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 5

TRANSCRIPT OF PROCEEDINGS

March 7, 2008 - Pages 1 through 211

BEFORE THE HONORABLE MARK RINDNER
Superior Court Judge

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

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PROCEEDINGS

THE COURT: We're on the record outside the presence of the jury in the State of Alaska versus Eli Lilly 3AN-06-5630.

There are a number of pretrial issues that the parties want to take up. Before we do that, I wish to disclose the following: On Wednesday, I -- in the afternoon, I was assigned a case and received a phone call from the other court where the masters do their work asking me to do a representation hearing in a case involving a gentleman whose name I'm not going to disclose where the -- in a case that involves a commitment to API and a request for involuntary medication. The basis of the representation hearing -- the gentleman had been appointed a public defender to represent him in that matter and the basis of the representation hearing is that he wished to have Mr. Jim Gottstein who, I believe, that some of you are aware of who he is -- I believe that all of you are aware of who he is -- represent him in this matter.

And so it was set on my calendar for yesterday at 3:00 o'clock for a representation hearing. Prior to -- shortly

prior to the hearing, and I don't know when exactly it was filed, but I didn't see it until after court yesterday, Mr. Gottstein filed a lengthy pleading that sort of indicated that he wanted these matters considered as part of whether or not he was going to come into the Court -- into the matter. It included some briefing. It included a bunch of affidavits, none of which I have read, none of the affidavits which I have read. I started reading the pleading itself and realized he was talking about Zyprexa and side effects -- he was talking about all of the second-generation antipsychotic drugs and the effects of those antipsychotic drugs. I saw that that was the topic and stopped reading.

I didn't read any of the affidavits and decided that it would be inappropriate for me to handle that case given that I felt there would be discussions of side effects of second-generation drugs and some of the issues that might be raised in that case that are in this case, except I wouldn't have any of you there in this case, and I didn't think it was appropriate for me to handle that case.

So I didn't read the substance of any of the stuff, other than to see what the topics was, and I went on the record and arranged with the presiding judge and then on the record and explained that I was recusing myself from that case, and that case was assigned to another judge.

I felt that it was important that I advise the parties of that. I believe that nothing, absolutely nothing that occurred in that case, basically, since I tried to avoid reading any real substance would prevent me from being fair and impartial in this case. But if anyone has applications to make, they are free to make them.

But they'll need to make them today.

MR. ALLEN: We have none.

MR. LEHNER: Thank you. No, thank you, Your Honor. We're fine.

MR. JAMIESON: Can we get the case number, Your Honor?

THE COURT: Unfortunately, yes and no, Mr. Jamieson. The way you'd have to get the case number is to go back to my -- the file is now with

Judge Michalski, if you look at -- see what's on, I will even tell you it's at 3:00 o'clock. I think that's when he set it although it may be being canceled. When I announced what Judge Michalski had said he would set it for, somebody had a conflict and I think they were trying to make arrangements with him to move it, so maybe it's not on his calendar.

But it's possible that if you looked on my calendar from yesterday, which I don't have a copy of -- Mark, do you, by any chance?

THE CLERK: I have the log number with the case number.

THE COURT: We'll get you the case number.

MR. JAMIESON: Thank you, Your Honor.

THE COURT: And the -- one other issue that I would -- well, a couple of other issues I have. I've been getting a number of pleadings, particularly from the Defendants. My secretary has asked to remind you that the rules require that those pleadings get two hole punches on the top. She's tired of punching your pleadings, so if you could keep that in mind and make her life a little

bit easier.

There is a pending motion that was filed yesterday, I guess, in the morning to exclude evidence regarding speech protected by the Noerr-Pennington doctrine and common-law privilege. When am I going to get an opposition from the State?

MR. ALLEN: Well, I can -- Judge, I think I can give you an opposition here on the record that may suffice. I mean, I can't -- I don't have the manpower to do the pleadings every time. Let me just say this: Speech can be protected -- we're not making a cause of action for recovery of money damages against them for their speech. They have stated here right on the record in court that doctors are still prescribing at the State hospital. We haven't done anything, and what I was able to develop in the deposition of Ms. Eski is that when the State has tried to do something and we have documents to prove it, they, being Eli Lilly, literally formed Alaska State Action Teams, a truth squad, a Partners in Crisis Alliance. They hire lobbyists and public relations firms to go to the legislature and the regulatory authorities and they also engage in a letter-writing campaign.

They prepare letters for doctors to put their signatures to to send to the governor's office, the state legislators' office, the state senators' office, regulatory authorities. That's protected speech. There's nothing wrong if they want to do that. But they're not -- when you talk, you're not entitled to a cloud of privacy around your speech. When you make your speech public, we're entitled to discuss it. I'm not making a claim for recovery. I'm entitled to show that they did talk, and so that's our response.

THE COURT: Okay. Mr. Brenner.

MR. BRENNER: Your Honor, I think you're particularly attuned to these issues, because I know you had a case recently --

THE COURT: I am and I think Mr. Allen is right. The issues of Noerr-Pennington tend to be claim preclusion issues, not evidence preclusion issues and that if -- just because you bar a claim, if evidence is relevant to another claim that isn't barred, I think that evidence can come in even though it might otherwise be protected if you were trying to bring a claim based on that happening.

And in saying that, I am not making a determination of the relevance of the evidence -- I'll tell you, Mr. Allen, I understand that you want to use it, but I'm less than clear how it fits into the case that they're going to the government and doing these teams.

MR. ALLEN: Okay. Well, then, that --

THE COURT: And I suppose we'll have to go take that up as I go over the Eski deposition designations.

MR. ALLEN: Yes, sir and I'm going to do the Eski -- we don't have those ready. We don't have -- we'll have those to you on Monday. Let me just briefly explain how they're relevant. Ms. Gussack in her fine opening statement, talked about the fact there's no doctors -- I'm paraphrasing -- that have complained. Everybody continues to prescribe it.

There's a regulatory mechanism called the Preferred Drug List and there's an issue called Open Access, and when the government through either legislation or through regulation tries to put what's called prior authorization on Zyprexa or other mental health drugs, that is, before a doctor can write a prescription that

will be covered by Medicaid, he needs to get prior authorization for payment.

They get involved, literally with lobbyists, money, groups, alliances, Partners in Crisis, truth squads, letter-writing campaigns and they try and they've successfully tried and succeeded in preventing prior authorization from being put into place. So, in other words, the fact that doctors prescribe -- I mean, really the issue here is the fact that the State has not, quote, taken any action. When the State has even considered taking action against Zyprexa, even considered it, they have orchestrated a -- a huge campaign to prevent that.

And so it gives an unfair representation to the jury. It's like saying this, it's like saying this: People continue to drive down the street every single day and these people are making a claim for people driving down the street when the facts are, they have people with banners and signs that say, please drive through here. And so -- for them to say nobody's done anything -- when anybody has even given the hint of any type of restriction on Zyprexa or mental health drugs, they get an action with real

money, real lobbyists, real PR firms, real letter-writing campaigns.

So I'm entitled to rebut this presumed evidence that they have that no one has done anything against Zyprexa with showing what they've done to assure that that doesn't happen.

THE COURT: Mr. Lehner.

MR. BRENNER: Mr. Brenner this morning, Your Honor.

THE COURT: I'm sorry.

MR. BRENNER: Two things briefly. I think that actually proves our point. How would you ever link up that a letter-writing campaign or anything caused the government to act or not act? You have to take that up -- the only reason I rise, just so the record's clear, we respectfully disagree with your analysis of the cases. In fact, it goes beyond claims for money damages for the speech. First Amendment rights would be chilled if you were to permit exactly what the State is doing, that to buttress a claim, to enhance a claim, to try to make an element of claim, even separate and apart for a claim for money damages for the speech. Our reading of the cases is contrary to Your Honor's.

THE COURT: Why isn't this like a

claim where somebody is alleging that somebody bribed a legislature or something like that and somebody wants to bring in all the background of what people were doing to petition the legislature before the bribe took place? I mean, as long as it's relevant, the fact that it involves the legitimate portion of what was done is protected First Amendment speech. Doesn't that come in anyway if there's not a claim?

MR. BRENNER: I'm not sure it is. But i think the closer analogy and the cases we've cited to you are where in a products liability suit, personal injury suit. The Plaintiffs want to say there was no safety standard or the safety standard was modified by the acts of the Defendant and its industry to petition the government, to change the standard. The case law is in the briefing. We sent it to you. Most courts -- I'm not sure of any that haven't done this. Most courts say you can't introduce that evidence which is not a money damages claim for the speech. It's using the evidence to support a products liability claim, and saying, no, that is First Amendment petitioning activity. That's exactly, that is exactly the parallel we're saying here.

MR. ALLEN: That is exactly incorrect.
MR. BRENNER: Your Honor will decide that, I guess.
MR. ALLEN: Okay, but -- he's entitled to his opinion. I'm not using it to buttress a claim. I'm using it to refute a defense of the Defendants, that's No. 1. And No. 2, Your Honor, this issue of how you would ever prove the tie-up and causal link, as Your Honor told this jury the other day, there's direct evidence and circumstantial evidence. The fact you didn't see it snow doesn't that mean it didn't snow and when the facts are that they used money -- I assume when they used their money and their lobbyists and their PR firms they had a purpose. I'm sure they had a purpose in mind. And so I'm entitled to show what that purpose may be, but I want it on the record we are not using it to buttress a claim but to rebut their defense.
THE COURT: I think the critical here is rebut and I heard the openings that I heard. On the other hand, I'm in a much better position to judge whether you should be allowed to use this evidence and the relevance of the witness after I see what witnesses testify to in Lilly's case, and

it may well be that based on that it becomes more apparent and a clearer line can be drawn. And so rebutting a defense requires the defense to be put on and not just to have the opening statement made. And so I prefer you save your rebuttal for rebuttal.
MR. ALLEN: Yes, sir. I didn't look this evidence rule up last night, Your Honor and I do think I'm somewhat knowledgeable on evidence. I think it's probably in the 1s or 2s in the evidence book -- I bet you'll find it.
MS. GUSSACK: In that range.
MR. ALLEN: Do you want to put money on the table?
MS. GUSSACK: Somewhere in that range.
THE COURT: Can I hear what the rule is and then we'll worry about where it is.
MR. ALLEN: But I guarantee it will be in there. I hear Your Honor and you've said several times, well, we have to wait till we see the evidence. Evidence is allowed to come in predicated on the fact that other evidence subsequent to that will tie that evidence up. If you waited until all the evidence is in, a lot of evidence escapes you, so there's a rule that allows that, No. 1.
No. 2, when they stood up and made

the statement on opening statement, they've already done it, and if they then don't put on any evidence of it, it's out there. It's been here before the jury so I'm entitled to rebut it based upon their opening statement. But, anyhow, we'll let it for another day.
I'm going to get Dave Campana's deposition, who works for the State, and I'm going to get Joey Eski's deposition, who works for them, and we'll tie it all up together in a nice bow. So they don't -- the next time they say it, I'm going to be up on my feet. That's all I got to say for now.
THE COURT: Okay. For the time being I am denying the motion to exclude evidence regarding speech protected by the Noerr-Pennington doctrine and common-law privilege, provided that that evidence is relevant for some other purpose or claim. There are no Noerr-Pennington claims in this case.
As to -- and, again, the relevance determination may be easier for me to make, not on direct, but on rebuttal if, in fact, you're rebutting something.
The Plaintiffs have filed a motion

to limit the testimony of the -- the Defendants have filed a motion to limit the testimony of Plaintiffs expert witness of John -- you better pronounce it for me.
MR. FIBICH: It's Gueriguian.
THE COURT: And he's today?
MR. FIBICH: Yes, sir.
THE COURT: I first want to say that filing these motions, I guess it must have been filed sometime late yesterday, since it's got a file stamp received in my chambers on the 6th. Nothing I see in this motion couldn't have been brought in a motion in limine in a more timely fashion instead of on the eve. The same thing that happened with Dr. Brancati.
MR. FIBICH: Brancati.
THE COURT: Brancati, sorry.
But having read the motion and without giving the Plaintiffs much of an opportunity to respond or any, so far, opportunity to respond, to the extent that the doctor is going to be testifying outside the -- outside what I believe is fair notice and what was both with deposition and his report, just as I said yesterday, he's going to be precluded.

So if he didn't talk about the 2007 labels in his deposition and it wasn't supplemented, I'm not going to allow him to talk about the 2007 labels. On the other hand, the other portions of the motion about opining about the meaning about federal regulations and what a reasonable and prudent drug manufacturer would do, I think there is notice that he was going to testify to that.

The real question is: Does he have the expertise and is it helpful to the jury? Until I actually hear what his qualifications are, I don't know whether he's got the expertise. The helpful to the jury is a very slight burden, and so I probably would allow it if that's what it is. But whether or not he's got the qualifications and expertise to offer the testimony as to the other parts, I kind of need to take that up after we qualify him.

MR. BRENNER: I understand that, Your Honor. On the labeling, though, there is an additional issue. At deposition he testified he never saw or read the labels. Not just 2007, any of the labels. That meant there could be no deposition testimony --

THE COURT: That, you know -- again, I don't know if there -- there was discussion in his report or any of those kind of things. That's great cross-examination for you and I think it will go to the weight, but I need to hear his qualifications and I'll hear about that, and --

MR. BRENNER: And with Your Honor's indulgence, I may need to do a little more than a pro forma voir dire on his qualifications.

THE COURT: I understand that. I mean, and I'll allow you to do that.

MR. LEHNER: Your Honor, with respect to the Brancati motion, and I suspect this that we filed yesterday and this may happen a little bit more. That was based on the demonstratives that they had given to us. I think, consistent with your instructions earlier, we're trying to exchange these 24 hours in advance and when we saw some things in there, we filed this motion. I suspect when our experts come on, the Plaintiffs may raise some things too. We're perfectly mindful of trying not to file things at the last minute but that was occasioned by a few of the slides that we'd seen in the slide deck.

MR. ALLEN: I'll bet we don't do what

they've done. I'll put money on that, too.

THE COURT: You must be a poker player, Mr. Allen.

MR. ALLEN: Yeah, and they pushed all in, so here I am. They bet the farm.

THE COURT: Any other pretrial issues?

Oh, there actually is one. Mr. Allen -- I think it was Mr. Allen, has filed this morning a letter, basically saying he thinks we're still dealing with do things come in in rebuttal or are they coming in now or the door is --

MR. ALLEN: The door is flung wide open but we don't need to -- Your Honor is a great judge and smart man. Just read my letter and I'm sure they'll file a detailed response.

THE COURT: They'll file a response to that.

MR. ALLEN: They've got people working on it right now.

THE COURT: Again, I think we did discuss this, and we decide to handle things informally, but pleading paper is a little bit better than letter paper, if you can do it.

MR. ALLEN: I apologize, Your Honor.

I've got an ink pen and a notepad.

THE COURT: Can I ask: This is probably not my burden, other than it's been raised a couple of times about what's happening. I've seen some stuff on the Feldman Orlansky. Are they gone --

MR. ALLEN: No, sir. You know what, I'll be glad to put it on this note paper. This fine paralegal from South Carolina somehow got ahold of my stationery. I have no idea how.

THE COURT: That's also something. These letters have to be documented and filed with the file if I'm going to read them. I'd remind everybody again about two-hole punch stuff.

MR. ALLEN: I'll two-hole punch it personally.

THE COURT: And that's less something I care about than my judicial assistant, but her requests to me I take very seriously.

MR. ALLEN: I do, too. Two-hole punch.

THE COURT: Anything else we've got for this morning?

MR. FIBICH: Two things, Your Honor. I have two additional documents that I want to offer

into evidence that Mr. Lehner may have objections to and, additionally, I may want to publish some of these documents to the jury. May I do that directly, or do I do that through your in-court?

THE COURT: I'm not sure what --

MR. FIBICH: Have the jury see the documents themselves?

THE COURT: You ask me may these documents be published to the jury? I say, yes, you can just pass them around. You don't have to have the in-court pass them around. And if I haven't said this before, I think I know how to control my courtroom, but I also believe that lawyers should get a chance to use it, and so as long as everybody's behaving properly and nobody is bothering the jury unduly, which I will protect, or the witnesses, you can move around the courtroom and do what you need to do to do your jobs. I care more about that everybody is acting professionally and you guys have done nothing but that.

And so just so you know.

MR. FIBICH: Your Honor, at this time, the State of Alaska would offer into evidence Exhibit No. 988 and Exhibits -- Exhibit 4436. I think Mr. Lehner may have objections to these. I'm

not sure.

MR. LEHNER: Your Honor, I think if you look at first at 4436, which I think is the psychotropic label overview for diabetes mellitus --

THE COURT: Okay.

MR. LEHNER: -- we would object consistent with our motion in limine concerning foreign regulatory matters which we had filed and you rejected, so with respect --

THE COURT: That objection is preserved, but I'll overrule the objection. 4436 may be admitted.

MR. LEHNER: And then with respect to the other exhibit, I think we had filed a motion in limine concerning adverse events that had not been objected to by the Plaintiffs, and it was to be admitted consistent with that motion in limine which goes to notice as opposed to --

MR. FIBICH: That's right, Your Honor. We're not offering the adverse events for the purpose of establishing causation, which is what their motion went to that we agreed to.

THE COURT: What is it being offered for?

MR. FIBICH: Notice.

MR. LEHNER: Notice.

THE COURT: Then I will admit 988 only for the purpose of showing that Lilly was on notice of the matters contained -- discussed in the document, and if Lilly wants a limiting instruction advising the jury that they're only to consider the exhibit for that limited purpose, I will give it.

MR. LEHNER: The other thing that deals with -- is that all on these evidentiary matters, then?

MR. FIBICH: That's all on evidentiary matters.

THE COURT: Do you want me to advise -- if this document is being offered -- do you want me to advise the jury they're only to consider it for the limited purpose?

MR. LEHNER: Yes. Correct.

And then, Your Honor, with respect to the deposition designations that we've been dealing with, I looked at them last night and I provided Mr. Allen this morning, we would ask only that one of the numbered ones that we had to Denise Torres be added into theirs. I gave Mr. Allen that page number. And I think we had about 20 or so of John Lechleiter's snippets that we

thought ought to be added in theirs. And now I think there are just six that I suggested would be added in there for completeness consistent with Your Honor's ruling for context. The rest we're happy to play in our segment.

THE COURT: So we've got one for Torres and six for --

MR. ALLEN: That's if I agree. They keep on saying consistent --

MR. LEHNER: That's exactly right, Your Honor. We had -- we did what you had said. We tried to do it. We have six --

THE COURT: So there's basically no agreement on the one or the six?

MR. ALLEN: I don't even -- he gave it to me this morning. I think two of the six, if I recall, but I can't keep all these facts in my head without looking at the deposition again. They gave me a whole list in Lechleiter and a whole list in Torres. I agreed to two in Lechleiter, and I think two -- I think, but I can't tell right now without going back to my office or my hotel room. I think two of the six he has this morning are two already agreed to. The rest of them I do not -- they keep on saying consistent with Your Honor's ruling.

Your Honor's initial ruling was this was not going to occur. And I want to point out, Your Honor, just the logistical problem of all this. We get our depositions cut. We have people up all night, a small group of people. I get them cut, then they want to add something into it. I can't keep on cutting -- this guy right here can't go to sleep, if I have to keep cutting and recutting to put his stuff in. So, if, in fact, there's things that need to be put into context, then we can turn off our tape if that's what the Court decides, and they can turn theirs on --

THE COURT: That may be what we have to do in order to get it done. I'm aware of the logistical problems of cutting and editing and doing tapes and stuff, and that's the only way we can do it. But if I decide that needs to be done for fairness, then that's what's going to be done.

MR. ALLEN: Then that's fine --

THE COURT: But to the extent it can be done seamlessly, I prefer it to be done seamlessly. I realize there are burdens on everybody.

MR. ALLEN: Right. Now, that being said, what I am concerned about is we keep on having

this -- what do people call that -- this creep that seeps in from the Court's original order that said this is not the way to do it. And -- and the fact that what they call completeness is they don't like the evidence that I'm presenting. That is proper for cross, and so I am going to look at what he has tonight. I have added in two of his Lechleiter's from yesterday. I will look at these other six or four. I'm certain I am going to probably object, because I looked at them all last night --

THE COURT: Again, if you can give me the -- as I understand the six -- two of them are fine, so we're down to four, and we've got the ones -- Torres -- so there are five cuts in dispute. If you can give me the page -- if you can't agree and you can give me by the end of the day the page and line numbers, I'll decide whether it's a completeness issue or whether it's a don't-like-what-we-say issue, and make a determination of what -- whether I think this belongs in cross or whether I think it belongs in completeness. Than's kind of going to be the lines in my determination. So you've got to give me the stuff, and the sooner you give it to me by the end of the day, I'll work on it along with the next two

problems along this way deposition issues and I'm going to give you something on Monday morning as to what's going on.

