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 15

TRANSCRIPT OF PROCEEDINGS

March 21, 2008 - Pages 1 through 199

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. We're outside the presence of the jury. Counsel are present. I understand there are some issues to take up.

MR. LEHNER: Good morning, Your Honor. We just wanted to -- I think we filed our motion with respect to Patrizia Cavazzoni, and we wish to be heard on that.

THE COURT: Okay. Does the State need an opportunity to respond in writing or --

MR. SUGGS: I don't think we need to in writing, Your Honor.

MR. JAMIESON: Good morning, Your Honor. Please feel free to cut me off. We're going to take a little trip down memory lane as to what happened, I guess.

THE COURT: I'm going to cut you off, Mr. Jamieson. I read your brief and I would really like to hear from is the State.

MR. JAMIESON: Very good, Your Honor. Lilly would like to participate to the same degree the State has been able to participate and benefit from the MDL proceedings.

MR. SUGGS: Your Honor, Dr. Cavazzoni's deposition --

THE COURT: Well, let me just ask you, Mr. Suggs: Hasn't the whole sort of history of how this litigation been done, been predicated on the idea particularly coming from the State is we've got all these MDL depositions; we're going to use all these MDL depositions; we'll bifurcate the trial and we don't need to take a lot of depositions. All we need is a few State depositions; limited discovery, ten, let's move this along. We've got the whole MDL going.

Isn't sort of the whole idea being that everybody was going to use all the MDL -- hasn't that been kind of what -- the depositions -- hasn't that been the whole flavor of the arguments for the State to move this along faster, to get this done quicker, to get this case bifurcated.

Don't all the transcripts and the motions that the State made in regard to that seem to suggest that everybody was going to use the MDL? And there were all these depositions in the MDL that could be taken and we would

predicate the management of this case based on that?

MR. SUGGS: Your Honor, I don't ever remembering that we were going to waive the rules. The rules are that a deposition can be used against any party who was given notice of it and who was present and attended there. When Mr. Fibich issued the notice of the deposition, he did that as part of the MDL, not the State of Alaska.

THE COURT: That would certainly be the rules, and if we didn't have this history, I would say those were the rules and there wasn't notice. But the history seems to be that regardless of whether or not Ms. Cavazzoni or someone was noticed on this case -- and I recognize also that there have been depositions in this case that were taken by lots of different people. And -- but to the extent that there would have been an argument that Dr. Cavazzoni wasn't noticed particularly for this case, hasn't it been waived by all the arguments that the State has made? I guess that's the guts of the issue.

MR. SUGGS: I don't think so. None

of the attorneys who were representing the State of Alaska were there in that capacity at that deposition to represent Alaska's interest. Moreover, they told us that they were going to bring Dr. Cavazzoni here to testify live. They were going to bring her here in our case in chief and we were perfectly happy with it. And now all of a sudden --

THE COURT: And you told them that you weren't going to call Dr. Hopson in your case in chief, and you did. So there's been some changes, and my question has been all along, just as it is with Dr. Hopson, what's really fair given the history and those kinds of things? And given that I mean, you got ten extra depositions and if Dr. Cavazzoni had been really important for you to take, you could have retook her as part of your ten, correct?

MR. SUGGS: We could have --

THE COURT: And you didn't do that.

MR. SUGGS: We chose not to.

THE COURT: What I'm saying is, isn't everybody on notice that all the depositions in the MDL were going to be used here, particularly if people were listed as

witnesses along the way?

MR. SUGGS: As I read the transcripts and the materials submitted with their brief, Your Honor, I don't see anything about we were somehow waiving the rules here. I think the rule is very clear. I just don't see that there's any waiver of it. I mean, I've looked at the transcripts that they've attached there. I have not seen anything that says we're waiving the rules here.

THE COURT: Wasn't there a whole bunch of discussion about the need to redepose witnesses and whether you should have to ask permission to redepose witnesses or whether you should be able to designate your ten. I mean, wasn't the whole suggestion of this --

MR. SUGGS: There was lots of discussion about that, Your Honor, and lots of other things but I don't see anything in there that we were waiving Rule 32 in this case.

MR. JAMIESON: Your Honor, on that point my I be heard? It wasn't a waiver -- it was a waiver, we think. But in addition, it was the order of this Court. If you look at the transcript from the January 8th status

conference, at page 67, which we've attached to this brief as Exhibit C, I believe.

The Court: You'll participate in the discovery that's part of the MDL.

Mr. Sanders: Is that an order or a question?

And the Court: Both, I think. And then you went on.

And the concern of the State at that time was not that they wouldn't be able to use the MDL, but that they needed to redo some MDL depositions that they didn't like the way that those MDL depositions were taken for -- for the Alaska-specific issues or any issue at all.

They were free to go redepose ten. They got the ten freebie rule, which is what Your Honor ordered. And they could -- and Mr. Sanders came back to this Court a couple months later and said, you know, Your Honor, we're -- if somebody from Texas -- he actually said if somebody from Texas does this deposition and I don't like it and Your Honor said, that's what you got the ten freebies for.

And that was the order of this Court. It wasn't something that happened by

accident; it happened on purpose and tremendous benefits have flowed to the Plaintiffs as a result of the discovery in the MDL.

MR. SUGGS: Your Honor, you said -- he points to language that you said on January 8th, 2007. You'll -- you will -- participate in the discovery that's part of the MDL. That statement was six months after the deposition of Dr. Cavazzoni was taken. We have an unqualified right to use depositions of their folks where they were represented. They do not -- under Rule 32, they don't have the right to use depositions unless the party was represented and I don't see any order --

THE COURT: What's Dr. Cavazzoni's status?

MR. JAMIESON: Her status?

THE COURT: Yeah.

MR. JAMIESON: She's not going to be here at trial.

THE COURT: Where is she?

MR. JAMIESON: She's an employee of Eli Lilly.

THE COURT: Where is she?

MR. LEHNER: She's in Indianapolis,

Your Honor. She is a single mother. She's had a lot of trouble sort of scheduling. She has a very difficult family situation. We thought we had her for a day. It didn't work out.

THE COURT: What I'm asking really, to front is there a way to do a telephonic deposition of her to fill in this alleged gap?

MR. LEHNER: I'm not sure what the gap is, Your Honor, because -- I mean -- it seems to me either we are able to use the material of the MDL. I mean if you want to take time from the Court to do a telephonic deposition --

THE COURT: I mean if the question is notice. If that's a problem I can cure that.

MR. LEHNER: I don't think it's really notice, Your Honor. She was deposed twice on all of the generic issues that have been at issue in this court. She has no Alaska-specific information.

THE COURT: If she had Alaska-specific information and it was important for the State to depose, I assume that the State would have listed her as one of your ten? I mean, you didn't use your full ten, did you?

MR. SUGGS: No, we didn't, Your

Honor.

THE COURT: So, I mean --

MR. SUGGS: I'm sorry, what's your question, sir?

THE COURT: So my question is, I mean, to the extent that the question is we didn't get to use her for Alaska purposes because she wasn't noticed to Alaska purposes. You could have used her for Alaska purposes. You chose not to.

MR. SUGGS: Your Honor, I wasn't there. Mr. Allen wasn't there representing the State of Alaska. This was June of 2006.

THE COURT: Right. But we ended up -- what you just pointed out to me is we ended up with the ten freebie rule if I that's what I can shorthand call it after she was deposed; correct?

MR. SUGGS: Yes.

THE COURT: So you could have gone back if it was critical to redepose her and --

MR. SUGGS: Your Honor, we didn't think we needed to redepose her because we didn't think she was going to be coming here because of Rule 32. I mean, Rule 32 says they can't use

it unless they retook it.

THE COURT: Wasn't she on the witness list from Day One? Wasn't she talked about in the opening statement?

MR. SUGGS: Yeah, and they were entitled to bring her live. They could have brought her live. This is a person who's--

THE COURT: I mean, haven't we had a lot of talk about documents authored by Dr. Cavazzoni? I'm sorry, Mr. Suggs, but if you tell me you didn't think she was going to be here or wasn't going to be a witness in this case I have some problems with that.

MR. SUGGS: Your Honor, I have no problem with her coming here at all. I would love to have her on that witness stand, Your Honor. I would love to have her live.

THE COURT: I understand that and I understand what's really going on here, but --

MR. SUGGS: Your Honor, this lady is head, I think, of global safety.

MR. FIBICH: Can we call a time out? We need to talk. Let's call a time out.

MR. ALLEN: Can we talk? Can we talk?

THE COURT: Yeah. We'll be off record.
THE CLERK: Off record.
(Discussion off the record.)
THE COURT: Mr. Suggs.
MR. SUGGS: Your Honor, we have our objection, but we will withdraw it and let them play Ms. Cavazzoni's deposition.
THE COURT: Okay. Then what we need to do is designate those portions and deal with objections and all of those kinds of things and deal with counterdesignations of which I'm sure there's going to be a few.
MS. GUSSACK: I believe they've been submitted to the Plaintiffs.
MR. ALLEN: Unfortunately, Your Honor, there's not much.
MS. GUSSACK: It's relatively brief on both -- I think both sides, Your Honor. But we'll make sure that you have whatever is in dispute.
THE COURT: Okay.
What's the plan for today?
MR. LEHNER: Your Honor, we're going to play depositions of Dr. Beasley and then

perhaps a brief deposition of 20 minutes, maybe 30 minutes of Dr. Toleffson and then bring Dr. Baker on as our live witness.
THE COURT: Okay. And again, I'll remind everybody, jury instructions.
MR. ALLEN: We do -- trust me, even I had to learn that yesterday.
MS. GUSSACK: Your Honor, on that subject, do you have in your schedule of you as to when next week you would want to have a conference on those?
THE COURT: Well, part of that will depend on -- what I need to know is -- I'm tempted to have fun with you, Ms. Gussack and I guess I'll say this --
MS. GUSSACK: It's Friday, Judge, you're allowed.
THE COURT: -- so a noncoy answer about when Lilly thinks they'll be done with their case and then a noncoy answer --
MR. ALLEN: Judge, I'm not coy. We can say a lot of things about me; coy is not one.
THE COURT: That's what Ms. Gussack said too.
MR. ALLEN: Yeah, but she wasn't

telling the truth.
THE COURT: I need to get a sense from the State as to what it's going to do on rebuttal. What I'll try to do is plan this and even if I have to send the jury home for a day while we take this up, but I want to do it at a point that it makes sense, and that will depend on when Lilly is likely to rest and how much rebuttal the State's going to have, because that will let me figure out when this case might actually be going to the jury and when you will be doing -- I'm assuming at this point, and please correct me if I'm wrong, that we'll have a whole day jointly for closing arguments and then if we have time that day, we'll instruct the jury and they can start deliberating.
If not, we'll bring them back in the morning and they can be instructed and start deliberating. I'll also consider, and you can all tell me what your views on this is. Sometimes people have -- given jury instructions before the closings and I'm willing to do that if -- I'm willing to think about that. I haven't done that in a case, but I understand why it might be a useful thing for everybody.

MR. ALLEN: We prefer it.
THE COURT: I'll let everybody think about it for a day or so. If that's the case, we'll figure that -- what I don't want to do is split somebody's -- split the closing arguments in any way at all. But if -- if we know we're going to do jury instructions and then closings and then they deliberate, start deliberating, I'll let them know that on that day they're going to start deliberating, they can expect to be here the whole day. So, as soon as you know and let me know when you are likely to be resting or what your plan is, you can let me know how much you've got in rebuttal.
MR. ALLEN: I have 12 minutes.
MS. GUSSACK: Your Honor, we -- in large measure informed by the length of cross-examination of our witnesses, we think realistically it looks like it could be Wednesday but, you know, that's really just an estimate right now. We'll certainly let you know as soon as we know more.
THE COURT: Well, again --
MR. FIBICH: Your Honor, I do not expect at this time that the State is going to

call any live witnesses in rebuttal. Obviously, I can be just as coy and say, well, that may change. But it's unlikely. Mr. Allen has 12 minutes that I think you are familiar with that is going to be offered in rebuttal. But we do not anticipate a lot of rebuttal testimony. There may be some short offers, but from our standpoint, we're not going to have --

THE COURT: So what I'm sort of hearing is it's possible that the case -- the evidentiary portion of the case may conclude on Wednesday subject to how long the cross-examination is. If you take a day and a half to cross-examine somebody --

MR. ALLEN: Did somebody do that?

THE COURT: -- I would anticipate that any live witnesses the State goes on -- that Lilly puts on might take that long, but the State will have to decide how vigorous their cross-examinations are going to be.

MR. FIBICH: Well, Your Honor, we appreciate the Court's questioning on this issue. And we don't want to get into what we've been told in the hall, but we need some definiteness about when they think they're going to rest.

THE COURT: Well, again, I understand how what they say is somewhat dependent on what you do on your cross. And I don't know how many live witnesses we have, and I've got to deal hopefully sooner rather than later with any of the Cavazzoni objections and cross-designations and those things before they can cut their tape.

MR. ALLEN: I think --

MS. GUSSACK: I think we have --

A SPEAKER: They've given us their designations.

MR. ALLEN: Objections? It's unlikely I would object.

MR. LEHNER: Counterdesignations.

MS. GUSSACK: I'm sorry, counterdesignations.

MR. ALLEN: I've instructed Mr. Suggs because I told him I wanted him to be brief like me with Dr. Baker today. He promised me he would.

MR. SUGGS: Your Honor, when he told me that, I laughed.

MS. GUSSACK: Your Honor, and I take it also about the issue about 12 minutes on

rebuttal is something that is still being held in reserve by the Court.

THE COURT: I assume that that was a comment sort of directed on the information in the Eski deposition that I haven't let in.

MR. ALLEN: That was exactly what it was.

MS. GUSSACK: So we could be finished much earlier then -- by 12 minutes?

MR. ALLEN: Twelve minutes early.

MS. GUSSACK: Thank you, sir.

THE COURT: I'll take a look at my calendar with this sort of generalized schedule, recognizing we're going to have to be flexible and try to figure out where I may have some time. What I'll do if I can, but I kind of doubt it, is if I can move something in an afternoon, we can take this up in the afternoon. I have a feeling I'm going to have to move a lot of things and that's a little more problematic. So we may just take a morning and not have the jury come in that day.

Anything else before we bring in the jury?

Then we'll give the jury a heads up

and we'll get started. We'll be off record.

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

Off record.

(Break.)

(Jury in.)

THE COURT: Please be seated.

We're back on the record and all members of the jury are present. Good morning, ladies and gentlemen.

Eli Lilly is ready to call its next witness?

MR. LEHNER: Yes, Your Honor. Thank you.

Good morning.

Eli Lilly and Company calls as its witness Dr. Charles Beasley, the distinguished Lilly scholar and chief scientific officer in the Global Patient Safety Group.

VIDEOTAPED TESTIMONY OF CHARLES M. BEASLEY, JR.

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

A. Yes. My name is Charles M. Beasley.

THE COURT: Are we going to put this screen up?

MR. LEHNER: Yes.
Q. Good morning, Dr. Beasley.
Would you state your full name for the record, please?
A. Yes, my name is Charles M. Beasley, Jr.
Q. And how old are you, sir?
A. I am 56.
Q. And are you married?
A. Yes, I am.
Q. And do you have any children?
A. No, I do not.
Q. Okay. And are you currently employed by Eli Lilly?
A. Yes, I am.
Q. And what's your current job title?
A. My current job title is distinguished Lilly scholar and chief scientific officer for Global Product Safety.
Q. And how long have you held that position?
A. I've held that position since the spring of 2003.
Q. Okay. And do you currently have any responsibilities regarding the drug Zyprexa?
A. No, sir, not directly. I -- my current

function is a consultant within Global Product Safety across a number of compounds as people would come and consult to me.
Q. Thank you. I'd like to go over some of your background. I believe you were born in 1950 in Tokyo, Japan; is that correct?
A. That's correct.
Q. And I assume your father was stationed there in the military?
A. That's correct.
Q. Okay. And then you received your undergraduate degree in psychology at Yale University in 1977?
A. That's correct.
Q. And you received your medical degree in 1983 from the University of Kentucky College of Medicine; is that correct?
A. That's correct.
Q. And then I believe you did an internship at Yale University in the Department of Psychiatry for a year?
A. That's correct.
Q. So that would take us up to 1984?
A. That's correct.
Q. Okay. And then you did a three-year

residency in psychiatry at the University of Cincinnati in Ohio between 1984 and 1987; is that correct?
A. That would be correct. I completed the residency in June of 1987.
Q. Okay. And I believe you became board-certified in psychiatry in 1988; is that correct?
A. That would have been correct. It's a two-step process, and I believe that I completed the second part in, I believe it was October of 1988.
Q. Okay. And you joined Eli Lilly as an associate research physician in July of 1987; is that correct?
A. That's correct.
Q. Okay. And can you briefly describe, in general terms, the positions you've held at Eli Lilly since joining the company in 1987?
A. Well, there's -- there's been about a 19-year evolution --
Q. I understand that?
A. -- evolution here. I joined with the title of associate research physician. And my first work in the company was with fluoxetine,

trade name of Prozac --
Q. Okay.
A. -- the antidepressant. And I managed and developed, supervised a number of clinical trials for Prozac. I don't remember the specific number. I believe it was someplace in the order of eight or ten.
Q. And then, continue, if you would, describing the positions you've held.
A. Okay. While I was working on fluoxetine, I also had responsibilities as the trial designer and -- for the molecule that was then referred to as atomoxetine. It was being developed as an antidepressant. This molecule was not taken completely through development at the time as an antidepressant. And this work occurred simultaneously with my work on fluoxetine, and took me -- takes me up to approximately 1991.
Q. Okay.
A. I did receive a promotion during that time from associate research physician to research physician. And 1991 was the point where I was assigned responsibilities for the continued development of olanzapine for trade name Zyprexa.

And I worked in this program on a global basis, both in the United States and in coordination with other physicians outside of the United States, up through 1997 as part of the olanzapine team. And there was an -- there was an evolution from the drug being developed as part of the general neuroscience team to a team focused specifically on the development of that molecule. So I took part in both of those.

Q. And during that period, were you developing and monitoring clinical trials that were in support of the new drug application?

A. Yes, I was.

Q. Okay.

A. In 1997, there occurred a significant organizational change. I also had been promoted in that period twice to senior research physician and then to Lilly adviser.

In -- in 1997 there was a -- a reorganization. The team leader for the Zyprexa team, Dr. Gary Toleffson, was promoted to president of the entire central nervous system unit. Dr. Breier was placed in charge of the team, and I transitioned off the team to report directly to Dr. Toleffson in a consultative role.

