Were you aware of that, sir?
A. No.
Q. So if that was done, that was something that was done without your knowledge?
A. Yes.
Q. Okay.

A. Zyprexa cause -- there is weight gain with Zyprexa.
Q. In fact, you and doctors in Lilly will admit that Zyprexa causes weight gain, correct?
A. Yes.
Q. But sales reps were telling doctors that it didn't cause weight gain; it only increased appetite.
Were you aware of that, sir?
A. No.
Q. If I can direct your attention to page 3. It says: If M.D.'s concern is weight gain only, own the issue. Don't let the competition frame it for our customers.
And then below that it says: Weight gain with Zyprexa is due to increased appetite, not a metabolic response, i.e., pill doesn't equal weight gain.
Do you see that language, sir?
A. Yes.
Q. Now, were you aware of the animal studies that Dr. Beasley talked about where animals on restricted diet who were administered Zyprexa gained weight?
A. Yes. There's some animal studies with

gaining weight. I'm not -- but I wouldn't know whether you're talking about the same ones.
Q. Are you familiar with animal studies done by Lilly which showed that if you put animals on a fixed diet where their calories were restricted, they still gained weight?
A. No, I'm not sure.
Q. So you're not familiar with those studies?
A. I'm familiar with studies of animals gaining weight. I'm not sure about the calorie restriction you're talking about.
Q. If in fact you did have studies as Dr. Beasley testified, where animals were fed, given Zyprexa, but kept on a restricted diet with no increased ability to take in more calories, then any weight gain that they would have had wouldn't have been an increase in appetite, it would have been a metabolic response, correct?
A. Possibly. I'd have to read the study.
Q. Possibly?
A. I'd have to read the study to know.
Q. And you never told doctors about that in any of your brochures or Dear Doctor letters, did you, sir?

A. I don't think so.
MR. SUGGS: Chris, could you go back to page 5, please.
Again, blow up the language in the last bullet point, currently.
Q. (BY MR. SUGGS) The document says: Currently, physicians are unaware of diabetes as an issue, but the competition will make it one, so when diabetes comes up, address it.
And your strategy was not to discuss diabetes with doctors unless it came up; isn't that right, sir?
A. No.
MR. SUGGS: Can you pull up Exhibit AK1962, please?
Q. What's a sell sheet, sir?
A. I think that's another word for brochure that the sales reps would use with doctors.
MR. SUGGS: And if you could go to the second page, please.
Highlight the second sentence. It starts off: The competition.
Q. (BY MR. SUGGS) It says: The competition wins if we are distracted into talking about diabetes.

Do you see that language, sir?
A. I do.
Q. That was a message -- this was a message that was being given to your sales reps, right?
A. No, not that I know.
Q. Go to the following page.
Handling the Diabetes AOC. AOC stands for area of concern, correct?
A. I'm not sure, but that sounds like it's probably right.
Q. And says: 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. I do.
Q. And --
MR. SUGGS: Chris, could you go to the following page -- before you do.
Q. (BY MR. SUGGS) They then say: If it does, please do the follow, cushion slash clarify the AOC. Handle by providing the verbatim.
What's the verbatim, sir?
A. Verbatim means -- I think what it means is that sales reps were given answers to

questions and told here's the -- here's how you would answer the question.
Q. And, in fact, as we'll see in a little bit, you coached the sales reps on how to deliver those answers, didn't you, sir?
A. No, I have spoken with sales reps to give them background, but, no, I have never worked with --
Q. We'll come back to that. This document goes on to say, Check for agreement. If not satisfied, then utilize the sell sheet. Restate the verbatim while utilizing the diabetes sell sheet. Check for agreement and get back to Donna.
Do you see that?
A. I do.
Q. Donna -- you know who Donna is, do you, sir?
A. No.
Q. You're not familiar with who Donna was?
A. No.
Q. You're not familiar that Donna was a prototypical type of patient description?
A. No.
Q. Okay. Can you turn to the next page,

please?
And could you highlight that box down at the bottom, Correct tone is everything. Stay confident and informative.
Do you see that language, sir?
A. Yes.
MR. SUGGS: Could I have Exhibit 8112?
THE COURT: Is this a convenient time to take our second break?
MR. SUGGS: Sure.
THE COURT: Ladies and gentlemen, we'll take our second afternoon break, and we'll be in recess for about 15 minutes.
(Jury out.)
(Break.)
(Jury in.)
THE COURT: Please be seated.
We're back on the record. All members of the jury are present.
Mr. Suggs.
MR. SUGGS: Thank you, Your Honor.
Q. (BY MR. SUGGS) Dr. Baker, before I continue on with the line we're on, I want to backtrack a little bit and ask you some

questions.
When Dr. Kahn was here, he played a video of an obviously deranged man who killed two policemen. I don't know if there was a specific diagnosis that the man was schizophrenic but I think there was the implication that he was. Are all schizophrenics violent, sir?
A. No, sir.
Q. In fact, there are some schizophrenics that make valuable contributions to society; is that correct?
A. I agree.
Q. For example, you know Dr. John Nash?
A. I'm familiar with his story.
Q. He was a mathematician. I think he won a Nobel prize. Although he's a mathematician, I think he won it in economics?
A. I'm not sure, but I saw the movie.
Q. You saw the movie, A Brilliant Mind?
A. A Beautiful Mind.
Q. He was schizophrenic, was he not?
A. I don't know, but that's what the movie suggested.
Q. And there are famous people with bipolar disease as well, correct, people who have made