MR. ALLEN: I have good news and bad news for you, Your Honor. Four or five -- you're going to get four or five more cuts today. Five more cuts today. Let me point out two things on what he's going to give you that I think is going to be the case. There are usually questions in the deposition that I am taking where I ask a question and if you look down, I object to the witness' answer as nonresponsive at the time. I am entitled to do that to preserve my objection. If, in fact, they want to play, in my case, in my case, a question and answer where I objected to their witness as being nonresponsive, and the Court determines that it's nonresponsive, and the Court determines that, even if, hypothetically, it would be offered for completeness, I should not be required in my case to present evidence to a properly objected to question at the time. Otherwise, I was wasting my time at the deposition from objecting.

And, second, I know that in some of the things they gave me last night that they want

to put into my deposition, they just had an answer with no question. So I don't think that should happen either.

THE COURT: Well, again, if you give me the four or five cuts that are done --

MR. ALLEN: Yes, sir.

THE COURT: -- and I get them by the end of the day, I will rule on them. I'd also like to get -- you said I'm going to get a couple of more cuts, four more or something.

MR. ALLEN: You're going to get five more, Your Honor.

THE COURT: So I'll have seven to maybe try to look at over the weekend.

MR. ALLEN: I think it will help the Court understand where the evidence is going also.

THE COURT: That may be, too, but I'm going to want -- do we have -- I'm going to call it the revised, just like I got last time, for these new five as well as the two I got? Do I have Lilly's very specific objections to the new stuff, or am I working off kind of the master list of objections?

MR. LEHNER: No. Your Honor, I can hand you up right now the page and line numbers,

whether it's going to be the five or the seven. As Mr. Allen says, he's not sure whether the two on here he agreed to or not --

THE COURT: I'll take it now. I'd like to know by the end of the day to know which ones I can read. If I have to only read five, I'd prefer to read five instead of seven. If I only have to read three, I'd like to read three instead of seven. Let me know by the end of the day what's in dispute. How fast can Lilly get -- for the two cuts I got yesterday -- I forget the witness' names -- as well as the new five I'm going to get, which you probably know better than me. To be quite honest, I mean, Friday nights are always sacrosanct to me in trying not to work as much as I did both in practice and in law school. But if I can get them, somehow if I meet somebody somewhere by noon tomorrow, it will -- because I've got chores I have to do in the morning -- it would let me have all of the stuff I need to try to work on as many of the seven and give you an answer to as many of the seven by Monday.

I'm not going to promise I'm going to get through all seven. It would be helpful, Mr. Allen to know --

MR. ALLEN: I can tell you right now --

THE COURT: -- we've gotten Torres and Lechleiter pretty much done subject to this -- the other stuff, and now I've got two more yesterday and I'm going to get five more, so that's nine depositions. When are you going to play them?

MR. LEHNER: Can I ask one question? Because -- we're sort of confused as well, Your Honor. With respect to sort of the mechanics, I've been fully aware of that. I've been trying to sort of set up meetings and it hasn't happened for a number of reasons and I'm not sure anybody is to blame for that. But we're really aware of the mechanics as well.

It would be really helpful if we could right now have a list actually of what we have -- what they are going with. As you know, there's been somewhat of a moving target. Depositions have been cut down; Mr. Allen has been trying to cut them down. If you can tell us who's with the judge now, and who's coming up, that would facilitate the process, we can turn these around very quickly.

THE COURT: Well, I don't want to get

into whether it's a moving target or not.

MR. ALLEN: Yes, that's just --

THE COURT: It seems that counsel is trying to be responsive to some things that I've said and to work things out with other counsel and trials, you both know that, trials are like this. What I'm trying to do is work as hard as I can given that I have other cases that also deserve my attention and to give you rulings in a timely fashion so that I don't disrupt when people are going to go on, and that requires both of you to get me stuff to rule on. And the weekend is going to be not entirely devoted to this case, but I'm going to spend a bunch of time precisely on this -- I think that's the primary thing for me to work on, is the deposition designation issue, and so I'm going to do that. And -- but it would help me to know in prioritizing which one -- because I don't know if I'm going to get through seven --

MR. ALLEN: Let me tell you that. There's going to be a meeting on my team this weekend on that subject, but I can tell you now which one that you need to focus on. You've done Torres and Lechleiter. I believe --

THE COURT: I would assume the two I

got yesterday would --

MR. ALLEN: George, I can only do one thing at a time.

I've given you Jordan and Bandick --

THE COURT: Spell the last one.

THE WITNESS: B-a-n-d-i-c-k, also spelled o-f-f dash l-a-b-e-l.

And --

THE COURT: So, are those the next two --

MR. ALLEN: No, sir, I can't say it but here's the one that I would like the Court to look at. I'm going to have a meeting. With your permission and with the opposing counsel's permission, I may be able to, as you said, meet you somewhere, send a note with them, and give you a better idea. But I'd look at Charles Beasley, Dr. Charles Beasley, I think will be played early next week. Lechleiter is going to be played first. You've taken care of that and if they have to turn theirs on and off, whatever. But Dr. Charles Beasley is I'd concentrate on, and that's where I am.

THE COURT: This is -- this is what

I'm going to say: I would like, as to the Torres and Lechleiter proposed adding for the defense cuts for completeness purposes, I'll -- if you give me -- let me know right now I've got one for Torres and seven listed for Lechleiter. Let me know by the end of the day which ones I really need to rule on.

As to the cuts for the new five I'm going to get today, if Lilly could give me --

MR. LEHNER: We could do them -- if we get those at some point today, we'll turn them around by noon tomorrow.

MR. ALLEN: I'll do it --

THE COURT: Noon tomorrow, and I'd like, if you could let me know -- I got seven. Here's the order we'd like to work them in, because this is the order they're going to play them in. If you can let me know by noon tomorrow, and what I'll do is meet both sides to get the stuff they're going to give me at noon in -- in the lobby in front of the registration desk of the Cook.

MR. ALLEN: By the way, Your Honor --

THE COURT: If that will work for everybody. All you're doing -- we're not talking about the case, because we won't be on the record. You're just going to give me the paperwork.

MR. ALLEN: Your Honor, you said Friday nights are sacrosanct for you and in Houston I always go get a margarita. I haven't had one -- where is the best place --

THE COURT: We have a disagreement here. There's a place called La Mex that I think a lot of people are fond of here in town. Mr. Borneman likes Las Margaritas. I'm not sure --

MR. FIBICH: We'll report back on our study Monday.

MR. ALLEN: Let me also say, Your Honor, just for the record. The rule that I was citing is 104(b), conditional relevance. I thought it was in the 1s.

MR. LEHNER: Your Honor, it would help, even before we get the cuts, if our people can start looking at them. If you could tell me the five that you're going to give him. Ask -- Scott, what are the five?

MR. ALLEN: Hold on. Beasley, Kinon, Toleffson, Taurel, and I'll mispronounce this -- Wojcieszek.

MR. LEHNER: Robin. I got it. Okay. That will help us, Your Honor.

THE COURT: So the plan is I'll meet

everybody at noon in front of the registration desk to get this information so that I can start working Saturday afternoon on my assignment.

MR. ALLEN: I can tell them and you right now, I'd concentrate on Beasley and Wojcieszek.

THE COURT: And you're going to get me these new five cuts sometime today?

MR. ALLEN: I've been told I am. Yes, sir. I promise.

THE COURT: I certainly can't do any of it without that.

MR. ALLEN: I promise, Your Honor. Under Rule 104(b), I promise.

THE COURT: Anything else?

MR. LEHNER: Last but not least, I mentioned to the clerk, in light of the publicity, if the judge would inquire of the jury if anybody has been paying attention to any of this, Your Honor, we would appreciate it.

THE COURT: I may not do it that way. I mean in some ways, I've instructed the jury several times on this, and they're being asked to do that. I realize it's better to know about it sooner rather than later, so rather than kind of ask

whether you've disobeyed my instructions, I want to give them instruction that sometimes people inadvertently see things that they're not supposed to see. If that happens I want to be advised of it. And that way the jurors can come forward --

MS. GUSSACK: Thank you, Your Honor.

THE COURT: I'll also be reminding the jurors, and I'll remind everybody here and hopefully myself, that Daylight Savings Time for some reason starts on Sunday. And so if people forget about that they're going to show up on Monday an hour late, and I'll be reminding the jury of that as well.

Oh, yeah, there was some discussion in when we did the voir dire of the questionnaire for -- was it Mr. Hinton?

THE CLERK: Ramsey.

THE COURT: Mr. Ramsey. I thought it was Mr. Hinton. It was Mr. Hinton. Where there was some question about that, and I'm going to make that -- make his questionnaire a part of the record, but make it sealed -- I'm going to seal it. That way, in case there's any dispute about the issue and what Mr. Hinton actually said on his questionnaire, we've got the questionnaire. The remaining

questionnaires I generally would not make part of the record unless I -- unless somebody wants them all to be made part of the record. They'd have to be confidential if they were and I'm not sure I see a reason for it. But Mr. Hinton's jury questionnaire we'll make confidential -- make part of the record, but it's to be made confidential.

Anything else?

Then why doesn't -- we'll give the jury a three- or four-minute heads up and get started with the evidence.

(Off record.)

THE COURT: Please be seated.

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

Good morning, ladies and gentlemen. And, again, I apologize for the delay. As I told you, we sometimes have pretrial matters and we had quite a few of them today.

A couple of things before we get started with the evidence. First of all, I want to remind you and I'll probably do it at the end of the day that for some reason we're starting Daylight Savings Time this Sunday, and if you forget to start -- set your clocks ahead on

Sunday, you're going to show up on Monday an hour after we're supposed to start. I'd like to remind everybody, if they'd please try to remember that.

Secondly, there continues to be a lot of pretrial -- or trial publicity in this case. I know I've instructed you and I'm assuming that none of you have done anything you're not supposed to do about not reading papers or listening to TV news if it's about the case or anything like that. But I also know that sometimes things happen by accident, and so I'm just going to instruct you that if for some reason you know you're not supposed to do that, but suddenly you find yourself wandering your eyes down the paper or anything like that and you happen to read an article about this case, would you please send me a note that this happened so we can make an inquiry.

VENIREPERSON: I have someone else's notes and would like to have them returned to who they belong to, and I don't know how we would then do it --

No, no, it's one single page.

Mark, do you --

THE COURT: Why don't you pass it around to the other members of the jury and --

VENIREPERSON: I don't want to read it.

THE COURT: -- whoever's handwriting it is if they could just grab it.

That's straightened up.

Just if anything inadvertent happens like that, don't discuss it with the other members of the jury. Just send me a note advising me what happened, and then we can deal with it. It's much, much better to deal with these things as they happened than two weeks after they've happened. Legally, it makes it much easier to deal with the problem.

One of the jurors asked a note at the end of the day yesterday if they could get the brand names matched up with the generic names for some of the drugs. And the parties were going to get together and agree on that. Did that happen?

MR. LEHNER: Yes, sir. It did, Your Honor. I can write it down and have the sheet for you if you want to do it at the first break here.

MR. ALLEN: I can do it now out loud --

THE COURT: Okay. Mr. Allen, why don't you do it out loud, but it might be actually helpful if nobody objects, if we write it down and give each juror a cheat sheet of -- these names are not easy to pronounce or easy to recognize, and if we could maybe have typed up at some point for each of the jurors a little cheat sheet that they could have with -- along with their notes as to this drug is this generic and -- but we'll let --

MR. LEHNER: Rather than -- as he indicated here, he's not a perfect speller.

MR. ALLEN: I'll finish it.

MR. FIBICH: Abilify.

MR. ALLEN: No, no, I'm surprising you. This is the hard one, Judge. If somebody could give me the spelling --

MR. SUGGS: A-r-i-p-i-p-r-a-z-o-l-e.

MR. FIBICH: Do Haldol, Scott --

MR. LEHNER: I think we're talking about the second-generation -- those are the second-generation antipsychotics, I think --

THE COURT: Okay. Did the jury want the first-generation antipsychotics? Would that --

MR. ALLEN: I'm sorry, you probably can't see that, but --
MR. LEHNER: If we can get a list typed up.
THE COURT: If we could get a list typed up and maybe a copy for each of the 14 jurors, that possibly would be useful. And one for me, please.
Is the State ready to call its next witness?
MR. FIBICH: Your Honor, we are. At this time, the State of Alaska would call Dr. John Gueriguian.
THE COURT: Doctor, if you could please remain standing, we'll administer an oath to you.
(Dr. John Gueriguian sworn.)
THE CLERK: For the record, Doctor, could you please state your full name and spell your last name for the record?
THE WITNESS: May I sit, sir?
THE COURT: Yes, please.
THE WITNESS: John Leo Gueriguian, G-u-e-r-i-g-u-i-a-n.
THE COURT: Mr. Suggs.

MR. FIBICH: Mr. Fibich.
THE COURT: Mr. Fibich. I'm sorry. It's a Friday.
MR. FIBICH: That's a blessing.

DIRECT EXAMINATION

Q. (BY MR. FIBICH) Dr. Gueriguian, would you pull the microphone a little closer to you so that we make be sure the people in the courtroom have the benefit of the testimony.
If you would, sir, state your name for the record?
A. John Leo Gueriguian.
Q. Dr. Gueriguian, how young a man are you?
A. I beg your pardon?
Q. How young are you?
A. I'm 73 years old.
Q. Where do you currently reside?
A. I reside in Rockville, in Maryland.
Q. Is Rockville, Maryland also the location of the United States Food & Drug Administration?
A. Yes. Except that they may have changed recently to some other locality within the Montgomery County.
Q. Okay. In the Maryland area?
A. Yes.

Q. Dr. Gueriguian, your accent is one of which I am not familiar. Will you tell the jury where you grew up?
A. I grew up in Egypt.
Q. And how did you end up in Egypt?
A. Because my parents were survivors of the Turkish massacre, so they just walked to Egypt where I was born later.
Q. So you were actually born in Egypt?
A. That's right.
Q. And did you attend what we would call our high school, grade school-type education in Egypt?
A. Yes, I attended the French baccalaureate system.
Q. Graduated from high school?
A. No.
Q. And how did you get your degree to allow you to go to medical school?
A. Well, the last two years of the French system of high school I worked as an independent candidate while working to support my mother, and I was a free candidate, and I passed with success the two final exams.
Q. And following that, what did you do?

A. I was pleased to be accepted at the University of Paris.
Q. And is that the -- at the Sorbonne?
A. It's called the Sorbonne. At that time it was the Sorbonne, yes.
Q. And is that a highly-acclaimed institute of higher learning in France?
A. Yes, according to the Peterson's guide, it is at par with Oxbridge -- Oxford and Cambridge.
Q. What course of study did you take in Paris?
A. Firstly I went through the arts -- liberal arts and science college where I satisfied my premedical requirements. Following that, I entered the medical -- the University of Paris Medical High School where over a certain number of years I fulfilled their three obligations to become a medical doctor.
Q. What are those three, sir?
A. The first one is to follow a six-year curriculum and pass all the exams. The second one is the obligation to prepare a scientific thesis, a medical thesis, and present it to a jury and have it accepted. And the third one is

to go through two years of internship and one year of residencies in an accredited hospital.
Q. Okay. And you talked about presenting your doctoral thesis to a jury. What do you mean by that?
A. Well, any doctoral thesis after its preparation has to be, quote, put into printed form, presented to the members of the jury, which are professors, expert in the matter under discussion or under scrutiny, and you have to make a presentation. You have to defend your positions in answering the questions by the various members of the jury, and at the end, you are or not, passed and obtained the doctoral degree.
Q. And your doctoral thesis, sir, was on what?
A. My doctoral thesis was on a method that I developed or rather -- a novel use of a method that was developed earlier to predict whether a testicular cancer in humans was of the lethal kind or of the less severe kind.
Q. Good. And was your doctoral thesis, did you meet the requirements for that thesis?
A. According to the jury, yes.

Q. And were you awarded a -- what we would consider the equivalent of a medical degree here in the United States?
A. Yes.
Q. How would you compare the rigors of the requirements for graduating from medical school in France to graduating from medical school in the United States?
A. Well, since I was a professor in two U.S. medical schools, I would say that it's at least just as rigorous. Plus the fact that we obtained in France a better sense of clinical examination and diagnosis and prognosis. So it's at least as good as the two medical schools where I was a faculty in the United States, one in Chapel Hill, North Carolina and one --
Q. We're going to get to that. Before we do, explain to the jury what degrees or what equivalent of degrees were bestowed upon you by the University of Paris.
A. There -- while I was preparing for my thesis and I went -- I had the -- the right, if you will, because I had succeeded in second, third and a year of medical school, to work simultaneously going back to the liberal arts and

science college where I obtained the equivalent of a master's in chemistry and endocrinology.
Q. So, you have a master's in endocrinology, a master's in chemistry, a Bachelor of Science in biology, and your doctor -- your doctor degree from the University of Paris?
A. It's almost that. One little correction, if I may. I have the equivalent of one master's which had chemistry as its major and endocrinology as a minor.
Q. Okay. And then were you accepted as a doctor in the United States? How did -- how did you become certified as a doctor in the United States?
A. Well, the certification of somebody who has obtained a foreign medical degree is through an examination that is the ECFMG examination, the FMG referring to foreign medical graduates. It's an equivalency test, and I passed -- I took that test and passed it.
Q. So were you licensed in the United States when you came to the United States?
A. No.
Q. But you passed -- what was the effect of

passing this test that you refer to?
A. It -- it gave me the opportunity, if I so chose to exercise it, to go to an accredited hospital and eventually obtain board certification, but I wasn't interested in doing that, because I was interested in research and being a professor.
Q. Okay. When did you come to the United States?
A. 1965.
Q. And why did you come to the United States?
A. I was asked by a professor at Harvard whether I would be interested in occupying a post -- a post-doctoral fellowship at the medical school. I said yes.
Q. Tell us about that post-doctoral fellowship. What did it encompass and what did you do and how long was it?
A. At the post-doctoral level, I had two main duties; No. 1, to perform research. And, No. 2, to organize certain laboratory -- laboratory examples of laboratory work with groups of the medical students ad hoc.
Q. And did you complete that fellowship?

A. Yes, I did.
Q. And following that fellowship, did you return to France?
A. Yes.
Q. Why did you go back to France?
A. Because I had a so-called J Visa which wouldn't allow me to stay in the United States.
Q. What did you do when you returned to France?
A. I had a dual position in France. I was chief of laboratory at the biochemistry department of the University of Paris Medical School, and, secondly, I was a research associate in the NIH equivalent in France, which is -- has the acronym INSERM.
Q. The NIH acronym that you refer to is what is known as the National Institutes of Health in the United States; is that correct?
A. Well, I'm referring to the equivalent of the National Institutes of Health in the United States, and the name of that institution in France is the one that I just provided.
Q. In general, can you tell what the National Institutes of Health is in the United States and what their function is?

A. National Institutes of Health comprises any number of institutes, and it is an incredibly rich place where all sorts of research is performed, trainings are offered, and most importantly, it is a very important place where money obtained by commoners for research is channelled to the various institutions and medical schools in the nation.
Q. And with respect to your job when you returned to France with the European equivalent or French equivalent of that -- that organization, what did you do?
A. I performed research. I published articles, and that's what was expected of a research associate at that institution.
Q. How many peer-reviewed articles have you published, sir?
A. I believe about 40 -- I estimate about 40 to 50.
Q. Did you then return back to the United States?
A. Yes.
Q. And why?
A. Because my mentor at Harvard Medical had moved to the University of North Carolina in

Chapel Hill, and he asked me if I would be interested in coming and working with him and for him.
Q. And did you do so?
A. Yes.
Q. In what capacity did you work for him?
A. I began at the pharmacology department at the university as a lecturer in pharmacology. And after that, I became an -- an assistant professor of pharmacology.
Q. Okay. And how long -- and what courses did you teach there at the University of North Carolina at Chapel Hill?
A. I thought -- taught pharmacology courses in a wide array of important topics in pharmacology, general and specific, to medical students, to pharmacy students, and to graduate students.
Q. And did you leave -- did you leave that institution?
A. After four years, yes.
Q. And where did you go then?
A. I went to the University of Minnesota at Duluth.
Q. And what did you do at the University of

Minnesota Medical School?
A. Well, I just -- essentially what I was doing there, but with a better salary and a better position.
Q. And that was, again, teaching the courses in pharmacology to graduate students, medical students?
A. Yes. We didn't have pharmacy students in that institution.
Q. And as a result of your performance at the University of Minnesota Medical School, were you accorded tenure?
A. Yes, I was.
Q. Would you tell the members of our jury what tenure is?
A. Tenure is obtained, or not, after a seven-year track which is called tenure track, where you're not tenured. And you have to prove to the professors who are tenured, the senior professors, whether you are worthy of obtaining tenure. And if you obtain tenure, essentially, you can stay where you are for life.
Q. Can't be fired?
A. Nope. Unless there are -- you know, illegalities or improper activities but not -- it

has to be for cause.
Q. So, did you leave this lifetime position of professorship at the University of Minnesota?
A. Yes.
Q. And where did you go?
A. I came to Rockville.
Q. And for what purpose?
A. The purpose was to say yes to an invitation to join the FDA by people at the so-called Bureau of Drugs at the time, which is the CDER, C-D-E-R today.
Q. I'm sorry, the Bureau of what?
A. Drugs. Those are the bureau of new drugs, in effect.
Q. And when did you start at the FDA?
A. 1978.
Q. And how long did you work at the FDA?
A. The period of time I had decided to stay at the FDA, mainly 20 years -- precisely 20 years, and I retired in 1998 almost to the day, 20 years plus one or two days.
Q. Dr. Gueriguian, comparatively speaking, do people with the educational background such as yourself, being at the institute of -- University of Paris, Harvard Medical School, tenured

professorships, do people with your background make the same income at the FDA that they would make if they were out in the private practice?
A. No.
Q. Why did you go to work for the public sector in working in public health?
A. Well, simply stated, doing research was fine, but the opportunity to be useful to the U.S. and its citizens was -- and performing exciting duties and interesting projects, was something that I couldn't resist.
Q. And so you spent 20 years at that institution, the Food & Drug Administration; is that correct?
A. Twenty wonderful years. I enjoyed it.
Q. When you first got to the FDA, what position did you hold?
A. For a while, since the division where I -- I went to, or were assigned to, the endocrine and metabolic drugs division, at the beginning they didn't have a permanent director, so while I was hired as a group leader and medical officer, I was also asked to be an acting director until a new director was found.
Q. So this was a temporary position?

