IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of STEWART DOLIN, deceased,	)	
Plaintiffs,	)	
vs.	)	No. 12 CV 6403
SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation,	)	Chicago, Illinois
Defendant.	)	March 23, 2017 1:30 p.m.

VOLUME 7-B

TRANSCRIPT OF PROCEEDINGS - Trial

BEFORE THE HONORABLE WILLIAM T. HART, and a Jury

APPEARANCES:

For the Plaintiff: BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
BY: MR. R. BRENT WISNER
12100 Wilshire Boulevard, Suite 950
Los Angeles, California 90025
(310) 207-3233

RAPOPORT LAW OFFICES, P.C.
BY: MR. DAVID E. RAPOPORT
MR. MATTHEW S. SIMS
20 North Clark Street, Suite 3500
Chicago, Illinois 60602
(312) 327-9880

Court reporters: Judith A. Walsh, CSR, RDR, F/CRR
Charles R. Zandi, CSR, RPR, FCRR
219 South Dearborn Street, Room 2504
Chicago, Illinois 60604
(312) 435-5895
judith_walsh@ilnd.uscourts.gov

APPEARANCES (continued:)

For Defendant GlaxoSmithKline:

KING & SPALDING
BY: MR. TODD P. DAVIS
MR. ANDREW T. BAYMAN
MS. HEATHER HOWARD
1180 Peachtree Street N.E.
Atlanta, Georgia 30309
(404) 572-4600

KING & SPALDING, LLP
BY: MS. URSULA M. HENNINGER
100 North Tryon Street, Suite 3900
Charlotte, North Carolina 28202
(704) 503-2631

SNR DENTON US, LLP
BY: MR. ALAN S. GILBERT
233 South Wacker Drive, Suite 7800
Chicago, Illinois 60606
(312) 876-8000

(Proceedings heard in open court. Jury in.)

THE COURT: Thank you very much, ladies and gentlemen. Please be seated. We will resume.

You may proceed, sir.

MR. BAYMAN: Thank you, your Honor.

DAVID ROSS, PLAINTIFF'S WITNESS, PREVIOUSLY SWORN

CROSS-EXAMINATION (Resumed)

BY MR. BAYMAN:

Q. Dr. Ross, before we broke for lunch, I wrote down that you said that you were critical because "emotional lability" was buried in thousands of pages and not put in any tables, correct?

A. No, sir, that's not what I said.

Q. I think you said it was not the basis for summary tables that typically reviewers rely on?

A. No, sir, that's not what I said.

Q. All right. We'll come back to that in a minute. Turn, if you would, then in that PX 263 which is Tab 22, turn to Page 347149.

A. I'm sorry, sir. Could you repeat the Bates number?

Q. Sure. It's 347149.

MR. WISNER: Your Honor, I object. This is not a document that he's ever testified about or even seen. This is from Dr. Healy's direct.

MR. BAYMAN: It's from the same document I was

questioning him about right before we had lunch, your Honor.

MR. WISNER: You put it up on the screen, but I didn't have a chance to object.

MR. BAYMAN: Can you take it down?

You didn't object to it before lunch.

THE COURT: Well, ask your question. We'll see what...

BY MR. BAYMAN:

Q. All right. Have you found Page 347149?

A. I believe this is the correct page.

Q. And you see there are tables on that page, correct?

A. I do.

MR. BAYMAN: Okay. May I publish that to the jury?

THE COURT: Is this in evidence?

MR. BAYMAN: Yes, sir.

THE COURT: All right.

MR. BAYMAN: PX -- Plaintiff's Exhibit 263.

MR. WISNER: Objection, your Honor. It's not in evidence. It was never admitted into evidence. It was shown to the jury during Dr. Healy's deposition -- during his testimony but it was never admitted into evidence. Showing a different expert a different expert's documents --

MR. BAYMAN: Take it down --

MR. WISNER: -- right up there on the screen --

MR. BAYMAN: Take it down.

MR. WISNER: Just using hearsay, it violates the impeachment rule under 603. You can't impeach with extrinsic evidence that the expert has never seen, so I don't know what this is about.

MR. BAYMAN: Judge, these are --

THE COURT: It's not in evidence?

MR. WISNER: No.

MR. BAYMAN: It's not been admitted into evidence. It is a submission to the FDA with respect to --

THE COURT: You can ask him --

MR. BAYMAN: Sure.

THE COURT: -- if he's ever seen it before.

BY MR. BAYMAN:

Q. Have you ever seen this document before?

A. I don't believe so.

Q. For the record, this is Plaintiff's Exhibit 263. And it's a study No. PAR-2906007001 titled, "A double-blind comparison of paroxetine, amitriptyline, and placebo in patients with major depressive disorder with melancholia."

You've never seen that before?

A. I don't recall seeing it.

Q. Are you sure about that?

A. I don't recall seeing it.

Q. You know, though, that in that document, there are tables which show that emotional lability --

THE COURT: Wait, wait, wait. The document is not in evidence, sir. It's not in evidence.

MR. BAYMAN: You --

THE COURT: He hasn't seen it. It's not in evidence.

BY MR. BAYMAN:

Q. You are aware, are you not, and you've seen documents in which GSK has coded suicides and suicide attempts to the preferred term of emotional lability. We saw some right before lunch, correct?

A. So there's two questions there. Which one -- if you could repeat the one you'd like me to answer first.

Q. You've seen documents that GSK submitted to the FDA where GSK coded suicides and suicide attempts to the preferred term "emotional lability," correct?

A. With the understanding that I'm not aware of any rules that said that was how they should do it, yes.

Q. Okay. And you -- Dr. Ross, you told the jury yesterday morning that you reviewed the most current Paxil label as of January 2007 and that the current label still contains language that you think is misleading such as language on emotional lability, correct?

A. I believe that what I said, and I don't have the verbatim text, is that there is no way for anybody to know that emotional lability -- and for the record, I am not even sure that that is a term that's in the current list of terms used

by FDA, other regulators, or regulated industry. There's no way of knowing that that actually refers to events that involved attempted suicide.

Q. My question was: You said you reviewed the current label which is as of January 2017. You said you reviewed that a couple nights ago, correct?

A. Correct.

Q. Okay. And you said that language -- I mean, that the current label is still -- is false and misleading because you think it contains language that's misleading such as the language on emotional lability, correct?