I was still rather much involved with olanzapine, but in this different organizational system.

It was in about, I think, 1998 or '99 that I was assigned to be team leader for the development of a -- we call it a transition team for another molecule. Again, a central nervous system molecule intended for the treatment of anxiety disorders.

Q. Let me interrupt for a second.

What year was it that happened?

A. I believe that was either 1998 or 1999. I don't recall the specific date. And this was a molecule that did not come to NDA, and, in fact, I was transitioned off that team prior to -- the completion of that -- of that project.

In 2001, I transitioned completely out of the neuroscience area. I was requested to take the position of medical director for our compound tadalafil, also known as Cialis, in the cardiovascular area.

In 2003, I transitioned back to a -- a consultative position, pretty much across all the therapeutic areas within Lilly, although I reported directly to Dr. Gary Toleffson. So, my home organizational base was within central

nervous system, but worked across a broad number of compounds.

And then in 2004, was -- during another company reorganization, was asked to take the -- a position in global product safety. Dr. Toleffson had retired, and I was both, once again, promoted to my current position and given my current functional organizational responsibilities.

Q. Okay. And it indicates there that the molecule olanzapine, which was later marketed under the trade name Zyprexa, was first synthesized in April of 1982.

Does that square with your understanding?

A. That would be my understanding.

Q. Okay. And then the investigational new drug application was filed in 1986; is that correct?

A. To the best of my knowledge, yes, that would be correct.

Q. And that's sometimes referred to as an IND, correct?

A. That's correct. That's how it is abbreviated here.

Q. And an IND is something that a drug company has to file with the FDA in order to begin testing on human subjects; is that correct?

A. Yes. And, of course, that would be within the United States --

Q. Correct.

A. -- since it's filed with the FDA.

Q. And the document also indicates that the first human dose was in September of 1986; is that correct?

A. Yes, it does.

Q. Okay. And the first open-label clinical dose was in December of 1988, correct?

A. December of 1988, yes.

Q. Okay. And that phrase first open-label clinical dose, refers to a type of study where the drug is given to -- to subjects in a clinical setting, correct?

A. Yes. This would also be what we would call an uncontrolled clinical trial. It is a very preliminary observation of the medication in -- in patients with the disease that is -- that the drug hopefully treats or is intended to treat.

Q. Okay. And in order to receive approval

from the FDA to market a drug, drug companies have to perform various clinical trials, typically, involving placebo-controlled and double-blind studies; is that correct?
A. That's correct.
Q. And in this case, the first double-blind placebo-controlled dose was given in November of 1991; is that correct?
A. That's correct.
Q. And I believe you said you started working with Zyprexa in 1991. Were you involved in that very first clinical testing?
A. Yes, I was. Although I did not design those -- those clinical trials, I took over responsibility for the supervision of the molecule as those trials were beginning.
Q. Okay. And then the document indicates that the completion of core studies occurred in February of 1995. And can you describe for us what is meant by the term "core studies"?
A. Yes. These would have been the studies that would have been included in both the new drug application, the NDA in the United States, as well as the regulatory submissions in other countries.

Q. Okay. And the document also indicates that worldwide regulatory submission was filed in September of 1995; is that correct?
A. That's correct.
Q. And was there more than one regulatory submission filed at that time?
A. The two submissions that were filed almost simultaneously were the U.S. submission and the European submission.
Q. Okay. And in Europe it was submitted to what agency?
A. It was submitted to the European Medicine Agency.
Q. Okay. Is that sometimes referred to as EMEA?
A. EMEA.
Q. Okay. And am I correct that the largest of the core studies that was done was a study that was referred to as HGAJ?
A. That was the largest.
Q. And it had approximately how many subjects in it?
A. It had 1,996 subjects.
Q. Okay. And was it the largest, by far, of the various clinical studies that were done in

connection with the drug?
A. It was.
Q. Okay. Fair to say that the vast majority of the data that you had from clinical trials regarding Zyprexa was the data from HGAJ?
A. Given the four other trials, I think it remained the -- probably the majority. Again, I don't have a precise number, but I think it was probably just slightly over the majority.
Q. Okay.
A. In fact, if I can just -- in thinking, I think there were a total of -- of 2500 patients treated in clinical trials that were included in the NDA, and I believe there were 1300 in -- treated with olanzapine, Zyprexa in that trial. So I think that is slightly more than half.
Q. Okay. And in the HGAJ study, am I correct that patients were treated in that study for up to a year with Zyprexa?
A. Well, if I may, it actually had a rather complex design from a -- from a time perspective. There was an acute treatment period of six weeks. So all patients were treated up for -- for six weeks. If patients were not doing well, either because of tolerance or efficacy, and they

remained in the trial for three weeks, they could discontinue and be placed on open-label olanzapine. But that would have continued to be within this trial.
There was then a -- what we call an extension that, actually, ran past a year. It ran until the time that the drug was actually approved. So, there was no definite terminal period. The option available to patients was for them to actually be continued for longer than a year.
Q. Okay. And the other studies that were done in connection with the NDA, were they as long-term as HGAJ?
A. Yes. They were, in fact, longer term. We had placed for patients the -- within all of the studies -- the ability to take medication until the time that we either discontinued the -- the development project or the medication was approved in their specific countries. Obviously, for the patients that were doing well on the medication, that was viewed as an appropriate opportunity for them to continue to receive treatment.
Q. Am I correct that in that gap of time,

between February and September of 1995, the data was essentially cut off, collection data was cut off, and that there was then a period of time where the data was written up for submission?
A. That's -- that's partially correct. As I said, we allowed the studies to run until the drug was approved. So, there was a time when we declared the -- the collection of data for submission to the NDA to be finalized. And that was a period where those data were unblinded, a term that we refer to as locked. Those data were finalized, they were developed and written up.
Although, again, patients were continued and data were continued to be collected in these -- in these studies that were ongoing.
Q. Okay. And at the time that the data was locked up or cut off for write-up purposes, if I can use that phrase, page 6 of this exhibit indicates that there were about 3,000 people who had received more than one dose; is that correct?
A. That's correct.
Q. But only about 2,000 had received more than one month?
A. That's correct.
Q. And only about 875 had received more

than six months?
A. That's correct.
Q. And only slightly more than 300 had actually used the drug for more than a year; is that correct?
A. That's correct.
Q. Didn't your clinical trials show that there was increased cholesterol and also type 2 diabetes?
A. I do not recall the -- the specifics of the results of all the analyses of cholesterol. My recollection is that taking all of the data in total, we did not see an association between the drug and cholesterol. And with respect to diabetes, the same.
Clearly, cases were observed in what we would call temporal association when individuals in clinical trials did develop diabetes, a small number, and we did not, in looking at all the data, see the compound as -- given the date that we had, as there being an increased or excessive development within our clinical trial database.
Q. And the labeling that was in effect at that time when the product came out in the market

did not warn physicians that your clinical studies had found statistically significant increased incidence of high glucose in Zyprexa users, correct?
A. That is correct. But my recollection of the data as you have -- have asked your question, is that we would not have found that. We would have -- and what we did was we analyzed both the placebo-controlled data and the haloperidol-controlled data. There were three studies that include haloperidol on what we call an integrated basis. And my recollection is that those integrated analyses did not show or support the finding that we'd been discussing in J.
Q. Do you recall that the FDA approved Zyprexa for marketing in September of 1996?
A. I don't recall whether it was late September or early October.
Q. Okay. And am I correct that one of the last things that happens before a drug is marketed is the drafting of labeling for prescribing physicians?
A. Well, there is, actually a draft that is prepared as part of the new drug application.
Q. And it's submitted to the FDA as part of

the new drug application. The FDA then comes back and says whether they approve that language or not, correct?
A. That's correct.
Q. And oftentimes -- and there is interchange between the company and the FDA as to what's going to be in the content of the language, correct?
A. That's correct.
Q. And when the FDA saw the data, the FDA -- well, let me back up for a second.
When we talk about the labeling, that's the package insert material, correct?
A. That's correct.
Q. It's also contained in the Physicians' Desk Reference, which is a big, thick book which contains the labeling for all prescription products, correct?
A. I think for the majority. It's not all. And those are copies of -- obviously, intended to be kept current -- the prescribing information or the package insert.
Q. Okay. And that information, the prescribing information that is contained in the labeling is very critical for doctors to have;

isn't that correct?
A. It is intended to be a summary of the data that would allow the effective and safe use of the medication. That is correct.
Q. And it's absolutely necessary that the information in there is complete and accurate, correct?
A. Again, it's important that it -- that it allow for the safe and effective use of the medication. From a concept of complete, again, all 1.5 million pages can't be contained. So, the intent is that it is a summary of the most pertinent information that will allow the drug to be prescribed appropriately.
Q. And do you know who Dr. Ken Hornbuckle was?
A. Yes.
Q. And who is he?
A. He is a veterinarian and epidemiologist. He's our chief epidemiologist --
Q. Okay.
A. -- at Lilly.
Q. And is he still in that capacity?
A. Yes, he is.
Q. And who is Dr. Man Fung?

A. He was --
Q. By the way, am I pronouncing his name correctly?
A. Yes. that's correct. Man Fung. Dr. Fung was the physician responsible for Zyprexa, olanzapine in the pharmacovigilance and epidemiology division within the company.
Q. And what is the worldwide pharmacovigilance and epidemiology division?
A. This is a unit that serves a number of functions in terms of monitoring the safety of products, both drugs and administration instruments. They deal with the collection of the spontaneous adverse event reports, their organization, their analysis. They -- it's been an evolving organization.
They're also involved in potentially setting up epidemiological studies, intentionally suggesting prospective studies and then interfacing with regulatory. They sit as part of regulatory. This is, actually where, with a different name, my current position resides within this -- within this organization.
Q. Do you know who, back in 1998, Dr. Hornbuckle and Dr. Fung would have reported

to?
A. No, I'm not certain at this -- at this time.
Q. Okay. Would you -- did you have interaction with either of those gentlemen back in '98?
A. Yes, I would have.
Q. With respect to Zyprexa?
A. Yes.
Q. Okay. And describe the nature of your interaction with those folks back in '98.
A. Well, again, although I was not part of the olanzapine team, I did review aspects of safety from a product team perspective. So, I would have interacted with these individuals who also served to review safety data. So it was a -- we, in essence, formed a -- a larger team across several components of the corporation.
Q. And who is the "we" that you're referring to there?
A. Would have been Dr. Hornbuckle, Dr. Fung, other members of the product team, medical members of the U.S. affiliate, members of their -- additional members of the worldwide pharmacovigilance and epidemiology staff.

Q. And did that collection of individuals you've just described, did they have a name or a -- for that team or group?
A. No, there was no specific name for that group of individuals.
Q. Is there -- was there anyone who sort of led or headed up that group?
A. It was driven, I think, as sort of a joint effort with Dr. Fung, Dr. Hornbuckle, and myself.
Q. Okay. And I've seen reference to a Dr. Kenneth Kwong. Was he part of that pharmacovigilance and epidemiology group as well?
A. When Dr. Fung moved on to other assignments, Dr. Kwong took his place.
Q. Okay. Am I correct that one of the -- well, let's talk about these spontaneous reports and what they are. These are sometimes referred to as adverse reaction reports, or adverse event reports, correct?
A. Adverse event reports, yes.
Q. Okay. And they can come into the company from doctors or from consumers?
A. Among other people. There are a lot of sources. They can also come in from literature,

for example, as well as -- as well as other sources.
Q. Okay. You referred several times to a group known as the product team that was led by Alan Breier; am I correct?
A. That's correct.
Q. And can you describe for us what that product team consisted of or who was on that team?
A. That was a very large team of individuals that was responsible for this molecule exclusively from a worldwide and corporate perspective, primarily directed at doing research, but also with a global marketing component.
And that is in contrast to the -- the -- I guess, 190 international affiliates who actually did -- also did research and actually directly marketed the compound. So this is a -- this is a group that did general work with the compound. And I hope that's an adequate explanation.
Q. I'd like to probe a bit more in terms of -- you said it's a large team, and I don't expect you to remember all the particular

individuals, but were there different departments that comprised the components of that team?
A. Yes. There would have been a medical component. So, there were a number of physicians that were on the -- on the team.
Q. And you mentioned Dr. Breier. He's, obviously, a physician.
A. He was a physician -- but he was the head of the whole organization.
Q. Do you recall whether Drs. Kinon and Dr. Robert Baker were members of that product team?
A. I think they were actually members of the U.S. affiliate, so they would not have been members of the product team at least at this point in time. I don't think -- I think Dr. Kinon was briefly a member of the product team early when he came to the company, but then moved to the -- to the U.S. affiliate. And I don't think -- I think Dr. Baker when he came was -- came directly into the U.S. affiliate.
Q. Okay. I interrupted you. You were telling me that part of the product team was a medical -- well, it was led by Dr. Breier. There was a medical component. And that's when I

interrupted you.
A. There would have been a medical component -- I hope I get most of these. There would have been a statistical component. There would have been a very large component -- there would have been a systems component, people that actually worked with the computers in contrast to the statistical individuals.
There would have been what we call, for instance, medical plans. These are the individuals, usually with bachelor's or master's degree training that actually support physicians in the conduct and the interface with doing research. There would have been a medical writing component. Those are the ones that I'm familiar with. I may be missing a component or two -- a component or two.
Q. Let me direct your attention back to Exhibit 6890, and this agenda for Zyprexa medical marketing in December of 1998. Do you recall this particular meeting?
A. No. Almost seven and a half years ago, I don't recall the specific meeting.
Q. Okay. Do you see under the agenda, there's several bullet points. The middle one

is: Weight gain and link to diabetes, question mark. What does the data say and what is our action plan, question mark.
Do you see that reference?
A. Yes, I do.
Q. And then there's a handwritten note at the bottom relating to weight gain, correct?
A. Yes, there is.
Q. By the way, do you recognize that handwriting?
A. No, I don't.
Q. The handwritten note says: Weight gain and genetic vulnerability lead to hyperglycemia, correct?
A. Yes, it does.
Q. And do you agree with that medical concept?
A. I would characterize this as being not correct.
Q. Okay. In what way do you say it's not correct?
A. I would view both weight gain and genetic variability as risk factors for the development of hyperglycemia. Individuals who have these risk factors may or may not go on to

develop hyperglycemia. A lot of people gain weight who don't become diabetic, as with people -- there are people who become diabetic who don't gain weight.

Presumably, there is this element of genetic variability. Certainly, a strong hypothesis built on epidemiologic studies noting that it runs in families, but we have not identified the -- the gene abnormality that invariably leads to hyperglycemia or developing.

Q. And if someone has a risk factor, that means that they may develop that problem, correct?

A. That -- that puts them at increased risk. To be very precise, that puts them at increased risk relative to patients or individuals without that risk factor.

Q. And if, in fact, you have a group of people who are at increased risk, then those people -- some of them -- you may not be able to tell who, but some of them will, indeed, come down with the -- with the adverse event at the end of the day, right?

A. I -- I can't absolutely conclude that because, again, these things remain risk factors.

Some of them actually having a relatively low incidence of increased risk. So I cannot automatically know that because someone has risk or that a large group of individuals has risk factors, that somebody will definitely develop the condition within that --

Q. Let me restate the question.

Would you agree, sir, that if you have a group of people who are at increased risk of having some adverse event occur that it is more probable than not, at the end of the day, that some of those people will, in fact, develop the adverse event as a result of using the drug that increased their risk?

A. All I can say is that there is increased probability among those individuals with that risk factor of developing the condition if they -- than if they did not have the risk factor.

That would be correct.

Q. And, in fact, as we saw earlier, your clinical trials back in 1995 showed a statistically significant increased incidence of hyperglycemia with use of Zyprexa, correct?

A. And I disagree with that. As we discussed, there was one finding in one clinical trial of many analysis showing that finding.

Q. And by -- strike that.

When the clinical trials for Zyprexa was done before it was marketed, was the evaluation of the risk of diabetes with Zyprexa a specific goal of those clinical studies?

A. Although it was not a -- stated as a primary outcome in the protocol, it was clearly one of the many aspects of safety that was evaluated.

Q. If diabetes or hyperglycemia had been the specific goal of the study, would you have recommended that fasting glucose blood tests be taken as opposed to random blood glucose testing?

A. Actually, I would not have made that recommendation.

Q. And why is that?

A. My concern is with the compliance of patients that suffer severe mental disease, and knowing that you could get the possibility of really significant noncompliance in this patient population, so that if you thought you had fasting glucoses, in many instances you may well not have fasting glucoses.

Q. Okay.

A. That was -- that was my opinion at the time.

Q. Okay. And in item C in this e-mail it states: Charles Beasley reassures that regulators have felt satisfied with Lilly's explanations and Lilly's commitment to conduct new clinical trials and to continue to do proactive post-marketing safety surveillance.

Did I read that correctly?

A. Yes, you did.

Q. And who did you work with on that project?

A. There were a number of people that I worked with -- and this actually represents a number of projects. And, again, I don't recall specific conversation with Edmundo, but there were several activities that were going on at the time.

I worked with the pharmacovigilance individuals and the -- the team -- the product team to produce a review, very detailed review of both the spontaneous data and the -- and the clinical trial data that -- substantial amount of which had accumulated since the drug had been

released. We had also made the decision to conduct -- and this was in part of agreeing with this senior leadership cross-functional team, to conduct some studies of potential mechanisms of inducing hyperglycemia. So that we -- we had intended to study ways in which the medication might cause patients to become hyperglycemic, if it did.

Q. This -- as you referred to it, detailed review of the spontaneous data and clinical trial data in 1999, was that for the purpose of addressing the hyperglycemia issue?

A. The -- the topic of hyperglycemia, yes.

Q. Okay. And who was it that directed you to undertake that review?

A. No one, actually directed that review to be undertaken, to the best of my recollection. It was Dr. Kwong in pharmacovigilance, his group, and myself that felt it would be appropriate to conduct a very, very thorough --

Q. Okay.

A. -- and comprehensive review. I believe that it began in early 1999.

Q. Okay. And would it be fair to say that you and Kenneth Kwong were the principal drivers

for undertaking that review?

A. Yes, directly. But, again, Dr. Breier had put together this team that, I believe, he actually convened earlier than 1999. I'm not sure when he actually convened this team to look at clinical data, preclinical data for both weight gain, which was -- which there was recognized data of an association, and potentially develop treatment methods, potentially do studies to investigate potential treatment methods, and that this piece of work that Dr. Kwong and I decided to undertake, we actually viewed as a component of this overall activity.