valuable contributions to society?
A. I agree.
Q. I think Beethoven has been recognized as a bipolar person, correct?
A. I'm not sure.
Q. How about Mark Twain?
A. I'm not sure whether Mark Twain had bipolar disorder. I'm familiar that some have conjectured that.
Q. How about Churchill?
A. I've heard the same conjecture.
Q. Rosemary Clooney, Francis Ford Coppola, Dick Cavett; are they all bipolar folks?
A. I don't know.
Q. Who do you know that you would recognize as someone famous having made a valuable contribution who is bipolar --
A. I don't know that --
Q. -- or reported to be at least?
A. Yes, I know -- for example, Hemingway has been felt to be bipolar. I don't know that firsthand, but that's what physicians have written.
Q. Okay. Anyone else?
A. Some have argued Churchill, as you've

mentioned.
MR. SUGGS: Okay. Doctor, I want to hand you -- Well, I'll tell you what. Let's pull up Exhibit 1941 first.
This is a Zyprexa Frequent Areas of Concern or FAOC, and it's a document that consists of a series of questions and then answers. Can you go to the one that's on page 2 of the document.
There's a question about diabetes. Can you blow that up, please?
Q. (BY MR. SUGGS) Sir, do you recognize this question and answer?
A. No, I recognize some of the content, but I don't know what it is.
Q. You do recognize -- you do acknowledge that sales representatives were presented with possible questions from physicians and then given answers or directions on how to respond to those, correct?
A. Yes, that's the general practice.
Q. Okay. And in this particular one, the question is: I am concerned about diabetes.
That is a question being expressed by a physician, correct?

A. I'm not sure. It appears that's what it is.
Q. Okay. The sales rep is supposed to cushion that by saying: Thank you for sharing this concern with me.
And then to clarify by asking: Is this something you've seen or heard about?
And then the sales rep was to address the AOC by saying: I understand your concern. The incidence of diabetes is two to four times more common in mentally ill patients than in the general population. In every study examining this subject, no causal relationship has been established between patients being treated with Zyprexa and onset of diabetes.
The incidence of diagnosed treatment-emergent diabetes with patients taking Zyprexa was comparable to those patients treated with Risperdal, Haldol and Depakote in every clinical study conducted by Lilly or by our competitors.
Let me stop right there.
So, basically in that answer, there are three components to that. First is the component that there's no higher risk -- pardon

me -- that the incidence of diabetes is higher in mentally ill folks, correct? That's one concept that's expressed in there?
A. Right. Doctors should expect this to happen commonly.
Q. The second element of it is that there's no causal relationship between patients treated with Zyprexa and diabetes, correct?
A. That's what it says.
Q. And then the third concept that's in there is that Zyprexa was comparable -- pardon me -- that the incidence of treatment-emergent diabetes was comparable between Zyprexa and the other drugs, correct?
A. That's what it says.
Q. And, sir, that message there is completely contrary to what the company's outside experts told Lilly to do back in October of 2000; isn't that correct, sir?
A. No, I'm not sure what you mean.
MR. SUGGS: Can you pull up Exhibit 1453, please? And in particular -- Chris --
Q. (BY MR. SUGGS) This is a series of e-mails regarding the NADAB, or the North American Diabetes Advisory Board -- you were

present at that meeting?
A. I was.
Q. You testified about the e-mail and so forth. If I can direct your attention to the third physical page.
Can you blow up the third paragraph of Dr. Beasley's e-mail, please? I -- there you go.
According to Dr. Beasley, he wrote: 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.
You see that language, sir?
A. That's right.
Q. And in your answer to the question about diabetes you do deny that there's a causal relationship. You say that the incidence of diabetes is higher in mentally ill people, and you claim that rates are comparable, correct?
A. Yes, but -- what are you referring to as my answer?
Q. My question was: About the question and answer that we were looking at before, that was

given to the sales reps --
THE COURT: When he's saying you, he didn't mean you personally. He meant Lilly.
MR. SUGGS: I should restate the question.
A. I'm sorry.
Q. (BY MR. SUGGS) I'm sorry for the confusion.
A. Thank you.
Q. In the question and answer that Lilly provided to sales reps in answering questions about the concern of diabetes, there were those three elements in the answer provided by Lilly to the sales reps. One was that there was no causal relationship between Zyprexa and diabetes, that the rates were comparable, and that the diabetes rate was higher in folks who were mentally ill, correct?
A. Yes, that was all in the thing you showed me.
Q. By the way, while we're on the subject of these e-mails in that meeting. The meeting occurred on October 9, 2000, correct?
A. That sounds about right.
Q. Okay. Where were you on November 1,

sir, 2000?
A. I don't remember.
Q. If you had a meeting on November 1, 2000, would you rely more on an e-mail that you wrote at the time describing what happened in that meeting or your recollection today, seven years later?
A. Well, that depends. In case of November 1. I don't remember it, so -- I'll probably look at the e-mail.
Q. This meeting that you had with the North American Diabetes Advisory Board was an important meeting, was it not?
A. Oh, yes, it was very helpful.
Q. It was a discussion about a very important topic regarding one of Lilly's most important products, correct?
A. I agree.
Q. When you wrote your e-mails, you tried to state things as accurately as you could at the time, correct?
A. Sure.
Q. Again, you expected Dr. Beasley and the other folks who responded to those e-mails and Mr. Brodie and everyone else that they were