A. That's one of several reasons --

Q. Okay.

A. -- why it is false and misleading.

Q. And you know from your review of that label because Mr. Wisner asked you in 25 or 30 years and you corrected him, in 25 years, had these warnings been changed, and the label today currently has the same warnings that it had in it in 2010. Do you remember that line of inquiry?

A. I noted that the placement of "emotional lability" had been moved to the first position in the current label, that is, the January 2017, after the word "frequent," I believe.

Q. And you know, though, from your review of that current label that Mr. Wisner asked you about that the warnings with respect to the risk of suicide are the same in that label as

they were in the 2010 label at the time Mr. Dolin was prescribed generic paroxetine, correct?

THE WITNESS: Your Honor, could I ask that that question be read back?

THE COURT: Read it back.

(Record read.)

BY THE WITNESS:

A. So there's a couple of different concepts here, so let me try and answer this as succinctly as possible. The label for both branding Paxil and generic paroxetine, which has to follow the brand name, has not been updated with the Paxil-specific information in any way, shape, or form, so you are correct.

BY MR. BAYMAN:

Q. Thank you. And I'm sure that when you saw the label that you looked at, you know that the holder of the Paxil NDA today --

MR. WISNER: Objection. Move to strike.

THE COURT: I haven't heard the question yet.

MR. WISNER: The question is prejudicial. May I sidebar, your Honor? You explicitly ruled this out, and they agreed not to do it, and he's about to ask the question.

THE COURT: All right. Let's have a sidebar.

(Proceedings heard at sidebar:)

[redacted]

(Proceedings heard in open court:)
BY MR. BAYMAN:
Q. Doctor, I want to ask you now about GSK's April 2006 label change. You're familiar with that, correct?
A. I am.
Q. And if you would, turn in your notebook to Tab 10, Exhibit 101.
A. Yes.
MR. BAYMAN: And it's Defense Exhibit 101, your Honor, which is in evidence per your March 9, 2017, minute entry.
BY MR. BAYMAN:
Q. Let's take a look at that. You're -- you've reviewed this before, correct?
A. I believe so, yes.
Q. And you said yesterday that there is a lot of back and forth that occurs between a manufacturer and the FDA when a manufacturer attempts to change a label, correct?
A. In some instances, yes.
Q. And that includes sending correspondence back and forth, correct?
A. Among other things, yes.
Q. And that can include having meetings between the drug company and the FDA, correct, to discuss labeling changes?
A. Yes.

Q. That can include having telephone conversations between the FDA and the drug company to discuss labeling changes, correct?
A. Yes.
Q. That can include email back and forth between the FDA and the company about proposed label changes, correct?
A. Yes, with the understanding that any communications, be it email or telephone, do not represent final agency action.
Q. What you're saying is at the end of the process, the agency issues a letter, a formal letter, correct?
A. Correct.
Q. Okay. But that's part of the back and forth that occurs, those kinds of exchanges, correct?
A. Yes.
Q. Okay. So here in this document, if you will look, the second page, the first paragraph, "Conclusions and proposed next steps," do you see that?
A. Yes.
Q. It's -- what's happening is GSK is telling the FDA about its findings for suicide attempts in adult patients with major depression, correct? That's what this correspondence is about?
A. It is informing the FDA of the results and GlaxoSmithKline's interpretation of those results and GSK's regulatory conclusions.
Q. That's -- that's the analysis that we discussed with GSK

and that you discussed with Mr. Wisner on direct with the 7.6 increased risk in major depressive disorders on the secondary end point, correct?

A. So I kind of want to make sure I'm answering your question, understanding it correctly. When you say "2.76," that is the odds ratio --

Q. I'm sorry. I misspoke. I meant 6.7 which was GSK -- the odds ratio GSK found.

A. Okay. They're informing FDA of their finding confirming that there is a sharply increased odds ratio among individuals exposed to Paxil with regard to suicidal attempts.

Q. 6.7 with respect to the secondary analysis of definitive suicidal behavior, correct?

A. Actually, I don't believe it says "the secondary analysis" here.

Q. But you know that that was the secondary analysis?

A. They do not say that here. They do not qualify it in that way as a secondary analysis.

Q. Understood, but you know that from your review, correct, with me? We went over this earlier this morning.

A. I'm just telling you what I'm reading here in plain language. It doesn't say "secondary analysis." It actually does not include those words.

Q. But you know that was a secondary analysis? We talked about this this morning, Doctor.

THE COURT: All right. Go on. Another question.
BY MR. BAYMAN:
Q. The letter goes on to say:
"Based on these most recent findings in the adult patient data set, GSK concludes that some statements in the approved prescribing information will need to be amended to reflect the results from this analysis following completion of the entire analysis."
Did I read that correctly?
A. You did.
Q. Okay. And so basically, what GSK's saying, to try to cut to the chase here, Doctor, is, "We want to amend our label to present this data," correct?
A. The first line says, to make sure that I put this -- my answer in context, "GSK believes that labeling revisions and direct communications with healthcare professionals, HCPs, should be undertaken only after completion of the entire analysis but is willing to discuss earlier labeling changes, communications with HCPs if so desired by the agency."
So they are saying that they believe that it should be undertaken after they finish the entire analysis but are willing to discuss, not commit to revising the label earlier or earlier communications with HCPs.
Q. But you know from your review of the record that GSK actually provided proposed labeling to indicate the data with

respect to the MDD finding, correct?
A. As inadequate as it was, they did submit that in a changes being effected supplement which they could submit 30 -- I'm sorry, implement 30 days after submission to FDA.
Q. You said "as inadequate as it was"?
A. That's correct.
Q. You agree that the May 2006 labeling changes that GSK implemented included the accurate statement that an increased risk in suicidal attempt was observed in MDD patients of all ages, correct?
A. That statement by itself without context is accurate but does not -- I'm not referring -- the word "inadequate" does not refer to that statement alone.
Q. I just asked you if it was an accurate statement.
A. Taken out of context, yes.
Q. Turn to your deposition, Page 279, Doctor.
A. Yes.
Q. "Question: And you agree that the May 2006 labeling change that GSK implemented included -- included the accurate statement that an increase in suicide attempt risk was observed in MDD patients of all ages?"
Your answer was, "Yes, I do agree with that," correct?
A. I just agreed with you a few seconds ago, yes.
MR. BAYMAN: Can we put up Joint Exhibit 5 and blow

it up, please, Roger, and scroll down to -- go to the...
BY MR. BAYMAN:
Q. You would agree with me -- you would agree with me that the warning that GSK issued in May of 2006 that there was an increased risk in patients of all ages that took paroxetine compared to placebo for the possibility of a suicide attempt, correct?
A. That statement was in the CBE supplement that they submitted.
(Pause.)
THE COURT: What are you waiting for, sir?
MR. BAYMAN: I'm just going to have him show it.
BY MR. BAYMAN:
Q. This is what we were talking about, correct? Keep scrolling down. Well, you agree that GSK put that in that label?
A. I do.
Q. Okay. Now, turn in your tab -- turn to Tab 29 in the notebook.
Put that back up. You got it?
Here's what I was trying to pull up earlier. GSK put the data about the MDD finding and then GSK said, "These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of age 24," correct?