A. Yes.
Q. And did you serve in the position of acting director of the endocrine and metabolic division?
A. Yes.
Q. And when they found a full-time director, what did you -- what did you do then?
A. I went to other space and other responsibilities.
Q. What did you then hold?
A. Group leader and medical officer.
Q. What is a medical officer?
A. Medical officer of the Food & Drug Administration is the person in charge of two important tasks, the review of INDs and the review of NDAs together with any number of other subsidiary obligations.
Q. Dr. Gueriguian, we need to talk about acronyms. NDAs are what?
A. Well, NDAs come after the INDs.
Q. Well, let's start with INDs -- what does IND stand for?
A. IND stands for investigational new drug application. The A drops off because we can't tolerate acronyms for more than three letters.

Q. What does NDA stand for?
A. NDA stands for new drug application.
Q. And how are these related?
A. The IND is sent to the FDA by a drug company. In it the drug company has performed all the studies and chose the studies that were performed and, in effect, they're asking the FDA, here's the IND that shows, in our opinion, that we can begin testing the drug in humans. So that's what an IND is. But it's more than that.
The testing of humans is performed under the IND, and, again, the studies are performed --
Q. Under the IND or NDA --
A. IND. It's performed under the IND. And, again, the studies are performed, all of them, by industry. Again, they choose which studies to perform, and they are then obligated to send to the IND all the information of all the studies that are performed, together with other obligations.
Q. And then how does that go to the NDA?
A. At some point in time, the industry decides that it has performed sufficient studies to meet the statutory and regulatory requirement

for a new drug approval.
Q. And who determines whether the drug company has met the statutory and regulatory requirements?
A. In the first line, it is the -- the medical officer in charge of the NDA that determines and makes a recommendation. And as in any other institution, it works its way upwards where it is eventually approved or not approved or simply found to be approvable.
Q. Approvable means there's something else needed, correct?
A. Yes.
Q. Okay. So, as a medical officer, you would get the IND and determine whether or not you wanted to make a recommendation as to whether it's approved, not approved or approvable?
A. No, I would get the IND to make the first recommendation which says, yes, you can begin human testing. And then upon receiving and reviewing the NDA, I would at the end of the day make a recommendation of approval or nonapproval or approvability.
Q. Okay. And then how does that then go to a NDA, a new drug application?

A. Well, the NDA is -- has been received at the end of the IND work.
Q. Okay.
A. That is, once all the studies has been performed, and industry has decided it has performed enough studies to prove efficacy and safety of the drug, then it makes the NDA file and it sends it to the FDA. And usually your NDA file has anywhere from 500 two- to three-inch thick volumes up to 1500 and more. So it's a very, very immense --
Q. Amount of information?
A. That's right. To the point that nobody can be expected -- no medical officer can be expected within the time frame where he or she is supposed to determine whether the NDA can be approved or not, you can't read all the pages. It's just impossible.
Q. Okay. You mentioned -- as a medical director, you are the person in charge of the IND and the NDA; is that correct?
A. Medical officer, yes. The medical officer is in charge of the scientific aspects of the NDA -- the IND and the NDA.
Q. And that would be your position as a

medical officer?
A. My position and the position of the other medical officer in the Food & Drug Administration, yes.
Q. During -- and you mention that there's an immense amount of information that comes in with these application; is that correct?
A. Yes, it's enormous. They truckload it.
Q. Does the FDA do any testing itself?
A. No. Not generally speaking, no.
Q. Where does the FDA -- where is the testing done that allows you to determine whether a new -- or a drug application should be safe enough to then test in humans and then safe enough to be approved for dissemination to the American public?
A. The testing is done at localities of the -- which -- which the pharmaceutical company chooses, and according to protocols that it has developed.
Q. I didn't mean where physically. Who does all the testing?
A. The -- either the scientists working for a drug company or scientists outside the drug company. The drug company then outsources those

studies to such institutions and organizations, yes.
Q. During the 20 years that you were with the Food & Drug Administration, how many new drugs did you have come under your responsibilities?
A. Slightly over 100, I should think.
Q. Okay. And of those 100 drugs plus, how many were approved by you, sir?
A. The number -- a little bit over 100, minus three.
Q. Okay. And of the drugs that you had approved, were any of those -- and by the way, when you approve a drug, do you make a determination that the benefits of the drug outweigh its risks?
MR. BRENNER: Excuse me, Your Honor. We've drifted far from qualifications.
MR. FIBICH: This goes into his background as an FDA expert, Your Honor.
MR. BRENNER: It sounds like you need a proffer.
THE COURT: I'll give you a little bit of latitude, Mr. Fibich, but get back to qualifications.

Q. (BY MR. FIBICH) Let me ask you this way: Of the 100 drugs that you approved, were any of them later determined to be taken off the market?
A. No.
Q. Okay. Professionally, what do you currently do?
A. After leaving the -- in 1998 the FDA, I got called by clients calling me and asking me to be a drug consultant.
Q. And have you worked as a drug consultant?
A. Yes.
Q. And for whom have you worked as a drug consultant?
A. I've worked for industry. I worked for law firm. Mostly for Plaintiffs, but on occasion Defendants. And I work for the media. Anybody who wants my services under conditions that I be objective in my rendering an opinion is welcome as a client.
Q. What drug companies have you consulted with following your tenure at the FDA?
A. I remember Bristol-Myers. I remember Johnson & Johnson. I remember Sanofi. It wasn't at the time Sanofi-Aventis -- it was -- the

merger hasn't occurred.
Q. Dr. Gueriguian, are you charging for your time here as an expert?
A. Yes.
Q. Dr. Gueriguian, would you explain to our jury how you used the disciplines of chemistry, pharmacology and the principles of internal medicine in the performance of your duties as a medical officer at the FDA?
A. Well, the drug -- review of a drug's characteristics fall under various categories. No. 1, physical chemistry and manufacturing; No. 2, animal studies or pharmacology; and No. 3, clinical trials or human testing.
In addition, they are the disciplines of epidemiology or statistics or pharmacology that are needed for the medical officer to have an overview in order to determine whether the -- as mandated by the statutes and the regulations -- whether or not the drug in question, its benefits exceeds its risks for the indications it has been tested. That is to say, for the diseases -- the diseased patients in which the drug was tested.
Q. And Dr. Gueriguian, did you use the disciplines of epidemiology, statistics,

chemistry, pharmacology, and internal medicine principles in the performance of your duties during the 20-year period you were at the FDA?
A. Yes.
Q. Dr. Gueriguian, is the label an integral part of the new drug process?
A. Yes.
Q. Please explain.
A. The label is the link to prescribers, and prescribers need to know everything that is important about the drug in order to determine for one of their patients whether a particular drug is indicated or not.
That's very important.
Q. In the 20 years that you were with the FDA, did you regularly rely on and use the Code of Federal Regulations with respect to labeling issues?
A. Yes, I did.
Q. And how frequently was that coming under your purview?
A. Well, a medical officer receives in the NDA a labeling proposal entirely written by the drug company, and the medical officer has to look at all the data and see if the label is

appropriate to inform the prescriber and says yes or no and what are the flaws, if any.
Q. And was that something you regularly dealt with in dealing with labeling with drug companies that had new drug applications?
A. Yes. Part of the duty.
Q. And did you have meetings and discussions with other members of the FDA regarding the interpretation and application of the federal regs with respect to labeling?
A. Yes. It stands to reason that industry's interest is important, and if you do something at the FDA or if you propose something to industry that is not acceptable by the statutes and the regulations, they're going to cut you down and that's normal. So you learn and you try your best to do everything that you do in strict accordance with statutes and regulations.
Q. Are you familiar with the Code of Federal Regulations with respect to labeling?
A. Yes, inasmuch as I have used them for over 20 years. I mean, 20 years, not over.
Q. Are you familiar with the policy of the FDA on the regs insofar as they apply to labeling?

A. Yes.
Q. Are you familiar with the custom and practice of the FDA as to how it applies the federal regs with respect to labeling requirements?
A. Yes.
Q. Dr. Gueriguian, did you also have a subspecialty as a medical officer dealing with antidiabetic drugs?
A. Yes, for 20 years -- except for the last couple of years, for 18 years exactly, I was the only medical officer in charge of all the diabetic drugs.
Q. Have you heard Lilly referred to as the diabetic care company?
A. Yes, I have had very good relationships with Eli Lilly for a number of years, and I'm completely familiar with what they do and what they say about what they're doing.
Q. With respect to the antidiabetic drugs?
A. That's fine.
Q. Did you work with Eli Lilly with respect to their antidiabetic drugs?
A. Yes, yes, absolutely. In very significant ways, I may add.

Q. Dr. Gueriguian, the FDA was referred to as a cop on the beat. Is that a characterization that you would accept?
MR. BRENNER: Your Honor, no qualifications --
THE COURT: We're clearly getting beyond qualifications. Are you offering him at this point?
MR. FIBICH: Yes, sir. Your Honor, at this time we would proffer Dr. Gueriguian as an expert based upon his background, experience at the FDA, his scientific and medical training. We offer Dr. Gueriguian as an expert in the area of labeling as to the practice and custom of the FDA and labeling requirements, in the field of pharmacology, epidemiology, diabetology --
THE COURT: You need to move a little slower for me, Mr. Fibich. We've got labeling, we've got practice and custom of the FDA.
MR. FIBICH: And in the fields of pharmacology, epidemiology, diabetology and medicine as they deal with matters before the FDA.
We believe that the testimony of Dr. Gueriguian that I have just elicited would show that he has expertise such that he would

educate the jury in accordance with the Alaska rules.
THE COURT: Mr. Brenner.
MR. BRENNER: Voir dire, Your Honor?
THE COURT: You may. Ladies and gentlemen, just so you understand the practice, when someone is offered as an expert, the attorney who is offering the expert has an opportunity to present the witness' credentials and the basis and areas in which they're an expert. The other side, before I rule as to whether I'm going to consider them an expert or whether you should consider them as an expert, has an opportunity to do what I'm allowing Mr. Lehner to do, to also ask some questions about that subject. And then I'll make a ruling as to whether or not I will recognize the witness as an expert or not and in what areas.
Again, you are the sole determination of the credibility of the expert and how much weight you want to give to their testimony. Please, Mr. Lehner.
VOIR DIRE EXAMINATION
Q. (BY MR. BRENNER) Good morning, Doctor. We've not met. My name is John Brenner.
Doctor, you've never read the labeling

for Zyprexa before you rendered your report, did you?
A. Well, you're referring to something that happened during a deposition in April of 2007.
Q. I'm just asking you a fact, sir. You never read the labeling for Zyprexa before --
MR. FIBICH: I'm going to object. What he's read is not a part of his qualification --
THE COURT: Let him answer the question.
A. I read about -- in documents that were not -- the labeling -- that were not the labeling itself. I read and extracted an awful lot of information that pertained to labeling.
As to whether I read or not, I think that at the end of the day, after being asked the same question three times, I answered in a manner that could be misinterpreted to mean that I didn't read it. But that's not -- was not my intent.
Q. Let's make sure we understand your intent, sir. There's a thing called a label or package insert for every drug in the United States that's approved for sale, correct?
A. Yes.
Q. Before you gave your deposition, you

never read that package insert or any package inserts for Zyprexa, did you?
A. I read -- no, I didn't.
Q. Thank you. You left the FDA in 1998, correct?
A. That is right.
Q. And the division you worked in there was the endocrine and metabolic division, correct?
A. Yes.
Q. There's another division at FDA called the division of neuropharmacological and drug products, isn't there?
A. Yes.
Q. You never worked in that division?
A. No.
Q. That's the division that was responsible for Zyprexa, correct?
A. That is correct.
Q. You never worked on the Zyprexa new drug application?
A. No.
Q. Now, within the FDA there's another division known as the division of drug marketing, advertising and communications, right?
A. DDMAC.

Q. That's called DDMAC. D-D-M-A-C, right?
A. That's right.
Q. And DDMAC's job is to review prescription drug advertising --
THE COURT: Mr. Fibich.
MR. FIBICH: Objection; this does not go to the scientific or expertise background, Your Honor. It's just cross-examination on other issues that should come out on cross.
THE COURT: That's overruled.
Q. (BY MR. BRENNER) Doctor, DDMAC reviewers have responsibility for reviewing prescription drug advertising and promotional labeling, correct?
A. That is correct.
Q. Okay. Now, within FDA there's also an office of chief legal counsel, right?
A. Yes.
Q. You never worked there, did you?
A. I worked with them as I worked with DDMAC as I worked with neuropsychology.
Q. But it was not the division you worked in?
A. No.
Q. The office of chief legal counsel, they have attorneys principally that work there,

right?
A. Yes.
Q. And one of their responsibilities is the drafting and reviewing of all proposed and final regulations of Food & Drug Administration, correct?
A. I don't know what is their precise obligations.
Q. Could I have TD 151, Mike? Blow that up a little bit, the major functions part.
Doctor, you have that on your screen in front of you. This is pulled from the FDA's web site. This is the home page for the office of counsel. As you looked at No. 4 -- they look --
THE COURT: Again, now I do think we're moving outside of qualifications.
MR. BRENNER: I have one more question. We can take this down. Take that down, Mike.
Q. It's the office of chief counsel in the FDA that's responsible for promulgating the FDA's formal position and interpretation and interpretation of regulations, right, Doctor?
A. Well, I worked with that counsel office several times and the understanding was that

under the FDA -- FDC & A -- FD & C Act, science was the obligation of the determining of the scientists while the legal counsel was to put it in a form that was legally acceptable.
Q. And when a regulation had to be formally interpreted or promulgated by the FDA, that was the principal job of the office of chief counsel?
A. I don't think so. The legal -- the legal determination of matters relating to scientific and medical things are first in the purview of the scientists and the doctors.
Q. And then it goes on to the office of chief counsel?
A. Yes.
Q. You never looked at the entire new drug application for Zyprexa, did you?
A. No.
Q. You never looked at the entire IND for Zyprexa, did you?
MR. FIBICH: Your Honor, I object. This is beyond voir dire.
THE COURT: No, this I will allow because the limits of his work and what he did may affect what I decide.
Q. (BY MR. BRENNER) You've never looked at

the entire IND that was submitted by Lilly for Zyprexa, did you?
A. Neither the IND nor the NDA were supplied. And if supplied, I couldn't have read it.
Q. You've not reviewed all the correspondence between the Lilly and the FDA regarding Zyprexa?
A. No, I didn't review everything that is concerned with this question, which I'm sure occupies the size of this room, probably.
Q. You've never read all the FDA reviews and evaluations, the internal FDA reviews and evaluations of the Zyprexa application, have you?
A. You're right.
Q. You've never spoken with anybody at the FDA about the Zyprexa application?
A. I -- we're not permitted to speak to people -- to the FDA on matters that are confidential.
Q. Doctor, am I correct, you are not licensed to practice medicine in any state, are you?
A. No, I'm not.
Q. You never conducted any private practice

of medicine within the United States, have you?
A. That is correct.
Q. You're not a psychiatrist?
A. No.
Q. You're not an epidemiologist?
A. No, but I understand and use epidemiology, and I invented even a system of immunoepidemiological observational studies.
Q. You're not a board-certified endocrinologist in the United States?
A. No.
Q. You don't know the symptoms of schizophrenia, do you?
A. No, sir. As an expert, no.
Q. You don't know what cluster of symptoms are required to make a diagnosis of schizophrenia --
MR. FIBICH: Your Honor, we're not offering him for these purposes. It goes beyond --
MR. BRENNER: If that's true, Your Honor, I'll stop.
THE COURT: My understanding is that was not one of the topics. Psychiatry or schizophrenia was not one of the requests that I recognize him as an expert.

MR. BRENNER: If that's the agreement, it may be of some significance later. Your Honor, those are all the questions I have of this witness, but I do have an application regarding this witness.
THE COURT: Okay.
MR. BRENNER: I can take it sidebar out of the presence of the jury. I can do it sidebar.
THE COURT: No, I have a feeling it's going to be a little bit longer.
MR. ALLEN: They usually are.
THE COURT: Mr. Allen, I really wish you wouldn't.
MR. ALLEN: Sorry.
THE COURT: Ladies and gentlemen of the jury, I need to take a matter outside of your presence. We'll try to keep it short and so I'll ask you to go back to the jury room at this time. Please stay close, however.
(Jury out.)
THE COURT: We're outside of the presence, and, Mr. Allen, I have more tolerance for good-natured banter outside the presence of the jury than I do in front of the jury.
MR. ALLEN: I got it. I apologize,

Your Honor.
MR. LEHNER: Your Honor, can I just make one comment with respect to that? I'm not going to rise every time but I would out of respect and regard for Mr. Allen, maybe give him a copy of these notes that you had prepared in your courtroom where it indicated that if he's prepared to treat the other side as Saddam Hussein, then he has to accept the consequences and the judge will notice the stratagem. And I'm going to provide them to Mr. Allen because --
MR. FIBICH: Don't do that.

MR. LEHNER: -- the comments about off-label and Mr. Bandick were really out of hand.
THE COURT: I think everybody is pretty aware of what I expect. I don't know if you've seen it, Mr. Allen, what Mr. Lehner's referring to -- excuse me, Mr. Brenner --
MR. BRENNER: It's a long trial, Judge. You'll get it.
THE COURT: I'll get it right at the end -- now that I made it for both sides. I have a little handout that people get.
MR. ALLEN: I have it, Your Honor.

THE COURT: But I'm quite capable -- I'd like to think I'm quite capable of letting people know what I'm expecting of them and letting them know if they're going over my rules and over my line, and I've done that. And I understand it's an important trial to both sides and that at times emotions may run high and, again, I have more of a tolerance for good-natured banter which is how I took that, as outside the presence of the jury than I'm going to tolerate.

MR. FIBICH: Your Honor, Mr. Allen did apologize to the Court. I know it's Friday and I'm testy but we don't need them to lecture us on anything and by the same token --

THE COURT: I'll give the lectures, at least on courtroom decorum.

MR. BRENNER: Your Honor, please.

THE COURT: Mr. Brenner.

MR. BRENNER: There are really three parts to this application. The first is really quite narrow. Dr. Gueriguian just confirmed that he did not ever read the labeling for Zyprexa. That being the case, he should not be allowed to offer any testimony about its adequacy or about anything related to the labeling. Had he done so and

prepared his report and been prepared to testify about it, we could have cross-examined him about it. We don't. This is not so much qualifications as no foundation. And so, in this whatever testimony he's proffered for, he should not address label issues related to Zyprexa. That's No. 1.

No. 2, with respect to regulations, we gave Your Honor a brief on that, as of course as many Courts say, there's only one expert on regulations in the courtroom and that is the judge. Witnesses, lay witnesses in particular who had no direct dealings with regulations should not be offering opinions regarding how regulations are interpreted nor how they're applied.

And third, I'll state this by way of a concern in terms of the proffer, Your Honor. My concern is this: This is a witness through whom I am afraid are going to be poured like a conduit, a number of internal documents, various documents of Lilly, and he will express a personal opinion about them. Lilly wasn't good. Lilly didn't do something it should have done.

There will be no standard. There is no expertise being brought to that. What

there is is the imprimatur of an expert, someone Your Honor finds qualified in some discipline, who then gets to say, oh, I've looked at that document, that document, that document, and I can tell you, jury, as an expert that Lilly acted improperly, that Lilly failed to act as a responsible company. That's something that is in his report. That, Your Honor, respectfully, is personal opinion. Looking at e-mails or looking at internal documents is not under Rule 703 a type of evidence upon which an expert would reasonably rely and I don't believe this witness should be permitted to give that kind of testimony. That is our application.

