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

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| 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 20, 2017<br>1:30 p.m. |

VOLUME 4-B

TRANSCRIPT OF PROCEEDINGS

BEFORE THE HONORABLE WILLIAM T. HART, and a Jury

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(Proceedings heard in open court. Jury out.)

[redacted]

(Proceedings heard in open court. Jury in.)

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

You may proceed, sir.

MR. BAYMAN: Thank you, your Honor.

DAVID HEALY, PLAINTIFF'S WITNESS, PREVIOUSLY SWORN

CROSS-EXAMINATION (Resumed)

BY MR. BAYMAN:

Q. Dr. Healy, when we left off, we were talking about your Zoloft healthy volunteer article. I just want to finish that line of questions briefly.

A. Okay.

Q. You have that article?
A. No, I don't actually. I'm in the Miller deposition -- actually, it's over here, yes.
Q. If you'd pull up the article.
A. There's going to be a very big heap here, but all right.
Q. Are you ready?
A. Yes.
Q. Okay. In your article, you stated that the cases described in this paper appear to have become suicidal on sertraline with no easy means of explaining what happened other than by invoking an SSRI-induced suicidality; is that correct?
A. That actually sounds like it probably is correct, but you haven't pointed me to the spot.
Q. Sure. It is -- do you see that there on the screen?
A. Yes. It's from where, which bit?
THE COURT: Page, sir, and the exhibit number, sir, for the record.
MR. BAYMAN: Yes, sir, your Honor. It's the exhibit that we've been talking about, which is Defendant's Exhibit 7002, and I believe -- let me see if I can find the -- I think it's Page --
BY MR. BAYMAN:
Q. It's Page 27, Doctor.
A. Yes. Yes, I do.

Q. That's what you wrote, correct?
A. Yes.
Q. Okay. But, Doctor, isn't it true, one of the subjects Isabel Logan, had a family member die during the course of the study, and she thought that caused her extreme stress?
A. No. It caused her stress, but it didn't cause this reaction. It didn't cause her to become suicidal.
Q. But isn't it true that as a result of the death of the family member, she became so worn out and weary that she was annoyed, miserable, unhappy, and angry on reboxetine?
A. I don't know that that is the case. You're testing my recollection here, and I don't have her folder actually here in front of me. She's on a few occasions since said very clearly that she attributes what happened to her to the drug rather than to the death of anyone in -- at the family.
Q. Turn back to that transcript that we were looking at before lunch, if you would, to Page 322. Have you got that?
A. I have, yes.
Q. Okay. Look at Page 322, Line 21 to 25. The question was:

"In fact, she became so worn out and weary that during the second week, she was annoyed, miserable, unhappy, and angry during the reboxetine period."

Do you recall that?

A. I do, yes.
Q. And your answer was, "I do, indeed, yes, yes," correct?

A. Yes.
Q. And then --
A. This deposition, just so the jury is aware, this is happening 16 years ago, this particular testimony that you're asking me.
Q. I understand.
A. Okay.
Q. A lot closer in time to the Zoloft trial than today, correct?
A. Yes.
Q. The healthy volunteer trial. And she -- and, in fact, by the time she started Zoloft, she was under great stress, miserable, angry, sad, unhappy, and annoyed, correct?
A. Yes, but she apparently had been exposed to reboxetine beforehand, and this may well have been the cause of her feeling that way rather than anything else.
Q. And when she started sertraline, or Zoloft, she experienced nausea, lethargy, and uncomfortable symptoms, correct?
A. She did, yes.
Q. And you also conceded that she had a history of lucid dreaming including both sleepwalking and sleep-talking in which she had what you called suicidal ideation; to this day, she doesn't know whether that was a dream or whether she thought about it when she was awake, does she?

A. No, that's not exactly the case. First of all, lucid dreaming, so the jury and the Court is aware, it's a very technical term, and it's something that many members of the jury may have. And it can be caused by an SSRI. It's where you're dreaming but you feel like you're awake, fully awake so it's -- it's not a pathology as such. It's a particular kind of dreaming that people can have.

Q. But she didn't know whether -- when she was experiencing what she thought was suicidal ideation, she doesn't know whether that was in her dream or whether she was awake?

A. No. She described it as being like being in a lucid dream. She was very clear that it was happening when she was awake.

The other point about it is, we didn't get full details from her because working in a mental health unit, she thought if she told us what was happening, they would lock her up. It's one of the things about a healthy volunteers trial, people may not volunteer everything that is happening to them. They figure I might be so concerned, I'll detain them in a hospital.

Q. Turn, if you would, to Page 324, Line 7. Have you got it?

A. Yes.

Q. The question was:

"Isn't it also true, Dr. Healy, that even under ordinary circumstances, Isabel Logan was, quote, prone to

lucid dreaming including both sleepwalking and sleep-talking and when she had what you call suicidal ideation, to this day she doesn't know if it was a dream or if she had that thought when she was awake."

And your answer was:

"Let me be absolutely clear, Mr. Wheeler. I've offered to the Court both the studies. I mean, on the issue of what happened, whether it was caused by Zoloft or communications between the subjects, between me and them, I thought the best way to handle the issue, this issue was to bring the two subjects here to the court, and they've agreed to be brought. Isabel Logan's testimony, I believe, would reveal the fact that she had recorded much less of what was happening to her and has since told me much less of what was happening to her because if she told anyone what had been happening to her on this drug, given that she worked in a psychiatric unit, she was worried about the fact that our response would be that, hey, you're seriously ill, and you need to be treated."

And the next question is: "Is the answer to my question yes, Dr. Healy?"

And your answer was, "I think in the context that I've given you, the answer is yes."

Did I read that correctly?

A. Well, no, I'm not sure you did because you left out a whole load -- first of all, I want the jury to be clear that I offered -- both Isabel Logan and the other healthy volunteer offered to come along to court and let a jury hear what had happened to them, and Pfizer declined to bring them.
Q. Your counsel can ask you about that on redirect. I just want to know if I read your testimony correctly.
A. I don't know that you about because it's a bit confusing. The question that I'm actually answering yes to here is a little confusing.
Q. Doctor, you formed your views that SSRIs can cause suicidality due to akathisia, emotional blunting, psychotic decompensation in the early 1990s, didn't you?
A. That's correct.
Q. Yet in these -- this healthy volunteer study, you didn't -- in your disclosure to these healthy volunteers in 1999, you said that these two drugs, reboxetine and sertraline, which is Zoloft, had been selected because they were as close to entirely safe as any two agents can be and that they neither should detract from your daily function -- and that neither should detract from your daily functioning significantly. Didn't you say that there?
A. That's the information that they were given, and that was before, for instance, I had been in to GSK's healthy volunteer files. So I had no reason to believe that our healthy

volunteers at that point were going -- that at least two of 20 were going to become suicidal.

Q. But you had already had an opinion that SSRIs can induce suicidality?

A. Yes, but I guess I expected, like lots of other people, that it would be less frequent than we found it, and also that I didn't expect at that point in time healthy volunteers would become suicidal. I'm not sure I'd have done the trial if I had expected that, if I had a strong expectation that that was likely to happen.

Q. Thank you, Doctor. You can put that down, and we'll move to a new topic.

A. Okay.

Q. You testified last week about there being many different types of data sources. And you said it's important to be looking at data from all the different kinds of sources that you can, correct?

A. Correct.

Q. The FDA, though, disagrees when it comes to analyzing SSRIs and suicide, doesn't it?

A. I don't know that it does. When you talk about FDA, as you I've indicated before, it's a very large beast, and the safety arm of FDA, for instance, probably would agree completely with me.