A. That is what that text says.
Q. And this is new information that was appropriate to be in the label per a CBE, or changes being effected?
A. If it is accurate and reliable, it would have been.
Q. You don't believe that's accurate and reliable?
A. No.
Q. What's not accurate or reliable about it?
A. Well, if we could highlight the previous sentence, so this states that the majority of these attempts for paroxetine, eight out of 11, were in younger adults aged 18 to 30, but we know from the paper published by GSK employees, Carpenter, et al., that actually eight of 11 were in adults aged 25 and older. There's actually an entry in the table they have that says that.

So when you say the majority were in people older, 18 to 30, that does not state that you could also slice the data so that it was in older adults older than 25. So not having that statement in there, that there are -- you could slice it in more than one way means that the following statement suggests that the higher frequency may extend beyond the age of 24 is at best misleading and at worst false.

Q. Okay. We're going to get to -- Tab 29, Defendant's Exhibit 107.
A. Yes.
Q. Got it? You've seen that before, correct?

A. I believe so.
Q. That is -- that is a record of a conversation between GSK and the FDA, correct?
A. That is GSK's record of the conversation, yes.
Q. And, in fact, Mr. Wisner showed you some FDA conversation records from the 1990s during your direct examination, correct?
A. Can you refresh my memory? When you say "FDA conversations," I'm just trying to make sure I know which ones you mean, if there's an exhibit. I'm not disagreeing with you. I just want to -- I can't recall exactly what you're referring to right now, is what I'm saying.
Q. You recall talking with Mr. Wisner about a record of a conversation that Dr. David Wheadon recorded following his conversation with Dr. Tom Laughren of the FDA about the submitting the reanalysis of the suicide and the suicide attempt data in 2002 and 2003?
THE WITNESS: Your Honor, respectfully, permission to read back the first question here, "You recall there were" -- I believe it was FDA records.
MR. BAYMAN: No, I said conversation records. I'll help you out. Look in your notebook, Plaintiff's Exhibit 124.
THE WITNESS: I'm sorry. I'm responding to the wording of that question so --
THE COURT: Do you want to hear it again?
THE WITNESS: Please, your Honor.

THE COURT: All right. Read it back.

(Record read as follows: "Question: You recall talking with Mr. Wisner about a record of a conversation that Dr. David Wheadon recorded following his conversation with Dr. Tom Laughren of the FDA about the submitting the reanalysis of the suicide and the suicide attempt data in 2002 and 2003?"

THE WITNESS: I apologize. I think the more specific question is where I had gotten -- an earlier question about the general topic of records, conversations in the '90s with FDA. I just want to make sure I'm remembering that correctly, so I think it was a little bit earlier than this specific reference. And again, I'd ask the Court's indulgence.

BY MR. BAYMAN:

Q. Okay. I asked a broader question because he also showed you some from the 1990s, correct?

A. Yes. I just want to understand what exactly it is you said. Let me -- in the interest of time, I thought you might have said, and if I've got this wrong, I really apologize, I thought you might said FDA records of conversations from the '90s.

The only point I wanted to make was the only documentation I've seen of conversations between GSK and FDA staff have been records, documents that were made by GSK. That's all.

Q. Okay. But Plaintiff's Exhibit 124 which is in evidence, do you see that document? Let's put that up.
A. Is this -- I'm sorry, Mr. Bayman. Defendant's Exhibit 107?
Q. No. Plaintiff's Exhibit 124.
A. I'm sorry. Which --
Q. In the other notebook, the notebook Mr. Wisner gave you.
A. Yes.
Q. All right. My only point was, you've seen -- and I can show you others that are in that same notebook -- documents like this reflecting a record of a conversation with GSK and the FDA about labeling or about safety issues.
THE COURT: I don't think -- that's not an issue, is it?
MR. BAYMAN: Well --
THE COURT: Why don't we just go on.
MR. BAYMAN: Okay. Well, I want to show you what's been marked as Defense Exhibit 107, which is a record of a conversation that took place between GSK and the FDA on April 20th, 2006.
THE COURT: Put it on the screen --
MR. BAYMAN: Okay.
THE COURT: -- so he can see it.
MR. BAYMAN: Yes. Sure.
THE COURT: What's your question?
MR. BAYMAN: My question is --

MR. WISNER: Objection, your Honor. I object to this document as hearsay.

THE COURT: Is it in evidence?

MR. WISNER: No.

MR. BAYMAN: Not yet, your Honor. I was getting ready to put it in evidence, and it's the very same kind of conversation records the plaintiff has shown him all day the other day.

THE COURT: That's not necessarily controlling. You have an objection to it?

MR. WISNER: Objection, hearsay.

THE COURT: Okay. May I see the exhibit, please, Mike?

MR. WISNER: May I approach, your Honor?

THE COURT: No, not yet, not until I see the exhibit.

MR. WISNER: Yes. This is the exhibit.

THE COURT: Have you got it there?

MR. WISNER: Yes.

THE COURT: So this is the writer's report of what was said at a conversation, right?

MR. BAYMAN: And he says it's part of the dialogue between the company and --

THE COURT: All right. We've heard that. But as to this particular document, without going into the content, your argument is that it's something that was prepared by someone

who cannot be cross-examined? He said hearsay.

MR. WISNER: Yes, your Honor. And it's -- to the extent that they're arguing an admission, it's not by a party opponent. It's their own party, so they can't use it, whereas --

THE COURT: The objection will be sustained.

BY MR. BAYMAN:

Q. You know that GSK was having discussions back and forth with the FDA about the language of that label?

THE COURT: It's already been covered now, Mr. Bayman. We've been over this several times. The jury doesn't want to hear it over and over again.

