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

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of STEWART DOLIN, Deceased,	)	
Plaintiff,	)	
-vs-	)	Case No. 12 CV 6403
SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, a Pennsylvania corporation,	)	Chicago, Illinois April 5, 2017
Defendant.	)	1:30 p.m.

VOLUME 14-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
Mr. Michael L. Baum
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 Reporter:

CHARLES R. ZANDI, CSR, RPR, FCRR
JUDITH A. WALSH, CSR, RDR, RMR, FCRR, CCP
219 South Dearborn Street, Room 2128
Chicago, Illinois 60604
Telephone: (312) 435-5387
email: Charles_zandi@ilnd.uscourts.gov

APPEARANCES: (Continued)

For the Defendant:

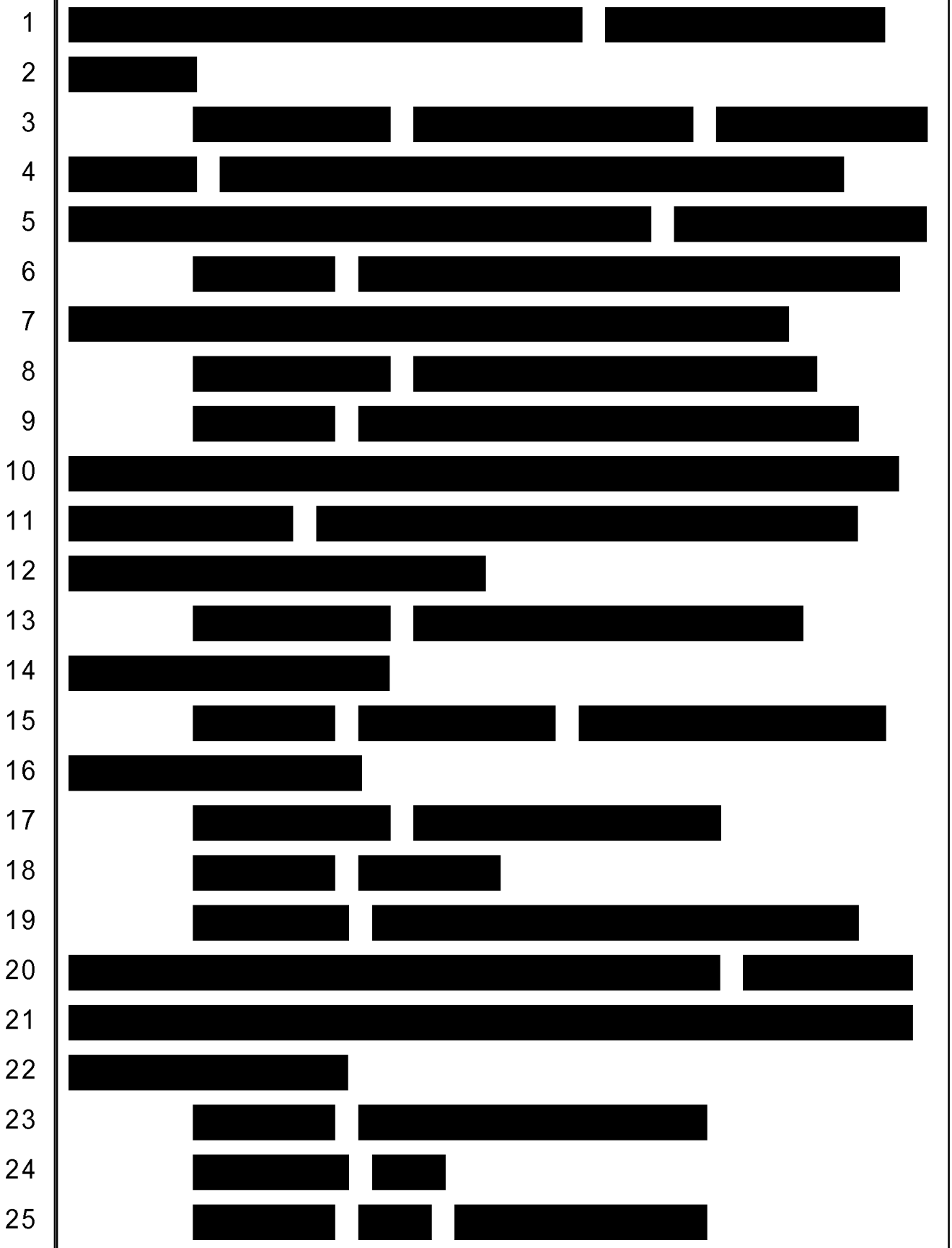
KING & SPALDING
BY: Mr. Todd P. Davis
Mr. Andrew T. Bayman
1180 Peachtree Street, N.E.
Atlanta, Georgia 30309
(404) 572-4600

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 Scott Gilbert
233 South Wacker Drive
Suite 7800
Chicago, Illinois 60606
(312) 876-8000

(Proceedings heard in open court, jury not present:)

[redacted]



(Jury enters courtroom.)

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

You may proceed, sir.

MR. WISNER: Ladies and gentlemen.

ROBERT GIBBONS, DEFENDANT'S WITNESS, PREVIOUSLY SWORN.

CROSS-EXAMINATION (Resumed)

BY MR. WISNER:

Q. Doctor, did you have a chance to review Defendant's Exhibit 25 over lunch?

A. I did, thank you.

Q. Great. Now that you've had a chance to review it, you would agree with me that the six suicides listed here are suicides that occurred during randomized controlled clinical trials, correct?