trying to be as truthful and accurate as they could in their recollections about the meeting as well, correct?
A. I would expect that.
Q. Okay. And you never thought those e-mails would see the light of day, did you, sir?
A. I assume that I would have wanted people to read the e-mails, if that's what you mean.
Q. When you wrote those e-mails back in November or October of 2000, did you ever think they'd be shown in a courtroom here in Anchorage, Alaska?
A. Oh, no.
Q. We talked a bit about your work with the sales force, and I think you said that you did not coach the sales force on how to answer questions. Am I remembering your testimony correctly?
A. Yes. What I said is that I would -- a number of times had a teleconference or something with the sales force giving the scientific background and giving my answers, but, no, I wasn't preparing their answers.
Q. And all of that was part and parcel of training the sales force on tone of the message,

correct?
A. No. My role in speaking to the sales force would be summarizing for them what information we had in answering questions that they may have about the medical information.
Q. I'm going to hand you, sir, what is marked as AK8112.
Sir, this document has a heading at the top entitled Diabetes slash Hyperglycemia, correct?
A. Yes.
Q. And it -- in the -- there's some numbered items in the left-hand column and right below No. 2 it refers to you working with a Q & A conference called -- strike that.
It refers to you having diabetes Q & A conference calls with select districts, correct?
A. It says, Continue Dr. Baker diabetes Q & A conference calls with select districts.
Q. And then on the following page at the bottom, under E, refers to you having continued audio conferences with select districts, correct?
A. I see that, yes.
Q. Okay.

MR. SUGGS: Your Honor, we'd move for admission of 8112, please.
MR. KANTRA: No objection, Your Honor.
THE COURT: AK8112 is admitted.
MR. SUGGS: Can you pull up 8112, please?
Q. (BY MR. SUGGS) And this document is reporting on market research, is it not?
A. I'm not sure what it is, but it does mention market research.
Q. Okay. And it reports on the findings of the market research and then what the company is going to do in response to that, correct?
A. I don't know.
Q. Well, let's take a look at market research fact No. 1 at the very top. It says, Market research fact No. 1: 80 percent of respondents recall a discussion about weight gain and Zyprexa, however, only 37 percent of respondents recall a discussion about Zyprexa and hyperglycemia.
Do you see that language, sir?
A. Yes.
Q. And the respondents that are being

referred to there were doctors who were contacted as part of market research to get their opinions, correct?
A. I don't know.
Q. Well, who else would -- Lilly wasn't going out and talking to patients, were they?
A. Usually not.
Q. Lilly did, in fact, conduct market research with physicians, correct?
A. That's my understanding.
Q. Because it's the physicians who make the prescription of the drug, correct?
A. Yes, because our contact and our information is for physicians.
Q. And that's who you're selling the drug to, really, is physicians, correct?
A. I guess you could think of it that way.
Q. Well, a drug's not going to get used unless a doctor prescribes it, right?
A. Right.
Q. So the doctor is the gatekeeper for the drug, he's the one that you need to influence in order to have him decide whether or not to use your product, correct?
A. I think doctors are very important in

deciding which products to use.
Q. You didn't have any marketing of Zyprexa? You didn't have direct marketing of Zyprexa to patients, did you?
A. No.
Q. I mean, unlike a lot of other drugs that we see on TV, thankfully, we never saw any Zyprexa ads on TV, did we?
A. No.
Q. So it was the doctors that you were focusing on, correct?
A. Mostly.
Q. Okay. And according to this, 80 percent of the respondents could recall a discussion about weight gain, but only 37 recalled a discussion about Zyprexa and hyperglycemia, correct?
A. That's what it says.
Q. And then, Chris, could you blow up the objectives below that, items No. 1 and 2, and then also that first A that's below that?
Item No. 2 says: The objective is to work with sales training on coaching reps on tone, targeting, frequency and other implementation issues around the hyperglycemia

message.
And the first idea that they list there is: Continue Dr. Baker diabetes Q & A conference calls with select districts.
Do you see that language, sir?
A. I see the language, and I think it refers to the direct knowledge in the first objective.
Q. So you personally would have conference calls with the sales reps about diabetes, correct?
A. On several occasions, I did.
Q. And you were giving them what Lilly's question was about diabetes, correct?
A. Again, I would speak with them about the medical information that we had and our medical conclusions.
Q. And the purpose behind that was so that the doctors and sales reps could hear from you about the issue of diabetes and then take that information and present it to physicians, correct?
A. No. The reason was for them to ask questions that they'd have about the information and me give the medical answer.

Q. If I can direct your attention to the following page -- Chris, could you blow up that language at the very top? It starts off with E and goes down through J.
Item E is: Reps coached on tone, targeting, use message with almost every customer and frequency at the September district meeting. Continue to coach at future meetings.
Do you see that language, sir?
A. Yes.
Q. So you were -- Lilly was coaching its sales reps on the tone that they were to use when giving the diabetes message?
A. I don't know.
Q. That's what the document says, right?
A. I agree.
Q. And the reason why you were having to coach the sales reps on the tone was because your market research showed the Lilly reps were given the lowest rating of all competitive neuroscience reps on believability when discussing side effects; isn't that right, sir?
A. Possibly. I don't know.
Q. Let's take -- Chris, can you drop down to the next bolded heading, Market Research Fact