THE COURT: I'm going to take up the last two and then ask for some response from the Plaintiffs as to the first one. As to the question as to the -- how the FDA goes about doing things and regulations, I do find that by virtue of his background, training, experience, Dr. Gueriguian has sufficient expertise that I'll allow him to testify in that area. And to the extent that internal documents were shown to him or part of his report, which they clearly are in reviewing the report and I don't have his whole deposition but I have experts,

I think you're on notice of that. You can cross-examine him, and -- but -- and I note that the opening clearly was based on the FDA's the cop on the beat and the FDA takes care of these things, and I'm grossly paraphrasing it, obviously. But given that, what the FDA really does or doesn't do and what was seen by the FDA in this matter, which I think is part of what his report is about, is, I think, a very appropriate subject and I believe he has the training and expertise to discuss that.

The question of whether he's going to be allowed to offer an opinion about a label that he never saw, at least, and doesn't discuss in his report or never -- indicated he had never seen in his deposition doesn't so much go to his expertise as it does go to the notice question, and so that's my question for you, Mr. Allen.

MR. ALLEN: Yes, sir. And Mr. Fibich of course, is working with the witness, but I've been asked to answer these questions, and I believe the doctor tried to explain it. He had a wide variety of material. Within the material -- and I can show -- I can give examples if I can find the file, there is portions of the label within the material. In other words, for example, their

letter -- I'm just -- this is -- may not be an example for this witness. But their letter that they wrote -- "they" being Lilly wrote in 2007 is a letter. The label is attached as part of that letter.

Within the material the doctor reviewed, I believe he tried to express this, after a three-hour, whatever he said deposition, he reviewed a lot of material that had the label and materials with the label within it, as opposed to having the label, as opposed to having something by itself identified as the label. So the witness has reviewed portions of the label. The witness has the label within the documents. He doesn't have segregated out a label sitting by itself.

The fact that they chose, for whatever reason, not to delve into the matter and cross him and come before the Court now and say we're surprised is just not accurate. Again, as the Court's pointed out, I think earlier today. I think it was today -- I've already forgot it's today -- there are a lot of matters that are effective for cross-examination to peg them down to score points as opposed to disqualify them as

an expert.

MR. BRENNER: This is not disqualification, Your Honor. I'm not talking about the deposition. What he just said was I never read the labels --

THE COURT: What I understand -- what I hear the debate about, so I want to be very clear about, he said he never read the label package insert stuff. But was he -- did he see and read and were the documents that he reviewed and are discussed either parts of the label, portions of the label, the label attached to a letter. Here's the warning section, here's the adverse reaction section, it's that kind of a thing. And so while I might not let him opine about the entire label, I will certainly let him opine about to the extent he was reviewing documents that discussed the getting to the label, parts of the label, portions of the label, I think you're on notice of that.

MR. BRENNER: I'd be hard-pressed to tell Your Honor where he read parts of the label -- other than a very small portion.

MR. FIBICH: I am going to tell you, I get one -- probably the only benefit of being the oldest lawyer in the firm -- in the room is I can

always go back to when the court reporters did this sort of stuff with pen and ink; I'm that old. What we have now is computers that do these depositions and attached to Dr. Gueriguian's deposition are line and page where he discusses label. There's line and page where he discusses labeling. There's line and page where he discusses labels plural. There are over 100 references in here --

THE COURT: That may be helpful, Mr. Fibich, but I'm not sure, because he may have been discussing the process of how a label has got to in a very general sense, without discussing the Zyprexa label or portions of the Zyprexa label, or he may have been discussing the Zyprexa label quite specifically.

MR. FIBICH: Well, what Mr. Allen said was exactly right. He has gone through the records and certain records of Lilly, certain records that were given to the FDA, certain records that were in Lilly's possession, and made determinations as to how that would affect the label. Now I'm not going to hand him the 2007 label. I'm not going to hand him any label other than to talk about what he saw within the records that in his performance --

THE COURT: This is how I'm going to

cut it so we can bring the jury back. I'm not going to let him issue an opinion that says the label is adequate or inadequate or bad and good. I will let him say, I reviewed these records and I reviewed this portion of the whatever he reviewed and the adverse determination and what I reviewed was not in -- I assume this is what he's going to say, is not in keeping with what's appropriate with the FDA. I'm not going to let him answer -- offer an opinion about entirely the level -- the label, and certainly nothing about the 2007 label, but to the extent he -- he will talk about documents he reviewed that contain portions of the label or sections of the label or whether something was attached or it was just -- that's the subject matter of the matters he reviewed, I will let him talk about that and you can cross-examine.

MR. BRENNER: And, Your Honor, just to be clear, though, I will be alert that he is tying it to some specific document. I don't want that to be a document I saw there said. I think that's the only way Your Honor's ruling can be correctly applied.

MR. ALLEN: They can object. If it's like in open court, we can object, sustained,

overruled. Like a trial.
THE COURT: That's certainly -- you're fair to make objections and certainly to the extent that foundation is laid ahead of time of exactly specifically what we're talking about, that's going to happen and those documents can be admitted.
MR. FIBICH: One other matter, Your Honor.
When they filed their motion, they attached Dr. Gueriguian's report. They did not attach all of Dr. Gueriguian's report. There are amendments to his report that were provided at the deposition of Dr. Gueriguian. These also are voluminous. Now, they are his notes, but they took them, they marked them, and I'd like for the Court to have that insofar as these attempts to limit his testimony.
THE COURT: To the extent we need to make a full record of what kind of notice there was and because that generally is -- I mean, there's two issues lurking around here. One is the areas of his expertise which I would find are numerous, and a second is the notice question, which is mostly what we're talking about here. So to the extent I'm not going to admit the notes as an exhibit or something,

but we probably ought to have a record of that for purposes of review.
MR. BRENNER: Your Honor, one inquiry. I think at the start of the trial before you at least commended to counsel in appropriate circumstances, a continuing type of objection, and I do not desire to interrupt direct unnecessarily. I understand Your Honor to have overruled my application regarding this witness' ability to provide personal opinions based on documents I would contend don't meet Rule 703. In particular, I'm talking about Lilly e-mails or internal documents. Is it appropriate in your courtroom to have a standing objection so I do not interrupt Mr. Fibich's direct unduly?
THE COURT: Absolutely. Absolutely and I appreciate the offer, and I will give you a standing objection to that.
MR. BRENNER: Thank you, Your Honor. I have this list here if you'd like to give to the jury.
MR. ALLEN: Is there any particular reason -- this is the reason. That's the order the products came to market.
THE COURT: I don't think the jury

cares about the order.
MR. LEHNER: We did it alphabetical --
MR. ALLEN: I don't care. It's signed -- I signed it.
MR. LEHNER: Copies there for the jury.
MR. FIBICH: Your honor, before you bring the jury, can counsel take a two-minute break?
THE COURT: Counsel can take a few-minute break. We're already at 10:15. So why -- we'll let the jury take a little bit longer break. Everybody else, we'll take about a ten-minute break and do what people need to do.
MR. SUGGS: Excuse me, Judge. Did you say two-minute or ten-minute?
THE COURT: Ten. And that will be our first morning break.
(Break.)
THE COURT: We're ready to resume with the doctor. And ladies gentlemen of the jury, all of you should have gotten a stipulation of the trade names of atypical antipsychotic medications with the generic names. As I instructed you at the beginning of the trial, stipulations are facts that the parties agree on and you should accept them as true.

I will recognize Dr. Gueriguian as an expert in the areas of labeling, practice and customs of the FDA, pharmacology, epidemiology, diabetology, and medicine as dealt with matters before the FDA.
Mr. Fibich.
MR. FIBICH: Thank you, Your Honor.
DIRECT EXAMINATION, continued
Q. (BY MR. FIBICH) Dr. Gueriguian, with labeling issues, was it within the course of your employment that you dealt with certain adverse events would be placed in the warning section or the precaution section or the adverse event section?
A. Yes, including the box warning section which comes after the warning.
Q. Are you familiar with the regulations as they would be applied to those particular areas that I just mentioned?
A. Yes, and I applied them in numerous occasions.
Q. And how would you apply those? What do you mean by that? How would you apply those?
A. The procedure is, generally speaking, very straightforward. We have doc -- the FDA has documents sent to us concerning safety and

efficacy. And the medical officer and other members of the review team looks at these documents, the same documents that the company has generated, and we then look at the label and ask ourselves a simple, but very important question: Is all the important information there in the label so that the prescribers would know how to utilize this drug, since this is a new drug, and the label has to be clear.

The label has to be, with respect to safety issues, emphatic, if it needs to be emphatic. And the information regarding safety has to be communicated through the FDA, through the prescriber to the patient in a timely fashion. Those are the criteria that we follow.

Q. And do adverse events sometimes occur after a drug has been approved and disseminated to the public?

A. It always occurs that way, more or less. More than less. The simple reason is that in the NDA you have usually relatively limited exposure of the patients -- the humans to the drug, and the only thing you can see, by and large, is adverse events which are equal or greater than 1 percent. However, in the post-marketing period,

new adverse events come and they may be rare, because they haven't been observed in the NDA, but they may be extremely serious, and these have to be communicated as such.

Q. And with respect to the headings that we've been discussing, that is, there's a warnings section, there's a precaution section and there's an adverse events section, correct?

A. Yes.

Q. What goes in the precaution section?

A. The precaution section tells the prescriber what are the -- what may be the situations where he or she has to be careful in prescribing this drug to a specific patient.

Those are the precautions.

Q. For example?

A. For example, if a person is diabetic, you do not want to automatically prescribe, without precaution, something, a drug that may be causing or compounding the diabetes problem because diabetes is a very serious disease.

Q. What goes in the adverse events section?

A. In the adverse events section, you have a grading of frequency, and at one extreme, you have very frequently moderate adverse events,

that is to say, they're not dangerous, they're just moderate, there may be discomforting, but they don't put in danger the person. On the other hand, you have infrequent events, specific events, but they can be very serious, very severe, and sometimes they're lethal, they kill.

Q. What goes in the warning section?

A. In the warning section, you have to highlight something so important with respect to the safety of a drug that special effort should be made to attract the attention of the prescriber and have in encapsulated form the information that is clearly out there, clearly visible, and not hiding in long labels.

Q. Well, the label itself is long, is it not?

A. Usually the label is long, and that's why there is a necessity to have special ways to attract the attention of the prescriber to some important pieces of information.

Q. And in the course of working with the 100 new drug applications and INDs that you worked at in the two decades you worked at the FDA, did you routinely deal with drug companies on where certain adverse events or reactions to

their drug would be placed?

A. Constantly, yes.

Q. And with respect to a warning section, you also mentioned that sometimes there is a bolded warning?

A. Boxed warning.

Q. Called a black-box warning?

A. Black-box warning, yes.

Q. And what is that?

A. A black-box warning is something that appears immediately at the top of the label. It's at the top of the label. It is usually bolded; the writing is bolded, and it is within a rectangular box so that the first thing that the prescriber sees when consulting the PDR or the label directly, he or she sees that.

Q. Okay. And you indicated that most of the adverse events oftentimes occur after a drug's on the market; is that correct?

A. Yes.

Q. And who is responsible for collecting that data, the adverse events?

A. Well, the FDA has the obligation to maintain an adverse report database, and everybody sends -- anybody can send an adverse

event report either to the company or to the FDA, and the company has the obligation to send all the things it -- the adverse events it has received to the FDA.

Q. Are you familiar with the term "a change being affected"?

A. Yes.

Q. What is a change being affected?

A. A change is being affected is a special regulatory concept and part of the regulation which allows a company to cut through the red tape if it feels that something of importance affecting safety, for example, has to be communicated quickly to the prescriber.

Q. Can a change being affected -- is it only limited to strengthening a warning?

A. A change is being affected can be doing anything the company thinks it should be doing.

Q. With respect to the responsibility of a drug company to change a warning when it receives notice of an association with its drug, are you familiar with that regulation?

A. Well, I don't recall the number off the top of my head, but, yes, I am --

Q. Let me show you what we've marked for

our blown-up, and this is the regulations --

MR. FIBICH: Your Honor, is that okay --

THE COURT: No, no, I'd rather the jury got a view of that. They don't need to see me.

Q. (BY MR. FIBICH) Can you see that, Dr. Gueriguian?

A. Yes, sir.

Q. Are you familiar with this particular regulation?

A. Yes, I've used it very often.

Q. Okay. And could you explain how this regulation works insofar as when a drug company should have a responsibility to amend its label?

A. Well, we're talking about serious events. We're talking about potentials -- hazards, safety hazards, and we're certainly talking about public health, protection of the public. That's what it's all about. So any competent company can determine whether this is the case, whether there are information -- they're available that -- mandated by the regulations to move an adverse event into a warning status.

Q. From what other status?

A. Well, you can have precautions. You can have the simple adverse events, which is a long list in any given label, and that's about the size of it.

Q. When is the labeling supposed to be changed, sir?

A. Well, the labeling is supposed to be changed upon essentially the perception of the potential risk and causality does not -- does not have to be proven at that stage.

Q. Why is that? Why is it important that it be done before causality is determined?

A. Well, causality is a very difficult proposition, and when a drug is approved, either the clinical trials and other experiences and studies performed by the company are sufficient to address causality, which is rare. You don't -- I mean, nobody has the time to wait for academia, for example, a few -- a number of years to prove causality.

Plus, when a drug is out there, it's very difficult to perform an epidemiological study. Nobody is interested in doing it. It costs money. So you don't have the practicality of proving causality while waiting that people are being, for

example, harmed, if that's -- if that's what's happening.

Q. So when the regulation says "reasonable evidence of an association of a serious hazard," a causal relationship may not be proved, the drug is under responsibility to change its label immediately upon knowing that there's an association, correct?

MR. BRENNER: Objection; leading.

A. If the situation warrants it, yes.

THE COURT: Hold on a second. Let me rule on the objection. Again, this is an expert witness. I will give some latitude in leading questions, but I'd also ask you to try to keep them down.

Q. (BY MR. FIBICH) When the drug company finds that there is evidence, reasonable evidence of an association of a serious hazard with a drug --

MR. ALLEN: Tommy, can you put that back up?

Q. (BY MR. FIBICH) When they find that, where are they supposed to put that information? In what part of the label?

A. Well, it depends on the degree of severity. Usually it's warnings that we're

talking about here.
Q. Now, is the label and where certain things go in the label something that is negotiated between the drug company and FDA?
A. Yes.
Q. Why is that, sir?
A. Well, first of all, it is only fair that each -- the FDA and the drug company sit down and defend their own position if the positions are different. But then if there's a disagreement, the proper thing to do is to call in outside independent expert authorities to cut the negotiation that is going on too long while people may be hurt. So that's the way it functions.
There's always a negotiation. Sometimes it drags for too long. Sometimes not.
MR. FIBICH: Your Honor, I need to use the ELMO. Is there somebody that can help me?
THE COURT: What do you need help with?
MR. FIBICH: Well, we can start with turning it on.
THE COURT: I think each team has got people that can do these things.

Q. (BY MR. FIBICH) Dr. Gueriguian, this is Exhibit 1596. You see this, sir? Can you follow it?
A. I don't see the number but I'll take your word for it.
Q. Well, assume with me it's 1596. It's an exhibit that's been offered into evidence, accepted into evidence.
A. Fine.
Q. And this has been produced in discovery, and there were certain redactions which were deemed appropriate.
It says, We anticipate different labeling, i.e., risk for hyperglycemia, treatment-emergent diabetes and related metabolic issues with our next submission. Expect label change in the precaution section at a minimum, more likely as a warning. Even if FDA attempts to class-label it could take six to 12 months to implement with other products. Analyst community has indicated this could be a trigger for Lilly disinvestment.
Do you see that, sir?
A. Yes.
Q. It goes on: There is substantial risk

in opening the Zyprexa label to a public advisory committee.
What is a public advisory committee?
A. I was at some point in time at the FDA a senior executive of our advisory committees, FDA advisory committees, formed by a number of expert scientists to help the FDA when the FDA is facing a thorny and difficult question. That's what an advisory committee is. And it's public. It's open to the public.
Q. What is meant by substantial risk in opening the label to a public advisory committee, if you know?
MR. BRENNER: Objection, Your Honor --
THE COURT: What's the objection?
MR. BRENNER: Your Honor, this is so far identified as an apparently internal document of Lilly. This witness can't comment on the state of mind of the writer of that.
THE COURT: That's a fair objection, but I think the question was qualified with an if you know, so --
Q. (BY MR. FIBICH) You know what's being referred to here, that there's a risk in a public hearing over opening the Zyprexa label to a public

hearing. Do you know what's meant by that? First of all, do you know?
A. I beg your pardon?
Q. Do you know?
A. Yes.
Q. Tell us.
A. First of all, as I mentioned, I was executive secretary of advisory committees. I dealt with these questions on a daily basis at times. Now, the advisory committee is asked a question by the FDA. For example, is this drug safe or not safe? Is this label must be changed in this fashion or not? And then the committee hears both sides and comes to a conclusion by addressing the -- by answering the question. And generally speaking, if the advisory committee decides by, say, a vote -- by eight members against one member that something has to happen, the FDA, generally speaking, follows the advice of the advisory committee. Those are well-known facts.
Q. Why would there be a concern, if you know, about opening the Zyprexa label to a public hearing as opposed to the position of the Zyprexa product team being in private negotiations?

MR. BRENNER: Same objection.
Q. (BY MR. FIBICH) What is meant by that, if you know?
THE COURT: Same objection. I'll overrule the objection.
Q. (BY MR. FIBICH) Dr. Gueriguian, do you know why Zyprexa preferred a private negotiation rather than a public hearing?
A. Yes.
Q. Tell us.
A. You can't control the advisory committee, except that you have ample opportunity -- each party has the ample opportunity to present their case and, therefore, that's what -- that's what defines an advisory committee.
On the other hand, when you enter into negotiations with the FDA, a number of things can happen. And, again, I'm going to cite facts that I know of.
You can have the FDA propose a labeling change. The company takes time to -- which is fair -- to look at it and comes back with a counteroffer, and this can go on for a long time -- for as long as the company, in effect, decides. And

that's its right.
But, at some point in time, I've heard, myself, and other medical officers discussing these negotiations say, look, we have an important piece of information here, we have to get it out, it's been six months or a year that the negotiations are going on. So it's better to have something out rather than nothing out. So they compromise. So that's what happens.
Q. Doctor, you mentioned six months to a year. Did you see the language up here: Even if FDA attempts to class label, it could take six to 12 months to implement with other products.
That seems like an inordinate long time. Does it sometimes take that long?
A. Yes.
Q. Dr. Gueriguian, down here on the last paragraph it says: The position of the Zyprexa product team is that private negotiations, in advance of a submission, provide the opportunity to better influence the outcome and that the timing of any outcome should be considered in the context of corporate performance.
Did you sometimes get the feeling that drug manufacturers that would deal with the FDA

would time their negotiations to influence corporate performance?
MR. BRENNER: Objection, Your Honor.
THE COURT: What's that one, given that it doesn't specifically relate to --
MR. FIBICH: I'll withdraw the question, Your Honor.
Your Honor, I'd like to publish this particular exhibit to the jury, if I may. Not the highlighted copy.
MR. ALLEN: It's 7822.
MR. FIBICH: May I do so, Your Honor?
MR. LEHNER: Your Honor, we previously had raised an objection to this exhibit.
THE COURT: And I believe I've overruled the objection.
MR. ALLEN: It's been admitted --
THE COURT: It's been admitted, and I'll allow it to be published to the jury.
And what that means, ladies and gentlemen, is they're going to circulate it so that you can all take a look at it individually.
And do you need your regulations up here, Mr. Fibich.
MR. FIBICH: No, Your Honor.