A. Just to be clear, these six suicides, five of them occurred during active comparator trials that did not have a placebo arm.

Q. Sure. But they were all well-controlled, randomized controlled trials, right?

A. They were randomized controlled trials. They were not randomized placebo-controlled trials.

Q. Now, you stated in your hierarchy of evidence that the highest level of evidence was randomized placebo-controlled trials. Do you see that?

A. I do.
Q. And the reason why you like randomized controlled trials is because it helps eliminate bias, right?
A. Within the context of that trial, yes.
Q. You know that the people who were put into the treatment group or the placebo group --
MR. WISNER: There's some feedback there, so I'm just going to talk loudly, and if that's a problem, let me know.
BY MR. WISNER:
Q. In the placebo -- sorry, in a randomized controlled trial, the patients are assigned randomly and blindly into either a treatment group or control group, right?
A. That's correct.
Q. And sometimes the control group is a placebo control, right?
A. Yes.
Q. And sometimes it's a comparator control, right?
A. Yes.
Q. In both of those circumstances, though, the data collected in those trials are from well-controlled RCTs, right?
A. They're well-controlled RCTs in that they involve randomization. The presentation here is a comparison between the placebo events, which were part of placebo-controlled events, and what is the majority in paroxetine events from active control trials. So, the comparison that you're making

between placebo and paroxetine in this table is inappropriate.
Q. Doctor, I've made no comparisons. I simply asked you, there were six completed suicides in well-controlled trials; yes?
A. There were five controlled -- there were five completed suicides in well-controlled active comparator trials. We don't know how many suicides were in the active comparator arm from this table. And there was one in a placebo-controlled trial for a patient on paroxetine and none on placebo.
Q. Now, you recall the interrogatory response that I read to the jury involved studies 513 and 559, correct?
A. Yes.
Q. Now, if you look down here, there's a paragraph that reads, "In addition to these 18 cases, two patients died in the placebo run-in" -- I'm sorry. It's the paragraph before that. Sorry, Doctor.
"All but two of these 18 cases came from RCTs with an active comparator but no placebo." So, that means of the 18 deaths, 16 were in those active control trials, right?
A. That's correct.
Q. "These two cases" -- and that's referring to the placebo-controlled deaths, right?
A. No. That's referring to -- so, 18 -- so, what this says, which you need to read a few times before you can really figure out what it means, is that all but two of the

18 cases -- the 18 cases are all deaths. This memo is about deaths. It's not a suicide report. It's a memo about deaths.

So, there are a total of 18 deaths. There were 11 non-suicidal deaths on paroxetine, one on placebo, and then suicides, there were six and zero. So, there are total deaths of 17 on paroxetine and one on placebo.

All but two of those were from trials that were randomized but did not contain placebo. There was no chance of dying in those trials on placebo. And --

Q. But my question, Doctor --

A. I'm not finished. I'm sorry.

Q. Oh, sorry.

A. And one of those patients was taking paroxetine, committed suicide.

So, essentially what we have here from the placebo-controlled trials, we have one suicide on paroxetine and none in placebo.

Q. That actually was my question. I wasn't trying to mislead you. Of the two deaths, two of them occurred in placebo-controlled trials, right?

A. That's correct.

Q. Okay. And of those two deaths in the placebo-controlled trials, only one was a suicide, right?

A. Correct.

Q. And that suicide was in a patient taking Paxil, right?

A. That's correct.
Q. You see right here, it says, "These two cases came from study 813." Do you see that?
MR. BAYMAN: 083.
BY MR. WISNER:
Q. Sorry, come from study 083. Forgive me.
A. Yes, I see that.
Q. So, this is yet another study, placebo-controlled, where a patient committed suicide while taking Paxil, correct?
A. Yes.
Q. Now, in your analysis of the MDD trials, you had zero suicides, right?
A. I had zero suicides from the placebo-controlled trials that met the specification for inclusion in the FDA meta-analysis. So, I don't know whether or not that 083 study was actually one of those studies that met that criteria.
Q. Well, we know, because that suicide, the one from 513, and the one from 559, didn't make it into the study because you never saw it, right?
A. So, in the FDA analysis, there was one patient on paroxetine that committed suicide and zero on placebo. I'm not certain that's the same patient that we're referring to here.
Q. I can help you out there, Doctor. These are all depression trials. Do you see that?

A. I do.
Q. So, the one that you're talking about occurred in a social anxiety disorder trial, correct?
A. I recall that, yes.
Q. So, it couldn't be that one.
A. Again, I -- you know, I don't have the details exactly of -- of which trial that particular patient came from. All that I have are the data that I relied upon, which were the final data that were a part of the GSK 2006 study and also the FDA trial.
Q. Now, if you go to the next table, Doctor -- you had a chance to look at that as well, right?
A. Yes.
Q. Now, this is a table that reflects the deaths that occurred in locally-funded clinical trials, right?
A. These are the deaths that are described as -- trials that were not in the central database, whatever that means. I'm not sure that means that they were locally funded or what, but they were not part of the central -- that's how they're described in the memo.
Q. Okay. And if you look at the number of deaths here, we have five completed suicides on paroxetine IR. Do you see that?
A. I do.
Q. And this is referring again to well-controlled RCTs;

however, we're not sure how many of them are active- versus placebo-controlled, right?
A. Right. Unlike the previous table where there was a breakdown of only two of the 18, for this trial, there is no breakdown. We don't really know what kind of trials these were.
Q. But it would be fair to say that there were five completed suicides with patients on Paxil in these clinical trials that were not in GSK's central database, right?
A. It would be fair to say that the number reported here, assuming it's accurate, is that there were five suicides among randomized clinical trials, not necessarily randomized placebo-controlled trials.