Q. Well, since the late 1990s, FDA's general approach to

assessing the risk of suicidality with antidepressants compared to placebos has been to look at only placebo-controlled clinical trials or active-controlled clinical trials post-randomization and not to look at data from uncontrolled trials, correct?

A. Well, as we've seen, it's not clear how closely FDA look at anything.

Q. Well, but in terms of --

A. You put all the information up there --

Q. What they requested --

A. -- for the jury to see.

Q. What they've requested from the sponsors is only data from placebo-controlled clinical trials or active-controlled clinical trials post-randomization, right?

A. And that's quite different to FDA's view, you know, particularly at the safety side of FDA, FDA's view as to what the best way to look at risks are. It is absolutely true that in the case -- in 2006, for instance, the FDA asked the companies for their controlled trials. That doesn't mean FDA thinks this is the only valid form of information.

Q. And they've been asking for control data, I think in your words, since the late 1990s, correct?

A. I'm not sure that's my words. It certainly wasn't the late 1990s. It's 2002 when we got the Davies report.

Q. Okay. Let's -- can we look at your deposition testimony?

A. We certainly can.
Q. I want you to turn to Tab F and ask you to go to Page 363, Line 2 to 11.
A. I'm sorry. Page what?
Q. 363, 3-6-3.
A. Okay. Yes.
Q. Are you there? The question was:

"And you do know -- you do know, would you agree that at least since the mid-1990s, FDA's general approach to assessing the risk of suicidality with antidepressants compared to placebo has been to look at placebo-controlled clinical trials or active-controlled clinical trials post-randomization and not to look at data from uncontrolled trials?"

And your answer was:

"I think this is probably more the case that it was in the late 1990s. I think this is when FDA got back to GlaxoSmithKline, for instance, and said, 'We want you to present your -- that we want the data actually presented in the form broken down as you've outlined so we can see the placebo-controlled data. We can see the active controlled data'" --

THE COURT: Not so fast, Mr. Bayman. It's not an exercise for the court reporter.

MR. BAYMAN: Yes, sir. I apologize.

BY MR. BAYMAN:

Q. "We -- that we want the data actually presented in the form broken down as you've outlined so we can see the placebo-controlled data, we can see the active-controlled data quite apart from that, and we can see the uncontrolled data separately."

Did I read that correctly?

A. You did, yes.

MR. WISNER: Objection, your Honor. His answer actually continues on for the next two lines. I'd like it to be read in its entirety.

MR. BAYMAN: Sure.

MR. WISNER: I'll read it.

MR. BAYMAN: Okay.

MR. WISNER: It goes on:

"Answer: This is about 1999, though. You sort of mentioned to me that it was the mid-'90s. I think it was more 1999, 2000. That was the watershed."

BY MR. BAYMAN:

Q. And I said late 1990s, in the late '90s.

A. Well, you read for the Court, mid-1990s --

Q. In your answer, you said late '90s?

A. Well, yes. I think that's a particular bias. My view was the late '90s, early 2000s, and it's 2002 before GSK gave FDA that kind of data. It was a lengthy interchange within GSK

debating on how they were going to handle these issues before that.

Q. But certainly since -- in your view, since the late 1990s, FDA has asked for data from randomized placebo-controlled clinical trials and active-control --

A. My view is --

Q. -- trials --

A. -- I'm not sure what the data that FDA actually asked for. I know the date GSK gave it was 2002, but it was on GSK's radar before this that that was heading their way. This was the train coming down the line.

Q. Well before 2006, correct?

A. That's before 2006, yes.

Q. Yes. Okay. Now, you testified on Thursday about the analysis of antidepressants in suicide that FDA conducted in 2006 --

A. Yes.

Q. -- right?

I'd like you to turn to Tab 17 in your exhibit notebook.

MR. BAYMAN: It's Defendant's Exhibit, your Honor, 1117.

BY MR. BAYMAN:

Q. Have you got that?

A. I do indeed.

Q. This is Hammad 2006, and it's entitled, "Suicide rates in short-term randomized controlled trials of newer antidepressants." It's published in the Journal of Clinical Psychopharmacology, correct?
A. Yes.
Q. And you've -- you followed the statements by the FDA scientists on the issue of whether there's a risk in adult patients who take SSRIs, correct?
A. I'm not sure that this qualifies as a statement from FDA scientists. This is a paper that's come out of FDA, and there's been a number of different papers that have come out of FDA.
Q. Sure, but Dr. Hammad was with FDA, correct?
A. He was at that time, yes.
Q. Right. And he published in this scientific publication, correct?
A. He did.
And Dr. Laughren was also with FDA at that time before becoming an expert witness for SSRI companies.
MR. BAYMAN: Your Honor, I move to strike that.
THE COURT: Yes, that may go out.
BY MR. BAYMAN:
Q. One of the authors, Dr. Laughren, you said, in fact, you said last week he was one of the key people within the FDA who was responsible for SSRIs and other medications used for

mental health purposes?
A. He was one of the people who was there right from the start through recently, as I say, until he changed career.
Q. Would you turn, if you would, to the paper itself.
MR. BAYMAN: Your Honor, may I publish the paper to the jury?
THE COURT: Yes.
MR. WISNER: Objection, your Honor. I don't believe the foundation has been laid that this is one of the teachers.
THE COURT: All right. Yes. You have to lay the foundation first. Then you have to ask him whether he considers it authoritative or not.
BY MR. BAYMAN:
Q. Do you consider this publication by the FDA in the Journal of Clinical Psychopharmacology to be authoritative?
A. No, I don't particularly. It's labeled a brief report to begin with so clearly, it's not going to be authoritative.
Q. You don't agree that the Journal of Clinical Psychopharmacology is a publication referenced and relied on by people in your field?
A. Well, as I said, this is a brief report. Right at the top, the first two words are "brief report." Secondly, the journal is not among the most prestigious journals, no.
Q. You agree with me, though, that this brief report outlines the FDA's findings in 2006, correct?

A. I'm not sure it outlines FDA's findings. What we're getting here is an article by Drs. Hammad, Laughren, and Racoosin. It's not clear that this should be called FDA's findings.
Q. Well, it describes FDA's analysis, does it not?
A. I'm not sure it does describe FDA's analysis. That same year, we have a different document from FDA, a much more comprehensive one by Stone and Jones which doesn't give the same results as you have here.
Q. And we'll get to Stone and Jones in a minute, but you will agree with me that the FDA considered only events that occurred in the post -- I mean, the FDA excluded events that occurred in the post-double blind period, that is, after the controlled phase of the trials were over, in order to avoid confounding results from an array of treatment scenarios that occurred after the end of a given trial, correct?
A. That may well be the case. If you ask me whether these authors did that in this paper, they may well have done so but -- but, you know, I'm not fully sure what your point is yet.
Q. Well, my point is that the FDA did not consider events that occurred after the controlled phase of the randomized clinical trials were over, correct?
A. These authors appeared not to have. Whether that's a good idea or not is a completely different issue, and I think it

may well not be such a good idea, and it's also the case that they probably don't consider all trials.
Q. Well, Doctor, the reason that they didn't do it is because patients, after the trials were over, took all kinds of medicines once the SSRI treatment ended which confounds or compromises the results if you count those events, correct?
A. And as I've outlined to the jury, in GSK trials, the patient took Prozac who had been on placebo and had committed suicide and was counted as a placebo suicide, and FDA were probably trying to avoid just that, yes.
Q. They were trying to avoid confounding or compromising the results because of another medication, correct?
A. Such as another SSRI causing patients being on a placebo to commit suicide.
Q. And they also -- it was also the FDA's view, at least per Dr. Hammad and Dr. Laughren, that rates based on pooling data from both randomized control trials and open-label extension trials are subject to bias and can lead to misleading conclusions, correct?
A. Oh, absolute -- all studies including randomized control trials including placebo-controlled trials are subject to bias. There's a major bias in the placebo-controlled trials here which is that GSK didn't look at people becoming suicidal. This is a huge bias that cannot be overcome simply by virtue of the fact that you've got a placebo-controlled