THE COURT: Just a little bit of clarity. Up until now, I've been tolerant of this, but I'd kind of like one attorney for one witness.
Q. (BY MR. FIBICH) Dr. Gueriguian, when we were talking about your background, there was a question posed to you about other divisions within the FDA, particularly the legal department, what was known as DDMAC, and the metabolic division; is that correct?
A. No, actually it was -- if my memory serves right, the neurology and psychiatry division.
Q. Okay. And in the course of your performance as a medical officer, did you interchange and work with those organizations, those divisions?
A. Yes.
Q. And tell us how you would do that.
A. Well, first of all, the -- the counsel's office, as I stated -- and that's based on the very important piece -- the statutes under which -- which mandate the FDA, this is a remarkable document where science and legality have fused to a wonderful -- I mean, if I stayed so long at the FDA, it was because this document

was an admirable one.
So, the rule one was, when I was there for 20 years, we listened to the medical officers, listened to the legal counsels. The legal counsels listened to the scientific and medical arguments, and they try imitating the statutes to come up with something that satisfies both sides, which is essential to the job of the FDA. The FDA is -- that's its job. It has to obey the law and satisfy the scientific and medical obligations. So that's the -- the first one. That's how it happened with the counsel's office.
Q. And the other two?
A. The DDMAC is a very interesting situation because they constantly ask medical officers to come and advise them on matters under their purview, and I have gone -- been asked by them several times to go and, again, contribute to them the scientific and medical issues that are pertinent to a given case that they're adjudicating.
As to the neuropsychiatry --
Q. What does DDMAC stand for?
A. DDMAC stands for promotions --
Q. That's okay -- how many languages do you

speak, Doctor?
A. Five.
Q. And the last one, you were going to tell us about the last one.
A. Yes, the neuropsychiatry, when a division has purview of a drug but doesn't have, for example, the expertise to deal with cardiovascular knowledge, then that division sends to the cardiovascular division a request for review, complementary review -- this is how we function. And in the instance of the neuropsychiatry division, they had sent me when I was at the FDA a request to look at fluoxetine, which is Prozac, Eli Lilly's Prozac, to determine what were the metabolic changes included in there. What was happening? They weren't expert -- we were expert in that situation, so I offered our expert opinion on that subject.
Q. Also, in response to a question, you said that you could not talk to the FDA.
A. That's right.
Q. Why is that?
A. Well, I can talk to members of the FDA on a friendly level, but I cannot ask any question that is confidential because that would

be a breach of the law and putting them in a very delicate position. That's not done.
Q. And are you aware of the legal prohibition that precludes members of the FDA from giving testimony in cases such as this?
A. Well, I'm very well aware, based again on factual experience, that you have to obtain the permission of the FDA if you're asked to appear as a witness in some cases.
Q. Dr. Gueriguian, the jury has heard yesterday Dr. Brancati give testimony that Zyprexa causes diabetes.
Is that an opinion you share?
A. Yes.
Q. Yesterday Dr. Brancati gave the opinion that Zyprexa and clozapine are associated with the greatest degree of weight gain, highest occurrences of diabetes and dyslipidemia.
Is that an opinion you share?
A. Yes.
Q. Now, you indicated in response to my question a couple minutes ago that lawyers can't talk to the FDA such as my co-counsel here, but the drug companies can talk to the FDA, can they not?

A. Yes.
Q. Earlier I asked you if you agreed that a proper characterization of the FDA would be the cop on the beat. Is that a characterization -- a characterization that you believe is accurate or descriptive of what you do?
A. No.
Q. Why not, sir?
A. Well, frankly, it's -- it's sort of insulting to the police force as well as to the FDA. We're both agencies in different types of ways protecting the public and as such, we deserve respect.
Q. Dr. Gueriguian, I want to show you some of the evidence that has been admitted in the trial. I may have to get Scott Allen to come show me how to do this.
MR. ALLEN: You have to pull it back some.
MR. FIBICH: Thank you.
MR. FIBICH: The first thing I want to show you is this is a document, 1586, which is an executive summary of the schizophrenia advisory panel that occurred in December of 1995 in San Juan, Puerto Rico.

Do you see that,sir?
A. That's right.
Q. Do you recall when the drug Zyprexa was first approved?
A. I think it was in 1996.
Q. On the second page it references who all appeared at this advisory panel meeting.
Do you see that, sir?
A. Yes.
Q. And I believe it was 10 of 11 schizophrenia specialists who served on the panel were present along with medical, research and marketing executives from Eli Lilly and Company.
Do you see that, sir?
A. Yes.
Q. And then, if you would, we'll go to the next page. And this is some references with respect to information that was in Lilly's knowledge prior to the drug being approved.
You see that, sir?
A. Yeah, that seems to be a fact.
Q. And it says that: For all patients treated with olanzapine for any amount of time, 40 percent gained an excess -- equal to or excess of 7 percent body weight. Patients who remained

on olanzapine for 12 months gained an average of 24 pounds at the end of 12 months.
Is that clinically significant weight gain, sir?
A. Yes.
Q. Why do you say that?
A. Well, weight gain is very well known as a risk factor. Weight gain may well be consistent with increase in good cholesterol, decrease in bad cholesterol, increase in triglycerides, and all of these measurements are independent risk factors of cardiovascular disease. And we shouldn't forget -- and that's a fact, that cardiovascular deaths are the No. 1 reason for why the diabetics die.
Q. And if you go on to the second paragraph or the last paragraph -- by the way, this was a Lilly advisory committee; this was not an FDA advisory committee, right?
A. No. It's my understanding that Lilly was seeking outside opinion, scientific and expert opinion, presenting data and asking their feedback.
Q. Yeah, but this was not an FDA advisory opinion?

A. No.
Q. Okay. In the last paragraph it says: Several advisers commented on the association of olanzapine with weight gain and encouraged Lilly to subject the data to full analysis. Clinically significant weight gain is a risk factor for other conditions such as increased blood pressure, increased cholesterol, type 2 diabetes.
And is that what you were just telling us, the concern of weight gain?
A. Basically, yes.
Q. Sir, I want to call your attention to some information that was taken from the HGAJ trial. You have that information that is before you that compares olanzapine -- olanzapine with Haldol.
Do you see that?
A. Yes.
Q. And what is the significance of these findings to -- to you as a scientist at the FDA?
A. Well, I think the word "significance" is the important word. If you look at this line here, which is the lowest yellow line, it says "high." It means that there are certain subjects in this clinical trial who had a high level of --

what is it, glycemia, yes, glucose, nonfasting, blood sugar values. And you see at the end that the -- at the right-hand end of the P value, .031. Expert statisticians and epidemiologists consider that any P value -- that's a measure, mathematical measure of the event -- if it is less than .05, they call that statistically significant. And if it's statistically significant, then studies should be performed to find out whether it is clinically significant, that is to say, does it give diseases? Does it produce diseases?
Q. Doctor, if you would, look at the next page of this same data. And if you could, explain what is represented by these figures as well.
A. Yes, this time the comparison -- I failed to mention previously that this was a comparison between olanzapine and haloperidol, which was the comparator.
This was, again, a comparison of now the cholesterol in the blood in those patients who had a high level -- an increased level of cholesterol. And, again, the P value here is .023, which is already better than .031 and it is, again,

therefore, more statistically significant.
Q. And, Doctor, I think the -- the findings of this were -- they're dated June 19th, 1995. You see that at the top right?
A. That's right.
Q. So prior to the drug Zyprexa being approved by the FDA, what, in your opinion, was the significance of this data in the findings of their advisory committee?
A. What is customarily stated in such a situation is to say there's a strong signal for potential adverse events.
Q. And those -- and that signal -- and that's a term of art, is it not?
A. Yes, it is a term of art.
Q. What does "signal" mean?
A. A signal means that there's sufficient worry and concern to mandate addressing the question with additional studies.
Q. Sir, let's go to the next exhibit which is also in evidence.
Can you tell the ladies and gentlemen of the jury what this is?
A. This is a letter sent by the FDA on November, 1996.

Q. And this was shortly after the drug was approved; is that correct?
A. Yes.
Q. And to whom -- to whom was it sent?
A. It was sent to Mr. Charles Perry, Jr. for Lilly -- Eli Lilly and Company.
Q. Okay. Sir, I've highlighted a paragraph of this particular letter, and is this letter sent out by DDMAC?
A. Yes.
THE COURT: Just for the record, Mr. Fibich, can we get an exhibit number?
MR. FIBICH: Yes, sir. I apologize. That's 1169.
A. Yes, and finally I am remembering what is the DDMAC about, Division of Drug Marketing, Advertising and Communications.
Sorry about that.
Q. Okay, sir. And in this letter to Lilly shortly after their drug was on the market, the FDA had a concern about a number of labeling pieces for Zyprexa which was a multi-page detail ad. You see that?
A. Yes. Those are -- those were promotional materials.

Q. It goes on to talk about the concerns that this -- that this letter concerns other promotional activities such as an interactive telephone conference held on October 2nd, 1996?
A. It does.
Q. And the Division of Drug Marketing, Advertising and Communication considers these promotional labeling pieces and promotional activities to be false or misleading and in violation of the federal Food Drug & Cosmetic Act.
Do you see that?
A. Yes, I do.
Q. Why is it important that the FDA regulate what they're referring to here?
A. The companies have two ways of communicating with prescribers. One is the label, which is under the control of the FDA directly. The other one are promotional material and other such activities that are considered to be promotional.
And there, it's an honor system. It is after the promotion has been done that DDMAC may decide that it was false, misleading, violating of the Act because of certain comments that they make.

This is what you're doing that is wrong. This is what you're doing that is misleading. This is what you're doing that is not correct. That kind of thing.
So, it's a way to communicate which is not immediately under the purview -- I mean -- the FDA can only correct a fortiori, after the fact, most of the time.
Q. Go to the next slide I have, sir and this is another paragraph in this same letter, same Exhibit 1169, talking about a promotional campaign including the above-identified labeling pieces and others submitted with the form 2253S. Says: Is lacking in appropriate balance, thereby creating a misleading message about Zyprexa. The promotional materials emphasize efficacy data, but do not provide sufficient balance relating to adverse events and cautionary information. Further, they do not adequately or prominently discuss several important adverse events specifically selected for emphasis in the approved labeling.
These events include -- and it goes on -- one of which is weight gain. You see that?
A. I do.

Q. What is meant by fair balance?
A. Fair balance goes to the heart of the 1962 enactment of the Act mandating the FDA to do its job. You have to appreciate the benefits of the drug and you have to appreciate the risks of the drug and they have to -- the benefits have to overweigh the risks.

In the same fashion, when you make statements talking about the qualities and the advantages of the drug, you still have the obligation to also inform about the deficiencies, the dangers of the drug. And what is meant by lack of balance is usually that you're maximizing the benefits and you're minimizing the risks.

Q. And how is the promotional materials disseminated to doctors and people that prescribe these drugs? Is it by salespeople and promotional materials?

A. Promotional materials can be used in a number of fashion. Information relayed through representatives is one of them, or you can invite doctors to special presentations, seminars, meetings, or there are any number of ways that you can communicate the content of a promotional material to the prescribers.

Q. And this is something that all drug companies do, correct?
A. Yes.
Q. And if I understand what you're telling us, that the law is that the drug companies when they go out, whether it's a seminar, a luncheon, a salesperson in a doctor's office, talking to formularies of State Medicaid or whoever cannot emphasize the benefits without telling about the risks; is that fair?
A. That's right.
Q. Would you look at the next bullet point that I pulled out of this letter? And, again, would you explain to the jury what the Division of Marketing is -- DDMAC at the FDA is doing here?
A. Well, now it's going back to the efficacy side of the equation and talking about the lack of balance in saying what are the advantages and the disadvantages from a neurological or neuropsychiatry point of view. And they're saying it lacks balance, and they're also adding that it disagrees what you said with the approved labeling, the FDA-approved labeling in that you are, again, favoring the efficacy and

the good side of the drug as opposed to its adverse events.
Q. It's talking about extrapyramidal reactions and tardive dyskinesia. Can you tell us what that means?
A. Yes, the concern with tardive dyskinesia, for example, is due to the fact that the first-generation antipsychotics caused this situation -- condition which is a very serious condition. And work was done to develop the second-generation antipsychotics. And at the tail end of that, there were the second-generation atypical antipsychotics -- bear with me -- which Zyprexa -- Zyprexa belongs to that class.

Now, if you overstate the fact that the second-generation antipsychotics were less able to give dyskinesia, then you're not giving a balanced opinion, particularly since the document says from DDMAC, that situation -- that condition is included in the warnings of the approved label.
Q. So, tardive dyskinesia is in the warning section of the Zyprexa label?
A. That's what it says.
Q. And is it also in the adverse events

section?
A. I would assume so.
Q. Well, it's on your document there, sir.
A. As a frequent adverse event, yes.
Q. So a drug company can put something in its adverse events section as well as its warning section, correct?
A. Of course. The adverse events have to contain essentially everything, and some of the events graduate, if you will, to more serious attention in the -- not only in the warnings, but also in the contraindications, et cetera.
Q. Let me go through, again, a few of these, sir.

On another page it indicates that no dosage adjustment for most elderly is misleading?
A. That's what it says.
Q. And it appears to say that the labeling states caution should be using in dosing the elderly, but evidently there was some promotional material that said no dosage adjustment for most elderly?
A. Well, it's contradicting the approved label and, therefore, it's not permissible.
Q. If you would, read the -- the bullet

point under No. 6. If you'd read that out loud, sir.
A. Page 19, Presentation of Zyprexa's pharmacologic profile is misleading. The labeling states that the mechanism of action is unknown --
Q. Slowly. Read it slowly for this court reporter.
A. Sorry. The mechanism of action is unknown and provides proposed theories of the drug's activities. However, Lilly has presented Zyprexa's activity as a fact and implies that there are less adverse events, such as extrapyramidal motor function due to the selective action. However, a low incidence of extrapyramidal effects is not due to the selective modulation of pathways implicated in schizophrenia.
Q. Doctor, the last paragraph, if you would read that out loud.
A. The other labeling pieces identified above contain one or more of the violations enumerated above. They are all lacking in balance relative to adverse events and precautionary information, and present a

misleading impression of Zyprexa as a superior, highly effective, virtually free of side effects, easy to use product. This impression is contrary to the approved labeling.
Q. Now, you indicated that when the drug companies disseminate promotional materials, they're on the honor system; is that correct?
A. Yes.
Q. Does the FDA catch all of the offenders that violate that honor system?
A. I think not.
Q. I want to go to one more paragraph of this FDA letter, and it deals with Dr. Tollefson, who is a physician there at Eli Lilly. And evidently he was asked about weight gain -- I'm reading the letter -- and his response misleadingly turned an adverse event into a therapeutic benefit.
He states, So we went back and analyzed our data and saw that the vast majority of weight gain reportedly initially as an adverse event, in fact, was weight gain occurring in patients who had baseline before starting treatment had been below their ideal weight. So we really look at this with a majority of the patients as

being part of a therapeutic recovery rather than an adverse event.
And that data, I think, is fairly compelling because it was included in our labeling. He goes down to say that the information of weight gain was indeed in the labeling, as Dr. Tollefson said, but as an adverse event, not therapeutic. And he goes on the chastise Dr. Tollefson? Do you see that?
A. Yes, I do.
Q. It's inappropriate for doctors at seminars to state things outside the letter -- the label; is that correct?
A. Not only that, but what they say has to be factually correct.
Q. Sir, let's go to the next exhibit. This is a -- let me publish that, Your Honor, the previous one to the jury, if I may.
THE COURT: This is a preapproved admitted document?
MR. FIBICH: Yes, it is.
THE COURT: Please feel free to publish -- is it 1169?
MR. FIBICH: 1169, Your Honor.
Q. (BY MR. FIBICH) And, Doctor, based upon

the exhibit that I have on the screen -- can you tell us what this is?
A. This is a piece of good work because adverse event reports in post-marketing period are usually more instructive for epidemiological studies in the first -- or the first two years of -- following marketing and the reason can be blamed -- explained by me.
Q. It's a piece of good work, but what is it that we're looking at?
A. It is a census, which means we gathered everything, a census of spontaneous reports for olanzapine during the first two years of marketing from -- in '96 and '98, September to September.
Q. Two-year period, correct?
A. Yes.
Q. And it's produced or bears the name of Dr. Hornbuckle, who I presume is a veterinarian and Dr. Fung, and it bears the title of Worldwide Pharmacovigilance and Epidemiology at Eli Lilly and Company, right?
A. That's correct.
Q. If you would go to the next part of this report, Doctor --

THE CLERK: What is that exhibit number?
THE COURT: What was the exhibit number that --
MR. FIBICH: I'm sorry, Your Honor. It's in evidence. It's 988.
THE COURT: Thank you.
Q. (BY MR. FIBICH) And this lists the endocrine metabolic -- endocrine adverse events for that two-year period, correct?
A. Yes.
Q. Hyperglycemia, which I think the jury has heard a lot about, diabetes mellitus, and goes down to diabetic acidosis.
What is diabetic acidosis?
A. Well, it's a condition where the diabetic has -- a change in the pH or acidity of the internal body -- the blood. The blood in the body has to be maintained within pH 7.4. If it goes to the acidity, problems develop. Organs begin to stall, if you will, and it is a very severe condition.
Q. Diabetic coma; what is that?
A. Diabetic coma is when -- it follows acidosis. The patient loses conscience.

Q. Okay. These are serious conditions, sir?
A. Yes. And all these terms are used together to appreciate the hyperglycemia factor and events for a given drug.
Q. So Doctor, as of the end of '98, the two-year period following the approval of this drug, there were 194 unduplicated reports of adverse events of various kinds dealing with blood sugar elevation; is that right?
A. It is correct, 184 reported events.
Q. Do all adverse event -- do all adverse events get reported?
A. No, they don't.
Q. Is there a standard in the drug industry or within the FDA that you use as to what percentage of adverse events go unreported?
A. There's a consensus among epidemiologists which are the expert opinion -- authoritative opinion in this case.
Q. And what is that, sir?
A. And it states that -- depending on the situation, 1 to 10 percent only of actual events are reported to the FDA.
Q. So, if 10 percent of the adverse events

are reported -- you say to the FDA; do you mean to the drug companies?
A. Well, yes, but --
Q. Either one?
A. Absolutely, yes.
Q. So if 10 percent is 194, what would be a statistical representation of the number of actual adverse events that had occurred during this two-year period based upon that standard?
A. The actual census of actual events would be 1,940, which is 10 percent -- a correction of 10 percent to 100 percent.
Q. What would 1 percent be?
A. One percent would be ten times more, so it's 19,400.
Q. 19,400?
A. That is correct.
Q. So, potentially, as of 1998, using the standard accepted by epidemiologists, there were 20,000 adverse-event effects dealing with blood sugar elevation from the use of Zyprexa?
A. Well, to be fair, anything between 1,940 and 19,400.
Q. Doctor, by the time that this census information was compiled, which was 1996 to 1998,

from the time that Eli Lilly had the information and had the information from the HGAJ information, and had the concerns of the schizophrenia advisory committee, do you have an opinion as to whether Eli Lilly and Company was on reasonable knowledge of an association between their product, Zyprexa, and weight gain, hyperglycemia and diabetes such that they were required to put this information in the warning section?
A. I do have an opinion, and the opinion is yes.
Q. If Eli Lilly had chosen to put this in the warning section, could they have done so by means of a change being effected submission?
A. Changes being effected submission, yes, they could have.
Q. I'm going to go to the next document, which is another Lilly document marked "Confidential" telling about hyperglycemia, weight gain and olanzapine.
Look at the page that I have brought up, sir, and, if you would, talk about the highlighted portions and what the significance to you would have been had you had this information as

a medical reviewer of this drug.
A. Well, the first one -- the first bullet says registration trials, and it says they had a total of 2,500 patients receiving olanzapine, Zyprexa, and 1.7 percent of these 2,500 experience treatment-emergent hyperglycemia. Treatment-emergent hyperglycemia is FDA talk saying that it is during the treatment that hyperglycemia was observed in the clinical trial.
Q. And while we're on that, what is nonfasting blood glucose?
A. Nonfasting blood glucose is the least precise measurement of blood glucose, sugar in the blood or glycemia.
Q. Is that a significant number?
A. Yes, it is.
Q. If you would go down to the retrospective study by Dr. Casey.
A. The second bullet. Dr. Casey was supplied, I suppose, by Lilly, charts for 136 patients, and these patients had taken Zyprexa for four months or more, and the average duration of the treatment for these patients was 17 months. Now, this is in opposition to the so-called registration trials which were six to

eight weeks in duration. Now here we have patients who have been on average 17 months on the drug. So we're looking on the long-ranging effect. And 50 percent of these 136 patients showed a weight gain of seven pounds or more after the treatment of olanzapine began. Seven of these 39 patients, which represent 18 percent of that group, who had normal blood glucose at the beginning, before Zyprexa, developed treatment-emergent hyperglycemia. So, the blood sugar levels went up, whereas at baseline, before receiving the drug, blood sugar levels were normal. Now they became abnormal.
Q. What's the significance of this, Doctor?
A. Well, hyperglycemia is one of the signs and symptoms of diabetes.
Q. And would you give the jury the benefit of your background with respect to the findings on the animal studies dealing with rhesus monkeys?
A. First of all, these studies were done, if memory serves, using clozapine, not olanzapine. That's the way it was done.
Q. What's the significance of clozapine relative to its relation with olanzapine? Why is

this being stated in the summary? What's the significance of this?
A. There's no significance, but it's a fact that in an IND and an NDA concerning Zyprexa, the only animal studies that I was able to find, excepting the rat studies, were using clozapine and not olanzapine.
In any event -- these were rhesus monkeys -- and two of them had fasting hyperglycemia. Now, fasting hyperglycemia is a better measure of blood sugar than nonfasting hyperglycemia that was used in humans, but the monkeys here are lucky. They are getting a better measurement of their blood sugar levels. The average weight gain was 26 percent.
Now, in addition to the -- the fasting methods, they also were measured -- their blood sugar level was measured with the HbA1c method, which is the top quality method. Again, they received something that was better than what humans underwent.
Now, all these monkeys, all ten of them had levels of HbA1c which were above the upper limit of normal.
What does that mean? You have to

define what's abnormal and what's normal in any test, and you have to do it in the matter that is unquestionable. It has to be statistically and mathematically developed.
So you take normal people, you study them and you find out, Where is the upper limit of normal for 95 percent of these normal people having normal blood sugar levels? And anything above that is above the limits -- the upper limit of normal or ULN, upper limit of normal. If you have greater than three times upper limit of normal, it's statistically and clinically significant in most cases in any measurement.
Q. Doctor, I want to move along if we could. There's another provision in this document that I have blown up that says: The incidence of treatment-emergent hyperglycemia among 2500 patients studied was 1.7 percent, where nonfasting hyperglycemia was defined as blood glucose in excess of 250 milligrams per deciliter. Do you know if that is the standard by which hyperglycemia is accepted to occur, 250 milligrams per deciliter?
A. No, my knowledge -- my -- what I know is that the WHO and the American Diabetes

Association, the World Health Organization and the American Diabetes Association have put that upper limit of normal at 126 milligrams per deciliter.