What would not be fair to draw an inference about is the difference between 5 and 1. So, these have to be restricted to placebo-controlled trials.
Q. I'm not going there. I'm just talking about the suicides for now.

Now, there is a way for us to figure out, at least we think, how many suicides in these trials were placebo-controlled. Let me show you.

If you go to attachment 2, and you see the first part of the attachment has the listing of deaths occurring on drug within 30 days of last dose of double-blind paroxetine or placebo in depression trials. Do you see that?

A. I see the title, yes.
Q. Okay. And if you go to the next page, this is the same results, but this is for the ones that weren't in the central database, correct?
A. It's a little hard to see it on the screen, but --
Q. I'm sorry. I thought when you reviewed it, I thought you would notice that. But do you see that this is -- do you see it now, Doctor?
A. Yes. I don't see where -- oh, cases from the non-central database are --
Q. Yeah.
A. These are all listed there as from non-central -- yes, I see that.
Q. Okay. Great. So, if we go into here and we look at the actual study numbers, you've got 559 and 513, don't we?
A. Yes.
Q. And as I read to the jury a minute ago, those are placebo-controlled trials?
A. These -- again, I don't remember the details of those two particular trials.
Q. Well, I'm saying I read this to the jury a minute ago. Do you recall that?
A. Oh, from -- from this --
Q. It's not in there, Doctor. I read to the jury an interrogatory response; and it said for 513, "It is believed

that study 513 was placebo-controlled," and for 559, "Local study 559 was placebo-controlled."

So, according to what I've read to the jury, these two studies are placebo-controlled, correct?

A. Local studies, investigator-initiated, believed to be placebo-controlled. I don't know anything about the experimental design, the length of treatment, the length of follow-up, whether or not these would -- you know, when the events occurred, none of that information.

Q. You don't know --

A. All that I know that GSK did was to provide the pills.

Q. Isn't it true, Doctor, that you don't know because GSK has never told you what those studies were about?

A. I do know that the -- in FDA's meta-analysis, those studies were not included.

Q. Okay. So, it looks like we've got three completed suicides in placebo-controlled trials for major depressive disorder that GSK knew about, they put it in their report, that never made it into the 2006 analysis that you testified to this jury about, correct?

A. That's because the 2006 analysis included all of the GSK studies, not investigator-sponsored or initiated studies that we have no idea of the quality of those studies.

Q. Let's cut to the chase, Doctor. Not a single one of these 11 suicides in these well-controlled trials, whether they be

active or placebo, were considered in the 2006 analysis that you discussed, correct?

MR. DAVIS: Excuse me, your Honor. I think Mr. Wisner misspoke. He said 11. I don't know where the 11 comes from.

BY MR. WISNER:

Q. If you add six plus five, you get 11, right, Doctor? There's five, and there's six, so that's 11, right, Doctor?

MR. DAVIS: I would object because it misstates and mischaracterizes the submission, your Honor.

THE COURT: Overruled. Proceed. You can take that up on redirect.

BY MR. RAPOPORT:

Q. I've got a calculator, Doctor. Do you need a calculator?

A. No.

Q. Okay. So, there was 11 suicides in the clinical trials reflected in this report, correct?

A. There were 11 suicides, but those suicides would not have been included in any rigorous statistical analysis comparing the rate of suicide between Paxil, paroxetine, and placebo because the majority of those events occurred in studies that didn't even have placebo in it.

So, the -- they would not be -- they should not have been included by GSK in their analysis, and FDA would not have included them in FDA's analysis, and did not include them

specifically.
Q. So, to be clear, which is the question I asked earlier before the objection, so I want to get an answer now.
Of the 11 suicides that occurred in GSK or GSK-sponsored clinical trials that were well controlled that GSK knew about, not a single one of them were considered in GSK's 2006 analysis, correct?
A. I don't know the answer to that, with the specification of the one subject that did.
Q. None of these 11 suicides were considered in the FDA's 2006 analysis, correct?
A. It would be wrong to have included them.
Q. So, it's your testimony to this jury that considering completed suicides in well-controlled clinical trials in a study evaluating suicide is wrong?
A. Yes.
Q. All right.
A. It's wrong because the --
THE COURT: Doctor, your counsel will bring that out.
THE WITNESS: I'm sorry.
BY MR. WISNER:
Q. All right. While we're on the death report, let's -- do you mind if I call it the death report? Because you said it was a death memo. Is death report fine?
A. Fine.

Q. While we're on this death report, let's look at the -- let's look at what ages these guys were.

So, we've got the first suicide here, do you see that, male, 50 years old?