No. 3, and blow it up along with the paragraph below that.
Market Research Fact No. 3: Lilly reps were given the lowest rating of all competitive neuroscience reps on believability when discussing side effects.
And then below that it says: Weight gain discussion may still be dragging down the believability of Lilly reps when discussing issues. Additionally, physicians wonder how can there be comparable rates of diabetes if Zyprexa causes more weight gain in some patients. Striking the right tone around the hyperglycemia message is essential, both what the reps say and how they say it.
Do you see that language, sir?
A. Yes.
Q. And part of your job was to teach them how to say it, right?
A. No.
Q. So you just taught them what to say, but not how to say it?
A. My -- it was my job to look at the medical information and often to review the materials that they had and often answer their

questions, but, no, not to teach them how to say it.
Q. Well, you had conference -- audio conferences with sales districts, did you not?
A. Occasionally, yes.
Q. And you would tell them what Lilly's message was about diabetes, correct?
A. No.
MR. KANTRA: Your Honor, we've been over this a couple of times now.
THE COURT: I'll overrule the objection -- if the objection is asked and answered, I'll overrule it.
Q. (BY MR. SUGGS) You gave audio conferences to the sales reps, correct?
A. Sometimes, yes.
Q. About diabetes?
A. Sometimes.
MR. SUGGS: Chris, can you blow up the language at the top of that page, please?
Q. (BY MR. SUGGS) There's a couple of questions I wanted to ask you about here. One of them was Item F, develop and place diabetes advertorial in major journals.
The journals that are referred to

there are medical journals, correct?
A. Probably, but I'm not sure.
Q. And what were advertorials?
A. That -- I've heard that used for information -- sort of teaching on a disease topic that's not about the medicine, per se. It's just about a general topic.
Q. Well, and the topic that was at issue here was the comparable rates message, was it not?
A. I don't know. It says diabetes.
Q. Well, if you can turn to the page before that, Chris. Under Objective down at the bottom.
Starts off: Beat the competition in getting out our comparable rates message, and all these ideas that are listed there are part of beating the competition and getting out our comparable rates message; isn't that right?
A. That's where they're listed.
Q. If you go to the following page again, please, Chris, blow out that same section you had before at the top --
There you go.
Q. (BY MR. SUGGS) Item I there is coordinate with Marni Lemons for PR/media

opportunities.
Do you see that language?
A. I do.
Q. Marni Lemons is here in the courtroom today, is she not?
A. Yes.
Q. Where is she? Was she involved in getting out your comparable rates message as well?
A. No, not that I know of.
Q. And then Item J is: Ensure medical letters are continually updated to reflect new comparable rates data.
Do you see that language, sir?
A. I do.
Q. And you've talked today about the medical letters that were prepared?
A. I did.
Q. And, in fact, the medical letters -- they've handed out a big of them stack there -- those medical letters did contain Lilly's comparable rates messages, correct?
A. No, medical letters are not -- medical letters have the medical data.
Q. They, in fact, said that they were

comparable rates, did they not?
A. Yes. The information -- the rates information in the medical letters found that the rates were comparable. That's what our studies showed.
Q. You claimed the comparable rates message was included in your medical letters, correct?
A. No -- again -- no.
MR. SUGGS: EL3942.
Q. Now, at the same time that Lilly was teaching its sales reps to go out and give the company message about comparable rates with the right tone, other people in Lilly were admitting that blood glucose increases in Zyprexa were probably causally related in the Zyprexa-induced weight gain probably increases the risk of diabetes; isn't that right, sir?
A. No, I don't know what you mean.
Q. Well, that -- can you go back to AK1941, please?
This is the questions and answers that we were talking about before that had the question about diabetes. I'll represent to you, sir, that the database that Lilly has given to us indicates that this document was generated on

June 28, 2002.
Do you have any basis to dispute that, sir?
A. No, Mr. Suggs.
Q. Okay. By the way, Mr. Allen was nice enough to find this -- this document for me.
Do you still have the medical letters in front of you that you were talking about before?
A. I don't think that I do.
THE COURT: They may be up -- they were published to the jury, and so they may be in that stack of material over there.
MR. SUGGS: 3932.
Can I have the ELMO turned on, please?
Q. (BY MR. SUGGS) Exhibit 3932 is a December 27, 2000 letter to a Dr. Ravi Colley, and I believe this is the one you've signed?
A. Yes.
Q. And the bottom line -- literally the bottom line of your letter to Dr. Colley was: In fact, the analyses above suggest that the incidence of new hyperglycemia during treatment with Zyprexa is comparable to that during

treatment with clozapine, risperidone and haloperidol, correct?
A. Right.
Q. That was the bottom line of the letter, correct?
A. Right. That's what the study showed.
Q. And this is just one of many medical letters that went out with that type of message, correct?
A. Those studies would be included in a number of letters.
Q. Do you know how many physicians those medical letters went out to?
A. No.
Q. Can you give us just a ballpark? Are we talking one, are we talking hundreds? Thousands?
A. It would be more towards hundreds or thousands.
Q. Hundreds or thousands. And how many would have come here to physicians in Alaska? Do you have any idea about that?
A. No, I wouldn't know.
MR. SUGGS: Can you pull up Exhibit 7802, please? We've heard some testimony about this several times. Can you blow up the line