Q. By the way, are you associated with the World Health Organization in some fashion?

A. I was an expert on their biotechnology group or panel, whatever it is, for several years, yes.

Q. And I may be mistaken, I thought I read something in your background where you were involved in the standards committee for the World Health --

A. That's the one, yes. It's been such a long time.

Q. If it's 126 for fasting, what is it for nonfasting?

A. Well, the number has nothing to do with the nonfasting and the fasting. The difference between the two methods is that the nonfasting is much less precise than the fasting, and in addition, there is more fluctuation in the measurement of the nonfasting; therefore, reducing one's ability to observe a significant difference, and yet, despite that, as we've seen

in the high group glycemia, there was statistical significance as well as for the cholesterol -- high-cholesterol group.

Q. Is it a scientific fact known to anybody that deals with diabetes that nonfasting glucose measurement is an imprecise measure as opposed to HbA1c or fasting blood test?

A. That's correct.

Q. This is something that Lilly would have known?

A. Hey, they're the expert in diabetes.

Q. Let me ask you this question: Why would a company that is expert in diabetes be doing blood testing by nonfasting measures, if you know?

A. I don't know what motivated them. I have no idea. All I know is that wasn't the correct way to proceed.

Q. It goes on and says: As these trials are mainly short-term studies the actual incidence had patients been exposed to olanzapine for a longer period would be higher. Did I read that correctly, sir?

A. That's quite possible, yes.

Q. Sir, let's go to the next page, and this

deals, again, with weight gain and up there at the top paragraph -- it's not highlighted -- Dr. Bruce Kinon had analyzed data from 70 olanzapine clinical trials. He's talking about 55 percent of patients had weight gain of over 5 kilograms after a year of olanzapine treatment, and 16 percent had weight gain of 30 kilograms or more. Thirty kilograms would be how many pounds, sir?

A. 66, I believe. 66 pounds.

Q. And do you read this to mean that -- that weigh would have been gained over what period of time?

A. One year of treatment.

Q. Then at the bottom there's some language regarding fasting glucose. Do you see that?

A. Yes.

Q. And it uses the mean fasting glucose levels. Do you know why one would use a mean?

A. Well, science -- scientific information has to be reduced to a minimum as long as it's understandable. And the mean refers to a group of patients and it says that on average or the mean this is how this particular measure has increased.

Q. With respect to the 60 patients whose fasting glucose levels were taken, 39 had normal and 18 percent had increases in their fasting glucose, correct?

A. That's right.

Q. Back again, talking about the rhesus monkeys, can you explain the pharmacological significance of the findings of Dr. Casey's experience in administering clozapine to these monkeys?

A. Well, three very interesting measurements were done: No. 1, weight gain; No. 2, blood sugar measurements; and No. 3, measuring in the blood insulin levels. That's the hormone in the body that controls sugar levels and lipid levels to some extent. And weight gain was evident in an animal study, again, using clozapine, unfortunately.

The -- all the monkeys had abnormal measures using the best methos of measuring blood sugar, HbA1c. The two of the ten developed hyperinsulin, which means their insulin levels in the blood increased. What does that mean? It means that it's getting close to diabetic state, if not diabetic. Why? Because the target cells of the

body, the target cells of insulin action, to the muscle, the liver, for example, are not responding properly, normally to a certain amount of insulin that is in the bloodstream. They need greater amounts of insulin to produce lesser effect, and that's abnormal. And it means that there's an insulin resistance.

It gives an idea of one of the mechanism of how Zyprexa is effecting metabolic changes.

Q. And what is the pharmacological significance of clozapine to olanzapine or Zyprexa?

A. Well, clozapine in these measures appears to be a worse -- I mean, has worse effects --

Q. How are they structurally related is what my question is?

A. Well, they're both atypical antipsychotics. Same class as the olanzapine, Zyprexa and clozapine and others.

MR. FIBICH: Your Honor, I'd like to publish 4176 to the jury, which was previously admitted.

THE COURT: 4176 can be published to

the jury. Ladies and gentlemen of the jury, we've got a couple of documents all circulating that have been published to you. You're free to look at them as you wish. I just want to caution you, don't let that stop you from also listening to the testimony that's going on while the documents are circulating.

MR. FIBICH: One second, Doctor. I'll be right with you.

THE COURT: And I would remind you that documents that have been admitted will be available to the jury in the jury room when it's time for you to deliberate.

Q. (BY MR. FIBICH) Dr. Gueriguian, can you see the highlighted portion in the discussion section of this document?

A. Yes. Yes, I do.

THE COURT: What document is this?

MR. FIBICH: It's still 4176, Your Honor.

THE COURT: Thank you.

Q. And it says: Both postmarketing reports, retrospective study in patients in Veteran Hospital in Oregon, that's Dr. Casey, and animal studies suggest an association between obesity and treatment-emergent hyperglycemia in

patients treated with atypical antipsychotics.

Do you see that?

A. Yes.

Q. Do you believe the evidence at this time supports that conclusion?

A. Yes.

Q. This was an internal Lilly document?

A. Yes.

Q. Does it appear to you that they recognized internally that there was an association between obesity and treatment-emergent hyperglycemia in patient events treated with atypical antipsychotics?

A. Yes.

Q. Doctor, I want to show you what we have previously introduced into evidence as Exhibit 990. If you would, sir -- Doctor, I know you're squinting. Would you prefer to have a hard copy of that?

A. Well, I have to find it.

Q. That's okay if you can do this --

A. That's fine.

Q. Can you tell the members of the jury what this is? Describe what this is.

A. This is an Eli Lilly document dated

1999.

Q. It's actually 2000, sir.

A. I'll stand corrected.

Q. Top --

A. There is on the table a proposal to, in effect, change the labeling with respect to hyperglycemia.

Q. Okay. And would you tell -- if you can, from this page, the members of our jury, how on February the 21st, 2000, Lilly was proposing to change the label?

A. To state, as it says on their new statement that random glucose greater than 160 milligrams per deciliter in patients with baseline random glucose of greater than 140 milligrams per deciliter has been occasionally seen in clinical trials. According to this new statement that Eli Lilly makes.

Q. (BY MR. FIBICH) How are they going to characterize it as so far as its frequency?

A. Well, they're going to call it common -- common or frequent inasmuch as it's greater than 1 percent and smaller than 10 percent.

Q. And is -- based upon the knowledge or the information that you've seen within the

company of Eli Lilly, during this point in time, is this an appropriate change?
A. No.
Q. Why is that?
A. Because the facts are given under the how has this proposal arisen section, which says: Olanzapine clinical trials revealed that the incidence of treatment-emergent hyperglycemia -- that is to say the frequency that you see hyperglycemia during the treatment with olanzapine -- in the olanzapine group is 3.6 percent, and is higher than the placebo group which is 1.05 percent. So this is tantamount to a four-fold increase. And four-fold increase by anybody's stretch of anybody's imagination is not something that's seen in clinical trials.
Q. Doctor, at this time in 2000 -- you told us in 1998 it should have gone to the warning section, correct?
A. Yes.
Q. Let me show you another exhibit. This is 4858 again --
A. I don't have the date on it.
Q. Again, Doctor, this is a letter from the -- let me back up. This is a letter from the

FDA --
A. No, actually, it's from the Lilly. Lilly to the FDA.
Q. It was a letter to the FDA from Eli Lilly; is that correct?
A. Yes, it is.
Q. Okay. Can you tell the members of the jury what they're attempting to do here?
A. Well, they're coming forth using the changes being effected provision of the regulation to propose voluntarily a label change.
Q. And, sir, if you would, look at the next section. And would you tell the members of the jury what this applies to.
A. It applies to the frequency of hyperglycemic events in a comparative study between these events in olanzapine patients and a comparative group that is taking sugar pill or placebo.
Q. Is it your understanding that this is what went into the label in 2000?
A. Well, that's what they're proposing, and I'm presuming that the answer to your question is yes.
Q. And based on what you're reading here,

is this a change being effected; is that what they're trying to do?
A. Yes, it is.
Q. Is the language in this change being effected appropriate at this time?
A. No.
Q. Why not?
A. Because giving information by using a certain group of patients with respect to their level of hyperglycemia and with the end result that their .08 percent of olanzapine-treated patient that showed hyperglycemia, and .7 percent of placebo patients have hyperglycemia, there is no difference between .8 percent and .7 percent, and it has nothing to do with the fact that the difference. The infrequency in incidence due to olanzapine was roughly four times higher than the placebo. So it's totally different information. Totally incorrect.
Q. Dr. Gueriguian, do you believe this is a misrepresentation of a material fact relative to this drug?
A. Yes.
Q. Dr. Gueriguian, I want to go through a series of information that was obtained in

discovery with Eli Lilly, the first of which is a -- an e-mail. Do you see that?
A. Yes.
Q. It appears to be from Dr. Baker to a number of people within the Lilly organization that have been highlighted?
A. That's correct.
Q. One of which is Dr. Cavazzoni, which we believe will be a witness on behalf of Lilly.
A. You say so.
Q. If you would, sir, would you read for our jury the first paragraph of this --
A. For your information, it begins?
Q. Yes. FYI.
A. Yes.
Q. Just the highlighted portion.
A. The Lilly diabetes endocrine group held an academic advisory board meeting this weekend in Atlanta. Unfortunately, this consultation reinforced my impression that hyperglycemia remains quite a threat for olanzapine and may merit increasing even further medical attention and marketing focus on the topic.
Q. Okay. And go on down and continue to read the highlighted portion.

A. They were, however, concerned -- that is to say the advisers, scientific advisers, who were endocrinologists -- they were concerned by our spontaneous adverse event reports and quite impressed by the magnitude of weight gain on olanzapine and implications for glucose. Citing the methodological questions, at least the vocal members were not reassured adequately by our advisers, Lilly advisers, such as finding that relative risk was not higher than comparative drugs.

Q. Read the next sentence.

A. Disconcertingly, one member compared our approach to Warner-Lambert reported argument that Rezulin did not cause more hepatic problems than that.

Q. Was Warner another company?

A. Yes.

Q. Did they have problems with Rezulin?

A. Yes.

Q. Are you familiar with that drug?

A. Yes.

Q. Generally, tell the jury how you had knowledge of that product.

THE COURT: I'm going to maintain the

objection. I think it's outside of his report, isn't it?

MR. BRENNER: It is, Your Honor, among other things. 403.

Q. (BY MR. FIBICH) Let's move on to the next e-mail sir. And this, again, is an e-mail from Mr. Brody to Mr. Baker. You see that?

A. Yes.

Q. This deals with the same subject of the prior e-mail; is that correct?

A. Right.

Q. The meeting with the endocrinology consultants?

A. Right.

Q. Would you read this paragraph and tell us what the significance of what is being said here is relative to the issue of Lilly's problems with Zyprexa as it pertains to diabetes.

A. This group of endocrinologists who spoke up -- and I would rate those who did speak up as the leaders of the pack -- are very concerned with the approach Lilly is taking towards the issue that Zyprexa leads to diabetes. I can only hope that you all -- you and all of the team who attended this meeting are gaining the ear of

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

And the significance being that Lilly is being put on notice that expert endocrinologists consider, one, that there's a problem with olanzapine and diabetes and weight gain. No. 2, that they -- that their analysis -- the Lilly analysis -- of which we saw an example in the previous slide -- is not convincing them at all that there is no problem. And, thirdly, that they should come clean on this if they don't want the situation to get worse.

Q. Dr. Gueriguian, is the information and opinions and conclusions that are contained in these e-mails the sort of information that a drug company is honor-bound to give to the FDA?

MR. BRENNER: Objection, Your Honor.

THE COURT: Overruled.

A. Yes.

Q. (BY MR. FIBICH) Go to the next e-mail along the same subject. Again, this is an e-mail

from Baker to Beasley.

A. Yes.

Q. Another FYI?

A. Yes.

Q. Again, the academic endocrinologists are concerned about the weight gain and number of reports in the spontaneous adverse event database -- When they talk about spontaneous adverse event database, they're really talking about Lilly's database, correct?

A. Yes, because that's all they have. But the FDA database is usually richer because there are other people that do not -- that send it to the FDA without sending it to companies.

Q. I'm sorry. I didn't understand that.

A. Adverse event reports can be reported by anyone, nurses, pharmacists, doctors, kin, family, anyone. Now, generally speaking, this is not true in every case they send either to the company or to the FDA and the company has to send what it receives to the FDA and what it has observed in its own trials to the FDA.

Q. It goes on to say that the academic endocrinologists were predisposed to be skeptical of any analysis. It did not find hyperglycemia

rates on olanzapine than comparators.
A. That's what it says.
Q. It goes on down. It says, Alan, I believe that what the top is referring to is not the way Lilly typically does business are suggestions to more vocally assert that olanzapine may have a problem on the glucose issue and rather than moving forward with our analyses, turning all info over to an independent board for review, conclusions and dissemination. Neither strikes me as the appropriate step, but this alarmed the Lilly attendees when linked to the Rezulin comparison. Charles did let them know that already we have sent several volumes with all our info to FDA, but I'm not sure they fully appreciate that.
We would go to the next e-mail and this is --
MR. BRENNER: Excuse me, Your Honor. There was no question there. I object.
MR. FIBICH: Let's do it this way.
Q. What's the Rezulin comparison that Lilly keeps making reference to here, sir?
MR. BRENNER: Objection.
MR. FIBICH: I do want to argue the

relevance, if I may.
MR. BRENNER: Maybe we ought to do it out of the presence of the jury.
THE COURT: Why don't you approach.
(Bench discussion.)
MR. FIBICH: What they're worried about what is being said here is if we don't be honest about this, we're going to have a Rezulin problem. Our drug is going to be pulled off the market.
THE COURT: I don't doubt that there's some relevance here. My question is: Is this the witness to talk about what was going on with the Rezulin?
MR. FIBICH: Let me tell you why. He was the -- on Rezulin he was the one that pulled it off the market.
THE COURT: We have a notice. Where was this gone into -- was this gone into in his deposition?
MR. BRENNER: No, Your Honor. My problem -- he's interpreting someone he's never met, never seen. We're getting into drugs --
THE COURT: You can get into cross-examination as to that, but -- the letter

is -- the letter says what it is.
MR. FIBICH: They don't know what Rezulin is. They don't know what the problem with Rezulin is. We're leaving them in the dark.
THE COURT: You can take -- question the witness. This is supposed to be an expert to the extent that his questions in the record doesn't go into it, I've got -- that's the issue.
(End of bench discussion.)
Q. (BY MR. FIBICH) Okay. Doctor, now we're back on the e-mail to Alan Breier. If you go down to the last highlighted portion, sir, where it says: When you translate 1 to 2 percent gain of 40-plus kilos into the absolute number based on 5 million patients, the number is 50,000 to 100,000. 100,000 people putting on 90 pounds of weight is a lot.
And if you would then go to the last sentence before that paragraph it said: They believe we should aggressively face the issue and work with physicians to address methods of reducing weight gain.
My question to you, sir, is: Do you believe that dealing with physicians is a realistic way to help people lose weight that have gained 100, 90 pounds? Is that a realistic solution?

A. No.
Q. Why not, sir?
A. Because it's very difficult to stop smoking; it's very difficult to be on a diet. I have seen data of drugs that were supposed to reduce weight and on the long run they didn't. In fact, very -- very often there was a rebound effect, that is to say you ended up having a higher weight than the one you began when you took the drug. So, it's not realistic, because it has been proven not to work.
Q. Doctor, continuing with this same exhibit, it is talking about a concern about the use of categorical analysis in the first sentence.
A. Yes.
Q. Goes on: The issue is the arbitrary nature of any categorical analysis with respect to cut points defining a case.
There's another sentence: The problem is the arbitrary nature of the cut points and the potential for big shifts depending on those cut points and the fact that we chose the cut points -- not really, they came from the ADA, that's American Diabetes Association --

A. Yes.
Q. -- web site. They specifically referred to the data as being tortured. What is meant by cut points?
A. Well, cut points is one of the ways you perform a categorical analysis. You take the whole number of all the patients that were in the clinical trial and you try to begin finding subcategories. For example, people have gained 20 pounds, others have gained 40 pounds, and in principle, a categorical analysis is not necessarily bad, as long as you provide also all the universe of all the data to allow some outside agency or expert group to decide whether the general conclusions with all the patients coincides or not with some categorical analysis that you decided perhaps arbitrarily to maintain for reasons of your own. So you have to have all the data to make sure that the -- a given categorical analysis reflects the truth instead of reflecting something else.
Q. It goes on to talk about data that is tortured. And if we go down to the last -- next-to-last highlighted part, it said: I will say that I believe we should have a full-time

dedicated, sophisticated, statistical resource that does nothing but hyperglycemia. No meetings, no surveys, zilch, until we have completely tortured the data.
What is -- I think we all know what data is. We all know what torture is. What is torturing the data? Is that a term that people within a statistical -- epidemiologic universe understand?
A. If the context is properly set, yes.
Q. What is it? What does torture the data mean?
A. Well, you torture people or you torture data to make them say something that is not true. It's as simple as that.
Or you cannot torture -- you can torture people and they will sometimes tell the truth, sometimes not tell the truth. But when you torture data, usually data doesn't think; it's sitting there. And it's usually the analysis, the torture results in not telling the scientific truth of a question.
Q. It goes on: With regard to the marketing side of this issue of impaired glucose tolerance/diabetes, the message was clear, don't

get too aggressive about denial. Blaming schizophrenia or claiming no worse than other agents until we are sure of facts and sure that we can convince regulators and academicians. Warner-Lambert with Rezulin was the example. Sounds exactly what Dan Casey was saying.
What were they saying here?
A. Well, there are many things being discussed here. Which one do you what me to address?
Q. About them not getting aggressive.
A. Denial can be discreet or aggressive. Finding -- pointing fingers at other possible causes of the toxicity of Zyprexa can, again, be discreet or correct or incorrect or aggressive.
Saying that it's -- Zyprexa in this respect is no worse than the other atypical antipsychotics brings you back to the class effect. What is a class effect? The class effect is when all the members of the group have certain -- one feature in common in terms of toxicity.
Now, there are two ways of looking at it. Either all of them have the same amount of toxicity, the same effect on toxicity or some of them are more or less toxic than others. And if you

insist on the class effect while your drug is more toxic than other members of the class, then, again, you're not telling the truth.
MR. FIBICH: Your Honor, I want to publish 1453 to the jury, if I may. It's been admitted.
THE COURT: 1453 may be published.
Mr. Fibich, we're at the noon hour. Any time you find a convenient place for us to have a break.
MR. FIBICH: I would like to do that right now if I could, Judge. Thank you.
THE COURT: Ladies and gentlemen, we'll take our second break of the day. Once again, I would remind you, please don't discuss this case among yourselves or let anyone discuss it with you. Please keep an open mind until you've heard all the evidence in this case.
(Jury out.)
THE COURT: We'll have the jury be in recess. I'd like the attorneys to stay so we can go on record.
Doctor, you're free if you need to take a restroom break or something.
THE WITNESS: Thank you.