BY MR. BAYMAN:

Q. You know that as of -- as of this point in 2006, FDA had not yet completed its review of the data that GSK submitted?

THE COURT: If you know.

BY THE WITNESS:

A. I actually don't know because the only document I have here was prepared by GSK. I don't --

THE COURT: No, sir, just answer --

THE WITNESS: I'm sorry.

THE COURT: Just answer the question.

THE WITNESS: I don't know based on this.

THE COURT: We've got to move along.

THE WITNESS: I'm sorry, sir.

BY MR. BAYMAN:
Q. You know that FDA was considering GSK's changes being effected supplement, correct?
A. So it was that changes being effected supplement was submitted in April of 2006, and FDA completed its review in May of 2007.
Q. Okay. And so FDA still had the time, after GSK submitted it, to come back and disagree with the language in GSK's proposed label, correct?
A. You mean after the submission?
Q. Yes.
A. Certainly.
Q. Okay. I want to take you to Tab 30, Defense Exhibit 114, which is a letter from GSK to the FDA dated April 27, 2006.
A. Excuse me. Yes, sir.
Q. You've seen that before?
A. Yes.
Q. You've seen it as part of your review of the regulatory file in this case, correct?
A. Yes.
Q. And you're familiar with these kinds of letters, correct?
A. Yes.
Q. And so here on April 27th, 2006, this is the letter by which GSK submits to FDA its CBE labeling changes for Paxil, correct?

A. Yes.

MR. BAYMAN: Your Honor, I'd move now for permission to admit Defense Exhibit 114 into evidence.

MR. WISNER: Your Honor, we do not object to its publication, but we would object to its admission because it is hearsay, although under 703, on cross-examination, they can show hearsay documents but they do not get admitted.

THE COURT: Well, you may show it.

MR. BAYMAN: It's a business record, your Honor. It's a letter to the FDA. It's not a hearsay statement. It's --

THE COURT: It doesn't necessarily mean it's a business record, but you may display it.

BY MR. BAYMAN:

Q. Okay. Let's put it up, do this quickly. I'm just trying to put the chronology together for you, Doctor. Will you agree with me, this is the letter transmitting the CBE?

A. This is a -- appears to be. The reason I don't want to say absolutely is because if it were the actual letter, there would be a date and time stamp saying when it was received in the document room.

Q. Well, this is a letter from GSK to the FDA from GSK's files. You don't dispute that, do you?

A. This is a letter. If it is the letter, I'm just saying that there's -- I don't want to say an authentication stamp,

but if you -- for the sake of argument, you're prepared to say that you guarantee that this is exactly the same letter as was actually sent to the FDA, that's okay.

Q. We don't need to --

THE COURT: All right.

MR. BAYMAN: -- trifle over that. Let's turn to Joint Exhibit 4, which is in evidence, the May 2006 Dear Healthcare Provider letter.

THE COURT: What's the question, sir?

BY MR. BAYMAN:

Q. You're familiar with that letter, correct?

A. I am.

Q. Okay. This is where GSK is informing doctors around the United States about the CBE labeling change based on its analysis of Paxil and suicide attempts, correct?

A. Yes.

Q. And attached to the letter was GSK's new labeling for Paxil, correct?

A. I believe so.

MR. BAYMAN: Pull up the first paragraph of the letter, please.

BY MR. BAYMAN:

Q. It's just alerting -- this letter just alerts the doctors that it is changing the clinical worsening and suicide risks subsection of the warnings section for Paxil, correct?

A. I'm going to disagree with that statement, respectfully. And the reason is that there are three --

THE COURT: You don't have to tell him the reason.

THE WITNESS: I'm sorry, your Honor.

THE COURT: Just answer the questions now, and then we'll move along much quicker.

BY MR. BAYMAN:

Q. Is GSK -- is GSK saying, "We would like to advise you of important changes to the clinical worsening and suicide risk subsection of the warnings section in the Paxil and Paxil CR labels"?

A. That -- yes, with the understanding that if it was really a warning HCP letter, it should have said under the regs, "important drug warning information." That's 21 CFR 201.5.

Q. You don't think "important prescribing information" meets that requirement?

A. Actually, what the regulations say is if you are asking -- or I'm sorry, informing providers in a DHCP letter about an important drug warning which is what this is, the envelope that it's sent in, in order to get -- avoid having it just get tossed, has to be in huge type with a red rectangle around it.

"Important prescribing information" would be what would be on the envelope. It does not say anything on the warning. It would not have the same level of prominence. And that is why the FDA has these very specific regulations about

what's drug warning, what's prescribing information, and what is correction of information.

Q. The letter says, "These labeling changes relate to your adult patient, particularly those who are younger adults." Did I read that correctly?

A. That is what the text states.

Q. And it says, "Please read the full text of the added warnings following this letter. Full copies of the revised package inserts for Paxil and Paxil CR are enclosed."

Did I read that correctly?

A. You did.

Q. And then in the fifth paragraph, GSK tells the doctors in language that it was including in the label, correct?

A. Yes.

Q. And it says:

"Further, in the analysis of adults with MDD, all ages, the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo, 11/3455, .32 percent versus 1/1978, .05 percent. This difference was statistically significant. However, as the absolute number and incidence of events are small, these data should be interpreted with caution. All of the reported events of suicidal behavior in the adult patients with MDD were non-fatal suicide attempts, and the majority of these attempts, 8 out of 11, were in

younger adults aged 18 to 30. These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24."

Did I read that correctly?

A. With the understanding that except for the first sentence, the remainder of the sentences in the paragraph are false and/or misleading, yes, you did.

Q. Your Honor, that wasn't my question.

I just asked, did I read it correctly.

A. Yes.

Q. I know you've said you believe this is false and misleading. You know GSK put these documents on its website for anybody to look at, correct?

A. Yes.

Q. Okay. Then moving chronologically to try to get through this, in December of 2006, FDA convened a public hearing where it discussed the results of its 2006 analysis, correct?

A. I'm -- I'm sorry. I'm not sure which document we're on right now.

Q. We're not looking at a document. I was just asking --

A. I'm sorry.

Q. -- chronologically.

A. I'm sorry.

Q. Chronologically, GSK changed its label in the spring and

then in December, FDA convened a public hearing to release the results of its analysis?

A. I believe that's correct.

MR. BAYMAN: May I approach, your Honor?

THE WITNESS: Thank you, sir.