about the glucose nonfasting high and then also the legend down at the bottom. This is the data from the HGFU study.
Q. (BY MR. SUGGS) And I'll represent to you, sir, that the database that was provided to us by Lilly say that this document was prepared on June 24, 2002.
Do you have any basis to dispute that?
A. No.
Q. Okay. And if that information provided to us by Lilly is accurate, then this document was generated four days after the question and answer that we looked at just before which said that there was no causal relationship between Zyprexa and diabetes.
Do you accept that?
A. Sure.
Q. Okay. And what we see here is we've had testimony about before, and I'm not going to belabor it, but whoever it was that prepared this document after reporting on the incidence of high nonfasting glucose had those letter A there and the legend says that if it's got an A by it, that means that the event was probably causally

related.
Do you see that language, sir?
A. Yes.
Q. Okay. Now, you testified also that the data from this submitted to the FDA, correct?
A. Right.
Q. And you pointed out to the jury where that -- I believe where that data was, correct?
A. Yes, we looked at that.
Q. You didn't send to the FDA this notation here that the event was probably causally related, though, did you, sir?
A. I don't think so.
Q. And you never told the sales reps that the hyperglycemia that you were seeing in your studies was probably causally related either?
A. Right.
Q. You were telling them to tell doctors that there is no relationship between Zyprexa and diabetes, correct?
A. No. But we were telling them --
Q. You don't remember that the question and answer we just looked at said that there was no causal relationship between Zyprexa and diabetes?
A. That's right.

Q. Okay.
MR. SUGGS: Can you pull up Exhibit 8666?
Q. (BY MR. SUGGS) We've had a lot of testimony about this document. Do you know who Simeon Israel Taylor was? He was the author of the e-mail.
A. He was -- he was a Lilly endocrinologist.
Q. A Lilly endocrinologist. Did he work on the diabetes side of the company or the Zyprexa side of the company?
A. He worked on -- primarily on the diabetes side.
Q. Okay. And it's endocrinologists who are specialists in diabetes, correct?
A. Right.
Q. And Dr. Simeon Israel Taylor was, in fact, a specialist in diabetes, was he not?
A. He was an endocrinologist. I don't know whether he was focused on diabetes or other endocrine conditions, but he might have been.
Q. Well, he was an endocrinologist, which is a field which specializes in diabetes and he was working for the diabetes side of the company

with Lilly, and you don't know whether he was an expert in the field of diabetes?
A. To clarify, endocrinology is more endocrine disorders than just diabetes, and if I said if Dr. Taylor worked for diabetes, I might have misspoken. I know he was an endocrinologists. He might have been in the diabetes group. We also work on other hormones that are part of endocrinology. I'm not sure which he was working on.
Q. Chris, can you blow up the date of this e-mail? The date on the e-mail is June 27, 2002, which would have been the day before the question and answer that we were looking at before where you were telling the sales reps to tell doctors there was no causal relationship.
MR. SUGGS: And Chris, can you pull up the last two lines of the first paragraph and the first two numbered items of Dr. Taylor's e-mail -- actually, I should have had you blow up the line just above that too. I apologize.
Can you make that bigger so we can see it easier?
Q. (BY MR. SUGGS) Dr. Taylor says: However, I feel that we need to deal with the

scientific facts, whatever they are. Ultimately, I expect that a fair-minded, scholarly evaluation of the available data is likely to support several conclusions: Zyprexa, like other members of the class, causes weight gain; and, two, like other causes of weight gain, Zyprexa-induced weight gain probably increases the risk of diabetes.
Do you see that language, sir?
A. Yes, I do.
Q. Were you aware that Dr. Taylor was telling people that back in 2002?
A. No, not that.
Q. And when did he leave the company? How shortly after he wrote this e-mail did he leave the company, sir?
A. I'm not sure.
Q. He did leave the company, though, didn't he?
A. Yes.
MR. SUGGS: By the way, this e-mail went to Gary Tollefson.
Can you find his name and blow it up, Chris?
Q. (BY MR. SUGGS) Who was Gary Tollefson?

A. Gary Tollefson is a psychiatrist and he was one of the senior people in Lilly neuroscience.
Q. One of the senior people in Lilly neuroscience, in fact, he had been responsible for Zyprexa back when it went through the NDA process, correct?
A. That sounds right, but I'm -- that sounds right. I'm not sure.
Q. How high in the company was he?
A. He became president of neuroscience, which meant I guess he was over the neuroscience groups for the global team.
Q. Was he president of neuroscience back at this time in 2002?
A. I'm not sure.
Q. And he's being told that Zyprexa causes weight gain and like other causes of weight gain, Zyprexa-induced weight gain probably increases the risk of diabetes, correct?
A. It appears that way.
Q. Okay. And doctors were never told about this, were they, sir?
A. Doctors were told about weight gain, and doctors were -- but they didn't receive this

memo, no.
Q. They were told about No. 1. You didn't tell them about No. 2, though, did you, sir?
A. We didn't tell them anything other than what we found in our data about Zyprexa and diabetes.
Q. Don't you think that doctors who were going to be using this drug in their patients would have liked to have known that one of the endocrinologists in your company was writing e-mails to a guy who was president of the neuroscience division saying that Zyprexa-induced weight gain probably increases the risk of diabetes? Isn't that the kind of information that prescribing doctors needed to know?
A. No.
MR. KANTRA: Objection, Your Honor; calls for speculation.
THE COURT: I'll overrule the objection.
A. No. My experience was that doctors wanted to know what did our data show, what were our conclusions from the data.
Q. (BY MR. SUGGS) Your answer was, no, doctors didn't need to know that?