THE COURT: Where are we timewise? We're outside the presence of the jury.
MR. FIBICH: Judge, I probably have another 30 minutes.
THE COURT: Okay. Was this the witness who needed to finish --
MR. FIBICH: He'll be here Monday, I think.
THE COURT: That's what I was trying to make sure.
MR. LEHNER: Your Honor, the only question I have was the last exhibit that was admitted was admitted over a hearsay objection, and I think we'd ask that there might be some instruction as to the notice that it was being admitted only for notice.
THE COURT: Give me -- was this the only one or are there any others?
MR. LEHNER: That was the only one so far.
THE COURT: 1453, so the instruction you want is that they may consider it for the purpose of what? Notice and information Lilly had, but not for --
MR. LEHNER: Not for the truth of the

matter asserted. I'll double-check while we're on the break that if applied to any others.
MR. ALLEN: I have your homework. Judge, I'm going to give you and Mary Beth is going to give defense counsel the cuts and things -- Mary Beth, listen to me if I'm right, Beasley, Kinon, Tollefson and Wojcieszek?
A SPEAKER: Taurel.
MR. ALLEN: And Taurel? Sidney Taurel.
THE COURT: Okay. So there's the five extra ones and then I've got two more ready and then tomorrow at noon we're going to get the discrete Lilly objections to the seven depositions --
MR. ALLEN: Yeah.
MR. LEHNER: The only other exhibit that was admitted was the one about the adverse event, the census that was submitted for notice, not for the truth of the matter --
THE COURT: What's the number?
MR. ALLEN: This thing right here? 988.
MR. LEHNER: It's 988.
THE COURT: Okay. Thank you.
They were admitted. I've got to

give a limited instruction.
(Break.)
THE COURT: Please be seated.
Just a couple of things. One for the information of counsel. The Alaska Supreme Court decided a case today Southern Alaska Carpenters Health and Security Trust Fund versus Jones that involves preemption. It deals with ERISA, but having just scanned it, which is the most I think I've done, I think it supports my view that the common-law claims are not preempted. But I'm just letting you know about it.
The more concerning question is I've received a note from juror No. 1, Mr. Jump. The note reads as follows: I overheard a phone conversation discussing evidence presented today. Apparently it was a reporter for ADN. That's the Anchorage Daily News, question mark. I only heard a small amount, but it was negative.
I'd like to bring Mr. Jump in and we can all ask him what we need to ask him.
MR. FIBICH: Are we going to take him in your chambers, Your Honor?
THE COURT: No, we'll just take him

separately out here.
MR. FIBICH: Your Honor, before we do that, I don't know if you've noticed or not, I have a couple of whispering geniuses over here and they have advised me that I'll be going to longer than an hour.
THE COURT: As long as he's going to be here on Monday you're entitled to take what time you're going to take.
MR. FIBICH: I told you thirty minutes.
THE COURT: By the time we get done with this, we may not have an hour remaining.
MR. LEHNER: While we're talking about witness scheduling, we informed them we have a witness coming on Thursday morning. She's going to available there. We made arrangements.
MR. FIBICH: We need to talk about that. We also have a witness that's coming in on that exact same day. So I need to see if my witness can be available the next day or if your witness can be available the next day.
MR. LEHNER: We'd given you notice of this about a week or so ago.
MR. FIBICH: George, I'm not going to

argue with you what you've done. I just -- we need to talk.
THE COURT: Okay. Well, we need to work these things out. What's pretty clear to me is that we don't have any 15-minute witnesses here and everybody's on notice now. I'd like you to meet and discuss this today so that you can make the arrangements so that one of the witnesses can go Wednesday, one of the witnesses will go Friday. I will take witnesses out of order to accommodate schedules, but I can't fit two people into one space. So you guys will have to figure out how that's going to get done.
Mark, will you go get Mr. Jump?
THE CLERK: Stay on record, Judge?
THE COURT: We can stay on record.
Mr. Jump, I received your note that says you overheard a phone conversation today discussing evidence presented today. Apparently it was a reporter for ADN and you put a question mark. I only heard a small amount, but it was negative. Let me just ask you: What exactly did you hear this person saying and why do you think it was a reporter for ADN?
VENIREPERSON: I heard him say

something to the effect that they presented a lot of internal stuff from the company that showed they knew about it. Something like that.
THE COURT: Okay.
VENIREPERSON: And the way he said it was kind of negative. And he said, I don't know if we want to run with that or print that today or not or something like that, which made me think it was a reporter.
THE COURT: Do you see him in the courtroom?
VENIREPERSON: He was on the cell phone.
No, sir. No, Your Honor.
THE COURT: Let me ask counsel to ask the questions they want to ask.
Let me ask you -- anything about that -- do you think you can put whatever you heard out of your mind and decide this case based only on the evidence you heard?
VENIREPERSON: Absolutely, Your Honor.
THE COURT: Anything at all about what you heard today that you think will prevent you from being fair and impartial in this case?
VENIREPERSON: No, absolutely not.

THE COURT: Any questions counsel want to ask?
MR. FIBICH: I want to say to him, on behalf both of us, we appreciate you bringing to this to our attention.
VENIREPERSON: I apologize, Your Honor. I won't go out that way.
THE COURT: I don't want you to not have to do that. I'm sure -- is that the gentleman there, by any chance --
VENIREPERSON: Yes, sir, I think so.
THE COURT: You're a reporter for the Anchorage Daily News?
VENIREPERSON: New York Times.
THE COURT: One of the jurors was out in the hallway when you were phoning in your story or discussing your story, and I need you to be careful.
A SPEAKER: Okay. I'm sorry about that.
THE COURT: Go on.
MR. LEHNER: Mr. Jump, did you have any discussion with any of the jurors?
VENIREPERSON: No, I didn't say a word to anybody else.

MR. LEHNER: Thank you very much. I appreciate it.
THE COURT: Again, Mr. Jump, everyone else has commended you and thanked you for doing this, and I'll thank you, too. You did exactly what I asked to you do and I really appreciate it.
Any other questions that any -- the attorneys wish to ask?
MR. FIBICH: We have none, Your Honor.
MR. LEHNER: No, thank you, Your Honor.
THE COURT: Mr. Jump, why don't you return to the jury room?
Any applications from any counsel?
MR. FIBICH: Not from us, Judge.
MR. LEHNER: No, Your Honor.
THE COURT: Okay. Then I've considered -- I'll consider that this note has been resolved and that I won't take any action at this point other than to ask any of the reporters that might be in this case to be aware that when we take breaks, the jurors may be taking a walk or taking a stretch in the hall, and, please, I would prefer that if you're going to phone in a story or discuss matters during breaks, if you're going to phone in a

story, go down a floor and do it. That will solve the problem in the future.

If there's nothing else, then, why don't we give the jury a two-minute heads up and we'll bring them back in and resume the doctor's testimony. I'm not sure I see him -- oh, there he is. So we'll be in recess for about two minutes.

(Break.)

THE COURT: Please be seated.

Ladies and gentlemen of the jury, before we resume the testimony in this case, two of the documents that have been admitted that have been circulated to you, it's the document identified as the State's Exhibit 1453 and also 988 have been admitted for a limited purpose. Sometimes documents are to be used by you only for certain purposes and not for others. The purpose of this -- purpose of those documents is, you may consider the document as for the limited purpose of showing what Lilly was aware of at the time the documents were written. In other words, it's a question of what Lilly was on notice of. The actual truth of the matter asserted in the documents is not to be considered for you other

than that Lilly was on notice of these events, and was -- that these events were being discussed and known by Lilly.

Does that satisfy --

MR. LEHNER: Thank you very much, Your Honor.

THE COURT: Mr. Fibich.

MR. FIBICH: Yes, Your Honor, if I may proceed.

Q. (BY MR. FIBICH) Dr. Gueriguian, when we took our break we were talking about the exchange, the e-mail exchange that is on the screen. And the last sentence was dealing with -- what we were talking about was it sounds exactly like what Dan Casey was saying.

Do you recall that?

A. Yes, I do.

Q. Do you recall who Dan Casey was?

A. Yes.

Q. Dr. Casey -- I think he was a veterinarian -- he was a psychiatrist, was the same one that was referred to on the fasting glucose provision of 4176.

You see that?

A. Yes.

Q. And this was information that Dr. Casey had given to Lilly the previous year in 1999.

You see that?

A. Yes, I do.

Q. And this was in a memoranda or summary on hyperglycemia, weight gain, and olanzapine that was protected from being made public without the express written consent of Eli Lilly and Company.

You see that, sir?

A. That is correct, yes.

Q. And again, Dr. Casey, who they were referring to in the prior exchange, was the same doctor that was involved in the rhesus monkey experiment, correct?

A. Yes.

Q. Also, a note down on bullet point No. 2 under results, it says: The HgA1c of all monkeys became abnormal.

Would you explain what the significance of that is, sir?

A. Only two monkeys had -- well, let me correct that. All the monkeys had at least an HbA1c value above the upper limit of normal. That's what it means. And you recall that HbA1c

is the gold standard of blood sugar measurements.

Q. And then Dr. Casey, again, was the doctor that did a chart review of the 136 veteran patients?

A. Yes.

Q. And would you tell the jury what his conclusions were having done that chart review?

A. That 18 percent of that particular group who had been on average exposed to olanzapine for 1.4 years, which is a good duration, then 18 percent had fasting glucose levels of 126 milligram per deciliter, which is the cutoff point given by the WHO and ADA as the separating point between normal glycemia and high glycemia.

Q. And, again, what measure was used to test that?

A. Nonfasting, I believe. No, that's not true -- I'm sorry -- I stand corrected. Normal fasting glucose levels, so it was the more rigorous. I apologize.

Q. What is the significance of the sentence that says: Whether the glucose levels truly represented fasting results cannot be ascertained.

What does that mean?

A. Well, that's what threw me off. I do not understand what it means except that the person who wrote this thing expressing supposedly Dr. Casey's opinion had some reason to believe that there's some doubt about the fact that these were fasting glucose measurements.
Q. And it also -- can you tell the members of the jury when and how Dr. Casey presented this material to Eli Lilly and Company?
A. Well, I think that it was -- if memory serves, in 1999, and he was invited to present the seminar by Eli Lilly.
Q. So it was by virtue of a seminar; is that correct?
A. That's right.
Q. So when the e-mail exchange occurred, where they said it sounds like what Dan Casey was telling us, that refers to the matters we'd just now gone over that Eli Lilly had in 1999, correct?
A. That's correct.
Q. I want to go to Exhibit 195.
You see this, Dr. Gueriguian?
A. Yes. October, 2000.
Q. October 11th of 2000. And can you tell

our jury what this exhibit represents?
A. Let's see. What's the exhibit number? I'm sorry.
THE COURT: 195?
MR. FIBICH: Yes, sir.
THE WITNESS: Okay. 195.
A. It's a letter from the FDA to Eli Lilly.
Q. (BY MR. FIBICH) And what is the substance of the letter?
A. They're stating a number of things that should be taken care of and in the adverse reactions laboratory change section, a description of random blood glucose level data was proposed, so they're talking about changes that have been proposed for the label. And now the FDA has reviewed the application --
Q. Is this the change being effected that you earlier criticized?
A. Yes.
Q. Okay. Go ahead.
A. Before this application may be approved, says the FDA, it will be necessary to perform some revisions. And those revisions entail the following: In the olanzapine clinical trial database as of September, 1999, there were

405,077 patients treated representing approximately 2,255 patient years of exposure.
That's quite a large amount of exposure. You multiply the number of patients by the number of time that each patient was exposed to the drug, and then you add those numbers for every patient. So you obtain 2,255 patient years.
Q. Let's go to the next page, then. And if you would, sir, read the last paragraph that's highlighted.
A. The descriptive data that is provided expresses a certain level of implied safety with respect to treatment-emergent hyperglycemia. This reassuring language is not appropriate for submission under 25 SFR 314.7, Subsection (c) as a special supplement, which is the changes being effected supplement. A more complete submission of glucose data and additional discussion of pooling and analysis of this data is necessary before an appropriate review of treatment-emergent hyperglycemia and diabetes can take place.
Q. So is this the FDA turning down the language that they have proposed about the olanzapine being 8 percent random glucose levels

versus placebo of 7 percent?
A. In effect.
Q. I mean, that's what they're doing, correct?
A. Yes.
Q. Let's go -- let me publish that to the jury, if I may, Your Honor.
THE COURT: You may.
Q. (BY MR. FIBICH) Doctor, I want to go to Exhibit 1111. This is the cover page entitled: Issues Management Planning.
You see that?
A. Yes.
Q. Answers that Matter?
A. Yes.
Q. Go to the second page.
You see this, sir?
A. Yes, I do.
Q. And this is a document from the Lilly files which deal with the issue of diabetes relative to their product Zyprexa?
A. Yes.
Q. And you see -- can you read the portion, Our Position?
A. Yes, I can.

Q. Would you read it out loud, please?
A. It says: Diabetes slash hyperglycemia may occur in patients taking antipsychotics and/or mood stabilizers, including Zyprexa, at comparable rates with the possible exception of clozapine.
Q. Okay. What is meant by "comparable rates"?
A. They're saying in effect that it's simply a class effect. That is to say all the atypical antipsychotics, including Zyprexa, but excluding clozapine have basically comparable rates of adverse events.
Q. Comparable rates of what type of adverse events?
A. The issue is concerned about potential weight gain and hyperglycemia.
Q. And what do you understand this issue management document to be?
A. Well, it's -- they studied what was happening with respect to prescribers. They came to some conclusion, and they want now to manage the situation with a response that they feel is necessary in their mind.
Q. Is it your understanding that this is

information that is given to the marketing department to use in dealing with doctors relative to the issue of diabetes?
MR. BRENNER: Your Honor, objection. I think this is outside what you qualified him for.
Q. (BY MR. FIBICH) What do you understand this document to be used for, if you know?
MR. BRENNER: Same objection.
MR. FIBICH: Rephrase my question.
THE COURT: I understand you rephrased your question. Is the objection dealing with outside the scope of his report?
MR. BRENNER: Yes, Your Honor and his qualifications.
THE COURT: I'm going to sustain the objection.
Q. (BY MR. FIBICH) Doctor, does Zyprexa have comparable rates of adverse events with other antipsychotics other than clozapine?
A. No, it doesn't.
Q. Is this a true statement?
A. It's a statement that is not supported by the facts that Eli Lilly was aware of. And, in fact, the opposite opinion is supported by those facts.

Q. Is this a misrepresentation of a material fact?
A. Yes.
Q. We go down to the Rationale for Position. Would you read that?
A. Showing that diabetes is a common occurrence for all antipsychotics and not just Zyprexa will help reduce the perception that diabetes is linked specifically to Zyprexa and in turn will help to eliminate this risk from the risk/benefit equation.
Q. Would it be appropriate for this rationale to be used to sell Zyprexa?
A. No.
Q. Why not?
A. Well, simply stated, it's putting, apparently, profit over concern of the consumer.
Q. Okay, Doctor, the highlighted portion, what we know: They said that olanzapine does cause modest elevations of mean random glucose; is that correct?
A. Yes.
Q. And what is the significance of the second line: Greater than placebo, greater than Haldol, but equal to risperidone and less than

clozapine?
A. The atypical antipsychotics that have been studied in addition to haloperidol, just belie the statement that they're all alike except clozapine.
Q. So is that a true statement?
A. Well, that's what Lilly knows and it is reasonably true -- close to the truth.
Q. Go to the next page, sir, and this is diabetes -- entitled Diabetes, Desired Evolution, Action Steps: Drive in the minds of our customers that risk of developing diabetes is no different on Zyprexa than with other agents.
Do you see that?
A. Yes, I do.
Q. Would it be appropriate, knowing what you know about this drug and the issue of Zyprexa being related to diabetes and hyperglycemia, to try to enforce that as an action step?
A. No, it's not appropriate.
Q. Would it be appropriate to try to maneuver doctors to get a desired outcome that lower the percentage of customers that directly link Zyprexa with diabetes?
A. No, it isn't.

Q. And then under "timing" it says, ASAP, currently the affiliates have all the information from a product team other than SO13 -- the euglycemic clamp.

Do you know what that refers to?

A. Well, it looks like a supplement, and it looks like a study done with a so-called euglycemic clamp.

Q. Okay. Do you know anything about that clamp study?

A. I don't know anything about this particular study except that they're using a machine that maintains over a period of time by giving small amounts of glucose through the vein to maintain a constant amount of glycemia, and then I don't know what they're doing to see what additional outside event will affect how much glucose you're giving as a function of time to taken that normal level.

Q. That's what a clamp study is?

A. That's what clamp study is. There are different types of -- different ways to do clamp studies.

Q. But you don't have any familiarity with what study they're referring to here?

A. I don't know at all what study they are exactly referring to.

Q. Doctor, can you give us a date of this particular piece of things down at the bottom left-hand corner.

A I don't have it.

Q Bottom left-hand corner, November --

A. Oh, yes, that little thing, 11/28/2001.

MR. FIBICH: Your Honor, I'd like to publish this to the jury, if I may. Exhibit 195.

THE COURT: 195 may be published.

MR. FIBICH: I'm going to have to get another one.

MR. LEHNER: Your Honor, I don't think it's this one. This isn't 195, it's 1111.

THE COURT: Yeah, I think it was 1111, too. Thank you.

MR. ALLEN: It is.

THE COURT: 1111 may be published to the jury.

Q. (BY MR. FIBICH) Doctor, let's look at the next exhibit which is 1962, and it is entitled hyperglycemia/diabetes sell sheet implementation. Do you see that?

A. Yes, I do.

Q. This is another Answers that Matter Lilly document?

A. Yes.

Q. Do you know what a sell sheet is?

A. Well, yes. Basically, it is a document that tells you how to sell or how to convince prescribers to prescribe.

Q. Okay. On the next page it says: Proper implementation is the key. Our goal and focus is on creating a market with Donna. The competition wins if we are distracted into talking about diabetes. So stand strong against their ploys and answer the AOC concisely and with confidence.

What are they talking about here?

A. The reference to Donna, which was a name that was created by the company and it means this is a lady who has moods, stress, nothing psychotic, mind you, but mood behavior and mood changes, and depression, that kind of thing. So it has to do -- Donna was used with the direct primary-care physicians. Physicians who are not experts in psychiatry.

Now, obviously, the competition are the other drugs and they are talking about the problems of Zyprexa and diabetes.

So now, how should a representative attack that problem? So, we're going to see, I suppose, what is the advice of Eli Lilly --

Q. AOC stands for area of concern?

A. Yes.

Q. Let's go to the next page. Again, entitled Handling the Diabetes Area of Concern, AOC. This is a highly competitive-driven issue. Therefore, we will not proactively address the diabetes concern, but rather only when it arises from an M.D.?

A. Yes, it says don't open up the diabetes issue, just wait and only answer if the physician asks you questions what's the deal with Zyprexa and diabetes.

Q. And it says, restate the verbatim while utilizing the diabetes sell sheet. What does that mean, sir?

A. Well, verbatim is a document that is given to representatives, that they should quote verbatim, that is to say word by word. And it is meant to help them answer the question without faux pas or misstatement or whatever.

Q. Now, at the time this sell sheet is being disseminated in 2001, was Eli Lilly and

Company on notice that there was an association between diabetes and Zyprexa?
A. Yes.
Q. In your opinion, was it inappropriate for Eli Lilly to be using these type of methods in dealing with physicians that were considering the use of Zyprexa?
A. Yes.
Q. Why, sir?
A. Well, simply stated, you shouldn't -- the rep is supposed to go to the physician and tell the physician the good sides of any drug and the good -- the bad sides of any of that drug.

Now, if you don't talk about the problems of Zyprexa proactively, then you're hoping that some of them will not raise the issue so you don't have to talk about it.

And if others raise the issue, then you have been given exactly what to say in order to reassure them.
Q. It says: Check for agreement and get back to Donna. Do you know what they're referring to here when they say check for agreement?
A. Well, if you have convinced with the

verbatim, the physician not to worry about Zyprexa and diabetes, then now is the time to talk about Donna, which is an off-label use, and try to convince the physician --

MR. BRENNER: Objection, Your Honor. We're going to need a sidebar on that one.

(Bench discussion.)

MR. BRENNER: Two objections, Your Honor. First, maybe it was inadvertent, but off-label -- the second is he's now really talking about marketing efforts, and I don't think this is what he's offered for and I don't think he's qualified for that --

THE COURT: No, I think he's talking about marketing efforts, but it's in the context of warnings and I'll alow it for that purpose. I did hear him say the term, it's an off-label use. The question is do you want an instruction or don't you want an instruction? But I have to tell the jury that off-label uses are not part of the issue in this case except as I would let them know that it relates to marketing as it relates to warning issues.

MR. BRENNER: I would request that instruction, Your Honor.

THE COURT: Okay. Ladies and gentlemen of the jury, the doctor used the term off-label use. The question of off label uses is not one that you're being asked to consider in this trial other than if that issue relates to the questions of warnings which you are being asked to consider in this case, and so if you hear the term "off-label use", it's only to be considered in the context of whether or not appropriate warnings were given and you'll get jury instructions on how you determine that at the end of the trial, but the question of whether or not off-label use is a proper use or an improper use is not an issue that's before you in this trial.
Q. (BY MR. FIBICH) Doctor, let's go to the next exhibit.

Same exhibit, next page rather, it says what are the facts to convey and where do you find them with the sell sheet.