trial here.
Q. I don't think that was my question, Doctor. My question was: The FDA said that rates based on the pooling of data from both randomized control trials and open-label extension trials are subject to bias and can lead to misleading conclusions, correct?
A. And I'm saying that they're no more likely to lead to misleading conclusions than placebo-controlled trials that have been designed to look at the issue in question.
Q. Okay. I think you agreed with me there.
A. I'm not fully sure we're on quite the same page. We'll leave it to the jury to decide.
Q. Sure. Exactly. So when the FDA, when it did its suicidality analysis of SSRIs, it excluded events from what you called the withdrawal period, correct?
A. Well, we're not talking about FDA here. We're talking about three authors, one of whom was actively involved in trying to gag other FDA authors who were raising these issues.
MR. BAYMAN: I move to strike that, your Honor.
THE COURT: It's a volunteered statement. It may go out.
MR. BAYMAN: Thank you.
BY MR. BAYMAN:
Q. You didn't talk about this article in your direct examination, correct?

A. That's correct.
Q. Now, you told the jury last week that in the FDA's analysis in 2006, the two big areas were suicidal ideation and behavior, correct?
A. Correct.
Q. And, in fact, you said the FDA study characterized the analysis of ideation as the primary analysis, correct?
A. Well, no. They had a combination of ideation and behavior, I believe, as the primary outcome measure.
Q. You don't --
A. Is that not correct?
Q. You don't recall saying that ideation was the primary analysis?
A. I remember us talking about primary. I thought -- well, certainly what I intended to say was a combination of ideation and behavior rather than behavior being the primary analysis or outcome measure.
Q. No, I think you said ideation was the primary.
A. Perhaps I did. We'd have to have a look at a transcript, and I may have been speaking too quickly for the court reporter to get it all. I'm impressed that you have a transcript from last week already.
Q. I'm going to show you the transcript at Page 436 at Line 18 to 24.
A. Okay.

MR. WISNER: Your Honor, I'm not entirely sure what the purpose of this is. I think he just explained what the fact was. This is an improper impeachment.

THE COURT: Well, we'll let him read it, and then we'll hear what the question is, sir.

MR. WISNER: Okay.

THE WITNESS: What do you want me to turn to?

BY MR. BAYMAN:

Q. 436, Line 18 to 24.

A. Yes.

Q. You were asked, "Now, the FDA study characterizes the analysis" --

THE COURT: What -- ask him a question, sir.

BY MR. BAYMAN:

Q. Okay. Did you not say that ideation was the primary analysis of done --

A. Well, I don't think I did. Mr. Wisner says that, and I think he may have made a mistake to some extent. Certainly, my understanding at that point was that ideation and behavior, a combination of the two rather than behavior on its own was the primary analysis.

Q. But when he asked you the question, "Now, the FDA study characterizes the analysis of ideation as a primary analysis; is that right," you said, "yes," correct?

A. Well, it may well have been that this came up in the pages

beforehand and at this stage, we're into using shorthand, as it were.

Q. And when he asked you, were behaviors the secondary analysis, you said yes, correct?

A. Yes, that's correct.

Q. All right.

A. But it can still be correct with ideation and behavior being the primary analysis.

Q. Okay. So you would agree with me, the primary outcome in the FDA's analysis was not just suicidal ideation but was completed suicide, suicide attempt, preparatory acts towards imminent suicidal behavior, and suicidal ideation, correct?

A. Correct.

Q. Thank you, Doctor. Now, you told the jury on Thursday that one of the ways GSK supposedly hid the risk was through what you called coding maneuvers.

A. Yes.

Q. But in the FDA's analysis, the FDA didn't rely on the way the manufacturers or the clinical investigators originally coded suicide-related events, correct?

A. When FDA came to analyze the data in 2006, they asked the companies to produce the case reports from different patients using a different approach. They weren't asking for coding terms like emotional lability, that's correct.

Q. In fact, the FDA asked manufacturers to use a specific set

of search terms to find events that might relate to suicide, correct?
A. Correct.
Q. Uh-huh. And they asked for both what we call preferred terms as well as verbatim terms, correct?
A. Correct.
Q. And the FDA also told the manufacturers to -- also searched the comment fields within the trial so if investigators made comments, those would be searched, also, correct?
A. Well, it depends. In the case of any clinical record that GSK has, for instance, there may be several different clinical records on the same patient. Like if one of the jurors was in their trial, there might be four completely different clinical report forms or sets of material on that juror, and GSK may well have searched one of those rather than all four.
Q. But -- and when -- Dr. Healy, when GSK ran the searches, it didn't just immediately share the results with FDA; in fact, GSK sent the entire case file for each patient to independent expert reviewers at Columbia University, correct?
A. It may well have done so, but when I say -- hang on. No, I would disagree with you. I am pretty certain GSK did not send the entire case file.
Q. That's your understanding?
A. That will be my understanding based on my experience of

GSK's case files.
Q. And the Columbia experts reviewed the information GSK provided with each event and made an independent determination as to which category from a list of categories the event should go in, correct?
A. Correct.
Q. And once the experts made that -- at Columbia made that classification, Dr. Posner and colleagues, GSK sent that information along with the details of the events to the FDA for analysis, correct?
A. Correct.
Q. You told the jury there's a wide body of data, and anybody who's trying to work out what's actually going on, they need to take it all into account. We talked about that this morning, correct?
A. Well, I think that would be self-evident to the jury, if no placebo-controlled trial has been designed to look at the question of, can people become suicidal on Paxil, then anybody who is going to look at this question wants to look at material other than the placebo-controlled trials.
MR. BAYMAN: I want to turn, if you will, in your exhibit book to Tab 11-D -- which is Joint Exhibit 13, your Honor, that's already in evidence.
THE COURT: This is Joint Exhibit what?
MR. BAYMAN: 13, your Honor.

THE COURT: Okay.

MR. BAYMAN: It's behind-- it's 11 and then capital letter D.

THE COURT: Okay. Gotcha.

MR. BAYMAN: Can you put the first page of this document up?

BY MR. BAYMAN:

Q. This is the FDA's clinical review relationship between antidepressant drugs and suicidality in adults, correct?

A. Correct.

Q. And you're familiar with this document?

A. I am, yes.

Q. Turn, if you would, to Page 13-024.

A. Yes.

Q. Got that?

A. I have indeed.

Q. Now, this is -- we established a couple minutes ago that the primary outcome measure of the FDA analysis was completed suicide attempts, preparatory acts, and ideation all combined, correct?

A. Correct, yes.

Q. All right. And this -- and in Table 15 here that you're looking at, and it's on the screen, that presents the results of the FDA's analysis, doesn't it?

A. Correct, yes.

Q. And you didn't show Table 15 to the jury last week, correct?
A. Mr. Wisner didn't show Table 15, that's correct.
Q. And we see that as we look at that, for paroxetine, the odds ratio is .93, correct?
A. Correct.
Q. And you told the jury anything over 1 is an indication of risk, correct?
A. I told the jury repeatedly that drugs that can cause a problem can have an odds ratio of less than 1.0.
Q. But the finding on the primary outcome for paroxetine is less than 1, you would agree with that?
A. Yes, and I've indicated that I believe a drug that causes people to become suicidal can have an odds ratio of less than 1.0. I'm happy to explain exactly how it happens if you want.
Q. No. We've heard that. But this means the risk of suicide attempts, preparation, and ideation was lower on paroxetine when compared to the placebo, correct?
A. No, it doesn't mean that at all. What you're doing is the data that FDA has which is the data from a select group of trials having been boxed in by all the companies into asking for certain trials and not others, this is what the data comes out as. When you analyze this behavior on its own as we see, we get a very different effect.
MR. BAYMAN: Your Honor, I move to strike "having

been boxed in by the companies." There's no --

THE COURT: No, that may stand.