A. Yes.

Q. We've got another suicide, female, 42. Do you see that?

A. Yes.

Q. We have the 18-year-old suicide. Do you see that?

A. Yes.

Q. We actually saw that one earlier, didn't we, when we were looking at the NDA data?

A. I believe so.

Q. We have a 66-year-old committing suicide. Do you see that?

A. Yes.

Q. And then we've got a suicide by hanging in a 58-year-old female. Do you see that?

A. I do.

Q. Do you know the circumstances behind that suicide, by any chance?

A. No.

Q. All right. And then down here, we actually have two suicides, do you see that, in placebo run-in?

A. Yes.

Q. Now, placebo run-in, those are the suicides that were

counted in the original suicide submission by GSK in 1991, correct?
A. I believe so, yes. They were identified as placebo run-in.
Q. And if we go down to the next page, this is from the non-centrally-funded database, right, Doctor?
A. Yes.
Q. And we've got suicide by drowning, do you see that, female, 63 years old?
A. I do.
Q. We have another suicide, 46-year-old female. Do you see that?
A. Yes.
Q. We have another suicide, 32-year-old female. Do you see that?
A. Yes.
Q. We have another suicide, 31-year-old female. Do you see that?
A. I do.
Q. And below that, we have a 46-year-old male suicide. Do you see that?
A. Yes.
Q. We just went through all the 11 suicides, what their age is. All but one were over 30, correct?
A. Yes. But that doesn't matter at all.

Q. Okay. All right, Doctor. Let's get into -- let's get into the -- well, let's go back to the NDA. Now, a second ago, we were looking at the NDA that was submitted in 1989, right?
A. Yes.
Q. And that was Plaintiff's Exhibit -- I believe it was Plaintiff's Exhibit 75, right?
A. Yes.
MR. WISNER: Permission to publish, your Honor.
THE COURT: Proceed.
BY MR. WISNER:
Q. All right. So, this is the NDA submission that was sent to GSK. Now, Doctor, I just want to be clear. You know that they reported in all of GSK's clinical trials, all, open-label, uncontrolled, everything, that there were 42 suicide attempts, right?
A. I believe that's correct.
Q. All right. I was going through this document just last night, and I came to this table right here. It says, "Comparison of adverse experiences listed by preferred term within body system, intent to treat population, worldwide data, events reported in at least 1 percent of paroxetine patients."
Do you see that, Doctor?
A. I do.

Q. Now, my understanding is that the number of suicide attempts, based on the N of 2,963, was about 1.3 percent, right?
A. That's a percentage. That's not a number. You said it's 1.3. You said the number is 1.3 percent. That's not a number.
Q. Pardon me. The percentage was 1.3, correct?
A. That's based on what number?
Q. Okay. Well, let's just look at the document.
Okay. I'm trying to find that document, the table. Here we go.
All right, so, the suicide attempts -- here we go. Here we go. This is the chart. Do you recognize this table, Doctor? It's on your screen. It's a table.
A. I see it.
Q. Okay. And you see here the 42 out of 2,963?
A. I see that.
Q. Okay. And it has 1.4 percent, right?
A. Um-hum, yes.
Q. That 1.4 percent is 42 divided by 2,963, right?
A. Correct.
Q. So, in all the entire clinical database that they had at the time, of all the people randomized or given placebo -- sorry, given Paxil in some capacity, about 1.4 percent attempted suicide, right?

A. Yes.
Q. Okay. And the jury's already seen this part here about the 3 and the 2. Okay? So, we're not going to get into the wash-ins and wash-outs right now. We're just going to focus on, for now, this number right here. Okay, Doctor?
A. Yes.
Q. Okay. Let's go back to that table that we were at a second ago. And this purports to list out all the adverse events that occurred at 1 percent or greater, right?
A. Yes.
Q. Now, Doctor, I'm going to blow up this list right there. Do you see any mention of suicide attempt?
A. Not in this list.
Q. Now, there was 42 events, right?
A. Yes.
Q. Do you know what emotional lability is?
A. Yes.
Q. What is that?
A. It's variation in mood.
Q. It's not trying to kill yourself, right?
A. No.
Q. All right. Let's move on to the 2006 analysis conducted by GSK. Okay, Doctor?
Now, you understand that this analysis arose because the FDA wanted to review the adult suicide risk as it relates

to SSRIs generally, right?
A. I don't know that's how it arose, but I know those same data were submitted to the FDA that became part of their -- their meta-analysis. I don't know if that was the sole purpose of GSK doing this. I don't know what their purpose was.
Q. Yesterday, you went through the instructions given to the manufacturers for the data they were supposed to submit, right?
A. Yes.
Q. And they asked for just placebo-controlled clinical trial data, right?
A. Correct.
Q. And they did that because in a meta-analysis, it's very difficult to compare drugs to other drugs when you don't have a controlled comparator like placebo, right?
A. They did that because it's the appropriate thing to do scientifically.
Q. I'm sorry. That wasn't really my question. It's really difficult to compare drugs when you don't have a common denominator amongst those drugs, right?
A. I don't understand your question.
Q. That's fine. Let me get to another just point, then.
Doctor, all of the data, the suicide attempts, the suicides, in non-controlled and uncontrolled data, that was

all submitted to the FDA at some point, right?
A. Yes.
Q. But in their 2006 analysis, they looked -- they didn't look at any active-controlled trials, right?
A. Correct.
Q. They didn't look at any open label trials, right?
A. Correct.
Q. They didn't look at any observation studies, correct?
A. Correct.
Q. So, they excluded all of that data and just focused in on placebo-controlled trials, right?
A. Yes, appropriately so.
Q. Appropriately so. And in so doing, they actually got rid of all but one completed suicide in the clinical trials, right?
A. They didn't get rid of the suicides. They were not a part of the placebo-controlled randomized clinical trials.
Q. Fair enough. They ignored them?
A. They didn't involve that analysis because the analysis was defined in terms of the highest-quality data, which were the placebo-controlled RCTs.
Q. They ignored them?
A. They didn't ignore them. They --
Q. Well, they didn't count them, Doctor, did they?
A. They wouldn't be counted because they were not a part of

randomized placebo-controlled RCTs, just as the FDA specifically instructed them not to submit those data as a part of FDA's meta-analysis because they did not want to look at a lower-quality data that could be biased by the fact of not having a placebo control.