Q. And, Dr. Beasley, if I could refer you to the second physical page of the document.

A. Uh-huh.

Q. There's a heading towards the top of the page below the confidential label that says: Olanzapine labeling change on hyperglycemia for the February 21, 2000, GPLC meeting.

Do you see that?

And regardless of whether you personally drafted the text that's in here, would it be fair to say that you not only reviewed but

approved this language?

A. Yes.

Q. Okay. And by approving it, you believed that what was stated in there was accurate and truthful, correct?

A. At -- at the time --

Q. Sure. That's all you can do.

A. -- yes, recognizing that the basis for the specific numbers that had been included in here were from the very first preliminary analysis of our clinical trial.

Q. I'm not sure what you meant when you said that the basis for the specific numbers had been included in here were from the very first preliminary analysis of our clinical trial data. Can you explain that?

A. Yes. Thank you.

The numb -- the numbers contained in here were brought forward for review by the GPLC, and we clearly suggested and thought that a -- a labeling change was appropriate. The -- the basis for this, as I said, is someplace between 50 and 100 studies.

I brought forward to, I believe, Dr. Breier, Dr. Toleffson and other individuals

the results of the very first successful run of that -- of that data. And so that was the basis for what went in here.

Q. Okay.

A. It's -- it's very much like the first time that you run a long column of numbers on an adding machine and get a result.

Q. Is schizophrenia a risk factor for diabetes?

A. The data appears to be that there is an increased risk in the patient population with schizophrenia so that it would constitute a risk factor.

Q. So, it's Dr. Beasley's opinion that schizophrenia is a risk factor for diabetes?

A. That's my understanding of the literature and, therefore, that is my opinion.

Q. Dr. Beasley, let me just ask you a question or two about some of the exhibits that you've been asked about during your deposition.

First of all, if we could look at the Plaintiff's Exhibit 229. If you will recall -- and I want to look at page 4 of that. If you recall that, this is the one that contains the statement no routine blood monitoring

required.
Do you see that?
A. Yes, I do.
Q. Dr. Beasley, as a physician with respect to the prescription of antipsychotic medications, does that have some particular meaning to you?
A. Yes, it does.
Q. Can you tell us what that is?
A. This would be in the area of antipsychotic prescribing, a statement that we would -- that one would not need to routinely monitor white blood cell counts, which is the case with one antipsychotic that's available on the market.
Q. And is the monitoring of white blood cell count, does that have anything to do with blood glucose, or hyperglycemia or type 2 diabetes?
A. No, it does not.
Q. Dr. Beasley, do you recall questions put to you -- I think it was with respect to one of the particular e-mails that made a reference to two full-time people hired at Lilly to work on the Zyprexa and hyperglycemia issue?
A. Well, there were two full-time people

assigned. And these were -- these were people that were principally assigned in this area.
Q. I just want to ask you about those people. Who were those people, particularly?
A. That would be Dr. Cavazzoni and Dr. Missy Sowell.
Q. And those two individuals were assigned full-time to do work on the hyperglycemia issue with respect to Zyprexa?
Dr. Beasley, the question I want to put to you is: Who is Dr. Sowell that you made reference to?
A. Dr. -- Dr. Missy Sowell. She was an endocrinologist, diabetes and metabolism specialty physician holding both an M.D. and Ph.D.
Q. Now, Dr. Beasley, in reference to the two people you've testified about who were assigned to work full time on the hyperglycemia issue, were there additional resources other than those two people put to work on the hyperglycemia issue at Lilly?
A. There would have been statistical resources and system analyst resources.
Q. You were also asked questions about the

meeting in Atlanta with the endocrinology outside consultants; do you recall that?
A. That's correct.
Q. And there was mention in that one e-mail with respect to the fact that those individuals had advised Lilly to look at continuous-type analysis of the Zyprexa data.
Do you recall that?
A. That's correct.
Q. Did Lilly take that advice?
A. To my understanding, yes. There were a number of activities undertaken during the fall and into the winter with medical supervision by, again, Dr. Cavazzoni, involvement of internal statistical resources. I believe Dr. Sowell was probably involved to some extent. And then there were two separate outside consultants that were involved in analyses, Dr. David Allison, actually earlier in the year, and then later Dr. John Buse.
Q. And to the best of your knowledge, Dr. Beasley, has Lilly continued with the project of the continuous-type analysis of the Zyprexa data with respect to blood glucose?
A. I'm not familiar with the specifics of

subsequent analysis, but Lilly has certainly continued a number of projects and analyses in this area. It continues to be, obviously, an important area that is continuing to be studied and evaluated.
Q. Now, you were asked some questions about what is marked as Plaintiff's Exhibit 1349, and, in particular, about page 6 of that exhibit. I want to put that in front of you. That's the exhibit that shows the number of patients at that time in the Zyprexa clinical trials and the duration of exposure with respect to those patients.
Do you recall those questions?
A. Yes, I do.
Q. And let me just ask: This is the exhibit that shows the number of Zyprexa patients that got, for example, more than one dose of the drug, exposure to the drug more than a month, then those who had exposure to the drug more than six months, and those who had exposure more than a year.
Do you recall questions about that?
A. That's correct.
Q. Now, Dr. Beasley, was safety data

gathered from all of the patients in each of those groups?
A. Safety data was -- was obtained for all individuals who were exposed to the -- to the drug.
Q. Are there recognized international standards, Dr. Beasley, with respect to the duration of exposure in drug studies like the clinical trials performed on Zyprexa?
A. There are. There are what are referred to as the CIOMS guidelines that are generally used and recognized by most regulatory agencies. And these -- these are the guidelines that sort of dictate or indicate how many patients should be treated for how long before a new drug application can be submitted.
Q. Now, with respect to Zyprexa -- and, again, referring specifically to the international guidelines for the duration of exposure for patients in the clinical trials, what can you tell us about how the Zyprexa clinical trials matched up with those guidelines?
A. Well, the guidelines suggest a number of patients that should be treated for one or more doses, and that is 1500, and for one or more

doses with olanzapine or Zyprexa it was 3,139.
The guidelines actually recommend a range for six months or greater -- and this is 300 to 600. And the number with olanzapine was 876, and the guidelines for one year is 100. And the number of Zyprexa, olanzapine patients was 301.
Q. Now, I want to ask you about the -- what's marked as Plaintiff's Exhibit 1605, and particularly, page 11 of that exhibit.
If you'll recall, that's the exhibit that refers to study HGAJ and particularly the nonfasting glucose levels at any time.
Do you recall those questions?
A. That's correct.
Q. Now, you were specifically asked with respect to the Zyprexa patients about the percentage of patients who had a high glucose reading at any time during that study.
Do you remember that?
A. Yes, I do.
Q. And that percent is what?
A. That is 2.6 percent.
Q. Now, there's another value there for

Zyprexa patients; is that correct?
A. Yes, there is.
Q. Now, what was not asked of you, and I want to ask of you, is -- is there a value for the Zyprexa patients in that study for moving from normal or high glucose to a low glucose level?
A. Yes, there is.
Q. All right. With respect to the 7.7 percent for Zyprexa patients, can you tell us, what does that signify?
A. Well, that signifies the number of individuals who at some time during up to six weeks of treatment with values being measured weekly had what was defined as a hypoglycemic value, an abnormally low value of glucose.
Q. Now, can you make a comparison between the number of Zyprexa patients that went to low glucose as compared to the percentage that went to high glucose?
A. It was 2.6 percent that went to high and 7.7 percent that went to low. That's the percent for low, or the lows are probably about 2.8 times as many patients as went to high.
Q. All right. And with that many -- with

that percentage of Zyprexa patients going to a low glucose level, what does that tell us, if anything, about the significance of that, quote, at any time glucose measurement?
A. Well, that would suggest that it's -- it's very difficult to interpret these data as particularly meaningful. As I was suggesting, this is one analysis that we would take into consideration with the analysis of end point data, similar data at end point, and then mean change data, which would actually be mean change to high, mean change to low, and mean change to end point. So, we really consider five basic analyses in terms of coming to any final interpretation or conclusion.
Q. And overall, when all of the data is considered from that particular study, what did the data show with respect to glucose levels?
A. My recollection is that the interpretation was that there was no difference from haloperidol.
Q. Now, there had been questions during your depositions about clinical studies and controlled clinical trials on potential new drugs.

Do you recall questions like that?
A. That's correct.
Q. Did you have any experience in your residency program and training with respect to clinical trials of potential new drugs for psychiatric illnesses?
A. I was actually asked to take on a part-time job outside my residency by university faculty who were conducting clinical research on new drugs as a co-investigator.
Q. Let me ask you the same question I asked about medical school. Did you have any particular national honor or recognition during your psychiatric residency program?
A. I was -- during my senior year I was named a Laughlin Fellow.
Q. What does that mean?
A. Which was a fellowship to attend and participate in the activities of the American College of Psychiatrists, which is an honorary psychiatric society, I think for approximately 12 to 15 recipients throughout the United States and Canada.
Q. Now, I think you told us you started your job at Lilly after you completed your

residency in psychiatry?
A. That's correct.
Q. And what year was that?
A. That would have been 1987. It was 7/7/87.
Q. So you've been at Lilly now how long?
A. A little over 19 years.
Q. Now, during those 19 years, I'd like to ask you to tell us about the -- the nature of your work. And, first, with respect to the study and research on new drugs to treat -- treat psychiatric illnesses.
What has been your job with respect to that?
A. Well, that has been the core if -- or certainly a large component of my -- my job. Through my first 17 years or so here, I think I probably supervised, wrote, directed the analysis of probably something around 20 clinical trials in that -- in that time period with -- with several drugs we talked about yesterday.
Q. Now, would you tell us, what has been your job, if any part of it, at Lilly for the last 19 years concerning the evaluation and analysis of observed adverse events in patients

taking a drug?
A. Well, that's -- that's an integral part of running and analyzing any clinical trial. That has been very much sort of my focus and, frankly, the thing that -- that the company at this point views me as relatively expert in, which is why I'm in the consulting position I'm in.
Q. Tell us, were there specialists at Lilly in endocrinology and, in particular, in diabetes, who participated in the review and evaluation of this issue about hyperglycemia and diabetes as it concerns Zyprexa?
A. Yes. There were at several levels.
Q. All right. First, have there been specialists in endocrinology and diabetes at Lilly who were principally focused in their careers on these questions?
A. Yes. There have been a -- a series of -- of endocrinologists and diabetologists that were actually assigned to work on the Lilly team. So although not psychiatrists or neuroscientists, their principal assignment was to the team, the product team.
Q. And other than the specialists in

endocrinology and diabetes who were assigned to work principally on the team, have there been other individuals with those specialties who have been involved in studying the hyperglycemia issue as it concerns Zyprexa?
A. Yes, there certainly have been individuals. And we discussed one yesterday on -- I think it was on one of the e-mails. A number of the -- of the endocrinologists and specifically the diabetologists have had the opportunity to review data and give advice and suggestions about continued experimentation in the work.
THE COURT: Are we at a good spot to take a break?
MR. LEHNER: This would be a fine spot, Your Honor.
THE COURT: Ladies and gentlemen of the jury, we'll take a 15-minute break.
We'll be in recess.
(Jury out.)
(Break.)
(Jury in.)
THE COURT: Please be seated.
We resume with Dr. Beasley's

deposition?
MR. LEHNER: Thank you, Your Honor.
THE COURT: And the record should reflect that all members of the jury are present.
Q. Now, the questions that I want to ask you right now have to do with performing clinical trials with proposed new drugs, okay?
A. Yes.
Q. First, let's start with an uncontrolled trial. Can you explain, and if it's helpful, make a diagram, of what -- what you actually do in performing an uncontrolled trial with a new drug?
A. I can.
Q. And tell us what you're doing.
A. First off, I'm writing the title Uncontrolled. And this is the type of trial that's done early in development that we talked about yesterday where --
Q. All right.
A. -- there is only a group of individuals that are treated with the drug. There are no other treatments in this trial.
Q. All right. Now, tell us what you actually do in an uncontrolled trial with the

drug.
A. Let me illustrate some -- some individuals in this trial. We have ten people in this trial.
Q. And the circles represent what?
A. The circles represent the people. So, this group of ten people in this uncontrolled --
Q. You've got nine of them there. You better put one more.
A. Got to put the one more -- are treated for some period of time with the proposed drug. There is -- there is nobody else being treated with anything but the drug in this particular trial.
Q. All right. Then, what do you do?
A. Well, you observe these individuals.
Q. You observe them.
A. You do physical examinations, you do blood studies, you collect your history of medical problems, you collect the minor symptoms that they might be having, such as headaches, prior to being treated with drug. And then you repeat these examinations periodically during the course of trial.
Q. All right. Now --

A. You observe things.
Q. All right. Now, give us an example of what kind of observations are made in an uncontrolled trial.
A. Well, if we're talking about something like an adverse event, we could say flu-like symptoms, and a number of these individuals might have flu-like symptoms. Let's say there's seven of them. So we have seven, ten, flu-like.
Q. Now, Dr. Beasley, if, in your example the seven out of the ten patients in the uncontrolled drug trial were observed to have flu-like symptoms, what conclusions could you draw, if any, whether the drug caused the flu-like symptoms?
A. Well, in this particular trial, you wouldn't draw any conclusions about causation or causality. You would simply draw the conclusion that there were a lot of flu-like symptoms experienced in these individuals during this trial.
Q. Could you, in fact, make any conclusion with respect to the question: Does the drug cause flu-like symptoms?
A. No. That would not be considered

scientifically appropriate.
Q. Why not?
A. Because there are many things that could cause flu-like symptoms, since this is a -- very common occurrence. It could be the flu virus; it could be common cold viruses; it could be environmental exposures; it could be contaminated sushi that someone ate the evening before or, if it were served on an inpatient unit to all these individuals, lots of different potential causes.
Q. Now, if you would, could you tell us about a controlled trial and illustrate that on your diagram?
A. Well, that would be the -- the next step in terms of types of studies, and here we would have --
Q. What does the second box you're drawing represent?
A. This is going to be a comparison treatment, a comparison group with placebo.
Q. As you're writing the word "placebo" there, you'll have to tell us what that means.
A. This would be a -- an inactive substance. It could be cornstarch. It could be lactose. It is a -- it is a capsule or a pill

that looks identical to that given to patients who are receiving the drug, but it is an inactive or inert substance. It has no chemical action in the body.

Q. All right. And who is in the placebo group?

A. Well, generally, these would be done with similar-sized groups. So, obviously, in clinical trials the numbers are actually larger. But in this illustrating example, we're having ten drug-treated patients, ten placebo-treated patients. I'll just draw that to make it clear that that's all that one, and that was just the uncontrolled.

Q. All right. Now, are -- if you want a controlled clinical trial, you've described two groups and you initially described the observation of adverse events. Would that also be observed in the placebo group?

A. You would do everything identically to the individuals in the drug group and the placebo group.

Q. And provide an example for us regarding the observation of adverse events in the placebo group.

A. Well, if you had a similar number -- suppose we had seven of ten, okay.

Q. Now, what does that represent?

A. This represents seven of the ten placebo patients also experiencing flu-like symptoms.

Q. Now, if you, in fact, had a controlled clinical trial with the observations of adverse events that you have portrayed in your diagram, what, if anything, would you be able to conclude about whether the drug caused the flu-like symptoms?

A. Well, here's where we use the -- the mathematics of statistics to compare the -- the percentage, in this case it would be the percentages of patients. And given the very similar number, we would conclude that there is not a significant difference here. And the way that we would interpret that is that it would be unlikely -- because there is similarity, it would be unlikely that the drug caused the flu-like symptoms. We would conclude that other things unknown to us, but, again, with a lot of possibilities, would have caused the flu-like symptoms.

Q. Are you familiar with the term called

blinded as it refers to controlled clinical trials?

A. Yes, I am.

Q. Could you tell us what that means?

A. That means that neither the -- the doctors who are giving the drug or -- and/or evaluating the patients, performing the examinations, nor the patients know which patient is receiving drug and which patient is receiving placebo.

Q. And why is that important, if it is?

A. The reason that that is important is to prevent the -- the -- either the reporters, the doctors, or the reporters, the patients, from believing that they might have something -- some effect because they know what they're receiving and reporting consistent with their belief. It's done to do what we would call prevent bias in reporting.

Q. All right. Now, Dr. Beasley, if you would, could you draw a vertical line down your diagram there so we can let me ask you questions about a related but different topic?

And now I want to ask you: Are you familiar -- and we've already heard some

questions today about something called a spontaneous report of an adverse event.

Are you familiar with that?

A. Yes, I am.

Q. Can you tell us what that is and illustrate that for us, please?

A. That would be a report that would be received by the company from a wide variety of sources about a patient treated with the drug. When I say wide variety of sources, it could be from a physician treating the patient, a pharmacist who had heard about the patient, the patient, him or herself, a relative of the patient. Many different individuals that would call us and report that a patient had experienced a particular event, a spontaneous adverse event.

Q. All right. Now --

A. Which -- such as flu-like symptoms.

Q. Now, so, in your diagram when you put an X on the circle under the spontaneous column, what is that intended to represent?

A. That's intended to represent that the patient has had something that -- whoever the reporter was considered adverse in this case. So, in this case flu-like.

Q. Now, with a spontaneous report of an individual taking a drug who reports experiencing flu-like symptoms, what can -- what conclusions can you draw, if any, about whether the drug is somehow related to the flu-like symptoms?
A. Well, this does two things: One, what it does is alerts us to the fact that similar to this uncontrolled trial, we have an individual who was taking the drug who at the same time what we call a temporal association was having flu-like symptoms. Past that, we would draw no conclusions based on this -- on this report.
Q. And why -- why could you not draw any conclusions about whether the drug caused the flu-like symptoms in the spontaneous report?
A. It's because we really don't have a -- a control group with which to make comparisons. And this is particularly the case when you've got something that would be relatively common in the population that could be occurring due to a great many possible causes, or what we call etiologies.
Q. Now, tell us, Dr. Beasley, suppose the company received several or many spontaneous reports of -- following your example -- patients who took a drug and experienced flu-like

symptoms. And tell us what you're representing there.
A. This would be additional reports, spontaneous adverse event reports.
Q. All right, now, tell us what conclusions, if any, can be drawn from the receipt of numerous spontaneous reports from these patients who took a drug and then experienced flu-like symptoms.
A. Particularly with a common event, like flu-like symptoms, we would not be able to draw, again, any sort of -- of causal conclusion or association. It would certainly alert us to the fact that these things, again, had been reported in temporal association and would alert us to the need to further investigate this -- what had been observed as a temporal link in clinical trials, in prospective studies, in a number of potential ways.
Q. Dr. Beasley, the diagram regarding the controlled clinical trial and spontaneous events, we've not put an exhibit sticker on that.
Has that been marked as Beasley Exhibit 5?
A. It's been marked 5. I don't see a

"Beasley" on it.
Q. Let's add that. Has it now been marked as Beasley Exhibit 5?
A. Yes, it has been.
Q. Let me hand you what we've marked as Beasley Exhibit 6 and ask if you can identify that.
A. Well, this is a Zyprexa label. Let me --
Q. Can you look at the date on the last page and orient yourself?
A. Let me look on the back. This is marked -- this is dated 10/02/96. So I believe this would be the original label.
Q. Dr. Beasley, to whom is the product labeling or package insert directed?
A. This would be to the individuals who would be prescribing the medication.
Q. And who is it, Dr. Beasley, that decides what information is included in the Zyprexa labeling or package insert.
A. The FDA.
Q. Now, there have been questions during your deposition about weight gain as an adverse event observed in patients taking Zyprexa.