A. My answer was -- you had asked me a different question. My answer was, no, what doctors wanted from us is what we found in our studies and what was concluded from the studies.
MR. SUGGS: Sandi, can you read back the actual question I asked him before?
(Question read by the reporter.)
Q. And your answer was, no, sir, they didn't need to know that?
A. No. Again, they would need to know what our data found, what our overall medical conclusions were.
Q. And at least according to Dr. Simeon Israel Taylor, a fair-minded scholarly evaluation of the available data was supporting the conclusion that Zyprexa-induced weight gain probably increases the risk of diabetes, correct?
A. No.
Q. That's what he says on the e-mail, isn't it, sir?
A. No.
Q. Sir -- he says --
THE COURT: Why do you disagree with it?
THE WITNESS: Because Mr. Suggs was

saying that the -- that the review supported that. What he's saying in advance of review is that it is likely to support that. In other words, I'm not sure looking at this that this represents his review as opposed to a prediction.
THE COURT: Okay.
Q. (BY MR. SUGGS) This e-mail where Dr. Taylor said that Zyprexa-induced weight gain probably increases the risk of diabetes was about three days after -- after that data that we saw in the previous document where the conclusion was that the hyperglycemia was probably causally related. Were you aware of that, sir?
A. No.
Q. Okay. By the way, this e-mail from Dr. Taylor was never included in any of the submissions to the FDA, was it, sir?
A. Not that I'm aware of.
Q. And in none of your medical marketing pieces, none of your brochures, did you ever tell doctors that Zyprexa-induced weight gain probably increases the risk of diabetes, correct?
A. I don't think so, no.
Q. And that was never contained in any of your medical letters either, was it, sir?

A. No, I don't think so.
Q. Now, the medical letters that -- that we've talked about. They were not reviewed by FDA, were they?
A. Correct.
Q. And those messages that you were sending out to doctors in the medical letters were regarded by knowledgeable physicians as being deceitful, weren't they?
A. No.
MR. SUGGS: Can you hand me 2227?
Q. Dr. Baker, I'm going to hand you what we've had marked as AK2227.
A. Thank you, Mr. Suggs.
Q. Which is a series of e-mails in June of 2002, the same month that we've been talking in the last three exhibits. The one at the top of the first page is an e-mail from Dennis West to you and a bunch of other individuals about the subject diabetes.
Do you recall receiving this e-mail on or about June 20th as indicated? June 20th, 2002?
A. No.
Q. Do you have any basis to dispute that

you did, in fact, receive it?
A. No. To the contrary, it looks like I was one of the recipients.
MR. SUGGS: Your Honor, I move to have AK2227 admitted for purposes of notice and motive.
MR. KANTRA: No objection.
THE COURT: AK2227 is admitted for the purposes of notice and motive.
Q. (BY MR. SUGGS) Can you pull up the first paragraph of Dennis West's e-mail?
First of all, who was Dennis West?
A. He was -- he was part of the global medical team.
Q. Was he a physician?
A. No.
Q. Can you blow up the first paragraph there, Chris?
In his e-mail to you and others -- by the way, the other folks that were included in this e-mail, were Patrizia Cavazzoni, Jack Jordan, Bruce Kinon, Eric Prouty, John Richards, Margaret Sowell, correct?
A. Yes.
Q. And Dennis West says: I thought you

might be interested in John Newcomer's response to the mailing piece by John Buse. Also included is my original message to Dr. Newcomer, which precipitated his response back to me.
Do you see that language, sir?
A. I do.
Q. You know who Dr. Newcomer is, do you?
A. I do.
Q. At one time he was a consultant for Lilly, was he not?
A. Yes.
Q. He has published probably about a dozen articles in peer-reviewed journals on the relationship between antipsychotics and diabetes and hyperglycemia?
A. That sounds right.
Q. His articles have not been favorable for Lilly, have they, sir?
A. He's felt that olanzapine does have more effects than some of the others.
Q. Do you recall joking around with Gary Tollefson about having Cousin Guido go and to visit Dr. Newcomer?
A. I certainly don't.
Q. Can you blow that paragraph back up

again, please?
The other person that was mentioned there was Dr. John Buse, B-u-s-e.
You know him, don't you?
A. I do.
Q. You testified about him this morning. He was one of the people that attended the advisory board meeting and he was a guy that went on to become a consultant for Lilly, correct?
A. Yes, except he was already a consultant at the time.
Q. And, in fact, he has published several articles with people at Lilly about Zyprexa, correct?
A. Yes.
Q. And, apparently, he also developed a mailing piece that was sent out to physicians, correct?
A. I'm not sure. It makes reference to it, but I'm not sure what it's referring to.
Q. Let's skip down to it -- bottom of the first page. Below this e-mail that we've just been talking about is an e-mail from John Newcomer to Dennis West, correct?
A. Yes, it looks that way.