Q. So, those 11 people who died in GSK's clinical trials while taking Paxil, they never got counted?

A. You've already showed me that in these tables, there were a similar number of patients who died by suicide in active comparators, other drugs that are not even in the class of SSRIs, very similar rate. I -- it has nothing to do with placebo-controlled trials.

Q. All right. Let's have you turn in your binder to Plaintiff's Exhibit 9. Let me know when you're there, Doctor.

A. I'm there.

Q. What is Plaintiff's Exhibit 9?

A. This looks like a letter to Dr. Laughren.

MR. WISNER: Permission to publish, your Honor. It's already in evidence.

THE COURT: You may proceed.

BY MR. WISNER:

Q. So, this is a letter to Dr. Laughren, and it's from GSK, correct?

A. Yes.

Q. Do you see that up in the corner, GSK?

A. Yes.
Q. Dr. Laughren, he's your friend Tom, right?
A. I'm not sure I would call him my friend, but I certainly have worked with him in the past.
Q. Fair enough. Now, if you go to the letter, there's a section right here that says, "General conclusions of the comprehensive analysis revealed the following." Do you see that?
A. Yes.
Q. And this was the analysis sent by GSK to the FDA that GSK's own analysis had shown, right?
A. Yes.
Q. All right. Let's go to the second bullet point -- sorry, second bullet point on the second page. It reads, "In adults with MDD, all ages, there was a statistically significant increase in the frequency of suicidal behavior in patients treated with paroxetine compared with placebo."

Do you see that?

A. Yes, I do see it.
Q. You think that sentence is incorrect, correct?
A. No, I don't think it's incorrect. I think it states that the confidence interval on that 6.7 odds ratio was -- did not include the value 1. Taken all by itself in isolation, it was statistically significant.

It's a valid statement. I don't believe that it

indicates that paroxetine is the cause of an increased risk in suicide among -- in suicidal behavior among patients with MDD, all ages.
Q. I'm sorry. You said in isolation. Where does it say that in that paragraph?
A. I'm telling you what I think it is. You asked me what I thought it was. You asked me if I agreed with it, and I'm telling you what I agree with and what I don't agree with.
Q. Well, you mentioned isolation, confidence intervals, and all sorts of stuff. None of that's in that paragraph, right?
A. Well, statistically significant is all about confidence intervals, and statistically significant is all about the number of comparisons that you're doing. If you do lots of comparisons, that 5 percent level is no longer a 5 percent level. It's inflated because of the multiple comparisons.
Q. Let me ask you this question, and let's not look at this until after my question, until you answer my question. Okay?
My question is: In your opinion, do you believe that in adults with MDD, all ages, that there was a statistically significant increase in the frequency of suicidal behavior in patients treated with paroxetine compared to placebo?
A. Among these randomized placebo-controlled trials in this subgroup, yes.
Q. So, you agree with this statement, there was an increased association, right here?

A. Well, I agree with the comment based on the original analysis. As I've testified, I've reanalyzed these data using more modern methods, and it's no longer statistically significant.

So, I don't agree that there's a statistically significant association. That doesn't mean that I don't agree that if you simply look at the frequency, there are more subjects in this particular subgroup on treatment than placebo.

Q. I'm confused. Do you think there's a statistically significant association or do you not? Where do you stand, Doctor?

A. I do not think there's a statistically significant association.

Q. Great. You do not think there is. It says right here that there was, so you disagree with that sentence, right?

A. I disagree with the conclusion because I've reanalyzed the data using better statistical methods that didn't have to throw away the majority of the data, and I find that it's no longer statistically significant. The analysis that they had at the time was statistically significant. A better analysis is not.

Q. The better analysis you're talking about is the one you did after they hired you?

A. It's the one that I did. I would have done it the same

way whether they had hired me or not.
Q. So, to be clear, they say there's a risk or association or a -- strike that.
They say there was a statistically significant increase. You get the same data, do some stuff to it, and so, "Well, there's actually no risk there," is that right?
A. No. What I said is it's no longer statistically significant. I don't think there was a risk in the first place because this is one of about 90 subgroup analyses that were performed, so I don't think that that is a drug safety signal for paroxetine.
And I also think that the statement is factual, given the statistical methods they had available to them at the time. And I think that the -- but a better analysis shows that it's not statistically significant.
But it's the smallest point. As I've testified, there are numerous reasons to not believe that this is an effect of Paxil. The major one is that it's inconsistent with the other findings and that the -- what's producing it is an unusually low rate in the placebo group and not a high rate in the Paxil group.
Q. Now, Doctor, I want to back up a second. You said a lot of things there. I just want to unpack some of it.
The first thing was there was over 90 analyses done. Do you remember saying that?

A. Yes.
Q. You said that on direct several times, right?
A. Yes.
Q. Were there 90 different analyses done on whether or not there was a statistically significant increase of suicidal behavior in MDD patients of adults of all ages?
A. That's already one of the 90 analyses. That's the subgroup that is a part of that multiple comparison. You can't simply take that out of isolation and say, "How many were there?"