Do you recall that?
A. Yes.
Q. Let me ask you to turn over to page 2 of Beasley Exhibit 6, and I want to ask you, generally, were prescribing physicians provided information on weight gain observed with Zyprexa in the original product labeling or package insert?
A. Yes, they were.
Q. First, I want to direct you to Table 1 on the second page. Can you tell us what was -- what information was provided about weight gain as an observed adverse event with Zyprexa?
A. Well, again, this was both observed and the information provided here was in reference to what was both observed and then reported as an adverse event by the clinicians conducting the studies.
And it was reported that weight gain occurred, was reported in 6 percent of the olanzapine-treated patients and 1 percent of the placebo-treated patients. These data were the aggregation or the combination of all the placebo-controlled data on the medication.
Q. Now, let me ask you to turn over to

the -- essentially, the next table over on the next page. Do you see that one, called common treatment, emergent adverse events?
A. Yes.
Q. And would you tell us, please, what's reported about weight gain in that table?
A. Well, this is the table of -- that represents what were called common or the most common treatment adverse events that were reported at 5 percent or greater. And this reports the same numbers, weight gain 6 percent, and placebo 1 percent.
Q. Now, if I could direct your attention to the bottom of that page. And if you could tell us: Is there additional information about weight gain provided to the prescribing physician in the original package insert for Zyprexa?
A. Yes, there is.
Q. Tell us what that is, please.
A. In addition to restating the information regarding weight gain reported as an adverse event, this is a summary of information regarding what was observed when patients were weighed on scales to actually determine their weight.
And the first set of information

that is contained describes the olanzapine patients compared to placebo patients during the acute or short-term or six-week trials. And then it -- excuse me -- it goes on to describe the experience of all patients treated in the longer-term extensions of all studies. And it reports that the olanzapine-treated patients gain an average of 2.8 kilograms compared to an average of 0.4 kilogram loss in the placebo patients. And that when we look at the 7 percent or greater gain in body weight, that that was 29 percent of olanzapine-treated patients compared to 3 percent of placebo-treated patients. And, again, this is in the acute phase of the study.
Q. All right.
A. It goes on to describe the data to -- regarding long-term and, again, here's where all patients were used with a -- what we call a median or sort of a central point between the fewest number of days and the longest number of days of treatment being 238 days. And this reports that 56 percent of patients gained 7 percent or greater of body weight and that the average weight gain during this period was 5.4 kilograms. The additional information is

provided that the greatest amount of weight gain was seen in patients who, based on what we call body mass index or BMI, with patients with the lowest value for that at baseline.
Q. Now, there's also been some question during your deposition about the adverse events of hyperglycemia and diabetes and diabetic acidosis.
Do you recall that?
A. Yes, I do.
Q. Is there information about those adverse events observed in patients taking Zyprexa included in the original package insert?
A. They're listed in the other adverse events observed during the premarketing evaluation of olanzapine.
Q. And could you particularly let me reference you to under that column, the column of Endocrine System?
A. Yes.
Q. And can you tell us what is provided to a prescribing physician regarding the information about diabetes there?
A. That diabetes mellitus was observed infrequently and that diabetic acidosis was

observed rarely.
Q. Now, could I refer you to the Metabolic and Nutritional Disorder section and ask you the same question: What information was provided in that section regarding hyperglycemia observed in patients taking Zyprexa?
A. In this section, hyperglycemia was indicated to be an event that was observed with an infrequent frequency.
Q. Now, Dr. Beasley, because these events of hyperglycemia and diabetes and diabetic acidosis are included in the package insert for Zyprexa, does that mean Zyprexa causes them?
A. No. What that means is that they were observed during the conduct of trials in patients who were included in the clinical trials.
Q. Dr. Beasley, why was information about weight gain and hyperglycemia and diabetes included in the original package insert for Zyprexa?
A. That, along with the other information that's provided here, is so that physicians take the entirety of the information, judge, make the risk/benefit analysis for use in their patients and be aware of what had been observed.

Q. Now, we've had some testimony from you with respect to spontaneous reports of adverse events.

Do you recall that?

A. Yes, I do.

Q. And did Lilly receive spontaneous reports of adverse events from patients taking Zyprexa after Zyprexa was approved and went on the market?

A. Yes.

Q. Tell us, what did and does Lilly do, if anything, to monitor its receipt of reports of adverse events?

A. Well, this would be the -- the primary function of the pharmacovigilance and pharmacoepidemiology department, or now global product safety. And the first component is, actually, taking and receiving the reports. So, these are generally called in to us and entered into computer systems by individuals.

The next thing that is done with this group of individuals would follow up on these reports to attempt -- I really should emphasize attempt -- to obtain additional clinical information that might have been missing

from the -- the initial report when it was presented to the company.

Q. What do the people at Lilly actually do to try to follow up spontaneous reports of adverse events?

A. They can make telephone calls. They can send letters. This is the -- this is the collection process for the individual cases.

The next step in the -- in the process is for these to be reviewed as -- as groups of reports. And here there are physicians and what we call surveillance scientists that would be involved, along with pharmacoepidemiologists. And there would be a number of types of reports that would be -- that would be prepared.

There are periodic reports to the Food & Drug Administration, periodic reports to other regulatory agencies that -- that summarize these -- these data. There is the potential for what we would call ad hoc requests, meaning that an agency would send a specific request outside the -- the routine periodic reports for information. And then the group could also provide periodic internal review.

Q. Let me ask you about that, specifically.

And after Zyprexa went on the market and Lilly received reports of hyperglycemia, in particular, was there any particular internal review that Lilly performed with respect to those events?

A. Well, there was a -- there was a sequence of them. We had weekly or biweekly meetings. Actually, the pharmacovigilance function, the product team, the U.S. affiliate, to discuss all adverse events that were being observed.

My first recollection of a -- of a specific review of the topic of hyperglycemia was, I think, sometime early in 1997.

Q. All right. And what was done at Lilly?

A. I think there was something on the order of 10 to 15 cases, some with rather high glucoses. We felt that we should obtain the consultation from an endocrinologist/diabetologist so these cases were summarized and presented to one of our internal diabetologists who then provided us with a -- a verbal report.

Q. And what was the report with respect to

the review of the spontaneous reports of hypoglycemia at that time?

A. His belief was that the cases were sufficiently confounded to make it impossible to conclude that there was a causal association in these -- in these cases he reviewed.

Q. You've used the word "confounded."

Would you explain for us what that means?

A. That would mean that there were alternative -- multiple alternative risk factors or frank causes, in his opinion, or that the cases really did not show sufficient change to constitute an event that would not be expected as just fluctuation in the normal course of a patient with diabetes.

Q. After that internal review of the spontaneous reports of hyperglycemia, do you recall, Dr. Beasley, whether Lilly received any inquiry from a Dr. Wirshing with respect to that topic?

A. I believe that we received a -- a request for information from, at the time, Dr. Donna Ames and her -- subsequently, her husband, Dr. Wirshing. Our understanding was

that they were intending to potentially publish a case series, and they were requesting information from us on what had been observed in our clinical trials.

Q. All right. What specifically did Drs. Ames and Wirshing ask of Lilly, and how did Lilly respond?

A. Well, they asked what data we had pertinent to the -- to the topic.

Q. And did Lilly provide them with anything?

A. My recollection is that we provided them with a -- both a summary of the data from our integrated summary of safety analysis, and I believe that may have also included some summary of -- of the post-marketing data, but I'm less certain about that.

Q. All right. Let me hand you what I've marked as Beasley Exhibit 7 and ask you if you could recognize that and tell us what that is?

A. I need to --

Q. Surely. Take a look at it.

A. Review of Glucose Changes in Patients Treated With Olanzapine, and it says for Donna -- Donna Ames Wirshing. So, this was probably the

report that was provided. There's an internal date of September, 1997.

It's a -- it's a fairly lengthy document. It appears to be, again, based on our integrated summary of -- of safety, some of the analysis that we talked about. And let me see if there are -- just integrated database.

We also appear to provide them with a reference -- a reference list. So this would be information from both the -- the haloperidol-controlled clinical trials and the placebo-controlled clinical trials and a -- copies of a literature search on the topic.

Q. And, to your knowledge, Dr. Beasley, did Drs. Ames and Wirshing eventually publish?

A. This was an article I think we discussed yesterday in which they reported on a series of cases that they had observed.

Q. Dr. Beasley, at the time Lilly pulled together the information contained in what we've marked as Beasley Exhibit 7, what were the conclusions that were permitted by the data that Lilly had with respect to whether Zyprexa was causally related to hyperglycemia?

A. Well, given the data that we had at the

time of our submissions which are reflected here, we did not see an association.

And what we indicate that, given the exposure we -- it was considered that the number of events reported was actually quite small, and that post-marketing spontaneous adverse event reports of alterations in blood glucose are consistent with the safety profile observed in the clinical trials.

Q. Now, Dr. Beasley, you, I think, previously gave testimony that you were involved directly and primarily regarding Zyprexa through the early part or some early part of 2001; is that -- am I correct in that?

A. 2000 -- I had very direct involvement through early 2001. I had more focused involvement in that period from 1997 through 2001.

Q. And toward the end of your direct involvement with Zyprexa, were you involved in any review, overall review of the Zyprexa data?

A. Yes. I think this is something that we have discussed, that there was a large review undertaken primarily initiated out of both pharmacovigilance and myself representing the

team that I have referred to as the Beasley/Kwong analysis, I believe.

The work actually extended over a significant period of time with a lot of individuals involved in actual completion of that work that was ultimately submitted to the Food & Drug Administration.

Q. All right. Let me hand you what's been marked as Beasley Exhibit No. 10, which is a rather large document that I'll put in front of you.

Can you look at that and tell us what that is, please?

A. The cover letter says: Response to FDA request. Enclosed is our response to your May, 2000 letter requesting information about olanzapine. This -- this review had been, again, internally initiated and not in response to a request from -- from FDA, but toward the end of its preparation, such a request arrived. So, this document was provided to them.

Q. All right. Now, can you tell us, Dr. Beasley, what was involved and what kinds of data were included in the overall review that resulted in the document submitted to the FDA

we've marked as Beasley Exhibit 10?
A. There were a number of different aspects of data included. The ones that I'm most familiar with are the analysis of the clinical trial data, but also the spontaneous adverse event data. I believe this also includes a -- a review of the literature, both clinical and preclinical. And given that it was submitted to the FDA, I believe it would have included regulatory correspondence regarding hyperglycemia and diabetes as well.
Q. And, Dr. Beasley, based upon the review that you participated in and submitted to the FDA that we've marked as Beasley Exhibit 10, can you tell us the date of that submission?
A. This would have been -- let's see -- the cover letter, but also let me see if I can -- would have been July of 2000.
Q. Now, based upon the review that was submitted to FDA in July of 2000, Dr. Beasley, were any conclusions possible with respect to the question whether Zyprexa is causally related to hyperglycemia and diabetes?
A. Taking the data in -- in total, all the extensive material, we believe that the data did

not support an association between the drug and hyperglycemia/diabetes.
Q. All right. Thank you, Dr. Beasley.
Now, in addition to Lilly's review of the spontaneous reported data and Lilly's review and analysis of the controlled clinical trials with Zyprexa, were there other different types of studies that looked at the specific question whether Zyprexa was exerting some direct effect to cause hyperglycemia?
A. There were a large number of studies and activities going on both clinically and preclinically under this group that Dr. Breier had organized. I'm most familiar with two studies that were conducted in humans referred to as clamp studies.
Q. All right. First, tell us -- you said there were two studies referred to as clamp studies?
A. That's correct.
Q. All right. Tell us, first, what was it that the two clamp studies were directed at looking at?
A. Okay. Type 2 diabetes is thought to be caused by two types of what we call

pathophysiology together, or abnormalities in the body is what pathophysiology means. One is the -- the failure of what we call the insulin receptor. And this is a -- a molecule on cells in the body that insulin, which is a hormone, interacts with to allow glucose to move into the cells. So you've got to have this receptor working right in order for glucose to move into the cells so that you lower blood glucose levels and the cells are able to use glucose as energy.
Q. Are you familiar with the term, Dr. Beasley, insulin sensitivity?
A. Yes.
Q. Tell me what that means.
A. That would be a measure of how well these insulin receptors work.
Q. All right.
A. The other thing that is thought to be necessary for the development of type 2 diabetes, clinical type 2 diabetes, would be the failure of the pancreas, which is an organ that sits in the -- in the abdominal cavity, close to the stomach, to put out sufficient amounts of insulin.
The pancreas is signaled to release

insulin when glucose is high in the blood. It releases this insulin, goes to insulin receptors, and this allows glucose to be transported into cells. So, the thinking is to be frankly or actual clinical type 2 diabetes, you have to have failure of the insulin receptor, decreased insulin sensitivity, and a decrease in the pancreas' ability to make enough insulin to compensate for poor insulin sensitivity.
Q. All right. Let me ask you, first, about -- actually the second thing you mentioned. That is the failure of the pancreas to actually produce insulin or to produce enough insulin. Was there one of the clamp studies directed at that question?
A. Yes, there was. And, again, why did we take on these studies? The thinking behind this was that it was important to us to do a study that would look at whether or not olanzapine was causing the effects in the body that would lead to type 2 diabetes. So, that was the purpose in -- in doing the studies.
Q. Now, first, I want to ask you to describe the clamp study that was directed at the question whether Zyprexa exerted some adverse

effect that would cause the pancreas not to produce insulin or not to produce enough insulin?
A. Uh-huh.
Q. First, tell us what was that study called and how did you perform it?
A. That's a hyperglycemic clamp study.
Q. And please tell us in layperson's language how that's done.
A. First of all, you have your parallel treatment groups as we've talked about this morning. You have -- in this case it was placebo, another antipsychotic, and olanzapine. And before patients receive -- or, actually, these are what we call normal volunteers. These were healthy -- healthy subjects. They were tested. And the way they were tested was by this thing that's called a hyperglycemic clamp.
They have an intravenous line inserted into their arm. They are then given glucose, actually large --
Q. Glucose is what?
A. Sugar. Large amounts of glucose, blood sugar, into this line into their body. And then the pancreas has the opportunity to react to this. And what is measured is the amount of

insulin that the body produces in response to this -- this extra glucose. Then the patients, are -- or the subjects are treated.
Q. When you say "treated," what do you mean?
A. They receive double-blind either placebo, olanzapine or this other medication. In this case, they received it for two weeks, and then they were retested. I think it's probably worth stating that -- that this -- this type of sophisticated study was -- I did not design this study.
Q. Who did design it?
A. This would have been designed by our endocrinology colleagues.
Q. All right, Dr. Beasley, before we changed the tape I was asking you about the hyperglycemic clamp study. Now, let me just ask: Were the results of the study performed by Lilly looking at whether Zyprexa exerted an adverse effect on the pancreas to produce insulin -- were the results of that study published?
A. They were published in a peer-reviewed journal.
Q. Let me hand you what's been marked as

Beasley Exhibit 11.
A. Actually, it's not -- you need to add the Beasley.
Q. Let me write the Beasley on it. Sorry.
Let me hand you what's been marked as Beasley Deposition 11. And can you tell us what that is, please?
A. This would be the academic publication regarding the results of the -- the study we've just discussed.
Q. Now, Dr. Beasley, tell us, what did the results show of the study done by Lilly to see whether Zyprexa exerted an adverse influence on the pancreas such that the pancreas produced a little or insufficient insulin?
A. The results are summarized in the -- in the last paragraph of the abstract. We found no evidence that treatment of healthy volunteers with olanzapine or the other drug -- left that one out, decreased the insulin secretory response to a prolonged hyperglycemic challenge. The results of this study do not support the hypothesis that olanzapine or the other drug directly impair pancreatic beta cell function.
Q. All right. Dr. Beasley, let me ask you,

this hyperglycemic clamp study methodology, is that a recognized methodology to look at the question whether the pancreas is affected to produce insufficient or no insulin?
A. That's my understanding from my endocrine colleagues.
Q. Now, Dr. Beasley, turning to the second prong of these clamp studies, did Lilly perform a study looking at the question of whether Zyprexa produced insulin insensitivity?
A. Yes, that was what was referred to as the euglycemic clamp study.
Q. Just a moment. Do we have some more exhibit stickers, by any chance? If not, I'll just --
All right, the euglycemic clamp study, now, can you tell us, again, in layperson's language, what was the euglycemic clamp study looking at?
A. Well, this looks at insulin receptor sensitivity. And here in contrast to the last study, you first give a lot of insulin, and you also give some glucose. And you determine, essentially, how much glucose you can give at a fixed amount of insulin and how well the body

uses that amount of glucose.
Q. Let me hand you what we've marked as Beasley Exhibit 12 and ask, first, were the results of the euglycemic clamp study performed by Lilly published?
A. Yes, they were.
Q. All right. Now, let me ask you to look at Beasley Exhibit 12.
Can you tell us what that is?
A. This would be the academic publication of the -- of the study that we've just discussed.
Q. Can you tell us, Dr. Beasley, what were the results of the euglycemic clamp study performed by Lilly to look at the question whether Zyprexa affected insulin sensitivity?
A. That's probably, again, best summarized in the abstract, in the last part of the abstract. In summary, this study did not demonstrate significant changes in insulin sensitivity in healthy subjects after three weeks of treatment with olanzapine or a --
Q. Now, Dr. Beasley, given the results of the two clamp studies performed by Lilly, based upon the results of those studies, what conclusions, if any, did Lilly draw regarding

whether Zyprexa demonstrated a causal and a mechanistic effect on producing type 2 diabetes?
A. Well, these studies certainly did not support the hypothesis that olanzapine was causing either type of pathophysiology that would cause diabetes. It was not causing the things that would cause diabetes in these two studies.
Q. Dr. Beasley, do you know the general recommendations from the American Diabetes Association with respect to screening blood glucose for type 2 diabetes?
A. I -- I believe that I do.
Q. All right. Can you tell us what those are?
A. I think it's a recommendation of a fasting blood glucose every three years at age 45 and older. And I believe there is some discussion about if an individual is obese and has other risk factors, conducting these investigations or blood tests at an earlier age.
Q. And those recommendations by the American Diabetes Association for screening blood glucose for type 2 diabetes, to whom do they apply?
A. Well, all Americans. I mean, they --

that's a universal healthcare recommendation by this -- by this organization.
Q. So, I mean, do they apply whether the person is suffering from schizophrenia?
A. Yes.
Q. Or do they apply in people who are not suffering from schizophrenia?
A. To my understanding, yes. They don't draw any -- any distinction. The only -- the only distinctions are the -- the age cutoff, and then earlier if risk factors are present.
Q. And would those general recommendations regarding screening for type 2 diabetes by looking at blood glucose, would that apply to people who were taking antipsychotic medication like Zyprexa?
A. They would apply to -- as we've said, to anyone. I mean, again, irrespective of their -- of their health status with the exception of this -- of this age cutoff.
Q. And let me just ask: Would the general recommendations of the American Diabetes Association to have a screening for type 2 diabetes by looking at blood glucose also apply to people who were not taking antipsychotic

medication like Zyprexa?
A. Yes.
Q. Let me hand you what's marked as Exhibit 13, Dr. Beasley.
Can you tell us what that is?
A. Do you want to --
Q. I beg your pardon. I keep forgetting to write "Beasley" on there.
Let me hand you what's marked as Beasley Deposition Exhibit 13. Can you make reference to the date on the last page, and then tell us what that is?
A. Well, it's a -- it's a Zyprexa package insert, and I'll need to check the date.
I see a copyright 2006 date here. Literature revised as of March 20, 2006. So, this was the package insert that was approved as of that date.
Q. All right. Could you turn to page 8 of that document, please?
A. Yes.
Q. And, in particular, I want to ask you about certain language contained in the warning section related to hyperglycemia and diabetes mellitus.