BY MR. BAYMAN:

Q. Now, Doctor, as part of your work in this case and your regulatory expertise, you are familiar with this document, correct?

A. I believe that I have reviewed it.

Q. This is Dr. Thomas Laughren, his memorandum giving an overview for the meeting of the psychopharmacologic drugs advisory committee, the PDAC. That's the advisory committee, correct?

A. Yes.

Q. And the FDA, when it convenes advisory committees, it frequently, if not always, provides some kind of memo for the committee before the hearings, correct?

A. Yes.

Q. And that memorandum summarizes their official investigation into whatever matter they were studying, correct?

A. Yes.

Q. And this is -- you've seen many kinds of these -- these kinds of memorandum as part of your experience at FDA and as

an expert, correct?
A. Well, most often they have to do with specific products. There certainly are general meetings or hearings regarding class issues, but yes.
Q. This -- yes. This was a class issue, correct?
A. Correct.
MR. BAYMAN: At this time, your Honor, I'd move Exhibit, Defense Exhibit 435 into evidence.
MR. WISNER: Objection, hearsay.
THE COURT: I'll hear you on this later.
MR. BAYMAN: Okay.
THE COURT: Do you need it now?
MR. BAYMAN: I can move on. I can move on -- well, can we publish it without moving it into evidence?
THE COURT: Any objection to that?
MR. WISNER: I don't know if this witness has testified that he relied on it. If he does, then sure.
THE COURT: You can ask him.
BY MR. BAYMAN:
Q. You've reviewed this as part of your work in the case?
A. Yes.
Q. And this is a part of the information in the, what we call the regulatory file that you rely on in giving your opinions in this case?
A. I would say yes.

MR. BAYMAN: Okay. May I publish?
THE COURT: Yes.
MR. WISNER: Your Honor, just to correct the record, I just found out that this is actually already admitted, so we withdraw our objection.
MR. BAYMAN: Okay. I guess it's in evidence.
BY MR. BAYMAN:
Q. Look, if you would -- you had said earlier that what the FDA -- the purpose of what the FDA was doing was to calculate odds ratios with respect to these antidepressants and not to do anything with respect to labeling, correct?
THE WITNESS: I'm sorry, your Honor. I ask that that question be read back.
THE COURT: Read it back, please.
(Record read.)
MR. WISNER: Objection, ambiguous.
THE COURT: You may answer if you can.
BY THE WITNESS:
A. I would say that the -- my previous testimony which I stand by is that that analysis was done to address a specific question but -- as the direct purpose, but as you and I also discussed, I didn't say, well, it had nothing to do with labeling. I think it was -- as I've said previously, there's more things than just randomized controlled trials in making labeling decisions about safety.

BY MR. BAYMAN:
Q. To move along, I just want to call your attention to the last two sentences in this document in the first paragraph. "The purpose" -- the document says:

> "The purpose of the December 13th meeting is to update the committee with our findings from this meta-analysis. We will present our findings and our interpretations of the data, and we will generally discuss our plans for labeling modifications based on these findings."

Did I read that correctly?
A. Yes.
Q. And with respect to this hearing that the FDA convened, people got to come to the hearing and voice their views about what the product labeling should say in light of the FDA's analysis, correct?
A. Could you be a little more specific? When you -- are you referring to the open public hearing portion of the meeting or the members -- or if you could just clarify.
Q. Actually, both. People expressed their views on what the labeling should say, correct?
A. Yes.
Q. And FDA took those views under consideration, correct?
A. I would hope so.
Q. And after the public hearing -- after the public hearing,

then in May of 2007, FDA announced labeling changes concerning adult suicidality for all antidepressants including Paxil, correct?

A. Correct.

Q. Turn, if you would, to Tab 32, Defense Exhibit 122.

A. I'm sorry. Yes.

Q. That's a May 1, 2007, letter from the FDA to GSK, correct?

A. Yes.

MR. BAYMAN: And your Honor, I believe this is in evidence, but I'm sure Mr. Wisner will correct me if I'm wrong.

MR. WISNER: Yes, it is in evidence, your Honor.

BY MR. BAYMAN:

Q. This letter includes and attaches the labeling information that GSK -- that FDA told GSK and other antidepressant manufacturers to include in their labeling, correct?

A. In terms of, just to be clear, they had reviewed this, found it to be approvable, and the language that's used, "We are requesting revisions to your labeling." So I want to just again for the sake of accuracy say they didn't tell them. They requested it.

Q. Look at your deposition, Page 10 -- Page 303, Line 5, please.

A. I'm sorry.

Q. Are you there?

A. I am.

Q. Okay. The question was:

"Do you see that this -- this is a letter from FDA to GSK which includes and attaches the labeling information that FDA has told GSK and other antidepressant manufacturers that it wants in the labeling?"

And your answer was, "Yes."

Did I read that correctly?

A. I'm sorry. You're in -- on Page 103?

Q. On Page 303.

A. 303.

Q. Line 5.

A. Okay. Yes.

Q. Let's -- let's look at this document, Defendant's Exhibit 122.

A. Okay.

Q. Okay. This, the subject of this document is GSK's changes being effected supplement, correct?

A. Yes.

Q. That GSK submitted on April 27, 2006? I mean, it references -- it references GSK's submission, correct?

A. Yes.

Q. Let's look at the second and third paragraphs.

A. Okay.

Q. This is where -- it says:

"These supplements, submitted under changes being

effected, provide for labeling revisions to the warnings and information for patients section regarding suicidality in young adults based on your analysis of the paroxetine and adult suicidality data. We've completed our review of your supplemental applications, and they are approvable. Before these applications may be approved, you will need to make revisions to your labeling as outlined below so as to ensure standardized labeling pertaining to adult suicidality with all of the drugs to treat major depressive disorder, MDD."

Did I read that correctly?

A. You did.

Q. FDA states explicitly in the letter that the changes to the label are to ensure standardized labeling pertaining to adult suicidality with all the drugs to treat major depressive disorder, correct?

A. Correct.

Q. In other words, the FDA's requiring that the warning sections of the labeling for all antidepressants including Paxil say the same thing with respect to adult suicidality, correct?

A. With the understanding that they're not requiring that the -- there not be any product-specific content in there, yes.