For that particular subgroup, we know that there were analyses done on a primary end point and on a secondary end point, so there were at least two there; but then there were 15 different indications and three different age groups, so there were at least 90 and probably far more.

Q. Sure. And all of those 90, all of those 90 that you talked about, one of them looked at MDD, suicidal behavior, and adults of all ages, correct?
A. Correct.
Q. And it had a statistically significant 6.7 times increased risk, right?
A. Incorrect.
Q. Okay. You understand that this analysis that we're looking at right here -- I mean, this sentence was written by GSK. This analysis didn't include any suicides, right?

A. That's correct.
Q. It also goes on to say that, "The majority of these attempts for paroxetine, eight of 11, were in younger adults aged 18 through 30."
Do you see that?
A. I do.
Q. And it goes, "These MDD data suggest that the higher frequency observed in younger adult population across psychiatric disorders may extend beyond the age of 24."
Do you see that?
A. I do.
Q. So, GSK is stating here that just based on the MDD data, they're concerned the risk might extend for all psychiatric disorders beyond the age of 24, right?
A. They're positing that. They made that statement.
Q. And, in fact, isn't it true that Dr. Kraus, who helped prepare this analysis, has testified that that was confirmed and, in fact, consistent with the FDA's analysis of an increased risk for adults of all ages across all psychiatric disorders?
A. The -- the analysis that I believe you're referring to is the paroxetine analysis overall that shows the statistically significant effect in FDA's analysis, which they discounted due to the fact that there were a very large number of analyses. And they indicated that, "We saw a few

drug-specific differences that were statistically significant, but given the large number of analyses, we discount it."

Q. All right. Let's back up here. You said because there's a large number of analyses, they discounted them, is that right?

A. Yes.

Q. This is called multiple comparisons in statistical parlance, right?

A. Yes.

Q. It's the idea that if you conduct a bunch of different analyses, there's a chance that one or a couple of them might just happen to randomly be statistically significant, right?

A. By chance alone, yes.

Q. Right. And so you've got to be careful when you're doing so many things that you're getting consistently statistically significant results, right?

A. That's one way to judge whether or not the effect that you're seeing is real or not.

Q. I'm going to show you Joint Exhibit 13. It's been shown to the jury many a times. And I'm sure you have seen this chart that is chart -- table 16, and it relates specifically -- I'll just call it out here.

This is definitive suicidal behavior or worse, so preparation or worse, adults with all the psychiatric disorders, by drug and drug class. Do you see that?

A. I do.
Q. And here, we have the number the jury's seen a couple of times, paroxetine, 2.76, right?
A. I see that.
Q. And of all of the -- all of the drugs here of the SSRIs, at least, it's the only one with a confidence interval above 1, right?
A. That's correct.
Q. And interestingly enough, the upper end of that confidence interval is 6.6, isn't it?
A. Yes.
Q. All right. So, to be clear, your testimony is you'd want to see consistently -- consistently results like this, right?
A. Well, consistency would be I'd like to see the same result, for example, for suicidal ideation, the primary end point.
Q. Now, I want to back up there. You testified before under oath, Doctor, that ideation is a bad metric for looking at completed suicide, isn't that true?
A. First of all, the primary metric included suicidal ideation and behavior.
Q. That's not my question. My question is to this jury, you have previously stated under oath, penalty of perjury --
MR. DAVIS: Your Honor, I believe that's an improper impeachment. He can ask the question. If the witness

disagrees, he can then confront with the deposition.

THE COURT: Overruled. Proceed.

BY MR. RAPOPORT:

Q. You stated under penalty of perjury that looking at ideation, it has not been established that ideation is associated with completed suicide?

A. Number one, we're not looking just at ideation here. We're looking at --

THE COURT: Answer the question, sir.

THE WITNESS: I --

THE COURT: Answer the question, sir. You can explain it, but answer it.

BY THE WITNESS:

A. No, I don't recall testifying that ideation is unrelated.

MR. WISNER: May I approach?

THE COURT: Yes.

BY MR. WISNER:

Q. I'm handing you Plaintiff's Exhibit 325, Doctor. Do you see this document?

A. Yes.

Q. It's a report -- it's a declaration written by you, correct?

A. Yes.

Q. In the Nuerontin litigation?

A. Yes.

Q. Turn to the last-back of the page. That's your John Hancock right there, right?
A. Yes.
Q. This is before you ever worked for GSK, right?
A. I believe so.
Q. And it states just above your signature, "I declare under penalty of perjury, under the laws of the United States of America, that the opinions set forth in this document are my opinions to a reasonable degree of medical and scientific certainty and are true and correct."
You wrote that, right?
A. Yes.
Q. Turn to page 7, opinion No. 4. It reads, "The plaintiff's lawyers and experts take the position that the FDA alert provides support for their conclusion that gabapentin causes suicide."
Now, gabapentin, that's Nuerontin, right?
A. Yes.
Q. "I disagree with this position for the following reasons:
"No. 1, the FDA alert is based primarily on suicidal ideation, not completed suicide. The relationship between suicidal ideation and completion has not been established."
Did I read that right, Doctor?
A. Yes.
MR. WISNER: May I approach to retrieve?