Do you see that?
A. Yes, I do.
Q. All right. Now, could you read the first three sentences of that for us, please?
A. Yes. Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including olanzapine. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population.
Given these confounds, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood.
Q. Let me first ask you, Dr. Beasley, the reference there to an increased background risk of diabetes mellitus in patients with schizophrenia. Can you explain for us in layperson's language what that means?
A. I believe it means what we were

discussing yesterday, that there is the belief, understanding, and data to support that a higher percentage of individuals with schizophrenia and without schizophrenia, everything else being equal, would have diabetes.
Q. And then making reference to the increasing incidence of diabetes mellitus in the general population. Can you explain in layperson's language what that means?
A. I understand that to mean that there is a continuing increase in the number of new cases of diabetes being observed every year. So that it's becoming more frequent in the population.
Q. All right. And in the second sentence, is it those two things that are referred to as confounders?
A. Those two things would be confounders, given these confounders.
Q. Now, can you tell us just in layperson's language, what does "confounder" mean?
A. That means things that are present that make sort of understanding or interpretation difficult or impossible.
Q. And by the way, you told Mr. See something on direct examination that one of the

things we like to do in studies is to blind them so in order to prevent -- what's the word?
A. Bias.
Q. Bias.
A. On reporting by the investigator or the patient.
Q. And how does blinding prevent bias?
A. That prevents the -- both the -- both the investigator and the patient from knowing the medication they're on and because of knowing the medication they're on, making assumptions or coming to beliefs about what they're experiencing and then reporting it.
Q. Right. If you blind the study, if the individual does not know, the doctor doesn't know, such as a researcher, right?
A. Correct.
Q. And the patient doesn't know which medication they're taking, you're more likely to get an objective as opposed to a subjective biased analysis, correct?
A. That's correct. That is the intent of blinding.
MR. LEHNER: That concludes that portion, Your Honor. I think there's a couple

minutes that the Plaintiffs have.
MR. ALLEN: You're passing the witness?
MR. LEHNER: Yes. We'll have you play your section.
MR. ALLEN: Your Honor, the State of Alaska has two minutes and 16 seconds in cross.
THE COURT: Why don't you do that and we'll keep on moving.
CROSS-EXAMINATION
Q. (BY MR. ALLEN) When you testified to me earlier today and yesterday, was your testimony truthful and accurate?
A. Yes, it was.
Q. And when you wrote your e-mails concerning the clinical trials to the people throughout Eli Lilly, were your e-mails truthful and accurate?
A. To the best of my knowledge, those data were correct at the time I wrote them.
Q. And by the way, you also made it clear today and I don't think you discussed it with your lawyer. If I'm not mistaken, you said by 1999, in Europe, that hyperglycemia and diabetes

was in the equivalent of the warning section?
A. Yes, it was.
Q. So, by 1999 the patients and doctors over in Europe were being warned about hyperglycemia and diabetes?
A. There was a warning slash precautions in that label written in Europe.
Q. And where is the warning in the United States package insert like Europe's in 1999 on hyperglycemia and diabetes?
A. There is not one.
Q. Where is that black-box warning on Zyprexa in 2002 like Japan had concerning hyperglycemia, diabetes, diabetic ketoacidosis?
A. There is not one.
Q. Is there any particular reason why Eli Lilly and the doctors in the United States should be treated differently than the doctors in Japan and Europe?
A. From our perspective and my perspective we were, in fact, labeling the molecule appropriately. There are clearly differences in the labeling. Different countries evaluate materials differently and have different interests in their package insert.

Q. Lilly's interest is the same throughout the world, isn't it?
A. Yes.
Q. You want to give the doctors in the United States the same information in the same manner you give doctors over in France, don't you?
A. Absolutely.
Q. You want to give doctors in Japan the same information you give doctors in the United States and vice versa, don't you?
A. Yes.
MR. ALLEN: Your Honor, that concludes our offer.
MR. LEHNER: We'll take down the screen and I'll offer some exhibits.
THE COURT: Sure.
MR. LEHNER: Your Honor, at this time on behalf of Eli Lilly I'd like to introduce into evidence what's been marked as EL2169. It was referred to as Beasley No. 7 in his deposition. That's a review of glucose changes in patients treated with olanzapine September, 1997 for Donna Ames Wirshing, customer response team.

Exhibit 2175 --
THE COURT: Let's take them one at a time and see if there's --
MR. SUGGS: No objection to 2169, Your Honor.
THE COURT: EL2169 is admitted.
MR. LEHNER: The next exhibit would be -- is marked as EL2175. It was referred to in Dr. Beasley's deposition as No. 11, and that is the article published in the Journal of Clinical Endocrinology and Metabolism, entitled Hyperglycemia Clamp Assessment of Insulin Secretory Responses in Normal Subjects Treated with Olanzapine, Risperidone and Placebo, by Sowell, et al.
MR. SUGGS: Your Honor, we object to that in light of the Court's rulings on published medical articles.
MR. LEHNER: Your Honor, I think what we've been doing is in conjunction with previous articles publishing these to the jury and consistent with the Alaska Rule on medical articles.
THE COURT: Counsel, please approach.

(Bench discussion.)
MR. LEHNER: We had these marked for identification --
THE COURT: Previous articles that the State was introduced were introduced for notice purposes. Why isn't this introduced --
MR. LEHNER: Notice of what? These are really beyond notice.
THE COURT: They aren't necessarily notice.
MR. LEHNER: These are Lilly's studies, too. It's work that Lilly has done. I think it's more than notice.
MR. SUGGS: They're not notice of a potential problem.
MR. LEHNER: They're not notice. This is work that they did -- this is Lilly.
MR. SUGGS: You're offering them for the truth of the matter asserted?
MR. LEHNER: Sure. It's a published medical article. You can contest the truth of the matter asserted within them, if you want to. This is Lilly's work.
MR. SUGGS: I thought the Court's prior ruling was that with respect to --

THE COURT: The normal rule for published treatises is you talk about them, you can recognize them, you can do that, but you don't admit them unless there's some other reason.

MR. LEHNER: That would be true. I agree for articles that are not written by the company that are not based upon the company's own work. They are being admitted as this is Lilly's work. This is Lilly's efforts to produce. You can contest whether they're true or not.

THE COURT: Why isn't it a business record?

MR. SUGGS: I don't -- I don't think the company, Eli Lilly's in the business of writing published medical articles.

THE COURT: Well, they do have to do research on their drugs.

MR. SUGGS: The reason for the rule is because -- the rules recognize documents like this and published medical articles should not be given more weight. They carry with them sort of a mantle and that's why you can talk about them, but they don't go to the jury.

MR. LEHNER: That would certainly

be true for articles done by third parties, but this is based on Lilly research, and as Dr. Beasley testified, a large component -- and as others have testified previously -- a large component of what these companies do --

MR. SUGGS: I don't see anything in the rule that draws the conclusion of what goes to the jury or not --

THE COURT: I'm going to admit the articles, to the extent that information Lilly had or didn't have is an essential element of this case and both articles that were otherwise doing that -- it goes to -- it -- there's both a business record component of it, but it -- I would also find there's a reliability to the extent that Lilly had this article and knew about it, that's -- that's a relevant issue as well to the defense, and --

MR. SUGGS: I understand your ruling, Your Honor. If that is the case, would the Court be open to our on rebuttal offering the later clamp studies as notice?

MR. LEHNER: They may already be in.

MR. SUGGS: We had them marked as

identification --

THE COURT: I don't know if there's a relevance question about time with those, but you certainly can come in --

MR. SUGGS: Our cause of action precedes a day -- one of the studies was 2007. I believe there was another one that was 2006.

THE COURT: We can look at it with respect to the time of the label.

I'll admit 2175.

(End of bench discussion.)

THE COURT: 2175 is admitted, and objections are preserved.

MR. SUGGS: Same ruling with 2176.

THE COURT: Same ruling as to 2176, that must be admitted with the objections preserved.

MR. LEHNER: So Your Honor, I will move 2175 and 2176, which is the Evaluation of Insulin Sensitivity in Healthy Volunteers Treated with Olanzapine, Risperidone and Placebo, published in The Journal of Clinical Endocrinology and Metabolism.

THE COURT: I think I just admitted 2175 and 2176 with objections preserved, and

those documents may be published.

MR. LEHNER: Thank you very much.

THE COURT: Who is your next witness, Mr. Lehner?

MR. KANTRA: Your Honor, Eli Lilly and Company would call Dr. Robert Baker to the stand.

THE COURT: Mr. Kantra, you'll be examining Dr. Baker?

MR. KANTRA: I will be.

THE COURT: Dr. Baker, if you'll please remain standing and we'll get you sworn.

(Dr. Robert Baker sworn.)

THE CLERK: For the record, sir, please state your full name, spelling your first and last name.

THE WITNESS: It is Robert Baker, R-o-b-e-r-t, B-a-k-e-r.

THE CLERK: Thank you, sir.

THE COURT: Please be seated.

Mr. Kantra.

DIRECT EXAMINATION

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

A. Hi.

Q. Where do you work?
A. I work at Eli Lilly and Company in Indianapolis.
Q. How long have you been working there?
A. For eight years.
Q. What type of work do you do?
A. I'm a physician and I'm currently supervising the other physicians who oversee the safety of Lilly's products.
Q. Is that all of Lilly's products?
A. Yes, all of our products, all therapeutic areas.
Q. Does that include Zyprexa as well?
A. It does.
Q. How many safety physicians do you supervise?
A. About 25.
Q. During the time that you've been working at Lilly, was there a time where your responsibilities focused primarily on Zyprexa?
A. Yes, that's what I did when I started at the company.
Q. And can you describe the nature of your work on Zyprexa when you first joined the company?

A. Yes. I was responsible for working on Zyprexa's use in bipolar mania and particularly in helping to understand and communicate about that with physicians in the United States.
Q. And when you say communicating with physicians, can you say a little bit more about the nature of your job responsibility as it involved talking with physicians outside the company?
A. Yes. I was employed in the U.S. medical part of Lilly, and our job there was coming in as people who had practiced as physicians in the U.S. to understand about practice and the sort of questions and needs that doctors had, and couple that with expertise that we got from the company about our drugs, in order to be able to answer directly sometimes questions for them and also work with our marketing department and other groups who were preparing information to communicate with doctors.
Q. And as part of your responsibilities at Lilly when you joined, were you responsible for understanding and having a general overall appreciation for how Zyprexa was developed as a drug before FDA approved it in 1996?

A. Yes.
Q. I understand that you were promoted to medical director of the neuroscience group in 2005; is that correct?
A. Yes, that's right.
Q. And in that capacity, did you still have responsibility for Zyprexa?
A. Yes. That, along with the other neuroscience psychiatry products that Lilly had in the U.S.
Q. And then when did you take your current position in the safety group at Lilly?
A. I was promoted into this job toward the end of 2006.
Q. And in your work on behalf of Eli Lilly and Company, did part of your -- do part of your responsibilities include reading and understanding the literature as it relates to Zyprexa and diabetes?
A. Yes.
Q. And is part of the reason for your understanding the need for your understanding in that regard so that you can communicate with physicians outside the company with respect to Lilly's understanding of those studies and

articles?
A. That's part of it, yes.
Q. So, before we talk more about your work specifically on Zyprexa, I want to help the jury understand what you did before you came to Lilly.
And so tell us where you graduated from medical school.
A. Northwestern University in Chicago.
Q. And you had a year of general medicine internship after that; is that right?
A. Yes, at the University of Pittsburgh.
Q. And that was followed by a residency in psychiatry?
A. Yes.
Q. And where did you do that residency in psychiatry?
A. That was also at the University of Pittsburgh.
Q. Do you have a specialty that you have developed and been board certified in?
A. Yes. That's psychiatry.
Q. And why did you want to become a psychiatrist?
A. Well, I -- I was planning to be a psychiatrist when I came to medical school. My

father was a psychiatrist.
And as I grew up, he'd take me sometimes along with him to the hospital or to the office, and I'd see at church or other places people would talk to him about how he helped them or the family members. So I think that that's what made me interested in it. And then once I got to medical school, I wavered a little bit. But once I started seeing patients with mental illness, that's what I thought my calling was.
Q. When you finished your training, your residency in psychiatry, where did you go to work?
A. My first job out of training was for the Commonwealth of Pennsylvania. I worked at the State hospital for Pennsylvania for the first three years after I graduated.
Q. Can you describe for the jury the type of patients you treated at the State hospital in Pennsylvania?
A. Sure. In Pennsylvania, the State hospital would be for people who are very sick or who weren't getting better in other settings. So, when I was working there, people wouldn't even come into our hospital unless they'd been in

some other hospital for a few weeks and weren't getting better. So they tended to be people who were quite ill, and probably the majority of them were probably people with schizophrenia, but other disorders as well.
Q. Did those other disorders include bipolar disorder?
A. Yes.
Q. While you working at this State hospital in Pennsylvania, did you have an opportunity to participate in clinical trials of antipsychotic medications?
A. Yes.
Q. And did those clinical trials involve patients with schizophrenia?
A. Yes.
Q. Did the drugs that you were evaluating in those clinical trials include all of the approved atypical antipsychotics at the time you joined Lilly?
A. Yes, all of those, plus another one, Sertindole, that had never been approved in the United States.
Q. And that would have included, then, I assume from your answer that you did work on

clinical trials involving Zyprexa?
A. Yes.
Q. And that would have been one of the trials that actually supported the approval by FDA?
A. Yes.
Q. In your work on clinical trials, did you participate in clinical trials that occurred during different phases of development?
A. Yes.
Q. So you participated in phase 2 and phase 3 clinical trials; is that right?
A. Phase 3 and phase 4.
Q. After you finished working or while you were working at the State hospital in Pennsylvania, did you also do work at an institution called the Western Psychiatric Institute?
A. Yes. Western Psychiatric Institute was the hospital or the setting of the University of Pittsburgh Psychiatry Department. So after my first three years working in the State hospital, I moved into a faculty job at the University of Pittsburgh, although in that role continued to work for the next six or seven years still doing

some work at the same State hospital.
Q. And did you work -- did you develop a schizophrenia research program during the time you were affiliated with the State hospital?
A. That's right. The work I was doing at the State hospital was at a research unit that was jointly sponsored by the State of Pennsylvania and by the University of Pittsburgh, and I directed that.
Q. After you finished your work both at the State hospital and WPI, you moved on then to the University of Mississippi; is that right?
A. Yes.
Q. And can you tell the jury what you did while you were at the University of Mississippi Medical School?
A. I was there for three years and I would supervise the university's inpatient psychiatry facilities and also their psychopharmacology research that was ongoing.
Q. And you were at the University of Mississippi until when?
A. Until -- until 1999.
Q. So when you joined Lilly, you had been a practicing psychiatrist for about 12 years; is

that right?
A. Yes. I finished my training in '86, so 13 years.
Q. In addition to the responsibilities you've already described with respect to Zyprexa and then your safety work at Lilly, have you also been involved in committee work at Lilly that has watched over the movement of new products that are in development from the preclinical phase, before they go into humans into the clinical trial phase?
A. Yes.
Q. Okay. And are you generally familiar, then, with the process by which a drug moves from discovery to preclinical to clinical trials?
A. Yes.
Q. Okay.
And can you tell the jury, then, just briefly, what it is that happens after a drug is identified for testing? What is the first kind of testing that happens with respect to a new compound?
A. Sure. After a potential drug, a drug that we're hoping could be useful for patients is synthesized, all the first testing takes place in

a laboratory setting, more or less test tubes using models that look like they may be predictive of a therapeutic benefit, models that look like they might screen for side effects. All of that testing takes place first.
Q. Then does it move into animals after that?
A. Right. Actually most of them don't pass that first stage of testing but those that look like they have enough benefit and enough safety to be promising as drugs for people, would next be tested in animals, usually starts with mice or rats. And if it's successfully passing through that, then we move to other animal species.
Q. And what is the general period of time over which these kinds of preclinical studies take place?
A. Well, it varies quite a bit. I'd say the minimum is several years. The average is probably three or four years.
Q. And what -- how does testing actually then begin in humans after this preclinical phase is finished? What does a company need to do at that point?
A. Well, a couple of things. Firstly,

before we test the medicine in humans, we would -- we would make contact and talk with the regulatory groups that are overseeing the use. So, if we wanted to test it in the United States or if we were planning for its use eventually in the United States, we file an application. It's called an IND, which is investigational new drug application. That goes into the FDA and we tell them what we've known from testing so far, what our plans are with it. And if they don't object to it, then we move to the first human dose of the medicine.
That's an important -- very important time because we really need -- we've done all the screening through animals that's focused mostly on the safety. But before we put it into patients or before it goes into many people, we start testing the safety. That's typically in normal volunteers and the first human dose would be a very low dose, it would be a single dose.
You watch what happens and if that goes well, you build up to higher doses and you give it over a longer period of time, scrutinizing very much in particular what safety

findings, what laboratory findings might be caused by the medicine.
Q. When you say laboratory findings, would that include things like measurements of blood sugar levels?
A. Sure.
Q. This process that you described with healthy individuals participating in clinical trials of the drug, is that known as the first phase of clinical trials?
A. Yes.
Q. And are there two other phases that then follow after that?
A. Right.
Q. Can you tell the jury -- before a drug is approved for market. Can you tell the jury what those two phases consist of?
A. So after this first phase, if it looks like people are tolerating it, if our screening and that is again promising that it's going to be safe enough, then we go to what is called Phase 2. Phase 2 is where for sure you'd start testing it in patients who have the illness that you're thinking the drug may be effective for.
So in that phase what you're

testing for is can you get a signal that the medicine is going to work. Are you confirming your hypothesis or the idea that it's going to work? You're looking, can people tolerate it? How safe is it for them? Is it safe enough to go into wider-scale testing? And you're trying to get some sense of what's the right dose that you're going to use in your more definitive trials.