BY MR. BAYMAN:

Q. The confidence interval here by your standards is very narrow, .62 to 1.42?

A. That's correct, yes.

Q. And compared to the other SSRIs that paroxetine had the third lowest odds ratio in this chart, correct?

A. On that chart, yes, correct.

Q. Okay. And I think the finding is based on the -- we looked at the patient, the number of patients earlier. That finding is based on 8,728 patients on paroxetine and 7,005 patients on placebo. Do you remember that?

A. Yes. I suspect there's a lot of other paroxetine patients that aren't there.

Q. You told the jury last week, and I recalled it at the time because I wrote it down, that the paroxetine data in the FDA analysis may have been unusually reliable. Do you remember that?

A. Oh, I thought, yes, in some respects, it was, but there's other aspects to that question that I'd be happy to elaborate on if you want, which is when FDA asked --

Q. I'll let your counsel do that on redirect.

A. Fine. Okay.

Q. None of the SSRIs had a statistically significant

association with suicidal thoughts or behavior in the FDA's 2006 adult analysis?
A. Yes, but we know that I wouldn't use the term "statistical significance" there anyway.
Q. You also told the jury that based on the data from this analysis, the SSRIs as a group cause a problem, correct?
A. Based on the data -- yes. It's in the Stone and Jones report. When you look at behavior, they -- these drugs do cause a problem, yes.
Q. All right. Let's look at the finding for all SSRIs. In the line for all SSRIs, do you see that right there?
A. Yes.
Q. That odds ratio is .86, correct?
A. Correct.
Q. And the 95 confidence interval is .69 to 1.06, correct?
A. That's correct.
Q. And that's another narrow --
A. Yes.
Q. -- window, correct?
A. It is, yes.
Q. And the FDA found no increased risk between SSRI medications when they're grouped together on the primary outcome of suicidal thoughts and behavior in their adult analysis, correct?
A. That's correct, yes.

Q. And the FDA also found no association between all antidepressant medications that they looked at on the primary outcome of suicidal thoughts and behavior, correct?
A. Correct.
Q. And that finding by the FDA was based on 52,000 patients on antidepressants and over 45,000 placebo patients. Can we pull that table up, Table -- Table 7, Dr. Healy, which is at Page 13-18. Do you see those numbers at the bottom?
A. I do, yes.
Q. So you agree that the finding was based on 52 -- over 52,000 patients on antidepressants and over 45,000 on placebo?
A. As I've indicated to you earlier, I think this means it's a particularly messy data set. It's not a good data set.
Q. The FDA in this report which you're familiar with discusses the results, correct?
A. It does, yes.
Q. And that begins at Page -- if you would turn to again the same exhibit, Joint Exhibit 13, to Page 13-044.
A. We probably should say, when you say "FDA discusses," it's Drs. Stone and Jones. To say "FDA" may be a little misleading here.
Q. Well, they did the -- they're FDA employees, correct?
A. They are FDA employees, and I'm sure there were others within FDA who would have framed the issues differently.
Q. But they issued the report, correct?

A. They did, yes. So we're talking about the Stone and Jones report --
Q. Yes.
A. -- rather than FDA's corporate view.
Q. And they did the analysis, correct?
A. They did, yes.
Q. Okay. I want to turn you then to -- to Page 44, Section 5.2.
A. Yes.
Q. In the first sentence, FDA -- let's go ahead and highlight that, please.

FDA said, the pooled estimate -- or Stone and Jones of the FDA said, "The pooled estimates of studies of the adult population support the null hypothesis of no treatment effects on suicidality." Did I read that correct?
A. Well, that's on suicidality, yes. This is not on suicidal behavior as such.
Q. Another way of saying that is the FDA concluded that it doesn't believe use of antidepressants increased the risk of suicidality in its analysis?
A. I don't know that I'd agree with that.
Q. Okay. What's a null hypothesis?
A. Well, a null hypothesis is a thing that was introduced by Fisher. And FDA, in the analysis here, are not applying it in the way Fisher would have applied it. He would not have

applied statistical significance tests to the data you have here.

Q. And the FDA further goes down to say later at the end of that paragraph:

"The net effect appears to be neutral on suicidal behavior but possibly protective for suicidality for adults between the ages of 25 and 64 and to reduce the risk of both suicidality and suicidal behavior in subjects aged 65 years and older."

Did I read that correctly?

A. You did. It's very -- I mean, it's hard to know what the right tone of voice would be for an FDA person writing this talking about a complex situation where, for example, the data from 45 to 55-year-olds was exactly the same as under-25-year-olds.

Q. You didn't tell the jury last week about these findings, did you?

A. I didn't conceal them. I would have been awfully happy for the jury to get the full text of the entire document.

Q. You talked -- you talked about the findings on the secondary end point but not on the primary end point?

A. Well, as we explained, I think it makes no sense to talk about primary and secondary in this context.

Q. You showed the jury --

MR. BAYMAN: Pull up Table 16.

THE COURT: Page?
THE WITNESS: 36, your Honor.
MR. BAYMAN: 36, your Honor. Sorry.
MR. WISNER: Your Honor, it's 26 just in case you're looking for it.
THE WITNESS: Oh, sorry. 26.
MR. BAYMAN: Dr. Healy and I were both had the wrong page. It's 26.
THE WITNESS: Maybe we're just shortsighted. I saw 36 rather than 26.
BY MR. BAYMAN:
Q. You did show the jury this table, correct?
A. Yes.
Q. Okay. And that's titled, "Suicidal behavior risk for active drug relative to placebo, preparation or worse, adults with psychiatric disorders, by drug and drug class."
A. Correct.
Q. And that table doesn't show the primary outcome of the analysis but rather the secondary outcome, correct?
A. Well, what has been termed the primary outcome, yes.
Q. What the FDA terms the primary outcome?
A. Yes.
Q. And the 2.76 that you told the jury about, that appears in Table 16 --
A. It does.

Q. -- for paroxetine, correct?
A. Correct.
Q. And then I would turn you, if you would, Doctor, back to Page 23.
MR. BAYMAN: Pull up, if you would, Roger, that.
THE WITNESS: 23?
BY MR. BAYMAN:
Q. Yeah, the bottom of 23 below the table.
A. All right. Yes. Yes.
Q. The FDA explicitly stated, though, even though some of the results in Table 16, which we just saw, were statistically significant, the significance of these findings must be discounted for the large number of comparisons being made, correct?
A. Yes.
Q. And you didn't mention that last week to the jury, did you?
A. Well, I took pains to say that I think people shouldn't be putting undue weight on statistical significance in the first instance, but I've also made it clear that discounting a fact because of multiple comparisons is rather avoiding the elephant in the room which these trials were designed not to find the problem. So applying fancy statistical tests is really a bit of a waste of time.
Q. You've attended FDA advisory committee meetings that have been open to the public, correct?