Do you see that?
A. Yes, I do.
Q. It goes and says the highlighted portion, as the diabetes care company, Lilly takes this issue very seriously and will continue to offer solutions.

It says not written on the sell sheet, but used as a segue to the next point, and it goes on to say when you look at various agents that treat patients with mental illness, the rate of treatment-emergent diabetes is comparable across agents. Is that a fair and accurate statement?
A. No.
Q. Is it a misrepresentation of a material fact?
A. Totally. Particularly if it's addressing the Donna example.
Q. Doctor, I want to go to that -- I want to publish that, if I may, Your Honor.

THE COURT: 1962, you wish to publish?

MR. FIBICH: 1962 may be published.
Q. (BY MR. FIBICH) Doctor, was Zyprexa a product that was sold worldwide?
A. Yes.
Q. And do other countries have similar -- to your knowledge, do other countries have similar organizations to the FDA that regulates the promotion and promulgation of prescriptive drugs?
A. Yes. Particularly the European Union and Japan and other countries.

Q. Are you aware --
A. Canada.
Q. Are you aware that Japan was made to change its label -- or Eli Lilly was made in Japan to change its label?
A. Yes, I'm aware.
Q. I want to show you Exhibit No. 320, which is a Dear Doctor letter in Japan.
Can you explain to the jury what a Dear Doctor letter is?
A. A Dear Doctor letter is a letter written by the company either through its own volition or decision or because they have been asked by the FDA or some other regulatory authority to do so because there are important safety information that have been generated in the immediate past that seem sufficiently worrisome to send them big -- I mean, send thousands of letters to the doctors in that particular country telling them what happened and what is its significance.
Q. And is that something that is used in the United States, required by the FDA when the FDA wants to get information out to doctors about a serious matter?
A. Yes, it's now called Dear Health

Practitioner letter.
Q. As opposed to Dear Doctor letter?
A. Yes.
Q. I want to show you Exhibit 320, and -- and can you describe for the jury what this is?
A. This document is very interesting. What the Japanese authority has told it -- the company to tell the Japanese prescriber is that if a patient is diabetic or has a history -- a past history of diabetes, do not administer to this patient Zyprexa. And this is the very definition that the FDA has for the definition of contraindication, which is exactly the same way: Do not administer to a patient that we have identified such and suchly.
Now, then the second part is: If you give Zyprexa, obviously, to not the patient that has been defined in point 1, then you have to monitor -- you have to monitor the glucose level in the blood to make sure that it's not going the wrong way, and particularly it's not going very fast, very high in the wrong way. The third one is what we call compliance, that is to say you have to explain to the patient and the family members, because many diabetics are not -- need a family member to help

them be compliant with the treatment so that they understand the importance of this warning and they now know that they have to make an extra effort to comply with the advice that is given here.
Very good document.
Q. Doctor, I want to emphasize some things in this label or -- this Dear Healthcare Professional letter.
And the first thing I want to have you point out is: When does this letter indicate that the product came on the market in Japan? First sentence.
A. June 2001.
Q. And what is the date that this emergency safety information was given out?
A. April 2002.
Q. It goes on to state that nine serious cases, including two of death, with hyperglycemia, diabetic ketoacidosis and diabetic coma have been reported for which causal relationship with this product cannot be denied.
A. That's what it says.
Q. What does that mean, sir?
A. It means that during essentially less than a year from June, 2001 to April 2002, there

were reports, not actual cases necessarily, where nine serious cases of diabetes occurred and two of these people died as a result of it, and the seriousness of the diabetes is that there is not only hyperglycemia, but diabetic ketoacidosis which is to say that pH balance in the internal blood milieu has been acidified to a point where they can go to coma, which is the next thing, lose consciousness, and on the basis of that, and on the basis of other information, I suppose they had in the NDA that was submitted to Japan, the Japanese authority thinks that you cannot deny that there's a relationship with Zyprexa and these events.
Q. And that relationship is a causal relationship, right?
A. Well, let me -- let me carefully look at that. Yes, it says causal relationship, cannot be denied.
Q. Now, Doctor, it would appear that Japan took this action within ten months of the marketing of the drug; is that correct?
A. Yes.
Q. And what they said was you should not give this drug to patients who have a history of

diabetes; is that correct?
A. Yes.
Q. Why is that? Why was it important that patients with diabetes not get the drug?
A. Well, let me remind you of the statutes and the regulations. A drug is defined in the United States as safe and effective for the indication for which it has been tested. Now, the psychiatry patients were not diabetic patients. Therefore, the risk/benefit ratio gets worse for a psychiatrist -- psychiatry patient or a nonpsychiatric patient that is on top of a diabetic. It's a situation different than that which has been studied and on which approval of the drug has been based.
Q. Doctor, it says: During administration of this product, observe sufficiently with such as measurement of blood glucose; do you see that?
A. Yes.
Q. Is it -- do you have an opinion as to whether or not the manufacturer of this drug in the United States should have advised physicians to monitor their patients by measuring blood glucose?
A. Yes.

Q. Why is that?
A. Well, it's obvious that since you haven't tested in your NDA a diabetic group of patients, and since there have been cases where diabetic coma has been observed and so on and so forth in the United States, then you have to monitor what's happening to a given patient who has been given Zyprexa, so that you may do something if and when the values of the blood sugar shoot up. And there have been values reported that were in excess of 600 milligram per deciliter, and, of course, the upper limit of normal is 126 milligrams per deciliter of sugar.
Q. Doctor, when should Eli Lilly have advised patients that were taking Zyprexa that there should be regular monitoring of their blood glucose levels?
A. When they observed hyperglycemia, when they observed a fourfold difference of hyperglycemia events compared to in Zyprexa, given by Zyprexa in comparison with placebo, when they observed this very important average increases of weight gain, when they knew about the other metabolic problems of cholesterol and such, all of this increasing the probability of

morbidity and mortality due to these events, and the company had those information certainly in 2001 and even earlier.
Q. They knew it in 1995 in San Juan, Puerto Rico, did they not, some of them?
A. Yes, they did, but in 1995, the only -- the -- what they should have done after receiving that signal was to do proper studies or go and err on the conservative side. So even at that period of time, yes, if they didn't do the proper studies, they should have -- even if they did, they should have in the interim informed the prescriber to monitor glycemia and weight gain.
MR. FIBICH: May I publish 320 to the jury, Your Honor?
THE COURT: 320 may be published.
Q. Doctor, I want to show you now Exhibit 4436, another Lilly internal document Psychotropic Label Overview for DM. DM is --
A. Diabetes mellitus. That is the official name of diabetes. We doctors play these games.
Q. If you would, look on page -- the page is blown up. You see this, sir?
A. Yes, I do.
Q. And this is an analysis that appears

down at the bottom -- it looks like '02 or it may have been '03, you see that? Source?
A. Yes, it's been printed over, I don't see -- it's either '02 or '03.
Q. Okay. What is this, sir?
A. It's a comparison of the regulatory differences between the various countries whose name is given on the top part; U.S., European Union, Australia, Japan and Canada.
Q. And that is how those various countries treated this particular product in their respective areas, is that correct?
A. Yes, and with respect very precisely to the degree of rigor in each country's label.
Q. Okay. So, was there a warning in Europe in Japan before -- before there was a warning in the United States?
A. Yes.
Q. Was there a precaution in Europe, Australia, Japan and Canada before there was one in the United States?
A. Yes.
Q. Was it contradicted in the label in Japan prior to the United States?
A. It was contraindicated, yes, in certain

well-defined cases.
Q. Doctor, do these other regulatory agencies in other countries just do a better job than the FDA?
A. Well, all I can say is that Japan is No. 1 on this race, and European Union is No. 2. Australia and Canada are -- are in the third position, and I'm sorry to say the U.S. comes last among those countries.
Q. It's the same drug, is it not?
A. Yes.
Q. Why would the citizens of Canada, Japan, Australia and the Europe Union be entitled to a greater warning, a more serious warning than those of us that live in this country?
MR. BRENNER: Objection, Your Honor.
THE COURT: I'll sustain that.
Q. (BY MR. FIBICH) How do you account for the differences, if you know, in the level of warnings given to these other citizens of the other countries?
MR. BRENNER: Objection. I don't believe there's any qualification that he knows the worldwide regulatory scheme.
THE COURT: I'll sustain that

objection.
Q. (BY MR. FIBICH) I like to publish that to the jury, Your Honor.
THE COURT: 4436 may be published.
Q. (BY MR. FIBICH) Doctor, the next exhibit is another letter to Eli Lilly and Company, this is Exhibit No. 10094, Your Honor. Would you familiarize yourself with this particular communication, Dr. Gueriguian.
A. That's Exhibit 10094 or 84?
Q. I think it's 94. It's on the screen. Should be on your screen.
A. Well, okay.
THE COURT: Any disagreement that it's 94?
MR. LEHNER: No, it's 94, Your Honor, I believe.
A. Usually these dates on FDA letters appear at the end of document, so offhand I don't know what is the date of that document.
Q. Well, I'm just asking you to familiarize yourself with it at this time?
A. Well, that's what I'm doing.
Q. Can you tell the members of the jury what it is?

A. It's a letter from the FDA to a person in regulatory affairs at Eli Lilly --
MR. BRENNER: Your Honor, I apologize for the objection. Can we approach on this issue.
THE COURT: You may.
(Bench conference.)
MR. BRENNER: I'm concerned because he just said that he's familiarizing himself. This letter comes out right at the time of the deposition. I'm not sure if he had it at the deposition.
THE COURT: That's kind of the question. If he had it, if you want to take the minute or -- if he had it, I'm going to let it in, let him talk about it. If he didn't have it, I'm not.
MR. FIBICH: Judge, he did have it. It was discussed in the deposition. Now, if you want me to --
MR. BRENNER: If that's Mr. Fibich's representation, I'll accept the representation.
THE COURT: I'll accept your representation too, but if it turns out that he didn't, I'll strike that portion of his testimony.
MR. FIBICH: In light of that, why

don't we --
THE COURT: Mr. Suggs may have something that can help us right now.
MR. SUGGS: It was presented to him in their deposition, it's an excerpt from that document. They clearly had notice, Your Honor.
MR. BRENNER: Having said that, we weren't.
THE COURT: Again, I'm going to let you ask him about that based on the representation. I'm just telling you if the representation is wrong, then it won't be wrong. I'm just making clear what the line is.
(End of bench discussion.)
Q. (BY MR. FIBICH) Okay. Doctor, you familiarized yourself with the letter?
A. Yes.
Q. Okay. Could you tell the jury what this letter represents?
A. It represents a communication between the FDA and Eli Lilly with respect to a new product and its eventual approval -- new product, which is a combi -- combination product of olanzapine and fluoxetine, namely Zyprexa and Prozac.

Q. So this is a letter responding to Eli Lilly's IND or NDA?
A. NDA.
Q. For a new drug which is a combination of olanzapine and fluoxetine, which is Prozac, correct?
A. Yes.
Q. And what is the response of the FDA to this application?
A. They are making comments about their concern about certain aspects of the proposed labeling, that is to say, the labeling proposed by Eli Lilly.
Q. And we've got that highlighted and underlined in red. It says: In particular, we are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, hyperlipidemia that is associated with olanzapine use, whether taken alone or in combination with fluoxetine. You must fully address these concerns before being able to make a final action on this application.
This is in 19 -- I mean, 2006, correct -- 2007?
A. I think it's 2007.

Q. What month in 2007?
A. It's March 28, 2007.
Q. Referring to the application in September of 2006 for a new drug application for Symbyax, correct?
A. Yes, it's the letter of the FDA that is at the end of March -- dated at the end of March 2007.
Q. Doctor, what is the significance of the FDA as late as March of 2007, which was a year ago, stating that the labeling is deficient with regard to olanzapine alone relative to weight gain, hyperglycemia and hyperlipidemia?
A. Well, for whatever reason the FDA seems to have realized that they don't have all the information on that subject.
Q. Let's go to the next page. Why do you say that, Doctor?
A. Well, if they say that current labeling for either of these drugs does not provide sufficient information on the risks that we're talking about, and we fully intend to insure that these labels are enhanced with the best available information to characterize these risks, the implication clearly is they don't have the

information in their opinion to be able to fully characterize these risks.
Q. It refers to the New York Times. Do you understand what the relationship between a New York Times article is and this letter?
MR. BRENNER: Objection, Your Honor.
MR. FIBICH: I'm just asking if he understands the relationship.
THE COURT: I'll let him answer that yes or no.
A. Yes, I do understand.
Q. (BY MR. FIBICH) What is your understanding as to the relationship in this letter and this document?
MR. BRENNER: There, Your Honor.
THE COURT: Hold on a second, Doctor. You may approach.
(Bench conference.)
MR. BRENNER: All the New York Times-based information comes well after his deposition, that was not part of his exhibits at the deposition.
THE COURT: This letter was before -- and he was on notice on that. What this seems to say is if on the other hand, you were (inaudible)

for your own internal purpose, but not submitted, we ask you to submit them. Your recent response to our January 12th letter regarding the New York Times story, so the New York Times story I would have thought that you were referring to had to predate this.
MR. BRENNER: Perhaps I wasn't clear. The date -- the date that gets submitted in response to that story on the FDA comes well after Dr. Gueriguian's report in the deposition. I would object to him talking about any of those data in response to the letter.
THE COURT: I don't think that's what the question was about. I think the question is designed, quite frankly to elicit the fact that a bunch of stuff came out from the New York times that hadn't been disclosed before. To the extent he knows that and wants to say that, I'll let him.
MR. BRENNER: My objection to that is hearsay to the New York Times.
(End of bench discussion.)
THE COURT: As to your last point about hearsay, I don't think it's being offered -- if that's going to be the testimony, it's not being offered for the truth of the matter.

MR. BRENNER: I understand Your Honor's ruling.

Q. (BY MR. FIBICH) What did the New York Times article have to do with the position of the FDA in this letter, if you know?

A. Well, an investigative reporter at the New York Times was able to obtain certain documents. Those documents were of a nature to allow the New York Times to arrive at its own conclusion that --

MR. LEHNER: Your Honor, can we approach --

MR. FIBICH: Without telling us what the New York Times concluded, what --

THE COURT: Again, one of you can approach, but one person per witness.

MR. LEHNER: I'll approach on this, Your Honor.

THE COURT: The idea is I don't want objections being made by two different lawyers for one team.

MR. BRENNER: This implicates a motion in limine. On that point, I understand Your Honor's ruling.

THE COURT: Please approach.

Actually, we're at 1:30 anyway. Why don't I let the jury go home and then we can wrangle about this and take up the results on Monday.

Ladies and gentlemen of the jury, we've reached the end of our trial day and I will let you go for the day. Again, please remember not to discuss this case among yourselves or to let anyone discuss it with you, and please also keep an open mind until you hear all the evidence in this case and also, please, again, do not review newspaper articles, TV or do any Internet searches regarding the subject matter of this lawsuit and finally, I will remind you, once again, to set your clocks ahead an hour so that everybody shows up on time on Monday.

Did you have a question, Ms. Mitchell?

VENIREPERSON: Yes, Your Honor, will we be able to submit our questions for the Doctor tomorrow?

THE COURT: Not tomorrow, tomorrow's Saturday.

VENIREPERSON: Monday.

THE COURT: The way it works is that

when a witness is done being questioned by the lawyers completely, then it's your turn. And then, depending on what your questions are, I may let them ask more questions as well. But your turn comes after everything the lawyers have asked just to make sure that it may well be that you've got questions now and those questions will be cleared up later on down the road.

Did somebody else have a question?

VENIREPERSON: What do we do with these documents?

THE COURT: The documents that are circulating, you should keep with your notepads on your chairs, the one-page document that gave -- that I think I handed out to everybody that talks about the generic names and the brand names of the different atypicals. There are documents that have been circulating among all of you, and if those could all be put in the corner there by Mr. Jump. They're just to circulate so you could take a look at them while this is going on, but nobody should be keeping those at this point.

Have a nice weekend.

VENIREPERSON: Thank you, Your Honor.

(Jury out.)

THE COURT: And Doctor, you're free to step down if you want to or you can sit there if you want to.

THE WITNESS: No, that's all right.

THE COURT: But I'll see you on Monday, too. Let's take up this issue, and before I do that, I just would like to compliment the Eli Lilly counsel for the manner in which you've made your objections by not engaging in speaking objections and just giving -- just saying objection. It would also be appropriate if you want to, if you want to say objection, argumentative; objection, 403, something like that, that's permissible too, but I very, very much appreciate that you're not engaging in speaking objections and reserving that for either sidebar or what we're doing now.

MR. BRENNER: Thank you, Your Honor.

MR. LEHNER: Your Honor, I think the motion in limine, and I don't have it right here in front of me, with respect to the New York Times was, it was granted in part and denied in part. But the part that was denied I think was limited only to the response that we had made, the specific submission that we had made to the New York Times -- or to the FDA responding to the allegations that had been made

by the New York Times. I think any other reference, as I recall the motion in limine to the New York Times was not to be the subject of testimony and that was consistent with what your -- with what you decided in the motion in limine context. So all this questioning about how did it arise and all that is, I think, completely beyond the scope. If they want to use our response, that was what you said was appropriate.

THE COURT: I'm going to overrule the objection to that extent.

I think this is being done in the context of a letter Lilly wrote to the FDA, and it's just sort of explaining the temporal sequence as I understand it of that, and I don't think that information -- I think that information is relevant.

MR. LEHNER: Well, his response about that this was done by an investigative reporter, the New York Times came to certain conclusions. Well, the New York Times I don't think comes to conclusions, they report facts as they find them. I think that's completely prejudicial and that's why we sort of put the motion in limine in there. So I think you really -- I don't think it is a proper

subject for question, that was why we filed the motion in limine in the first place.

MR. FIBICH: Your Honor, I'm going to rephrase the questions on Monday that will get past this and get us clearly --

THE COURT: Why don't we try to do that. I mean, I don't have any problems of at least -- I don't really want to get into specifics of what the New York Times did or didn't do or that sort of stuff. What I'm trying to get to the jury, to understand the context of that letter, was what the temporal sequence, which I think is appropriate.

MR. LEHNER: Temporal sequence is fine, Your Honor, but I think characterizations are not.

THE COURT: Right and that's fair.

MR. ALLEN: There's an agreement also, Your Honor on these -- I can't remember what the count was this morning. I have agreed on the deposition of Denise Torres to put in what Mr. Lehner asked for so that's no longer on the table. Of the, I think we said six, I think we said six, I've agreed now to two of them, so there's four left.

MR. LEHNER: I'll double-check and

make sure.

MR. ALLEN: So really you have nothing, and we'll see if we can reach some more agreements between now and noon tomorrow in the lobby.

THE COURT: So the plan is at noon tomorrow I will meet you. You're going to give me where we stand and what -- to the extent there's a disagreement, the -- there's no disagreement on Torres. To the extent there's a disagreement on --

MR. ALLEN: Lechleiter.

THE COURT: -- Lechleiter, you're going to tell me which ones there's a disagreement on, and then you'll give me the cuts so I can review whether I think they are more akin to completeness or more akin to new material that ought to be in cross-examination. And then I'm going to get Lilly's response to the five new cuts that I've gotten of Beasley -- I can't read my handwriting --

MR. ALLEN: Beasley, Kinon --

THE COURT: Kinon, Collins, Taurel and Wojcieszek?

MR. ALLEN: No. Okay. It's Beasley, Kinon, Tollefson, Wojcieszek and Sidney Taurel.

THE COURT: -- and Taurel. Not only

will I get Lilly's response to those so I can read them, and I'm going to -- you've told me that Wojcieszek and Beasley are one and two or two and one.

MR. ALLEN: Yes, sir.

THE COURT: If you can give me 3, 4, 5, 6 and 7, that's how I'll take them up in case I don't get to all seven over the weekend.

MR. LEHNER: Your Honor, just now on the mechanics of how they're going to be played. They're going to play theirs, and then I guess we decide as whether we want to play them as counterdesignations in theirs or whether we save them and play them in our case -- is that how this is going to work?

THE COURT: That's correct.

MR. ALLEN: Okay. Thank you, Your Honor.

MR. BRENNER: Your Honor, may I pose a question to the Court. This is going to now -- we've had a break with the witness on the stand, I don't know if there's a rule or court procedure. Is one allowed to talk to a witness? It will impact us too when the court is in recess and the witness is sworn and not yet discharged. I just don't know

local practice.
THE COURT: I don't really think so.
MR. ALLEN: We'd sure like to take him to dinner and make sure -- put him in his hotel room --
THE COURT: They can do that. To the extent -- I mean, he's not -- well, I'm going to say I don't have any problem with it.
MR. ALLEN: Thank you, Your Honor.
THE COURT: I'll see everybody, then, Monday morning, 8:15. Hopefully we can get started on time and I'll remind all of you as well about Daylight Savings Time, too.
MR. LEHNER: Thank you.
THE COURT: We'll be off record.
(Court adjourned at 1:40 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 8th day of March, 2008.

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