And assuming all that works -- many medicines don't make it through these stages, but assuming that they do, then the next phase is Phase 3. That's where you do the big clinical trials in order to test the questions that the FDA is going to want to look at for the medicine coming onto the market. Is there enough evidence that the drug works? Is there enough evidence that it's safe in order for them to consider approving it for use.

Q. How many patients would typically be in one of these large Phase 3 clinical trials?

A. Well, that varies, but in Phase 2 you would might be starting with hundreds of patients whereas Phase 3 you're more likely to have 1,000 or more.

Q. After the company finishes its studying of various patients with the illness that's the subject of the trials and it wants to get approval from FDA, what does it do to obtain that approval?

A. It's a submission. We refer to it as submission but it's called NDA, new drug application. The company has to pull together all the information it has from all these phases of the trial as well as the company's conclusions from that information, and the company's proposal for what the drug label might look like, and sends that information into the FDA, which then starts reviewing it and considering the approval.

Q. Can you give the jury a sense of when you say the information is submitted as part of the NDA, what's the volume of information that's given to the FDA?

A. It's a lot. When this was in paper copies, it's boxes and boxes, and they'd send a tractor-trailer to carry it from Lilly to the company.

Q. What is your understanding once an NDA goes into the FDA of how FDA goes about reviewing the new drug application?

A. My experience has been that the FDA has scientists that more or less parallel what we would have at the pharmaceutical company. So they will have people that are experts in the drug's chemical formulation and things like how it would be manufactured and how stable the pill is. They have experts in toxicology, the animal results.

They'd have physicians who are expert in safety. Physicians who are expert in the therapeutic area that -- the type of illness that you're proposing it for. They have statisticians who are very good at the analysis and the whole team works together and they give recommendations to the -- to the director who has overall responsibility for deciding about approval and labeling.

MR. KANTRA: Can we bring up TG021? And for the jury's benefit, can we --

MR. SUGGS: Your Honor, I'm going to object to this. I sent an e-mail -- can we approach the bench, please?

THE COURT: Sure.

(Bench discussion.)

MR. SUGGS: I sent an e-mail to Mr.

Lehner last night telling him I was going to object to this. This man is a fact witness. The last date shown on here is 1996. He didn't start working with the company until 1999. He's got no personal knowledge of any of these things.

MR. KANTRA: As you heard through his testimony, he's been part of a committee at Lilly which oversees the drug development process and as will become evident in his testimony later as part of his responsibilities he went back and understood the filings and the development over time, and he's prepared to testify about that.

THE COURT: Subject to you tying up that he went back and reviewed the filings over time and that he would then be familiarized himself with this document, I'll allow the testimony.

MR. KANTRA: Thank you, Your Honor.

(End of bench discussion.)

Q. (BY MR. KANTRA) Dr. Baker, just one question before we go and look at this particular slide.

In your role, when you joined Lilly and in your time at Lilly, have you been privy to and do you understand the milestones that we've

just described generally as they pertain specifically to olanzapine?
A. Yes.
Q. Okay.
MR. KANTRA: With that, I would bring up TG021.
Q. (BY MR. KANTRA) And if we go all the way to the left-hand side of that screen, can you -- can you tell the jury when olanzapine was first synthesized --
THE COURT: Again, you've used -- I just want to be clear, you used TG021 --
MR. KANTRA: Sorry, Your Honor. That's just an internal reference for our purposes. It's a slide that Dr. Baker helped to prepare.
THE COURT: So this isn't going to be offered as an exhibit?
MR. KANTRA: No.
A. Your question was when olanzapine was first synthesized. More than 25 years ago, 1982.
Q. (BY MR. KANTRA) If we follow the timeline, the phase, what period of time were those animal studies and other preclinical studies conducted?

A. About four years.
Q. And then when would Lilly have sought permission from FDA to begin testing in humans in clinical trials?
A. 1986.
Q. Over what period of time did Lilly conduct clinical trials of Zyprexa before seeking approval from FDA?
A. Nine years.
Q. And in how many thousands of patients did Lilly conduct these trials on before submitting it to FDA?
A. It was a little over 3,000 people.
Q. And at what point did Lilly make this new drug application, this NDA submission that you've described?
A. Well, as you see above 1995 on the slide, it was September of 1995.
Q. And that submission to FDA in September of 1995 would have included the clinical trial data including things like blood sugar levels from patients who participated in those trials?
A. Sure. Just like I mentioned in general, all that information was sent in.
Q. And how long did FDA review the new drug

application before approving it?
A. They spent about a year reviewing it.
Q. And then approval came in September of 1996?
A. Right.
MR. KANTRA: Can we bring up AK8905?
MR. SUGGS: A copy for me, Counsel?
MR. KANTRA: That's your exhibit. We can get it if you want.
MR. SUGGS: I still need a copy of it.
MR. KANTRA: That's perfectly fine.
Nick, we're going to focus down on that bottom part of the screen there.
Q. (BY MR. KANTRA) Dr. Baker, if you take a look at this e-mail here, first thing you notice that the date on this is August 31st of 2000; is that right?
A. Yes.
Q. At about the time that you began to focus on diabetes-related issues and Zyprexa?
A. Exactly.
Q. And you are one of the people -- in fact, I think you're the first person to whom

this e-mail is addressed; is that right?
A. Yes.
Q. Let's look down at the bottom of this e-mail where it presents what's called a proposed plan. And, in particular, if you'd look at the second line of that, it talks about what I refer to as glucose issues.
You see that?
A. I do.
Q. And, in particular, it says Baker No. 1 after that, right?
A. Yes.
Q. Okay. Does that mean that you were the only physician at Lilly who was examining issues relating to diabetes and Zyprexa?
A. No, not at all.
Q. So, who else at Lilly from a physician perspective would have been examining that issue as of 2000?
A. Well, firstly, these folks in these e-mails were the other psychiatrists. There were four of us working for Lilly in the U.S. doing the job that I had mentioned earlier. Understanding about our product, communicating with physicians in the U.S. All of us had the

job of understanding the side effects, the adverse event profile, the safety profile of the drug, generally.

But then I became the one that was most focused on getting all the details and helping to educate and talk about that with my colleagues in the U.S. There would have been other physicians playing that same role working for Lilly in the other countries where the medicine was on the market in order to help answer questions for their doctors.

And the way that I did my role principally was talking to all the many physicians and scientists in the company who were working on the safety of Zyprexa. So, in the core group, what we called the product team, there were psychiatrists. There was an endocrinologist, safety physicians who were focused on the safety of Zyprexa. There was a pharmacovigilance department that would look at adverse events, things that we heard from doctors or patients and record those for Zyprexa. There were other endocrinologists, a number of endocrinologists in the company that were helping look at this particular question related to

glucose.

And then in addition to that, there were all the scientists and physicians who had worked on the development that we had talked about previously up to that point.

Q. When you talk about the psychiatrists on the product team that you would have been interacting with, would that have included Dr. Cavazzoni and Beasley?

A. Yes.

Q. Before your work --

MR. KANTRA: Go ahead and take that down.

Q. (BY MR. KANTRA) Before you focused your efforts on the diabetes issues, had Lilly evaluated the issue of weight and diabetes before August of 2000?

A. Yes.

Q. And can you tell the jury some of the kinds of things that would have included that kind of information that would have been submitted to FDA?

A. I'm sorry. Could you clarify the question?

Q. Sure. Before August of 2000, were there

submissions that Lilly would have made to the FDA that would have focused on glucose and weight gain?

A. Yes. Sure. That would have been part of -- information on that would have been part of the initial submission that came before the approval and other submissions that had been made after that, but there was also a submission that was focused just on this topic of glucose that had taken place in July of 2000. In fact, it was -- reading through that was one of the first things that I did when I took on my responsibilities in August.

Q. In addition to the NDA application and this reading of this special submission that you've just described, would there have been information in individual study reports about clinical trials that the company was conducting that would have been submitted to FDA?

A. Yes. As we finish each of our clinical patient research trials, we submit that information, a study report to the FDA. So that would have come with each trial over time.

Q. And as part of those individual study clinical reports would there have been

information about blood sugar levels in those as well?

A. There's a review of all the safety and laboratory findings, so that would include the blood sugar results, yes.

Q. During this trial, we've heard reference to the fact that the FDA was engaged in -- in ongoing analysis beginning in 2000 of weight gain and hyperglycemia as it related to atypical antipsychotics like Zyprexa.

Are you familiar with that?

A. Yes.

Q. Okay. When did Lilly first become aware of FDA's interest in this area?

A. FDA had communicated that to us in May of 2000.

MR. KANTRA: Can we bring up what's been marked as EL2581?

Q. (BY MR. KANTRA) I want to direct your attention to the top of this letter and ask you what the date is there in the upper right-hand corner?

A. May 1st, 2000.

Q. Do you recognize this letter?

A. Yes.

Q. And it's the letter in which FDA requests that the manufacturers of atypical antipsychotics provide comprehensive information on hyperglycemia to the FDA; is that right?
A. Yes.
MR. KANTRA: Nick, if we could go down to look at the paragraph that begins with "to assist."
Q. (BY MR. KANTRA) And that sentence there says: To assist us in fully evaluating the possibility that atypical antipsychotics may produce disturbances in glucose metabolism, we are requesting that the sponsors of these agents provide us with more extensive safety information.
How did Lilly understand this request from FDA in terms of what they were seeking?
MR. SUGGS: Objection, Your Honor. Lack of foundation as to what Lilly understood.
THE COURT: Can you repeat the question again?
MR. KANTRA: Yes, I said: In response to this request from FDA, what was Lilly's understanding of the request that was

being made of the company.
THE COURT: I'll overrule the objection.
MR. KANTRA: Thank you.
THE WITNESS: We understood that they were asking us to help them to assist them as they were evaluating this question about hyperglycemia and diabetes and to assist them through providing information about it.
Q. (BY MR. KANTRA) And was this request directed only at Lilly?
A. My understanding is that it went to all the manufacturers of atypical antipsychotics, so that would have included the manufacturers of Clozaril and -- clozapine, risperidone, quetiapine, as well as olanzapine.
Q. Did Lilly ultimately respond --
MR. KANTRA: Go ahead and take that down.
Q. (BY MR. KANTRA) Did Lilly ultimately respond to this request from FDA?
A. Yes. We provided a number of submissions in response to this request.
Q. When did it first respond to FDA's request?

A. The first was the July, 2000 submission that I mentioned a couple of minutes ago.
MR. KANTRA: Can we bring up EL2043?
THE WITNESS: Sorry.
MR. KANTRA: May I approach?
THE COURT: You may. And Mr. Kantra, feel free to move around the courtroom as you need to.
Q. (BY MR. KANTRA) Dr. Baker, I put this before you. Ask you to take a look at the first volume in particular. Tell me whether you recognize this.
THE COURT: Before we get into this, is this a good spot for a break?
MR. KANTRA: That would be great.
THE COURT: Ladies and gentlemen of the jury, we'll take our second break of the day, and we'll try to keep it to 15 minutes.
(Jury out.)
THE COURT: We'll be off record.
(Break.)
(Jury in.)
THE COURT: Please be seated.
We're back on the record and all

members of the jury are present.
Mr. Kantra.
MR. KANTRA: Thank you.
Q. (BY MR. KANTRA) Dr. Baker, I think we had left off, I had shown you what has previously been marked as EL2043?
A. Yes.
Q. And do you recognize that document?
A. Yes.
Q. And is that Lilly's July, 2000 response to FDA's request in May for information on Zyprexa and hyperglycemia?
A. It is.
MR. KANTRA: If you could bring up --
Q. (BY MR. KANTRA) Actually before we do that, let me ask you, Dr. Baker: Did you help prepare slides that would help the jury understand the submissions that Lilly made in response to the May, 2000 letter?
A. Yes.
MR. KANTRA: Okay. Can we bring up TG104? 5?
Q. (BY MR. KANTRA) And if we look up on this slide here, does this reflect a summary of

the information that was included in the response to the May, 2000 letter?
A. It does.
Q. Okay. And if we begin up at the top with respect to the literature that was sent in to FDA, about how many pieces of -- how many articles were sent to the FDA?
A. It was over 100. Lilly had reviewed the literature going back -- well, going back for decades looking for information about glucose abnormalities during treatment with antipsychotic medicines or associated with schizophrenia.
Q. And I see in the second bullet point up there, it refers to historical animal study data and clinical studies?
A. Yes. We've reviewed for the FDA the information that had come during the course of the drug's development that we had talked about earlier through the animal studies, Phase 1, 2, and 3, as well as studies that had been completed after the drug had been approved.
Q. And that next to last bullet point up there refers to a new analysis of clinical trial data; is that right?
A. Yes.

Q. And, roughly, there was a number at the end of that bullet point. What does that represent?
A. 6,374 people were in this analysis. So this made it a very important analysis. This was the biggest data set that was existing at that time looking at antipsychotic medicine, and this was a review that was done pulling all that together to look specifically at the blood glucose measures that had been drawn during the study in order to answer the question of how many people were having elevations from the beginning of the study to sometime in the course of the study that would suggest -- that might suggest that they were having hyperglycemia or diabetes.
Q. And then the last bullet point up there refers to a review of spontaneous adverse event reports after 4 million patient exposures.
Can you remind the jury what spontaneous adverse event reports are?
A. Yes. That's an important part of what we do in the safety division that I'm in, which is that spontaneous report is different than a report that happens in a clinical trial. This is information that we get that is not from our

studies, but comes in because a doctor communicates to us, say, through a sales rep or a pharmacist or a patient if they called our 800 number and said, hey, I'm having this discomfort.
We take that information and it's called a spontaneous adverse report, and we have to clarify the information and that's all reported -- we analyze it ourselves, but we report it also to the FDA.
Q. Did this submission also include copies of submissions that had been made to regulatory authorities outside the United States?
A. It summarized those.
Q. Would that have included information regarding a change to the European label regarding diabetes in 1999?
A. Yes.
Q. You mentioned -- turning back to that new analysis of clinical trial data, can you tell us what the two primary conclusions were from that analysis?
A. Yes. Two -- two important conclusions. One was that in looking at -- again, this was an analysis that was looking for the proportion of patients that developed hyperglycemia or

diabetes, presumed hyperglycemia or diabetes based on blood sugar changes in the course of their treatment. And we looked at olanzapine versus the other comparisons that were in this database. Placebo, risperidone, haloperidol.
What we found is that there was no difference in the rate of crossing those thresholds between olanzapine and the other treatments. That was one finding.
But the other important finding is that then they looked back taking all those patients who had crossed the thresholds and looked at the question of, hey, we know in the general population that there's some things that would make you more at risk of hyperglycemia, like older age or if you're obese when you come in, and we looked for did those sorts of risk factors hold up to indicate who's likely to have those blood sugar increases in the course of treatment. And indeed, not surprisingly, that's what we found.
Q. Did Lilly reach any conclusions as to whether labeling changes were made based on this July, 2000 submission?
A. Yes. Lilly looked at that question and

stated to the FDA that they felt that no labeling change was needed to what was already in the label at that time.

Q. And moving on to the -- the second submission that Lilly made in regards to FDA's response, I want to direct your attention to May of 2001 and ask you if that was the date or the month in which Lilly made another submission to FDA.

A. Sorry, could you repeat that?

Q. Sure. The second submission that Lilly made in response to the FDA's request was in May of 2001; is that right?

A. Yes.

MR. KANTRA: Can we bring up EL2127?

Q. (BY MR. KANTRA) Are you familiar with this submission, Dr. Baker?

A. Yes.

MR. KANTRA: And can we bring up, Nick, TG1071?

Q. (BY MR. KANTRA) And, Dr. Baker, using these slides that you've helped to prepare, can you describe for the jury the information that was contained in this submission to FDA?

A. Yes. This included new information that we had since the submission the year before. And so on this slide what's mentioned is it included the first two epidemiology studies that Lilly had done looking at this question about diabetes occurring in people taking antipsychotic medication.

Q. And let's take -- let's take the studies one at a time.

With respect to the first study, the GPRD study, what were the findings with respect to whether or not the risk of diabetes was increased over the general population?

A. This study was done in the United Kingdom, and it confirmed that people on antipsychotic medicine had occurrence of more diabetes during their treatment than people that weren't on antipsychotic medicine. This is comparing the antipsychotics to people that weren't taking antipsychotics.

Q. Was that a surprising finding to you?

A. No. This, again, confirms something that we had seen pretty strongly in the literature review that was sent to the FDA the year before, which is that people with

schizophrenia, for whatever reasons, are having higher rates of diabetes, significantly higher than people who didn't have schizophrenia.

Q. And was there a comparison that looked at the question of whether there was more diabetes observed in patients who were treated with atypical antipsychotics than the first-generation agents?

A. That's right. In this case it looks significantly more common on atypical antipsychotics than on the older typical, or first-generation, as you've called them.

Q. Was there enough information in that study to be able to make an assessment of the risk with respect to Zyprexa?

A. No. At that time Zyprexa was relatively newly available in the U.K. So about 75 percent of those patients were on risperidone and not olanzapine. There wasn't enough of a judgment to make a comparison of how it stacked up to other treatments.