Q. There cannot be any product-specific content in this

warning, correct?
A. I want to draw a -- clarify again what I said and repeat it. You're saying the warning, saying they said that, but they didn't say anywhere in here, product-specific information about suicidality cannot go in the labeling. It does not say that here.
Q. This letter, the FDA's letter, it's not limited to the boxed warning, correct?
A. No.
Q. And the FDA saying that before GSK's changes being effected, the supplement we talked about earlier, will be approved, GSK will need to make revisions to the labeling as outlined below, correct?
A. Yes.
Q. And if you look at the last paragraph on that page, it says:

"Based on the recommendations made by the committee, we believe that additional changes are needed in antidepressant labeling and medication guides to alert practitioners, patients, family members, and caregivers about an increased risk of suicidal thinking and behavior, suicidality, in young adults with MDD and other psychiatric disorders who are taking antidepressant medications."

Did I read that correctly?

A. You did.
Q. And the next sentence states:
"Changes are also needed to inform practitioners about an apparent favorable effect of antidepressants on suicidality in older adults and to remind them that the disorders being treated with antidepressants are themselves associated with an increased risk of suicidality."
Did I read that correctly?
A. You absolutely did.
Q. So the FDA is saying that label -- the labels for all of the SSRIs in all of the antidepressants must include this language, correct?
A. Yes.
Q. And if you look at the second page of the document -- keep going, Roger, the warnings -- you see that this is the text of the labeling change?
A. Yes.
Q. And the box warning is above it, correct, on the page?
A. Excuse me. Yes.
Q. Go to the box warning, Roger.
And again, this is FDA's language that it's sending to the drug companies, correct?
A. Correct.
Q. In the box warning, the third sentence required GSK to

say:

"Short-term studies did not show an increase risk -- increase in the risk of suicidality with antidepressants compared with placebo -- compared to placebo in adults beyond age 24. There was a reduction in Orisk with antidepressants compared to placebo in adults aged 65 and older."

Did I read that correctly?

A. You did.

Q. And the FDA's required box warning was -- also states, "Patients of all ages who were started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior," correct?

A. Correct.

Q. And you would agree at this point in time based on what we have seen earlier that the FDA was aware of the sub-group analysis finding for an increased risk for Paxil in suicidal behavior in patients over age 25, correct?

A. I would agree that they were aware that the CBE supplement which was being responded to here said that there's a risk across all ages. However, they also had been told by GSK that there were eight out of 11 of those patients were in the age group of 18 to 30. It is not clear to me from what I've seen if, as part of that submission, GSK told them that if you

slice the data another way, eight out of the 11 were in older adults.

Q. How many patients -- of those 11, how many patients were older than 30?

A. I can't recall off the top of my head. It would be at least, I believe, at least three, possibly four.

Q. Okay. We'll get to that. You did a table with the distribution, correct, on the ages in your report?

A. Actually, it was a graph.

Q. A graph. Sorry. Okay. We'll get to that.

When FDA announced the labeling change in May of 2007, it was certainly aware of the 2.76 odds ratio finding on paroxetine or Paxil, correct?

A. Yes.

Q. And when they -- when FDA announced the labeling change in May of 2007, FDA's language, the language of FDA's labeling did not include a reference to paroxetine's finding of a 2.76 odds ratio being statistically significant for suicidal behavior, correct?

A. Understanding that it's the sponsor's responsibility to put that in the label, not the FDA's, I would say yes.

Q. This is the FDA's language, though, correct?

A. I understand.

Q. And it doesn't -- it doesn't include the 2.76 odds ratio, correct?

A. As I discussed in my testimony earlier, the sponsor has the responsibility to ensure that that is accurate, that if the FDA doesn't do something, that does not relieve the sponsor of its responsibility.
Q. But we've established the FDA knew of the odds ratio, correct?
A. The one that they had calculated, yes.
Q. They knew the GSK odds ratio, correct? It's in the labeling that we -- that I showed you?
THE COURT: We've been over this now. It's been covered several times.
MR. BAYMAN: Okay.
THE COURT: Let's move on.
BY MR. BAYMAN:
Q. Your opinion yesterday was that GSK should have included language stating that paroxetine induces suicides in adults over age 24, correct?
A. Correct.
Q. But the boxed warning right up here says there was no increased risk of suicidality in adults beyond age 24, correct?
A. For all antidepressants taken as a group.
Q. And it's your opinion then that the language in the 2007 FDA label that FDA drafted, prepared, and ultimately approved is false and misleading, correct?
MR. WISNER: Objection, lacks foundation as to who

prepared and approved.

THE COURT: Overruled.

THE WITNESS: I'm sorry, your Honor. Could I --

THE COURT: You may answer the question.

THE WITNESS: If I could just have it read back.

THE COURT: Read it back.

THE WITNESS: I'm sorry.

(Record read.)

BY THE WITNESS:

A. In the context of the Paxil label because of the data from GSK, I would say yes.

BY MR. BAYMAN:

Q. The box warning wasn't the only section in the label in which FDA wanted class labeling, correct?

A. Correct.

Q. In fact, if we go to the second page of DX 122 halfway down the page --

A. Yes.

Q. -- there's a bracketed instruction, correct?

A. Yes.

Q. And it says, "The following changes should be made to the current language under the warnings, clinical worsening and suicide risk section," correct?

A. Yes.

Q. So that warning is class language, correct?

A. Correct.
Q. And every antidepressant manufacturer had to have that very same warning, correct?
A. Correct.
Q. Okay. That warning -- and the jury has seen it. That goes on for about two pages, doesn't it?
A. It does.
Q. Okay. Let's turn to the fourth page of the exhibit about halfway down. There's another bracketed instruction, correct?
A. Yes.
Q. It says, "The following changes should be made in current language under the precautions, information for patients section," right?
A. Yes.
Q. And that that precaution is class labeling also, correct?
A. That's correct.
Q. So -- and everybody, every antidepressant manufacturer had to have it verbatim?
A. Yes.
Q. And then below the precaution, there's another precaution, "clinical worsening and suicide risk." Do you see that?
A. Yes.
Q. That is also class labeling that every antidepressant manufacturer was required to have in its label, correct?
A. Yes.

MR. BAYMAN: May I approach, your Honor?

BY MR. BAYMAN:

Q. I'm handing you what's been marked Defendant's Exhibit 6323. You're familiar with this document, correct?

A. Yes.

Q. It's an email chain between Renmeet Grewal, G-r-e-w-a-l, at FDA and a Mary Martinson from GSK in May of 2007, correct?