BY MR. WISNER:
Q. The FDA's primary analysis involved ideation as well as behavior, correct?
A. Correct.
Q. The secondary analysis, the one up on the screen, that's just behavior, right?
A. Correct.
Q. And that shows a 2.76 elevated risk that's statistically significant for Paxil, correct?
A. Correct.
Q. Now, let's see if we can find some more of these consistently statistically significant results.
Sorry, the machine is not acting well right now. I've got to reboot it. Give me one second.
All right. So, we're back to Exhibit -- Joint Exhibit 13. All right. Let's look at table 24. Do you see this table, Doctor?
A. Yes.
Q. Do you see all the SSRIs listed?
A. Yes.
Q. Paroxetine, statistically significant?
A. Yes.
Q. Only one?
A. With an odds ratio quite similar to the others.
Q. And it's the only one of the SSRIs, correct, that has an

odds ratio -- has a confidence interval above 1?
A. Very consistent with the other drugs. The appropriate analysis to determine whether or not paroxetine is unusual with regard to its relationship with suicidal ideation or worse is to look for an interaction.

Is there -- saying that one result is different than the other simply because its confidence interval doesn't include 1 is not a sufficient way to determine whether or not there is a real effect that's unique to paroxetine.

We see very, very similar effects for all of the drugs here, except perhaps for sertraline, which is in the opposite direction; and the FDA commented on that in their analysis.

Q. So, my question was: Paxil, again, is the only one with a confidence interval above 1, correct?
A. In this particular analysis, for this particular age group, yes, it's the only one.
Q. Just like in the last table we looked at, it was the only one with a confidence interval that was above 1, correct?
A. That's due in large part to the large number of Paxil patients, and the larger the number of Paxil patients, the tighter the confidence interval.
Q. Let's see if we have more consistency, Doctor.

Again, looking at another chart, I see Paxil again, and I see a confidence interval above 1. Don't you?

A. I do.
Q. Okay. So, it's your testimony to this jury that the 6.7 increased risk in MDD for adults of all ages, the FDA's 2.76 increased risk, again for behavior, again, ages over 18, and the rest of these statistically significant results for Paxil, they're all, I think you said, anomalous, is that right?
A. Yes. They're the same result that's driving those two analyses.
Q. Same result. And this is from a database that didn't have a single completed suicide in the Paxil MDD arm, correct?
A. That's correct.
Q. You are aware that Dr. Kraus and Dr. Carpenter published a paper. It was published in 2011, right?
A. I don't remember the year, but I know they published a paper.
Q. You know the paper I'm talking about, right?
A. I do.
Q. And in that paper, there was a chart -- in fact, you discussed this on direct. Why don't we turn to it. It's Plaintiff's Exhibit 285. Let me know when you're there, Doctor.
A. I'm there.
Q. Okay. That's the paper we're talking about, right?
A. Yes.

Q. Okay. Great. And if we -- if we go down into the chart --

MR. WISNER: Well, I'm going to publish it, your Honor. Is that okay?

BY MR. WISNER:

Q. And if we go down into the chart, we have this analysis that's broken down by age groups. Do you see this? Table 6. This is actually what you discussed with the jury yesterday. Do you recall that? I have it popped up now.

A. Yes.

Q. Okay. This is actually the same data from GSK's analysis, right?

A. Yes.

Q. And what they've done here --

A. Their 2006 analysis.

Q. Yeah, exactly, the 2006 analysis, so this is the same data, right?

And if you look here, they've broken it down by all indications, all depression, MDD, IBD, all non-depression. Do you see that?

A. Yes.

Q. And they've done that by 18 to 24 and 24 through 64, right?

A. Yes.

Q. And if you look on the right side of the column, which is

definitive suicidal behavior alone, there is an entry for MDD. Do you see that?
A. Yes.
Q. And that has the 8-to-0 number that we looked at earlier, right?
A. Yes.
Q. Now, it says there that the risk ratio -- the odds ratio is infinity, right?
A. The upper bound -- yes.
Q. Obviously, it's not meant -- meaning that the risk is unlimited; it just means we don't know because there's a 0 in the placebo arm, right?
A. It's undefined.
Q. Now, you understand you can do a continuity correction, right?
A. Yes.
Q. And you did one, right?
A. Yes.
Q. I believe you said you believe it was 9-something and said 9.8 or something like that, is that right?
A. Yes, that's my memory.
Q. It's a near tenfold increase, correct?
A. Yes.
Q. When my colleague presented that fact to you in your deposition, you stated that you didn't care about that number,

didn't you?
A. I don't recall exactly, but that -- I'll accept that if that accurately portrays my deposition.
Q. Is it fair to say in addition to not caring about this tenfold increase, 9.8, sorry, you don't care about the 11 suicides that happened in non-placebo-controlled trials, right?
MR. DAVIS: Objection. Argumentative.
THE COURT: Overruled.
BY THE WITNESS:
A. I care about all suicides. I don't think suicides that occur in open label studies without the benefit of randomization and control are meaningful. I don't think that this result that we're looking at for MDD, the 8 versus 0, is statistically significant. And I think it's an anomaly that is exactly the same anomaly as the 11-versus-1 that we keep seeing. And it's that anomaly that is driving the overall result in FDA's analysis.
So, it's not as if this is an independent replication of this effect. It's the same thing. It's this one subgroup that has this anomalous result produced by an unusually low level in the placebo group. I think it's very straightforward.
BY MR. WISNER:
Q. I know. In this subgroup of adults 24 to 65, who have

major depressive disorder, there seems to be this clear statistically significant association, doesn't it, Doctor?
A. I don't see anything clear about it. If you look at the line above it for all depression, which is a lot like major depressive disorder, it's now in the direction of a 40 percent decrease in the rate of suicidal behavior that is on the verge of being statistically significant. The upper bound is 1.0.