Q. Let's look to the other study that Lilly submitted in May, and that's the AdvancePCS study. That study found that there was an increased risk as compared to the general

population?

A. Yeah, that's been consistent and it was consistent again here.

Q. And with respect to atypicals against the first-generation agents, this study found in contrast to the first study that there was no significant difference, is that right?

A. That's right.

Q. What about the comparison that looked at Zyprexa in this study against another atypical antipsychotic, risperidone?

A. Yes. This one was much bigger study than the U.K. study. This is a U.S. study, and the two atypical antipsychotics that were mostly in this one were olanzapine and risperidone. So we could make that comparison and we found that the rates of diabetes as measured in this study were no different between those two drugs.

Q. And were these published?

A. Yes.

MR. KANTRA: Could we have EL2013 and EL3385?

Q. (BY MR. KANTRA) Let's look first at EL2013.

Are you familiar with that article?

A. Yes.
Q. Okay. And does that represent the GPRD analysis that -- that Lilly did that you've just described?
A. That's right.
MR. KANTRA: Okay. And can we bring up -- yeah, bring up EL3385. Can we pull that up just a little bit?
Q. (BY MR. KANTRA) And does that show the AdvancePCS study that Lilly conducted and that you've described as well?
A. Yes.
Q. And these articles appeared and were published in peer-reviewed journals; is that correct?
A. Yes.
MR. KANTRA: Nick, if we could go back a minute, or not go back, but can we go to TG1072?
Q. (BY MR. KANTRA) And in addition to these two epidemiology studies that you've just described, did Lilly also take a look -- another look at the clinical trial data regarding hyperglycemia and diabetes and Zyprexa?
A. Yes. That's what's referred here as the

Allison clinical trial analysis. Dr. David Allison, who was somebody outside of Lilly working with us on -- on this question, helped Lilly in this analysis.
Q. And the study looked at glucose elevations in two different ways in this study; is that right?
A. That's right.
Q. And those two different ways -- can you describe the two different ways that the company did that?
A. Yes. I had mentioned in the last analysis, the submission of the year before, that what Lilly had looked at was comparing blood glucoses when the patient started treatment to what happened in the course of treatment to do -- we called a categorical analysis, to see what percentage of patients go above a certain level. This one repeated an analysis of that and looked at more different categories. Looked at it more ways.
Q. Can I stop you there.
When you say categories, categories that would be indicative of hyperglycemia or diabetes?

A. Exactly.
Q. Okay. What was the other way they looked at it?
A. The other way we looked at it was looking at all patients. What's the average change that they had from before they start on the treatment to when they finish treatment. So then you subtract the glucose at the end from what it is at the beginning, that's what you do for each individual, and you average it so it looks across everybody.
Q. Does this second analysis, the average change analysis that you just described, tell you whether patients developed diabetes or not?
A. No, that just tells you the average change across the whole population. It can't tell you for what percentage of people was that an abnormal change or one significant for disease versus what percentage is not an important change.
Q. Let's start with that second analysis that you've just described and look at the average changes.
What did that show?
A. Well, it showed that in olanzapine there

did tend to be increase from the time people started treatment to the time they finished treatment on average. It tended to go up some. Also, what we were doing that is comparing that to what we found on other treatment groups, to placebo, to haloperidol, to risperidone, to clozapine.
In one case there wasn't a difference between those, that was risperidone, the other atypical antipsychotic. The change from beginning to end was not different on average between olanzapine and risperidone. But compared to placebo or compared to haloperidol, there was a greater increase in the average glucose in patients on olanzapine compared to those other treatments. And compared to clozapine, there was significantly less increase than had been seen with clozapine.
Q. Why don't we turn then to the other analysis that you described that looked at potential cases of hyperglycemia or diabetes and can you tell us what were the findings in that analysis or that part of the analysis.
A. Yeah. Here's again one that looks at the rate of whether individual patients having an

increase varies from one treatment to another. This confirmed the previous analysis that there was no difference at any of the comparisons at any of the thresholds.

Q. Did Dr. Allison prepare a manuscript reporting the results of this study?

A. Yes.

MR. KANTRA: And if we can go back to EL2127, I believe -- yeah. And can you go to the last document there, which is going to be Tab 3?

Q. (BY MR. KANTRA) And Dr. Allison prepared a manuscript that was ultimately submitted for publication; is that right?

A. Yes. It was submitted.

MR. KANTRA: And go one more in, Nick, if you could. And can you blow up the title and the authors?

Q. (BY MR. KANTRA) Does that represent the manuscript that was prepared by Dr. Allison?

A. Yes.

Q. Why don't we turn to the third submission that Lilly made, and that was in October of 2002; is that right?

A. Yes.

Q. Okay.

MR. KANTRA: Can we bring up EL2032?

THE COURT: Did you say 2302?

MR. KANTRA: Sorry. 2032.

THE COURT: 2032.

Q. (BY MR. KANTRA) Do you recognize this submission?

A. I do.

Q. And was this actually the third submission that Lilly made to FDA?

A. Yes. This was the third.

Q. And what was -- what was the new information that Lilly was sharing with FDA in this particular submission?

A. There were a number of things. I prepared -- helped prepare a slide on that.

MR. KANTRA: Why don't we bring up TG1073.

Q. (BY MR. KANTRA) Up at the top there's a reference to literature studies; is that right?

A. Yes.

Q. And what did the company's survey of the literature show?

A. We reviewed and provided the things that

were new since our 2000 submission, and among those were a number of published pharmacoepidemiology studies. They were consistent on some points, but some variation from one to another in terms of whether they find differences from one treatment to another. That was inconsistent.

Q. And then there was -- there was a study which is identified on the slide as a TED clinical trial analysis.

What does TED stand for?

A. TED is an acronym, treatment-emergent diabetes, TED.

Q. And what did this study evaluate?

A. This, I think, was one of the most useful analyses that was done on Lilly's clinical trial, at least useful from the standpoint of helping clinicians. Because this one, again, looked at some of the questions that we had looked at in the past such as comparisons of apparent diabetes occurring during treatment on one drug versus another.

But this went beyond that to really emphasize who is most likely to get that diabetes happening in the course of treatment to help

doctors with giving them some notion among all these patients you have with schizophrenia, who are the ones that would be most at risk.

Q. This was an analysis that was in approximately 5,000 patients; is that right?

A. Right. Again, this was really the largest data set that was available at that time.

Q. And more than 20 clinical trials?

A. Yes.

Q. And what did this study tell us, then, in terms of what risk factors were most significantly associated with the development of treatment-emergent diabetes?

A. Well, this one confirmed what we had seen before, that which treatment was chosen was not a predictor. It wasn't a risk factor for the likelihood of having diabetes in the course of treatment. This one --

Q. When you say treatment, that would be whether a patient was assigned to Zyprexa or another drug?

A. That's right.

Q. Okay.

A. Or Zyprexa versus placebo as well.

Q. Okay.

A. But this one also, as I mentioned, looked at risk factors and among those, the most powerful was the blood glucose measurement before the person gets the medicine. In fact, what this found is that people who had borderline, somewhat elevation of their glucose when they started, not at a diabetes level, but elevated had more than ten times as much likelihood, more than ten times of getting diabetes during their treatment than if their blood glucose had been normal before they went onto the treatment.

Q. And was there any other factor that was also among the most significant risk factors for predicting diabetes?

A. Well, yes, we looked -- we looked beyond that -- that was a known risk factor. We looked the things that the ADA or general knowledge on diabetes would have told you are risk factors, like if a person is older or has hypertension or if they're obese. And if you look at those, they, again, hold up on this analysis.

And if a person has two or more of those risk factors versus somebody that has one or less, if you have two or more versus one or less, you're more than five times as likely to

get diabetes in the course of treatment. So this was important information for doctors.

Q. And was there an analysis of the extent to which weight gain was a risk factor for diabetes?

A. That's right. And it also found that if you had weight gain in the course of treatment, that that was a risk factor for being more likely to have diabetes in the course of treatment than you didn't have weight gain. A much, much weaker risk factor than the others we described, but it was a significant -- it was a significant risk factor.

Q. In addition to sharing this information with the FDA in October of 2002, was the information from this TED study that you've just described published in the peer-reviewed literature?

A. It was.

MR. KANTRA: Can we bring up EL3801?

Q. (BY MR. KANTRA) Dr. Baker, do you recognize this article?

A. Yes. This is the TED study, treatment-emergent diabetes.

Q. And this is titled A Retrospective Analysis of Risk Factors in Patients with Treatment-emergent Diabetes During Clinical Trials of Antipsychotic Medications and that's published in the British Journal of Psychiatry?

A. Yes.

Q. And that was in 2004 when that was published?

A. I'm thinking it's 2005.

Q. Okay.

MR. KANTRA: Let's look at TG1074 if we can for a minute.

Q. (BY MR. KANTRA) We heard Dr. Inzucchi testify earlier about some mechanistic clamp studies that found no direct effects on either the pancreas or on insulin resistance, and I wanted to ask you if you're familiar with those studies.

A. Yes.

Q. And were those studies disclosed to FDA in October of 2002?

A. Yes. Lilly had conducted two of them, and the results were in this 2002 submission.

Q. And those were also published in a peer-reviewed literature as well?

A. Right.

Q. The next --

MR. KANTRA: We're okay with that now, Nick, you can take that down.

Q. (BY MR. KANTRA) The next submission, the fourth submission that Lilly made to FDA regarding whether or not there were -- the important information with regard to Zyprexa and diabetes was in March, 2003; is that right?

A. Yes.

MR. KANTRA: Can we bring up TG1075 -- actually before -- before we do that, can we bring up EL2033?

Q. (BY MR. KANTRA) And does this -- let me give you this analysis as well.

Do you recognize this submission?

A. I do.

Q. And this is the submission that went into FDA in March of 2003?

A. Yes.

Q. This was --

MR. KANTRA: If we can bring up TG1075.

Q. (BY MR. KANTRA) And this reflected Lilly's analysis of spontaneous adverse event

reports after more than 9 million patient exposures; is that right?
A. Right.
Q. And it looked at spontaneous adverse event reports, and what did it conclude?
A. It reviewed -- Lilly reviewed these and found that there was no conclusion that could be drawn from these data regarding causation of diabetes.
Q. From these spontaneous adverse event reports?
A. From these, yes, sir.
Q. Let me go to a submission that Lilly made three months later in June of 2003. That would be the fifth submission that was made in this instance.
MR. KANTRA: And can we bring up EL2036?
Q. (BY MR. KANTRA) And do you recognize this submission?
A. Yes.
Q. Okay. This is the June submission to FDA and further response to its request in 2000?
A. That's right.
MR. KANTRA: Let's bring up TG1076.

Q. (BY MR. KANTRA) And this information included, again, more new clinical trial analyses that Lilly had conducted.
Can you describe these analyses for the jury?
A. Yes. Since the previous submission Lilly had completed two new analyses. The first one on the list is -- it's like the previous treatment-emergent diabetes submission, but whereas that one was looking at clinical trials for patients with schizophrenia, this was taking the same analyses in patient who had bipolar disorder.
Q. And what did it find in terms of whether or not the same risk factors were most predictive of developing diabetes?
A. This one was very consistent with the other one. It did not find that whether they were on olanzapine or the alternative treatment, placebo or other treatments for mania, it did not find any difference in likelihood of developing diabetes based on that. But, again, this held up that the nonrisk factors that they may have at baseline such as obesity, such as advanced age, were risk factors.

And again, by far the most powerful predictor was the blood sugar before they started treatment. If that was high, that was an important risk.
Q. There's a second study that's described up there as the PED study.
What did that represent?
A. Yes, PED is preexisting diabetes. So this was looking at patients who had already diabetes when they started treatment. We wouldn't have looked at those in the other studies of treatment-emergent diabetes. So this trial went back to those patients and looked at what happened to them when they got medicine.
Q. And looked at the question of whether their diabetes got worse over time? Is that right?
A. Exactly.
Q. And what did they find -- what did Lilly find in regard to this study?
A. Well, a couple things. One, as you'd expect in diabetes, that it's different from patient to patient. Some people are worsening; some are getting better in the course of treatment. But on average across all the

treatments, there's a little bit of worsening over time.
And then the other thing it found was, again, the comparison, is this different if you're on olanzapine than other treatments. In this case it was haloperidol was the one that we had the most patients to compare to and found no significant difference in that worsening.
Q. There's a third clinical trial report that was included in this analysis as well, which is described by the study code HGHJ. And that compared Zyprexa against ziprasidone, right?
A. Right.
Q. Ziprasidone is Geodon?
A. Right.
Q. That was one of the newer atypical antipsychotics?
A. Right. This was a brand-new study. This was a six-month-long study of treatment in schizophrenia and it compared olanzapine to the newest drug, ziprasidone, which appeared to have less weight gain effect than olanzapine or for that matter the others that were available at the time.
Q. And what did this study find with

respect to changes in blood sugar levels?
A. It found no difference in terms of average blood sugar from beginning to the end of the study. No difference between olanzapine and ziprasidone. And it also, again, looked at the question not of the average, but individual patients. Are there more on olanzapine than ziprasidone that got diabetes or hyperglycemia in the course of treatment? Well, first time with ziprasidone, but, again, the finding was no difference.
Q. And was that despite a significant difference in weight gain?
A. Yes. There was considerably more weight gain on average with olanzapine than there was with ziprasidone.
Q. Was there also as well in this particular submission additional literature that the company had become aware of with respect to Zyprexa and hyperglycemia?
A. I believe this one reviewed the literature again.
Q. Finally, let's talk about the most recent special submission that focused just on glucose that went into the FDA.

MR. KANTRA: And if we can take a look at EL2041.
Q. (BY MR. KANTRA) Dr. Baker, do you recognize this as the submission that went into FDA in February of 2006?
A. Yes.
Q. And in this particular analysis, was there a look at both the clinical trial data and the spontaneous adverse event data?
A. Yes.
Q. And what was found with respect to whether or not the findings in this analysis were consistent with the earlier analyses in regard to the risk of diabetes whether it was higher on Zyprexa or not?
A. This one was looking at the adverse events related to diabetes or hyperglycemia and it found looking at the adverse events in clinical trials were consistent with what we'd seen in clinical trials previously. It looked at the spontaneous reports and the conclusion that had been called in to Lilly the conclusion with those was, again, consistent with what we had seen in our earlier reviews.
Q. Now, we'd been talking about special

glucose submissions that focused exclusively just on the issue of whether or not there were differences in regards to changes in blood sugar elevations or differences in regards to diabetes and hyperglycemia. Would these have been the only documents that would have been submitted to FDA that looked at blood sugar levels, hyperglycemia, and diabetes?
A. No. These were the only submissions that -- during that time period that focused just on that question, but there were many other submissions in which that question would have been addressed as part of the submission.
Q. And can you identify the types of other ways in which information on blood sugar elevations would have been provided to FDA?
A. Yes. For all of our products there's -- there are periodic reports of new safety information. That's what our safety group will do on a regular basis.
Q. You supervised the people who actually prepare those reports?
A. I supervise the physicians, yes.
Q. Okay.
A. In addition to that, and I think I

mentioned this before, as we do new clinical studies, when those are reported -- completed and the analysis is completed, those are submitted as a study report to the FDA.
Q. And what about when -- when Lilly actually requests a new indication, it was approved originally for schizophrenia, but each time the company submits for a new indication, is there information relating to glucose for that?
A. That's right. Each of those submissions is somewhat similar to the first initial new drug application submission in that we submit all of the clinical data and other information that is supporting the new indication, the new treatment group that we're requesting in that.
And so they would include the safety information from those studies, it would include an overall summary of safety findings with the drug, and it would include, again, for the FDA to review the Zyprexa label and proposed changes to the -- to the label in each of those submissions.
Q. And when you say that they would be reviewing the labeling, that would include any review of the safety information in the labeling;

is that right?
A. Yes, sir, of course.
Q. Dr. Baker, are you familiar with the labeling and package inserts for Zyprexa, generally?
A. Yes.
Q. And are you familiar, in particular, with the package insert for Zyprexa from 1996 when the drug was originally approved?
A. Yes.
Q. Okay.
MR. KANTRA: Can we bring up 2954A?
If you go down to the bottom of that first page, Nick.
Q. (BY MR. KANTRA) See the date down there? 1996?
THE COURT: That's EL2954A?
MR. KANTRA: Yes.
Q. (BY MR. KANTRA) Is that the 1996 label for Zyprexa?
A. Yes.
Q. And moving from the 1996 to April of 2000, are you familiar with the labeling for Zyprexa as it existed in April of 2000?
A. Yes.

Q. Okay.
MR. KANTRA: Can we look at 2937A? And can we go to the last page of that document? And if we could look at the part that says literature revised.
Q. (BY MR. KANTRA) And is this the package insert that represents the literature as -- the package insert as it stood in April of 2000?
A. Right.
MR. KANTRA: Take that down.
Q. (BY MR. KANTRA) I want to ask you if you're also familiar with the labeling for Zyprexa as it stood in October of 2000.
A. Yes.
MR. KANTRA: And can we bring up EL2585? And, again, can we go to the last page of that document? You see the literature revised section there, Nick?
Q. (BY MR. KANTRA) And does this represent the October, 2000 package insert for Zyprexa?
A. Yes.
Q. Are you familiar with the labeling for Zyprexa as it stood in September of 2003?
A. Yes.
MR. KANTRA: And can we bring up

EL2953? And if we can go to the last page again. 2953 -- sorry, I misspoke on that.
Q. (BY MR. KANTRA) Does that represent the literature as it stood on that date in September of 2003?
A. Yes.
Q. Are you familiar with the package insert for Zyprexa as it stood in January of 2004?
A. Yes.
MR. KANTRA: Can we bring up 2945A?
Q. (BY MR. KANTRA) And if we can go to the last page, again, for that.
It shows a date of January 14th, 2004. Is that the January, 2004 package insert for Zyprexa?
A. Yes.
THE COURT: Again, that's an EL document?
MR. KANTRA: Sorry. EL2945A.
Q. (BY MR. KANTRA) And finally, are you familiar with the labeling for Zyprexa as it existed in October of 2007?
A. Yes.
MR. KANTRA: Can we bring up EL2958? Again, if we can go to the last page of

that at the bottom.
Q. (BY MR. KANTRA) You see where it says Literature Revised?
A. I do.
Q. And does that show the labeling as it existed as of October of 2007?
A. Yes.
Q. All right. I want to take you back for a minute to the October, 2002 submission that we talked about a moment ago.
And, in particular, I want to ask you if you were aware of a teleconference that took place between FDA and Lilly regarding the substance of that particular submission?
A. Yes.
Q. Is it Lilly's standard practice for its regulatory group to document interactions with FDA regarding Zyprexa?
A. Yes, Zyprexa or any of our products that we'd document.
MR. KANTRA: Can we have EL2037?
Q. (BY MR. KANTRA) You see this is marked as a note to file?
A. Right.
Q. And is it a note to file that would

capture Lilly's understanding of the interaction with FDA?
A. That's the point, yes.
Q. And does the title of this, the subject of the communication reflect October 17, 2002, FDA meeting and briefing document?
A. Yes.
Q. Okay. And if we go to -- let me just ask you: What was your understanding of the communication that took place between FDA and Lilly regarding the information that was submitted to FDA in October of 2002?
MR. SUGGS: Your Honor, can we approach, please?
THE COURT: You may.
(Bench discussion.)
MR. SUGGS: This witness wasn't part of this meeting. I mean, he's not copied on this thing. They're just using this to talk about these documents. He doesn't have personal knowledge if he's talking as a fact witness.
THE COURT: A curious objection coming from the Plaintiff.
Do you want to set a little bit of a foundation?