A. And just to be clear, the first page has correspondence with Dr. Arning from GSK.

Q. Okay. Okay. And this is some of the material from what we've been calling the regulatory file that you've relied on in forming your opinions in this case, correct?

A. I'd call this a correspondence subfile, but yes.

Q. Okay. And it's part of the back and forth between the FDA and the GSK about labeling, correct?

A. Yes.

Q. And we've established that the FDA communicates with pharmaceutical companies by email in the regular course of business, correct?

A. It does.

MR. BAYMAN: Okay. And your Honor, at this time, I would move for admission of Defense Exhibit 6323 and ask permission to publish to the jury.

MR. WISNER: No objection.

THE COURT: You may proceed.

MR. BAYMAN: Let's take a look at the --
MR. WISNER: I'm sorry. It's 6323?
MR. BAYMAN: Yes.
MR. WISNER: Defendant's?
MR. BAYMAN: Yes.
MR. WISNER: Okay.
THE COURT: It's also marked Defendant's 79.
MR. BAYMAN: It is 6323 in this case, your Honor.
THE COURT: All right.
BY MR. BAYMAN:
Q. Let's -- I want to take you to the -- these are like emails. The earliest one is the farthest one back.
A. Sure.
Q. Page 3. Do you see that?
A. Yes.
Q. And that is dated May 2, 2007, at 9:40 a.m. Do you see that up there?
A. Yes.
Q. And that's from the FDA's Dr. Grewal or Grewal to Ms. Martinson at GSK, right?
A. Yes.
Q. It's about the adult suicidality letter, that's the subject line?
A. Yes.
Q. And it says, "Dear Mary, please refer to the advisory

committee meeting held on December 13, 2006, regarding adult suicidality data in antidepressant drugs." Do you see that?
A. Yes.
Q. It says, "The agency has come to a decision with final language for the prescriber labeling and medication guide," correct?
A. Yes.
Q. And nowhere in this email, this email right here from the FDA, does it says -- say that the final language to which the reference is limited to the warnings or to the black box, rather, this is about the prescribing -- the labeling, prescribing labeling, and the medication guide, correct?
A. Well, the decision is always about the entire label, but with the proviso that this actually refers to sponsors in general, this is part of a general broadcast where they say, "Sponsor, we're requesting the sponsor submit prescriber labeling."

So this email is directed not just to GSK but all sponsors for this concept, I'd agree with you.
Q. Okay. But nowhere in this email does the FDA say that the final language for the label is limited to the warnings or the black box, correct?
A. No.
Q. The email continues, "Attached is a supplement request letter with new language," correct?

A. Yes.
Q. And it's attaching a letter from the FDA to Ms. Martinson at GSK that attaches the FDA's decided labeling for antidepressants including Paxil?
A. So I assume these are other products for which GSK is responsible. And it does treat them identically -- Wellbutrin, Parnate, and Paxil -- as just all members of the class, you're correct on that.
Q. Okay. Those are other antidepressants, correct?
A. I prescribed one of them.
Q. Okay. And attached to that letter is the FDA's decided labeling for antidepressants including Paxil --
A. Correct.
Q. -- correct? Okay.

And then Dr. Grewal at FDA writes, "We are requesting that sponsors submit revised prescriber labeling and medication guide verbatim as outlined in the attached letter within 30 days from today." Did I read that correctly?
A. You did.
Q. Okay. And "verbatim" means exactly as the FDA put it, correct?
A. They are requesting that sponsors submit revised prescriber labeling and medication guides verbatim. That is what they are requesting.
Q. And if we go then, what I would call, up in the email

chain, you see a response from Dr. Barbara Arning at GSK to Dr. Grewal, Monday, May 7, 2007, at 2:33 p.m., re. adult suicidality letter. Do you see that?

A. Yes.

Q. And Dr. Arning at GSK writes:

"Can I please ask for one clarification? Does FDA intend for Paxil and Paxil CR to keep the Paxil-specific paragraph on young adults that we added in April 2006 in the label in addition to the class labeling provided below, or do you ask us to replace the complete warning section on this topic by the new class labeling?"

Did I read that correctly?

A. So just to make sure I'm understanding, so they're asking, do you want us to keep our current warning that's specifical -- the Paxil-specific paragraph, and it states, on young adults, which I guess means the focus -- from their eyes, focuses on young adults, in the label and just replace that language with the class labeling, or just take it out and remove it on block, as we say, and then put in the new class labeling, yes, I would say that's it.

Q. That's not what I asked you. I said, did I read that correctly?

A. You did.

THE WITNESS: I'm sorry, your Honor.

BY MR. BAYMAN:

Q. Then Dr. Arning at GSK pastes into the email chain the entire section that she's talking about, correct?
A. Yes.
Q. And we know because we saw it earlier, that was the language that GSK had proposed in 2006 as part of its CBE, or changes being effected?
A. Right. This is what she refers to as the Paxil-specific paragraph on young adults --
Q. Okay.
A. -- correct.
Q. Now, go up to the last email in the chain at the top of Page 1. FDA responded to GSK's question on the very same day, May 7, 2007, correct?
A. Yes.
Q. And FDA wrote back to GSK in response to this question, "Please replace the previous warning section with the new language we provided to in the class labeling letter signed on May 9, 2007." Did I read that correctly?
A. You did.
Q. And FDA specifically tells GSK to replace the language that GSK had submitted earlier with -- that's in Dr. Arning's email with the language FDA provided, correct?
A. I'm sorry. Just to be very clear, the project manager said that, Dr. -- Lieutenant Commander Grewal.
Q. Of the FDA?