A. I have, yes.
Q. And you know that with respect to this analysis, the FDA publicly stated, while its analysis showed an increased risk of suicidal thinking in behavior, suicidality in young adults age 16 to 24 --
THE COURT: What are you reading from now, sir?
MR. BAYMAN: That's what the FDA said at the meeting, your Honor.
THE COURT: Where are you reading? Tell me what you're reading.
MR. BAYMAN: Tab 18 in the notebook. It's the FDA news release, Defendant's Exhibit 468.
BY MR. BAYMAN:
Q. Do you want to turn to that, Doctor?
A. Yes. I think I'm here.
Q. You're familiar with that news release, correct?
A. This is, FDA proposes new warnings about suicidal linking behavior in young adults who take antidepressant medications. I'm sure I've seen this. I'm not sure, if you'd ask me about it, that I would have been able to date it but...
Q. You've been actually asked questions about this in some of your depositions, correct?
A. I may well have been, yes.
Q. Okay. And this was an announcement that the FDA put out to doctors and to the public following the adult analysis,

correct?
A. Correct.
Q. And the FDA said that while its analysis showed an increase or risk of suicidal thinking and behavior, suicidality in young adults age 16 to 24, the scientific data did not show the increased risk older -- in adults older than 24?
MR. WISNER: Objection, your Honor. Hearsay.
THE COURT: Your objection comes a little late.
THE WITNESS: Can you point me to just the spot you're reading from?
THE COURT: Just a minute, sir.
MR. WISNER: I didn't want to interrupt. I'm sorry, your Honor.
THE COURT: This document is in evidence?
MR. WISNER: No.
MR. BAYMAN: No, sir. It's an exhibit, but it's not a joint exhibit.
THE COURT: Have you offered it in evidence? Have you offered it?
MR. BAYMAN: I have not yet, your Honor, no.
THE COURT: Well, you can't read from a document that's not in evidence, sir.
MR. BAYMAN: I would --
THE COURT: It will be stricken.

MR. BAYMAN: Well, your Honor, then I'll move for admission of the document --

THE COURT: All right.

MR. BAYMAN: -- and its indicated exception to the hearsay rule because it relays the results of a government investigation under Rule 803.

MR. WISNER: I object. This is hearsay. They have not laid sufficient foundation for that exception. This is a press release. This is not the actual analysis which we were looking at. This is the definition of an out-of-court statement being offered for the truth of the matter asserted.

MR. BAYMAN: He can rely on hearsay. He's an expert, your Honor. He said he was familiar with it, and he was at the meetings.

THE COURT: You could have brought this to my attention earlier. The objection at this point is sustained.

MR. BAYMAN: Okay. I'll move on.

BY MR. BAYMAN:

Q. In 2006, GSK also did an analysis of adult suicidality that you told the jury about last week, right?

A. Yes. That was brought into the frame.

Q. And you told the jury about the 6.7 odds ratio on the secondary end point in the subset of MDD patients, correct?

A. Yes. I hope I've conveyed that while it's a high odds ratio, I don't place all the weight on just that. The simple

fact that there's such a clear signal, whatever you -- you know, you call the odds ratio isn't a thing that I would be concerned about.

Q. There were also results for other groups of patients besides those with MDD in that analysis, correct?

A. Correct.

Q. You didn't tell the jury about those other analyses, did you?

A. No.

Q. And Mr. Wisner didn't ask you about any of the other results, correct?

A. He didn't. I mean, I was following what I was asked. I didn't go out of my way to tell the jury things that I wasn't being asked about.

MR. BAYMAN: I'm going to have you look at Tab 11-C which is the GSK 2006 submission. It's Defendant's Exhibit 103.

And it is, I think, a more complete version of what was, your Honor, admitted as Plaintiff's Exhibit 9.

THE COURT: Okay. We're at Tab 11, did you say?

MR. BAYMAN: Yes, sir. 11-C.

THE COURT: 11-C?

MR. BAYMAN: Yes.

THE COURT: All right. You may proceed.

MR. BAYMAN: And your Honor, at this point, I would

move for admission of Defendant's Exhibit 103 which, as I say, is -- it's the same document as Plaintiff's Exhibit 9. It's just a more complete copy.

THE COURT: All right. You may proceed.

MR. WISNER: No objection.

(Defendant's Exhibit 103 received in evidence.)

BY MR. BAYMAN:

Q. Let's look at the cover letter on April -- April 5, 2006. This is from GSK's senior director of regulatory affairs, Barbara Arning, to Dr. Laughren at the FDA, correct?

A. It's certainly from her. Is it to Dr. Laughren? "Dear" --

Q. "Dear Dr. Laughren."

A. "Remy" is what I'm looking at. The covering letter. Okay. You should have directed me to Page 2.

Q. Excuse me.

A. Okay. Fine. Okay.

Q. The very first paragraph, it says:

> "Reference is also made to our submission of March 8, 2006, which presided -- provided results from the first portion of a comprehensive meta-analysis to evaluate the risk of suicidality in placebo-controlled paroxetine trial in adults with major depressive disorders."

Do you see that?

A. Correct, yes.

Q. What happened was that GSK did the MDD analysis first and then submitted it to the FDA in March of 2006, correct?
A. In or around this time, GSK had analyzed more than MDD, but that's what I think you're going on to tell me or to tell the jury, isn't it?
Q. Well, but it did MDD first and it submitted first, then it ran the analyses of the other disorders, correct?
A. I'm not absolutely clear about this. I think GSK were trying for a good deal of time during 2005 to submit both MDD and IBDD together, for instance.
Q. The jury will hear from a GSK witness about the sequence, but we do know that the result you discussed with the jury, the 6.7, was actually presented in this March --
A. Yes.
Q. -- submission.
A. Yes.
Q. And, in fact, to my earlier point, as of April 5, GSK says it is submitting the results on MDD and now is submitting the results on the other indications because it had already submitted on MDD. If you look at -- let's pull up that in the submission.
A. Yes.
Q. Do you see that in the submission, "we are providing updated results?"
A. Yes. Okay. Yes.

Q. On the screen.
A. Yes.
Q. So they're submitting a new analysis from the non-MDD paroxetine trials?
A. Correct.
Q. And then you mentioned intermittent brief depression a minute ago and some other disorders. They're presenting the data for paroxetine being studied for these disorders, correct?
A. Correct.
Q. Okay. And it lists there about ten different illnesses for which paroxetine has been studied including anxiety conditions, correct, if we scroll down further?
A. Yes.
Q. Okay. And, in fact, if we -- if we go to the next paragraph, we see that not only is GSK providing data but it's submitting new warnings to go into the label reflecting this data, correct?
A. That's what they appear to be saying, yes.
Q. And it's -- it also says that they're going -- they're submitting a draft Dear Healthcare Professional letter for review by the FDA --
A. Yes.
Q. -- that it's considering sending to doctors to inform them of the data?
A. Yes.

Q. And it asked in the letter for a teleconference with the FDA to discuss these items, correct?
A. They may well have done so, yes.
Q. Okay. Let's turn now to -- you're aware that GSK submitted what's called a briefing document along with this submission, if you turn to Page 811?
A. Yes.
Q. That is the --
A. I'm sorry. 811 is what you want me to turn to?
Q. Yes. PAR811, I'm sorry --
A. Okay.
Q. -- in the lower right corner.
A. Yep.
Q. Okay. Can we blow that up?
That's the first page of the briefing document correct?
A. Yes.
Q. And it's titled, "Paroxetine adult suicidality analysis: Major depressive disorder and non-major depressive disorder"?
A. Correct.
Q. Look, if you will, at the clinical summary section which is on Page 6, Page 6 of this document, which corresponds with PAR9816. Do you see that?
A. I do, yes.
Q. Okay. The first bullet point under "Clinical summary,"

this is under "Major depressive disorder," correct?
A. Correct.
Q. And it says, "On the primary end point of definitive suicidal behavior or ideation, there was no statistically significant difference between adults with MDD treated with paroxetine compared to placebo," correct?
A. Well, I just repeat, first of all, there's no good grounds for saying this is the primary end point and, secondly, no statistically significant end stage, as the jury should be able to guess at this state, is not important to me, and the third thing I would throw in is that this is not necessarily all of GSK's trials.
Q. GSK's analysis, just like the FDA, did have a primary end point, though, correct?
A. This is an arbitrary thing, and it could have been the other way around. They could have decided to put suicidal behavior as the primary end point.
Q. But what -- the primary end point was suicides, suicide attempts, and suicidal ideation?
A. Yes, but there's no good grounds for that. If I'm trying to persuade the jury to accept, you know, my view about a particular thing, it will be useful for me to provide criteria for why I'm picking one option rather than the other rather than to have an arbitrary decision. This is an arbitrary decision.