MR. KANTRA: This is going in as a business record is the foundation that I'm setting up for this.
THE COURT: Okay. I'll allow this. You could cross-examine.
(End of bench discussion.)
Q. (BY MR. KANTRA) Let's take a look at the third paragraph on this, Nick.
And in particular, you see the first sentence there that says that Dr. Katz noted that the division was not in a position at this time to draw conclusions regarding glucose dysregulation?
A. Yes.
Q. And is that consistent with your understanding of the communication that was made between Lilly and FDA as of October of 2002?
A. Yes, as of this point.
Q. And if we go on further in that paragraph, to the next sentence it says that he stated they expected to have results from the VA study fairly soon, that they actually expected the results in the summertime. Then it goes on to say that Dr. Katz told us that Dr. Judy Racoosin was leading this effort and the division

could get back to us on the methodology of the VA study and the expected timing of the data being sent to the division from the VA.
Can you tell us a little bit more about what that VA study was?
A. Yes. This was an epidemiology study that was, again, looking at the risk of diabetes in patients with schizophrenia, and looking in particular at the question of whether rates would be different between antipsychotic agents, and it was conducted in the Veterans Administration system in the United States.
All the VA hospitals and clinics looking for patients with schizophrenia and exploring this question.
Q. And does -- does this refresh that the FDA was actually involved in helping to design that study?
A. Lilly's understanding was that, yes, they were in contact with -- close discussion with the investigators about this study throughout.
Q. Do you recall when the results from that study were first presented to the public?
A. It was around the end of summer of that

year, 2003.
Q. And do you recall what the results of that study showed?
A. Yes. They found similar diabetes risk between risperidone, olanzapine and quetiapine.
MR. KANTRA: Can we go then, to take a look at EL2016, and can we blow up the title there for a minute?
Q. (BY MR. KANTRA) This is an article entitled Diabetes Risk Associated with the Use of Olanzapine, Quetiapine and Risperidone in Veterans Health Administration Patients with Schizophrenia published in the American Journal of Epidemiology.
Are you familiar with this article?
A. Yes.
Q. And is this the article that includes the results that were first presented in August of 2003?
A. That's right.
Q. Okay.
MR. KANTRA: And if we can go, Nick, and look at table 4. And, in particular, if we can look at the last line of that table?
Q. (BY MR. KANTRA) Did this study include

information about the rates of diabetes across the atypical antipsychotic medications?
A. Yes. What you see on the bottom line here are the rates of diabetes. These rates, these numbers are per hundred patient years. So, in other words, if there's a doctor that's treating 100 patients with schizophrenia, which many of us would have in a typical practice, this is saying that you're -- that they should expect to see that four of those are going to be developing new diabetes in the course of a year on average.
And what you see going across, they're comparing the different treatment arms, looking for what's the relative rates, are they different on one of these atypical antipsychotics versus another? So, the first one on the list is olanzapine. 4 point --
MR. KANTRA: Just a second. Nick, can you go back up, just so we can see the top of the chart to see how the drugs -- thanks.
A. Okay. So I probably don't need to read it for you, then. You can see olanzapine, 4.1 per hundred; risperidone, 3.9 per hundred; quetiapine, 4.3 per hundred; clozapine, 4.9 per

hundred; and haloperidol, the typical antipsychotic, 3 per hundred.
MR. KANTRA: And if we can go to internal page 3 of this document. And, in particular, if we can go to the results section, look at the second paragraph. And, in particular the second and third sentences of that.
Q. (BY MR. KANTRA) And what were the conclusions of the authors with respect to whether or not there were significant differences among the atypical antipsychotics with respect to the risk of diabetes?
A. So, what you just looked at were the rates of diabetes, and then they did statistical analyses on those to try to control for other risk factors and looked at the risk of which atypical you're on. And what they said -- what they concluded is that the differences in risk, differences in risk between olanzapine, risperidone and quetiapine are negligible.
Q. And this was the study in which FDA was involved in the design; is that right?
A. Yes, it was a very important study and it was with one that the FDA had told us they were quite interested in.

Q. And the labeling change that FDA requested in September of 2003 was approximately a month after that?
A. That's right.
MR. KANTRA: You can take that down.
Q. (BY MR. KANTRA) I want to direct your attention to another issue that's been discussed in this trial, and that is with respect to a Japanese labeling change that took place with respect to Zyprexa in 2002.
And I'll ask you if you're familiar with that labeling change?
A. Yes.
Q. And was it that labeling change that included a contraindication for the use of Zyprexa in patients who had diabetes?
A. In Japan, right.
Q. Okay. And what is a contraindication?
A. Contraindication means the label is saying, don't use this drug in this situation. So in that case, in patients with diabetes.
Q. Did Lilly advise FDA about the fact that the Japanese had made a change to their label to add this contraindication?

A. Yes.
Q. And within what time frame did it do so?
A. I remember it was prompt. I don't know exactly how many days it was.
Q. Do you recall when the labeling change for the Japanese took place? In what month of 2002?
A. I believe it was in April.
Q. Okay. As you mentioned before, it would be Lilly's standard practice to document any interactions with FDA, the regulatory group would do that; is that correct?
A. That's been my experience, yes.
Q. Okay.
MR. KANTRA: Can we bring up EL2044? And, again, can we look at the subject of the communication which is -- I think that's going to be at the top of the document.
Q. (BY MR. KANTRA) And the subject of the communication shows it as being a communication regarding labeling change in Japan; is that right?
A. Yes.
Q. Okay.
MR. KANTRA: And if we go down,

then, Nick, to the beginning of the section, the first sentence of the discussion details.
Q. (BY MR. KANTRA) And it states there that on Friday, April 12th, 2002, Drs. Breier and Brophy -- let's pause on that for a second.
Dr. Breier, who is he in April of 2002?
A. He was the leader of the Zyprexa product team, the global Zyprexa team.
Q. And Dr. Brophy who is a part of the regulatory group there; is that right?
A. Dr. Brophy is the director of the neuroscience regulatory group at Lilly.
Q. So they contacted Dr. Laughren to inform the division of neuropharmacological drug products that the olanzapine label in Japan was being revised to include information regarding hyperglycemia and diabetes and the warnings and the contraindications sections?
A. Right.
Q. Is that consistent with your understanding of the information that was conveyed to FDA on that date?
A. Yes.
Q. Are you aware that Lilly submitted two

special reports regarding the Japanese label change to FDA?
A. We did.
Q. And did those submissions provide FDA with information on the specific adverse events on which the Japanese regulatory authority relied to change the label?
A. Yes.
Q. Okay. Did you personally review those adverse events?
A. Yes.
Q. Okay.
MR. KANTRA: Can we bring up EL2645?
Q. (BY MR. KANTRA) And do you recognize this as the submission that went into FDA with respect to the individual cases that supported the labeling change in Japan?
A. Yes.
Q. Okay. And by the way, how many cases supported that labeling change in Japan, if you recall?
A. There were nine -- nine people.
Q. Was there a second document as well that provided additional information from Lilly to the

FDA about this Japanese labeling change?
A. That's right.
Q. Okay.
MR. KANTRA: Can we bring up EL2629?
Q. (BY MR. KANTRA) And this is a document that's entitled Analysis of Japanese Data on Hyperglycemic and Diabetic Spontaneous Serious Adverse Events Associated With the Use of zyprexa. And the date on this document, as with the last one, is April of 2002; is that right?
A. That's right.
MR. KANTRA: And if we can go to internal page 6 of this document. And, in particular, if we can look at the first paragraph of section 3.
Q. (BY MR. KANTRA) And this reflects that there were a total of 13 cases that were reviewed of the nine that ultimately submitted that supported that change, and with respect to these cases, what did the review of these cases show in regards to these patients?
A. Well, it's summarized on the screen, but these were from Japan, the sort of spontaneous adverse events that we talked about earlier,

things that were communicated to Lilly. And what it showed was that for most of these patients -- it was not clear. It was not clear what was leading to problems for them in some cases and in other cases it was pretty clear that there were -- there were compounds, there were other issues involved. So, for example, two of these unfortunately were fatalities. Looking at those two myself, to me it was very clear that there were other things leading to their death, not olanzapine. But overall, we looked at these and our conclusion on these cases was that there could be no definite conclusion about -- about what it would mean for olanzapine.
Q. In some of those cases as reflected up there showed that a couple of patients weren't even taking Zyprexa at the time of the event, correct?
A. That's correct. Out of these patients -- out of these 13, two of them were not even on the medicine. They were on it sometime in the past.
Q. It also suggests up there that four of these patients had a known diagnosis of diabetes before they started taking Zyprexa?

A. That's right. There were at least four that had diabetes because it had been documented before they were even on Zyprexa.
Q. And another five of them that were suggestive of undiagnosed preexisting diabetes, right?
A. That's right. There were patients with things like fasting blood sugars that would have put them even in the diabetes range even if the doctor had not made an official diagnosis of diabetes before they went on to olanzapine.
Q. Did Lilly disagree with this labeling change in Japan?
A. Yes.
Q. Why?
A. Because we thought the con -- the conclusion was wrong.
Q. Based on the data that was available?
A. We'd looked at these cases and did not feel that these cases merited a change especially as you look at these patients in light of everything that we knew from cases we were getting, all these reviews that we had been doing, all the clinical trial data. We were confident, we are confident that -- that it

wasn't the right -- the right choice, scientifically, medically speaking.
Q. Did you believe -- did Lilly believe that a contraindication with respect to patients who had diabetes could be potentially harmful to patients?
A. Yes, we were very concerned about that.
Q. Why?
A. Well, because we know that Zyprexa -- is a medicine for some individuals is -- is the best choice for treating their mental illness, and we knew that this would mean -- this would mean that patients who had diabetes, it was taking away the choice from the doctor about weighing risks against that potential benefit for patients that may need it or maybe even patients that were already on it for whom it was working. That wasn't a good thing.
MR. KANTRA: Judge, I can either move into a new topic or we can take a break here. Either way is fine.
THE COURT: I take it that you've got quite some time left with this witness. Why don't you keep going until 1:30 and then we'll break.

Q. (BY MR. KANTRA) Why don't we talk, then, about the September 2003 label change and ask you, first, whether you recall that in September of 2003 FDA, in fact, asked Lilly to change its label to add a warning with respect to diabetes?
A. That's right.
MR. KANTRA: Can we bring up EL2135?
Q. (BY MR. KANTRA) Dr. Baker, do you recognize this as the letter that requested that Lilly change its labeling with respect to diabetes?
A. Yes.
Q. And this letter wasn't sent only to Lilly, was it?
A. No. My understanding was that the manufacturers of all the atypical antipsychotic drugs had the same request.
Q. And, in fact, that second paragraph of that letter says just that, doesn't it?
A. Oh, yes. It says it refers to all atypical antipsychotics.
Q. If we look --
MR. KANTRA: Nick, if we go down a little bit further to the actual text of the

warning itself. And if we can go in particular to the sentence that begins with "assessment of the relationship."
Q. (BY MR. KANTRA) Dr. Baker, this class labeling from FDA acknowledges that there is the possibility of an increased risk of diabetes in patients with schizophrenia, right?
A. Yes.
Q. And after three years of evaluating data, FDA didn't state in this warning that there was a causal relationship between Zyprexa and diabetes, did it?
A. To the contrary, it said that it's not completely understood what the relationship was between treatments and the development of these events.
Q. And the FDA didn't rank the atypical antipsychotics with respect to the risk of diabetes, did it?
A. That's right. Again, to the contrary. It said that the data available at this time were not sufficient for such a ranking.
Q. And in contrast to Japan, this labeling didn't tell physicians in the U.S. that Zyprexa shouldn't be used in patients with diabetes,

right?
A. Right.
Q. Now, the labeling also --
MR. KANTRA: If we can drop down, Nick, to the next paragraph.
Q. (BY MR. KANTRA) The labeling also included information about monitoring for patients, right?
A. Yes.
Q. Okay. And what kind of information did this labeling provide with respect to monitoring?
A. Excuse me. It said that any patients started on atypical antipsychotics should be monitored for symptoms of diabetes. All patients should be assessed for the risk factors for diabetes because of the -- the likelihood of developing diabetes during treatment.
Q. And with respect to patients who have diabetes, was there information on that as well?
A. Right. It said that patients who do have diabetes need to be monitored, have their sugars monitored in course of their treatment with the treatment with atypical antipsychotics.
Q. Were these positions of monitoring consistent with routine good clinical practice?

A. Yes. All of these things would have been part of routine good medical care, even before the labeling.
Q. How did the information that was included in this new warning that was put in the label as of October of 2003 compare to information that the company had been sharing with physicians outside the label before September of '03?
A. I think these changes echoed much of what Lilly had been sharing in other ways with physicians before this time.
Q. How did Lilly respond to FDA's request to change the label?
A. We agreed. We accepted the request.
Q. And why did Lilly accept this change?
A. FDA had asked for it and we made the change.
Q. Okay. What involvement did you have, in particular, with respect to the September, 2003 labeling change?
A. I was part of the team at Lilly -- at Lilly that discussed it and made the decision 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.
Q. 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?
A. Many different ways.
Q. Okay. And can you tell the jury some of those ways that Lilly communicated that information?
A. 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 or sales representatives and instructed them to let all the doctors 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 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 formats that doctors would use like the Hippocrates, some people use it as a electronic database for adverse events. And Lilly mailed letters to doctors in the United States describing this label change.
Q. And are you familiar with the letter that was actually sent to physicians?
A. Yes.
Q. And when was that letter sent?
A. It was sent very shortly after this change, within a couple weeks.
MR. KANTRA: Can we bring up EL2972?
Can you blow that up just a little bit, Nick?
Q. (BY MR. KANTRA) You see the date on this letter?
A. October 6th, 2003.
Q. Do you recognize this as the letter that was sent to physicians in regards to the change in labeling?
A. Yes.

Q. What is the information that's conveyed to physicians in regards to this particular letter?
A. It conveys in the cover sheet that the FDA had asked for this, and it included in this a copy of the press release describing the change.
Q. And -- as well it includes the package insert that includes the new warning?
A. As with any of these, it included our label, sent a copy of the new label.
Q. Had FDA requested of this letter -- actually, if we go down just to the bottom of that letter, can we see the signature there? You see the reference to Dr. Tohen?
A. Yes.
Q. That was set out by the leader of the Zyprexa product team?
A. At this time, yes, Dr. Tohen had taken over from Dr. Breier as the leader of the team.
Q. Had FDA requested that Lilly send out this letter as of October of '03?
A. No, Lilly sent this because we wanted physicians to know right away about the change.
Q. Did Lilly ultimately send out another letter at the request of FDA?

A. That's right.
Q. And was the substance of that Dear Doctor letter different from the letter that Dr. Tohen sent?
A. No.
Q. You were involved, Dr. Baker, with the most recent label change regarding hyperglycemia in 2007?
A. I was.
Q. Okay.
MR. KANTRA: Actually, as I'm looking at this, we're looking at another -- a different label change.
THE COURT: This looks like a good breaking point.
Ladies and gentlemen of the jury, we've reached the end of our trial day. Some of you have asked if we're -- as I understand it, if we're sort of still on schedule to have this case go to you towards the end of next week, and I think we are, at least for now. It's going to depend on a bunch of things, but that's what I'm hearing. So I'm just letting you know that.
When exactly, it's probably going to be towards the end of next week that we do

this, and it may be that sometime next week I may have to give you a day off while I do things with the lawyers to get it ready for closing arguments and jury instructions. I'll keep you posted when that goes on.
Once again, I'd remind you, please don't 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 read any or listen to any media or anything on the Internet that might have something to do with the subject matter of this case.
Have a nice weekend, and I'll see you all on Monday at the usual time.
(Jury out.)
THE COURT: Please be seated.
We're outside of the presence of the jury. Just a couple of things before we end.
You'll be getting me stuff, I take it, by the end of the afternoon so I can do work this weekend. I looked at my calendar and it appears highly unlikely that I can take an afternoon to deal with jury instructions. That kind of leaves me two choices. Either we'll

start at 4:15 one evening and do jury instructions then and go late, or we'll take a morning. Which of those two I will do will depend on what I need to do to get this case to the jury before the end of next week.
If it looks like we're going to need Thursday for evidence and those things, we're probably going to be working late Wednesday night or Thursday night. If it looks like the evidence actually closes towards Wednesday, I'm more inclined to use the day on Thursday, so then do what we need to do on Friday. We'll play that by ear for now and see where we're going.
The other thing -- and I don't really need -- the presiding judge was meeting with the paralegals association, I think, and suggested that it might be interesting for the paralegals association to get a demonstration of the technology that's being used in this courtroom, something that I continue to be impressed with. If we do that, what it might end up meaning is that I'll see if I can find some other judge's courtroom to do my afternoon hearings, and let you set up something during the day but I'll talk to the presiding judge.

Assuming that we can set that up, is that okay with the people that might have to do the demonstrations and do the work?

MS. GUSSACK: Yes, Your Honor.

THE COURT: I appreciate that and I'll talk to the presiding judge and let her know that and we'll see what we can work out.

MR. ALLEN: Judge, I'll put on the seminar for technology.

MR. LEHNER: I'll supply the yellow pads.

THE COURT: I'm surprised that some of the attorneys haven't been invited to the various trial lawyers or defense lawyers seminars, but I'll let the lawyers take care of themselves.

Anything else we need to talk about?

MS. GUSSACK: No, Your Honor.

MR. ALLEN: Margarita.

THE COURT: I think I gave you my -- we'll be off record now.

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

(Trial adjourned at 1:33 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 21st day of March, 2008.

_____

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