A. Yes.
Q. You're not suggesting she didn't have authority to speak for the FDA, are you?
A. No, that's not what I was suggesting.
Q. Okay. So you agree with me that GSK was told to replace the language that GSK had asked about earlier in the day that Dr. Arning had posted into the email -- pasted in the email with the language the FDA provided, correct?
A. I would agree that Dr. Grewal sent that email and that's what it says.
MR. BAYMAN: May I approach, your Honor?
THE COURT: Yes. From now on, just hand it to me.
MR. BAYMAN: Okay. Sure.
THE WITNESS: Thank you.
MR. BAYMAN: Okay. I'm handing you what's been marked as Defense Exhibit 6364, which is --
THE COURT: 6324?
MR. BAYMAN: 6324. Excuse me, your Honor.
BY MR. BAYMAN:
Q. Which is a May 11, 2007, letter from GSK to Dr. Tom Laughren at the FDA who we've heard about earlier, correct?
A. Yes.
Q. Okay. And you're familiar with this letter?
A. I am.
Q. And you reviewed this letter as part of your review of

what we've been calling the regulatory file in this case, correct?
A. Yes.
Q. And you -- this letter is one of the documents you rely on in support of your opinions in this case, correct?
A. Yes.
MR. BAYMAN: Your Honor, at this point, I would move for admission of Defense Exhibit 6324.
MR. WISNER: Your Honor, this exact duplicate has already been admitted as Defense Exhibit 126. So now he's entering in duplicates into the record. So I would ask that we just use --
MR. BAYMAN: We'll use 126. That's fine.
THE COURT: Use 126.
MR. BAYMAN: Sure.
THE COURT: I've asked many times to avoid these kind of duplications.
MR. BAYMAN: Your Honor, Ms. Hogan has pointed out, this is a different document because the other document does not have the attachments. This is the complete document. So I'd ask for admission of this one.
THE COURT: Very well.
MR. WISNER: Your Honor, I am looking at it right now. I'm looking at Defense Exhibit 6324. They're both four pages long and contain exactly the same content, so I don't

know what he's talking about.

MR. BAYMAN: Can I just use this one so we can move along, your Honor?

THE COURT: Yes.

MR. BAYMAN: Thank you.

BY MR. BAYMAN:

Q. Take a look at this document, and look at the second paragraph. GSK writes:

"We believe that the Paxil-specific paragraph on young adults that was added in May 2006 to the Paxil, Paxil CR, and Paxil oral suspension prescribing information would complement the class labeling by providing product-specific data based on the GSK-sponsored analysis of paroxetine trials."

Do you see that?

A. I do.

Q. So GSK is specifically asking FDA to keep the Paxil labeling that's cited on Page 2 of this letter, correct?

Can you pull up Page 2?

A. What they're specifically saying is we, therefore, propose maintaining the paragraph within the new class labeling. So that's what they're asking.

Q. Where does it say -- it says "complemented." Where does it say, "within the class labeling"?

A. So -- two, three, four, five, six -- on the seventh line

of the second paragraph on Defense Exhibit 6324, is it possible -- my eyes are just -- I need stronger glasses. So -- oh, I can touch this, can't? Yes. I'm sorry.

I don't know if that's visible to you, but that where it says, "We, therefore, propose maintaining the paragraph within the new class labeling."

Q. I misunderstood you. I thought you were suggesting that taking something out of the class labeling.

A. No, no. I'm sorry.

Q. All right. So and the Paxil-specific language that GSK wanted to include, that's set out at Page 2 at the top, correct? It's not a very good copy on the screen.

A. Yes. That's -- I mean, they've made an -- edited the text a little bit but yes, that's the text that they proposed retaining within the class labeling.

Q. They added the text a little bit to try to comport it with the class labeling because on the third line, I know it's hard to read on the screen, it says, "for all psychiatric disorders combined."

A. Yes. No, I agree. I don't believe that that substantively changes the meaning of the --

Q. But they're making edits to their prior submission --

A. Yes.

Q. -- to try to conform to what FDA was requesting, correct?

A. Well, I don't know what their intent was, but I certainly

don't -- I don't see any reason to find fault with it. Let me put it like that.

Q. Okay. Let's go to Tab 35 in your book, which is Defense Exhibit 127.

A. Okay.

Q. That is a May 15th, 2007, email exchange between the FDA and GSK, correct?

A. Yes, I believe so.

Q. And you've seen this email exchange before, correct?

A. Yes.

Q. It's part of the regulatory file that you reviewed in doing your work in this case, correct?

A. Yes.

Q. And it's one of the documents you rely on in -- to support your opinions in the case, correct?

A. Yes.

MR. BAYMAN: That's -- this one is in evidence, your Honor. This is 127, so let's put that up.

BY MR. BAYMAN:

Q. FDA tells GSK in response to the letter we just looked at:

> "Please submit your CBE application with your requests. We will be discussing all the sponsors's proposals during the last week of May. After we discuss everyone's proposal, I will have a response to your question."

Did I read that correctly?
A. You did.
Q. And we know that the question is, can GSK keep the Paxil-specific label -- language in the label, correct?
A. Within the new class labeling, is the request they've made.
Q. All right. Turn, if you would then, to Tab 36.
A. Yes.
Q. Got that?
A. I do.
Q. That's Defense Exhibit 133, a letter from GSK to the FDA dated May 23, '07, correct?
A. Yes.
Q. You've seen this letter before, also, correct?
A. I have.
Q. It's part of what you reviewed as -- in the regulatory file in this case?
A. Yes.
Q. It's one of the documents you rely on in support of your opinion in the case?
A. It is.
MR. BAYMAN: Your Honor, at this point, I'd move for admission of Defense Exhibit 133.
THE COURT: It may be received.
(Defendant's Exhibit 133 received in evidence.)
BY MR. BAYMAN:

Q. This letter constitutes GSK labeling submission in response to the FDA's announced labeling changes, correct?
A. This is a changes being effected supplement, so where they're putting -- so in other words, one that does not -- FDA can speak to but the sponsor could if they want to go ahead and implement. It's not a prior approval supplement.
Q. And GSK specifically attached proposed labeling to its May 23, 2007, CBE submission, correct?
A. They did.
Q. In the cover letter, the third paragraph, "We are herewith submitting" -- GSK writes to the FDA:

> "We are herewith submitting the changes being effected supplemental new drug application for Paxil, Paxil CR, and paroxetine reflecting the new requested class labeling and the medication guide."

Do you see that?
A. Yes.
Q. And then GSK continues in that paragraph, "The paroxetine-specific language is maintained under the warning section as outlined in our letter from May 11, 2007."
Did I read that correctly?
A. You did.
Q. And, in fact, they're just asking, "Can we maintain" -- well, they're saying, "We're maintaining that Paxil-specific language," correct?

A. Within the new class labeling, yes.
Q. This is a formal submission to FDA to ask FDA that GSK be allowed to keep the Paxil-specific information in the labeling that was the subject of the 2006 changes being effected, correct?
A. Within -- with the clarification that it is within this standardized class labeling, yes.
THE COURT: Let's take a recess, ladies and gentlemen. It seems to be time to stretch.
MR. BAYMAN: Thank you, your Honor.
(Recess from 2:55 p.m. to 3:10 p.m.)