Q. Was it an arbitrary decision by the FDA to pick the end point that they picked?
A. Yes, I think it was. It may have just been following the lead they got from companies which FDA has often done but without -- they haven't provided good criteria for saying this should be the primary end point rather than that.
Q. But suicides, suicide attempts and suicidal ideation, that's all suicide-related events, is it not?
A. Yes, but I think it's designed to hide the problem, as I've indicated earlier. Completed suicides and suicidal behavior are much firmer end points.
Q. On --
THE COURT: Excuse me, Doctor. Is it your understanding that the data related only to behavior -- or ideation and not to actual suicide?
THE WITNESS: Well, no. Your Honor, in the case of a person who commits suicide, there will be a suicidal act that's lethal --
THE COURT: Right.
THE WITNESS: -- and there would be suicidal ideation beforehand.
THE COURT: But what does this include?
THE WITNESS: Well, this includes ideation plus acts plus completed suicides, but as I've spent some time trying to explain on Thursday, acts and completed suicides are a much

firmer end point than ideation. And there's much more ideation. So when you throw ideation in, it's rather like adding Study 057 into the MDD studies, which is one of the maneuvers GSK adopted.

MR. BAYMAN: Your Honor, I move to strike that. We didn't -- we never talked about 057.

THE COURT: Yes. That will go out.

MR. BAYMAN: Thank you.

BY MR. BAYMAN:

Q. And on this primary end point, in MDD patients, GSK reported no statistically significant difference between paroxetine and placebo patients, correct?

A. As I've indicated, GSK did say it was not statistically significant. And if they're pleased with that, I'm happy for them, but I wouldn't have used those terms.

Q. The confidence interval goes below 1, does it not?

A. It does.

Q. And then in the next bullet under the -- looking there, the next bullet down below, it identifies the outcome you told the jury about, which was an odds ratio for suicide attempts, correct?

A. Correct, yes.

Q. That -- and that's the 6.7 that the jury has heard about?

A. Correct.

Q. That 6.7 didn't include suicidal thoughts, correct?

A. That's correct -- well, it would have included some suicidal ideation. There's very few suicide attempts that won't be accompanied by suicidal ideation, also. There's many, many, many suicidal ideations, four or five times the number of ideations that don't go on to attempts as there are attempts with ideation.
Q. Suicidal ideation led to an attempt, correct?
A. In these instances, correct.
Q. Okay. GSK in that same section wrote, "However, as the absolute number and incidence of events are very small," and it gives the numbers for paroxetine, 11/3455, .32 percent, versus 1/978, .05 percent for placebo, odds ratio equals 6.7, 95 percent confidence interval, 1.1, 149.4, p equals .058, these data should be interpreted with caution. Is that what it says?
A. That's what it says. Lots of people struggle over the difference between confidence interval and the p value here, but leaving that aside, I'd agree with GSK that these data should be interpreted with caution primarily because these trials were not designed to look at the problem. And if the trials had been designed to look at the problem, the confidence interval would have been much, much tighter and the odds ratio might have been a lot larger.
Q. Let's look at the patients in the trials involving the conditions other than MDD which starts on the bottom of Page

7, the next page. Do you see -- are you there?
A. I do, yes.
Q. I want to ask you about the relative size of the groups. We saw that the MDD-only group was a population of --
A. 3,000, roughly.
Q. -- 3,455 on paroxetine and 1978 on placebo?
A. Yes.
Q. Does that sound right?
A. Yes.
Q. But on the trials involving conditions other than MDD, there were a total of 8,958 paroxetine patients and 5,953 placebo patients in the data set, correct?
A. I'm not exactly --
Q. I'll pull that up.
A. I think the entire data set was that, so I think you have to subtract the 3,4, or whatever from the 8,5.
Q. Well --
A. I could be wrong.
Q. -- that's right. You're right. So if we subtract the MDD from the total --
A. Yes.
Q. -- the 8958, we know that there were 5,503 paroxetine patients?
A. Possibly.
Q. And 39 -- 3,975 placebo patients in the non-MDD trials.

A. Uh-huh.
Q. So that's about 2,000 more paroxetine patients and about 2,000 more placebo patients than were in the MDD data set, correct?
A. Sure, but as I've indicated to you before, this doesn't make the finding more robust. It points to the fact that these were even less well-designed trials.
Q. And you've made that clear this morning. And then GSK presented the results for the non-MDD conditions on Page 8, if you'll turn to that.

MR. BAYMAN: Can you blow that up, please?

BY MR. BAYMAN:
Q. The first set of the results that are up there on the screen is for the primary end point of all suicidal ideation and behavior, correct?
A. Correct, yes.
Q. And then GSK wrote:

"In placebo-controlled clinical trials in psychiatric disorders other than MDD, there was no evidence of an increased risk of suicidal behavior or ideation, primary end point, in patients treated with paroxetine."

A. And just below it, they show an odds ratio for behavior alone without ideation, but the odds ratio is greater in non-depression than for depression, 1.5 versus 1.2.
Q. My question was: GSK found there was no evidence in

psychiatric disorders other than MDD, there was no evidence of an increased risk of suicidal behavior ideation which is the primary end point in patients treated with paroxetine, correct?

A. GSK found an increased odds ratio compared with -- for non-depressed indications versus depressed indications.

Q. Well, let's look at the specific results. For all indications which includes MDD, the odds ratio is .9, correct?

A. And I'm looking at the one below, 1.2, which I've indicated the behavior is much more robust than ideation and behavior.

Q. Stick with me on this one.

A. I hope the jury is looking at both.

Q. The confidence interval is .7 to 1.3, again, that's narrow, correct?

A. That's relatively narrow, but in the case of trials that are not designed to look at the problem, it's relatively meaningless, also.

Q. And it's -- that finding is not statistically significant, correct?

A. In trials that are not designed to look at the problem, I think you will never hear me say the findings are statistically significant or not.

Q. For all depression which includes MDD, the odds ratio is a non-significant 1.1?

A. That's correct. For behavior, it's a little higher.
Q. And for non-depression which excludes MDD, the odds ratio is .7?
A. And for non-depression behavior, it's double that.
Q. The .7 odds ratio that includes all trials for anxiety disorders and other illnesses excludes MDD, correct?
A. Yes.
Q. And we saw that in these trials, that's 2,000 more patients in paroxetine and placebo than in the MDD group, correct?
A. Yes, but it doesn't make the finding more robust just because it's 2,000 more patients. And when we stick with the more robust end point of behavior as I say, the odds ratio --
MR. BAYMAN: Your Honor, I move to strike that. That was not my question.
THE COURT: Well, you know, it's pretty complicated, so I'm going to let him explain his answer.
THE WITNESS: Yes, I think from my point of view that the jury will have guessed that the more informative piece is the lower half of the page there.
BY MR. BAYMAN:
Q. But you didn't show the jury any of this data on Thursday, did you?
A. I think the jury had probably a lot of me. I'm not sure they could have put up with hours and hours more of me. I

would have been happy to keep talking for hours and shown the jury a lot more material.

Q. You showed the jury the secondary end point but not the primary end point?

A. But there's no basis -- if you are able to offer the jury a good reason for saying one is primary and the other is secondary, that's fine, we could argue about that and the jury could make up their own mind. I'm saying to the jury that the choice is arbitrary, and you haven't argued with me about that one.