Q. And apparently, according to the second page, and you don't need to blow that up, Chris, but apparently at this time Dr. Newcomer was still a consultant to Lilly, was he not?
A. I'm not sure.
Q. Well, last paragraph of his e-mail says: While I enjoy seeing an old friend and having the occasional debate, I'm a little puzzled about what the relationship with Lilly is at this point. Am I serving as a consultant in our time spent in meetings and e-mails? Please clarify.
Do you see that language, sir?
A. I do.
Q. So was he still a consultant at that time, sir?
A. I'm not sure.
MR. SUGGS: Chris, can you blow up the last line on the first page. We'll have to do this piecemeal.
Q. (BY MR. SUGGS) Dr. Newcomer writes to Dennis West and said: I was disappointed but the B-u-c-e -- apparently he didn't remember how to spell Dr. Buse's name -- information piece that came in the mass mailing last week. I saw this as deceptively arguing that the administrative

data sets --
MR. SUGGS: Can you go on to the next page?
Q. (BY MR. SUGGS) -- so he says -- he says: This mailing piece is deceptively arguing that the datasets indicate no differences across atypicals, without discussion of the exceptions and limitations you and I probably agree on. More importantly, there was no mention of the relationship between adiposity and diabetes.
Do you see that language?
A. I do.
Q. And adiposity means fat, correct?
A. Yes.
Q. And he goes on to say, Dr. Newcomer, that omission was a disservice to psychiatrists who really need to be educated on how to approach the problem.
And then dropping down to the last two lines in the paragraph, Dr. Newcomer says: It came across to me as a whitewash. If your strategic decision is to let the academics think what they will of Lilly while keeping the nonacademics prescribing, then Buse probably served you well.

Do you see that language, sir?
A. I do.
Q. And that wasn't the only complaint that you got about the medical letters from Lilly, correct?
MR. KANTRA: Objection; foundation.
THE COURT: I think this was preliminary to something.
MR. SUGGS: To the next thing I'm going to show him.
MR. KANTRA: He referred to medical letters as opposed to the Buse information.
THE COURT: I understand that objection. And the reference in this e-mail -- is it to a medical letter?
A. It doesn't look that way, no.
Q. (BY MR. SUGGS) Some other type of material that was sent out to physicians?
A. It suggests that -- I don't know what it is.
Q. Well, leaving that aside, then, you also got complaints from physicians about the content of your medical letters, did you not?
A. Possibly. I don't remember.
Q. Let's see if I can show you one.

MR. SUGGS: Can you hand me Exhibit 7213? Your Honor, this will be very short.
THE COURT: Why don't you finish up this topic and then we'll conclude for the day.
MR. SUGGS: Okay.
A. Thank you.
Q. (BY MR. SUGGS) Dr. Baker, I've handed you Exhibit 7213, which is a copy of a September 5, 2002 letter from a James N. Turnbull, M.D. senior vice president for medical services, Frontier Health, Inc. to Mark J. Bernauer, medical information administrator, Eli Lilly and Company.
Do you know who Mark Bernauer was?
A. I do.
Q. He was a person involved in sending out medical letters, correct?
A. Yes.
Q. In fact, he signed medical letters, the one that we looked at earlier that you also co-signed, correct?
A. That's right.
Q. And in this letter, Dr. Turnbull is commenting on his reaction to your medical letter, is he not?

A. It appears to, yeah.
MR. SUGGS: Your Honor, we move for the admission of Exhibit 7213.
MR. KANTRA: Objection on hearsay grounds.
MR. SUGGS: For notice.
THE COURT: I'll admit for the purposes of notice.
Q. (BY MR. SUGGS) In his letter, Dr. Turnbull -- can you blow up that paragraph there, that whole thing?
He says: This is to acknowledge the receipt of your letter of August 26, 2002, which included information about blood glucose changes with Zyprexa. It just confirms the theory that there are lies, damn lies and statistics. My personal experience with Zyprexa is that about 10 percent of our patients experience changes in cholesterol, triglycerides and blood glucose.
This is why I have singled out Zyprexa for attention from our physicians and insisted that every patient have baseline blood glucose, cholesterol, and triglycerides and that this be repeated three months after instituting

Zyprexa, six months, and at every six month intervals. We are not doing this for the other atypicals because our clinical experiences -- clinical experience shows that they are far less likely to produce changes in these three lab tests and, therefore, affect patients' lives than your products.

Do you see that language, sir?

A. Yes.

Q. Did you -- did Mr. Bernauer pass this on to you?

A. I don't recall.

Q. Now, the type of monitoring that he's telling you about in September of 2002 where every Zyprexa patient gets initial baseline blood monitoring and periodic blood monitoring thereafter, that wasn't included as a recommendation in your label until October of 2007, five years later; isn't that correct, sir?

A. Not all of it.

Q. Pardon?

A. Those -- it wasn't requiring all three until '07.

Q. Well, in fact, your labeling up to 2003 made no recommendation whatsoever about blood

monitoring, correct?

A. Agree.

Q. And in 2003, you only recommended it for patients who you said were at high risk for diabetes, correct?

A. Everybody should be assessed and then those at high risk should be monitored.

Q. Okay. So the type of monitoring that he's talking about here, you didn't have in your label until five years later in 2007, correct?

A. I agree.

Q. Okay. And, in fact, your label right now is the only label among the atypical antipsychotics which has that type of monitoring mandated by the FDA, correct?

A. Agree.

MR. SUGGS: Your Honor, we're right at 1:30. Do you want to break for the day?

THE COURT: Yes. Ladies and gentlemen of the jury -- well, before we do that, Mr. Suggs, can you just give me your sense of how much longer you have with this witness?

MR. SUGGS: I really don't know, Your Honor. It's going to be at least, I'm guessing, another 45 minutes or an hour or so.

THE COURT: Ladies and gentlemen of the jury, from what I heard earlier from the lawyers, they still think we're possibly on schedule to possibly conclude the evidence Thursday, which would mean we'd have argument and instruction on Friday.