Q. We'll have witnesses who will do that, Doctor.

A. Okay.

Q. GSK also reported the results for the secondary end point, but you want to talk about suicidal behavior --

A. Let's just call it behavior.

Q. -- which include suicides and suicide attempts, right?

A. Yes.

Q. Okay. Let's pull that up, right there. And GSK again, as with the primary end point, there was no statistically significant increased risk on either the all indications group or the all depression group or the all non-depression group, right?

A. You will never hear me talk about statistical significance about trials that are not designed to look at the end point in question.

Q. And you didn't show the jury this data either, correct?
A. No, I didn't show the jury this data either, but it was implicit in some of the earlier data that they were shown. Table 16, if they look at the odds ratio for overall behavior and for any of the jurors that are up with data and statistics, which gave an overall odds ratio for MDD and non-depression studies of 2.76 with a confidence interval that was relatively tight, the jurors would have been able to work out that that was a significant problem from the non-depression trials, also.
Q. And the jury will make up its own mind, Doctor. On direct examination, you talked about mechanisms by which you believe that paroxetine causes suicide. Isn't it true, you haven't identified any biological mechanism that would cause you to believe that any antidepressants in general or Paxil in particular increases the risks of suicidal behavior in MDD patients but not in patients taking it for other indications?
A. Let me be absolutely clear what you're asking me. You're asking me, is there a difference between the suicides that happen in people who are depressed versus the -- who are also taking Paxil versus the suicides happening in people who are anxious who may be taking Paxil? Is that what you're asking?
Q. No, no. I'm saying that you've not identified a biological mechanism that would cause you to believe that antidepressants in general or Paxil in particular increase the

risk of suicidal behavior in MDD but not in patients taking it for some other indication?

A. Let me be absolutely clear here. I'm saying the risk comes from the drug. It's a bit like alcohol. I would expect alcohol to make some people who are depressed become suicidal and perhaps try to harm themselves and people who aren't depressed become suicidal and try to harm themselves.

Paxil behaves the same way. There's nothing particular about its action when we are talking about people who are depressed, who for the most part people getting Paxil would have been labeled as being anxious 20, 30 years ago but they're not melancholic, for instance.

Q. But there's no mechanism that -- there's no biological mechanism for why Paxil would increase suicidality in MDD patients but not increase it in a patient with some other anxiety disorder, correct?

A. No, I would expect Paxil to be a risk for particular people -- as I've indicated before, we've all got different serotonin systems. We can still become anxious or become depressed or whatever. It's the nature of our individual serotonin systems that seems to shape the risk. Some people are at risk.

There's some depress -- some of us when we're depressed can take Paxil without great risk. Some of us who are anxious can take Paxil without great risk. Some of us who

have got a different serotonin system are at risk whether anxious or depressed or have BMDD. Actually, the highest rates, it seems, at which people become suicidal taking SSRIs who have PMDD, and I'm not sure whether there's a biological reason for that.

Q. But you would expect that the propensity for the drug to cause problems will be found in anyone --

A. Not anyone --

Q. -- healthy --

A. Not anyone, not anyone, no, no. Some of us are at risk from these drugs. Some of us are at more risk than others from these drugs.

Q. But you can't identify a biological mechanism why certain people would be more at risk -- certain major depressed patients would be more at risk than someone taking it for social anxiety, for example?

A. No, but I've kept saying to you that I think it's the nature of our serotonin systems. I can identify -- well, I think we're very close to being able to identify some people who are at risk of going on to commit suicide when they take an SSRI because there are people who seem to have a different serotonin system to rest with so that when they take an SSRI, they become alcoholic, and that greatly increases their risk.

Q. But you haven't identified a mechanism, not even akathisia, that would cause suicide in patients with MDD but

not in OCD or GAD, correct?
A. No -- well -- sure, sure. I think there's -- I mean, just -- I'm happy to keep talking about this, but I'm not quite sure where you're going --
THE COURT: Doctor, slow down. You went in two different directions at once there.
THE WITNESS: I'm sorry. I'm happy to keep talking about this. For instance, in our personalities, people with OCD when they become agitated in this way seem more likely from GSK's clinical trial data to become violent rather than to become suicidal. So there definitely are differences there.
And the people who should have been exploring these differences for all of our sakes are a company like GSK who have been making so much money out of this drug.
MR. BAYMAN: I move to strike that, your Honor.
THE COURT: That may go out.
MR. BAYMAN: That's inflammatory.
THE COURT: The jury will disregard it.
BY MR. BAYMAN:
Q. Back to my question, which was, you haven't identified any mechanism that would cause suicide in patients with MDD but not in OCD or GAD?
THE COURT: What is OCD again, Doctor?
THE WITNESS: That's obsessive-compulsive disorder, your Honor.

BY MR. BAYMAN:
Q. And GAD is generalized anxiety disorder.
A. Correct, yes. No, I've indicated all the way through that it's not a function of the disorder. It's a function of the serotonin systems that all of us have. Some of us are at risk. Whether we superficially get GAD or major depressive disorder or whatever, it's not the condition that determines our risk. It's the nature of our biology before we have the condition that determines the risk.
Q. Okay. And you -- when you discussed the 2006 analysis, the only -- with the jury last week, the only finding you pointed out was the finding in patients taking paroxetine for major depressive disorder, correct?
A. No. I think the findings I pointed out included the, all indications other than the IBD ones. That was the 2.76 figure. That wasn't just confined to major depressive disorder.
Q. You didn't point out to the jury that in every other indication whether it's SAD or OCD, PMDD which we've talked about, there was no statistically significant increased risk of suicidality, did you?
A. Well, there was an increased risk, and again -- you're just not going to get me saying "statistically significant." There's an increased risk for most conditions you mentioned except panic disorder. PMDD had a greatly increased risk.
Q. Okay. Doctor, you also -- you talked about some -- you

told the jury that we need to take all the data into account, correct?
A. Yes, and that's still my position.
Q. And look at every -- we should look at every kind of data. And you presented some articles, do you recall that? One is yours, it's what we call the Healy Fergusson article?
A. Yes.
MR. BAYMAN: And that's in evidence, your Honor. It was published to the jury. It's Plaintiff's Exhibit 165, Tab 22.
THE WITNESS: Yes.
BY MR. BAYMAN:
Q. I don't intend to go into depth. I just want to kind of briefly review these. You're an author on that paper, right?
A. I am, yes.
Q. Okay. And this study doesn't have any results that are specific to paroxetine, correct?
A. That's correct.
Q. You looked at all the SSRIs lumped together, correct?
A. Correct.
Q. You talked to Mr. Wisner about the results for suicide attempts, but I want to ask you about the results for completed suicides because this is a completed suicide case. Okay?
A. Okay.

Q. Look at Page 397, which I think is probably the fourth page in your collection. I think it says at the bottom "Page 4 of 7," Doctor.
A. Yes, it does.
Q. You got it?
A. Yes.
THE COURT: Excuse me. You're not on Exhibit 165?
MR. BAYMAN: I am on -- yes, your Honor, on Plaintiff's Exhibit 165 which Dr. Healy presented to the jury last week.
THE COURT: Yes. What page?
MR. BAYMAN: Your Honor, if you look at the lower left corner, it will say "Page 4 of 7."
THE COURT: Yes. Okay.
BY MR. BAYMAN:
Q. Are you with me, Doctor?
A. I am, yes.
Q. Okay. It says in the right-hand column, the end of the first paragraph, "In comparing fatal suicide attempts, we did not detect any differences between SSRI and placebo." And then you give some numbers, correct?
A. Yes.
Q. A fatal suicide attempt is a completed suicide?
A. Completed suicide, correct.
Q. And the odds ratio is less than 1, correct?

A. Correct.
Q. So for all of the SSRIs combined including paroxetine, you didn't detect any difference in the rate of completed suicides, correct?
A. Well, let's be clear. This is on the basis of published articles. It's not access to the data. And for the most part, these articles will have been ghost written, and it was difficult to get access to the data from many of the authors.
MR. BAYMAN: Your Honor, I move to strike this.
BY MR. BAYMAN:
Q. This is your own article.
A. Oh, yes. No, right, but this is based -- this is looking at the publications that are out there. We don't have access to the data. We've got access to publications and what the publications say the figures are. And in a number of cases, when the publications haven't mentioned figures, we make it clear that we contacted the authors to try and get the figures but haven't always been successful.
Q. On Page 398 which is Page 5 of 7 --
A. Yes.
Q. -- if you look in the second column under "Possible explanations for our findings."
A. Yes.
Q. You and your colleagues wrote:
"Estimates for patients with major depression favored

a decrease in suicide with SSRIs whereas patients with depression and other clinical indications may have as much as an eight-fold increase in the rates of suicide, thus resulting in an overall null effect."

Did I read that correctly?

A. Yes, you did.

Q. Okay. So in this study -- and you told the jury this was about the same size as the FDA study, correct?

A. Yes.

Q. You found that for patients with major depression, there was a decrease in suicide in patients taking SSRIs compared to patients taking placebo, correct?

A. We -- yes.

Q. Okay.

A. That's correct.

Q. And you didn't tell the jury about that finding last week, did you?

A. I didn't conceal it from the jury. We've indicated that overall when we take everything into account, we believe there's a risk from SSRIs for people becoming suicide -- well, going on to suicidal behavior.

Q. You agree with me, Doctor, that the FDA specifically knew of and reviewed this article prior to announcing its findings of the 2006 adult suicidality analysis of the 11 antidepressants, correct?

A. That's correct. They both refer to that when they introduce the Stone and Jones article and refer to some comparability between their figures and ours later at the end.
Q. And, in fact, the FDA commented on your study, did it not?
A. Yes, it probably did.
Q. You're familiar with the memorandum from Dr. Laughren that it -- to the members of the advisory committee?
A. Sure. This is Dr. Laughren's view, yes.
Q. Dr. Laughren of the FDA?
A. Dr. Laughren of FDA. There's probably a lot of other people like David Gray at FDA who would have had a very different view.
Q. The -- he wrote a memorandum to the members of the -- what's an advisory committee?
A. It's where there's an issue -- when a drug is going to be approved, for instance, FDA will convene an advisory committee of experts to look at the data that's the basis for the approval of the drug. They don't always pay heed to what the experts say. The experts may say, "You shouldn't approve this drug," and FDA may go ahead and approve it, for instance.
Q. And your -- Dr. Laughren then prepared a memorandum for the memo -- for the members of the committee --
A. He did, yes.
Q. -- the advisory committee as part of his work in investigating whether there was any link between SSRIs and

suicide in adults, correct?
A. He prepared a memorandum to open the day, yes. And he gave a talk to open the day.
Q. And you were there?
A. I was there.
MR. BAYMAN: Yes. Okay. Your Honor, I would at this point move for admission of Defendant's Exhibit 435, the memorandum for the FDA advisory committee.
MR. WISNER: Your Honor, objection, hearsay, to the extent that the exhibit itself is being offered for the truth of the matter. I don't believe any foundation has been laid that he relied upon any of those statements in forming his opinion, and so it doesn't constitute expert testimony either.
MR. BAYMAN: I think, your Honor, it -- again, it is part of the FDA's investigation which is a specific exception to the hearsay rule.
THE COURT: Well, he was present.
MR. BAYMAN: He was present, yes.
THE COURT: He heard the speech, and he can tell us what he thinks about it after you've called it to his attention.
MR. BAYMAN: Thank you, your Honor.
THE COURT: Thank you.
MR. BAYMAN: Go ahead and -- I just want to call to your attention --

THE COURT: Where are we now? What exhibit are we?

MR. BAYMAN: We're at Exhibit 435, your Honor. I moved it into admission.

THE WITNESS: Where would I find it in the binder?

THE COURT: What tab is it?

MR. BAYMAN: 23, Tab 23.

THE COURT: I have it. Thank you.

MR. BAYMAN: Are you there?

THE WITNESS: I am, yes.

MR. BAYMAN: They, if you look in -- let's go to Page 4, and highlight, Roger, with Fergusson.

BY MR. BAYMAN:

Q. Fergusson, that's your paper, right?

A. Yes, it is, yes.

Q. You see that the FDA stated in that paragraph in the last sentence, "There were serious limitations to this review, most important being a lack of any information on adverse events for 58 percent of the patients eligible for the analysis."

Did I read that correctly?

A. Correct, you did.

Q. Okay. And you didn't mention that the FDA said there were serious limitations to your study when you talked about it last week, did you?

A. Oh, I'm happy -- I mean, any study in this area and ours and FDA -- I mean, I indicated, I've indicated serious

limitations to the jury just a few minutes ago. We were relying on published papers.

Q. I --

A. In the same way, FDA has serious limitations to their study. Everyone has.

MR. BAYMAN: I move to strike that, your Honor. My question was, "You didn't tell the jury that?"

MR. WISNER: Objection, your Honor.

THE COURT: It may stand. Proceed.

BY MR. BAYMAN:

Q. And then if we go back, can we go back now to your paper --

A. We can.

Q. -- with Fergusson. Do you have that handy?

A. I have, yes.

MR. BAYMAN: And that's Plaintiff's Exhibit 165, your Honor.

THE WITNESS: Tab 22, your Honor, just the previous tab.

BY MR. BAYMAN:

Q. Are you with me, Doctor?

A. Yes.

Q. Okay. I want to show you the box on Page 7 that you showed the jury last week.

A. Yes.

Q. Do you remember?
A. Yes.
Q. Okay. And it says, "What is already known on this topic," and it says, "divergent studies exist on whether SSRIs are associated with an increase in suicidal events."
Do you see that?
A. Yes.
Q. And I read that correctly?
A. You did, yes.
Q. Divergent means they show opposite results, correct?
A. Correct.
Q. So you agree that not -- that there are studies that show that SSRIs are not associated with an increased risk in suicidal behavior?
A. GSK has authored lots of them, yes.
Q. And you said, I think, last week, people are on different sides of this debate, correct?
A. GSK has been on the opposite side to me, definitely.
Q. And but you did not show the jury any of these divergent studies that show no increased risk, correct?
A. I think some of them have come up. The Dunner and Dunbar, the Montgomery and Dunbar. Certainly, studies like this, I've been more than happy -- they represented in article form the data that GSK submitted to FDA complete with placebo run-ins without any asterisks.

Q. They don't conclude that SSRIs cause suicidality?
A. Exactly, they don't. They hide the problem and I think in ways that are very unfortunate.
Q. But you agree with me that there are studies that show SSRIs are not associated with an increased risk of suicidality?
A. I think there's very few that show that they're not associated with an increased risk but having trying to hide the problems. The ones that have been more genuine at least that haven't been trying to hide the problems show an increased risk.

You may say that the risk is not statistically significant, but there is a consistent increase in risk that most of these studies point to.

MR. BAYMAN: Your Honor, I'm getting ready to turn to something else. Do you want me --

THE COURT: Do you want to take a break?

MR. BAYMAN: Yes. I just thought it might be a good time to take a break.

THE COURT: All right. We'll take a break. Ladies and gentlemen, we'll take 10 to 15. Let's see how close we can come to 10.

(Recess from 2:58 p.m. to 3:10 p.m.)