I'm not sure.

It may be that we won't have argument until -- Monday is a court holiday, so that would be Tuesday. So that -- just to give you the best idea of what I have, I'll keep you posted so that you'll know when we're actually going to go to closings and do deliberations so that you have a fair warning of -- once we start deliberating, you'll be in deliberations for the full day.

I'll try to keep you as best posted as I can. I'm going to dismiss everyone for today.

Again, 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, and please do not view or listen to any media or Internet concerning the subject matter of this

lawsuit.

I'll see everybody tomorrow at 8:30 and we'll resume with Dr. Baker.

Thank you.

(Jury out.)

THE COURT: Please be seated.

We're outside the presence of the jury. Could someone see that Mr. Borneman gets back the exhibits that are both in front of Dr. Baker as well as the ones that are on the jury stand. I seem to have come up with what may be the original, but I'm not sure, of 3860. Maybe this is an extra copy for me and not the original, but it's got a sticker on it.

Mr. Suggs, I had given Mr. Lehner the packet of what I hope are going to be noncontroversial instructions --

MR. SUGGS: I received that, Your Honor, and I passed it on to the appropriate folks.

THE COURT: Okay. I just want to be sure. I'm going to be working on the other instructions. It may be that we'll go tomorrow evening, but I'm not positive. I'll try to let you know.

Anything we need to take up before recess?
MR. ALLEN: Yes. Are they calling Mr. Noesges tomorrow? Are they going to -- in order to prepare, we have 24 hours. Are they going to call him?
MR. LEHNER: I said this morning that he was on our witness list and we are going to call him depending on when you finish him and do videotapes.
THE COURT: My understanding is that before you call him you're going to do videotapes?
MR. LEHNER: That would be our intention.
THE COURT: And you have a couple of hours of videotapes?
MR. LEHNER: I think we'd probably show an hour and a half to two hours of videotape before we would call him.
MR. ALLEN: He's after the videotapes.
MR. LEHNER: The only -- I'll let you know this evening. His travel schedule -- we're not going to get him first in the morning.

MR. ALLEN: It would be helpful to us in our planning.
MR. LEHNER: He will be our live witness.
THE COURT: You all know what your case is like and what you'll take with people. It'll just my observation that if he comes out here on Friday, he'll probably be here on Tuesday.
MR. LEHNER: We would hope to get him on well before Friday.
MR. ALLEN: I think we're going to get through on Thursday. We're trying to figure out if he's calling Mr. Noesges.
MR. SUGGS: He's ever the optimist, Judge.
MR. ALLEN: We're going to be through on Thursday. We're going to be.
THE COURT: That would be great. I just haven't seen short cross-examinations on anybody. And that seems to be a critical issue.
MR. ALLEN: We'll be through on Thursday.
THE COURT: A critical issue.
MR. LEHNER: Can I raise another

issue, Your Honor?
THE COURT: You may.
MR. LEHNER: This is for re-reconsideration of your decision concerning Ms. Jackson. I think they opened the door to that issue with this e-mail from Mr. Clewell, and you heard the testimony where they solicited testimony pursuant to this e-mail that there had been contact with payors who expressed their views about our interpretation of the data and specifically referenced Medicaid agencies, specifically asked for the Medicaid agencies like the ones here in Alaska.
And I think it is particularly pertinent, having raised that issue that the plaintiffs made, that she be allowed to express the views that she expressed in her deposition. If you look at that e-mail, I think it's 3223 and the testimony thereto, I think you would agree that her views now are particularly pertinent in light of the testimony that they solicited.
THE COURT: Can somebody give me a copy of the e-mail and I'll view it tonight and look at that.
MR. ALLEN: Sure. Sure.

Your Honor, was -- it seems like to me, I'm going to state this for the record. Every time they get an adverse ruling, they get four bites of the apple, and they don't quit. If you made a ruling, we ought to stick with it. But if you want to open these doors, then let's go down that road.
They had a motion in limine, Your Honor, prior to this trial not to mention other drugs. You sustained it and they came up here today with 15 package inserts on other drugs. I just want to play by the rules. I object to this, but if we -- that's all -- I want it on the record.
THE COURT: Again, my understanding that this is not a motion based on same argument as much as an opening-the-door argument and I'll look at the exhibit, I guess I'll state, so that everybody can think about things.
MR. ALLEN: I'm recalling a red star.
THE COURT: If the door was opened, it sure was subtly at this point.
MR. ALLEN: I'm just recalling a red star and open the door, and where we want to

go from here, but I'm on record for our clients.
THE COURT: I hope everyone is aware that I am happy to let people make records, and -- but I'll look at the exhibit and I'll let you know tomorrow whether or not I think that the door was open to reconsider my ruling about Commissioner Gilbertson.
MR. LEHNER: And Commissioner Jackson.
THE COURT: And Commissioner Jackson.
MR. ALLEN: And Reggie Jackson and Jesse Jackson and the other Jackson Five.
THE COURT: Anything else?
MR. ALLEN: No, there's not.
THE COURT: Then we'll be off record, and I'll see everybody tomorrow morning.
To the extent that the -- that I hope are the noncontroversial jury instructions are, in fact, controversial, the sooner you can identify what those are to me, the better I -- because I know there'll be some issues about the other instructions, and I want to get these ones cleared up as soon as we can.
We'll be off record.

THE CLERK: Off record.
(Trial adjourned at 1:37 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 25th day of March, 2008.

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