So, it makes no sense that there would be a real finding, a real increase, a real risk in people with major depressive disorder but not in people with depression.
Q. You're a statistician, so you've probably heard of the phrase "data dredging," right?
A. Yes.
Q. How do you define data dredging?
A. Data dredging is doing analysis after analysis after analysis, in some cases subgroup analyses, until something becomes statistically significant and then reporting that statistically significant thing without the benefit of telling people that you did 100 different analyses to find that result.
Q. What about having one statistically significant analysis and then doing analysis after analysis after analysis to drown that one out?
A. That's not what was done here.
Q. I didn't ask you if that was done. I asked if that would

be a definition of data dredging.
A. No, I don't believe so.
Q. So, it's only when you're trying to find the result, not the other way around, Doctor?
A. Data dredging is about doing multiple analyses. Subgroup analyses in a particular subgroup like MDD is a different thing.
Q. All right, Doctor. Let's talk for a quick second about confidence intervals. Now, a confidence interval is one way that you as a statistician decide if something is the product of chance or not, right?
A. It's one of the ways. It allows us to look at the plausible range of estimates.
Q. All right. We're at 335 at this point. I'm going to write, "confidence interval." Apologize for the terrible handwriting. And let's do a spectrum here. Okay, Doctor? You have on the end here 0. Confidence intervals can't go below 0, right?
A. Well, they can, but not confidence intervals for an odds ratio.
Q. Precisely. And then we have over here, I'll just put 50. And you'll see why in a second, Doctor.
All right. So, you redid the 2006 analysis, right?
A. Correct.
Q. And that yielded a point estimate of 6.3, right?

A. Correct.
Q. So, I'm going to put on here 1, because that's important, and then I'm going to put in your 6.3. I'm not sure if this is exactly to scale, but I think it communicates the point.
Now, the confidence interval that you -- that you created for your modern analysis was .8 to 48.95, right?
A. That sounds right.
Q. All right. So, we'll do it from here to there, and now we'll do .8 and 48.95.
All right. So, Doctor, the way confidence intervals work -- and this is at the 95 percent level, right?
A. Correct.
Q. So, this is basically saying that based on the data that you show, the likelihood of the actual risk, whatever it is, if -- we would assume 95 percent of the time it would fall between .8 and 49; is that fair?
A. No.
Q. Okay. Why don't you explain it. Please explain it.
A. So, a confidence interval is saying 95 percent of the time, the true value is going to fall within the interval, not that the true value here is between .8 and 48.95. 95 percent of the time, the confidence interval will include it, whatever it is. It could be -- it's going to vary widely from study to study to study.
So, that's what a confidence interval is telling you.

It's not containing the truth. It's saying 95 percent of the time, the width of the confidence interval will, in fact, contain the true value.

Q. Now, the true value, the likelihood that it is .8, right, which would be a 20 percent decrease in risk, right?

A. Yes.

Q. The likelihood it has a 20 percent decrease in risk is just as likely as it having a 4,895 percent increase, right?

A. Well, I wouldn't describe it in that way. I think this confidence interval is simply telling us that there's tremendous uncertainty in this. And why is there uncertainty? We have a small number of events, and we have a relatively small sample size. So, we can't have a lot of confidence in whatever this estimate is, and that's what I think your picture is telling us from a statistical perspective.

Q. I didn't ask you that question, Doctor. I'll try it again.

The likelihood that it had a 20 percent protective effect, based on this confidence interval, is just as likely as it having a 48.95 increased risk, right? That's what that means?

A. Assuming the uncertainty is constant throughout this range.

Q. Okay. And so then as we decrease the confidence level, right, so we go from 95 down to 90 down to 80 down to 85 -- or

85 down to 80, as we do that, this confidence interval starts to shrink, right, and it converges on 6.3?
A. Yes.
Q. That's what's called the midpoint, right?
A. It's our estimate, yes, our point estimate.
Q. Our point estimate, 6.3. That is actually the best estimate that we have for what the data actually shows?
A. Well, I think these data show that there is no best estimate, and it is the point estimate for the confidence interval, so it is the --
Q. Let's do this by trial and error, then, Doctor. Based on your confidence interval, is the risk more likely 6.3 or 48?
A. I think this confidence interval shows that we have no idea what the risk is. In terms of the observed data, the 11 and 1, just the observed data have a risk that is going to be large. It's going to be increased.

I -- you know, in my reanalysis of these data, I didn't say, "Oh, well, my analysis says it's no longer statistically significant, so it's not important." It's something that we have to look at. It's a big number. The point estimate is 6.3.

And in my testimony, I've explained exactly why that estimate is 6.3. It's because the placebo group is really, really low in terms of suicide attempts, unusually low relative to all of FDA's other data. It's not that Paxil is

high.
Q. Well, the suicide completions are also unusually low, right, Doctor?
A. I don't know the answer to that. I mean, we have very few events in the entire FDA database to be able to do any meaningful analysis on suicide completions.
Q. I showed you 11 completed suicides. None of them made it in there, right?
A. You showed me completed suicides that did not have the benefit of a placebo arm. What you showed me --
Q. So they don't count?
A. No, they do count. They count for comparison to active comparators, other drugs, other classes of drugs that have nothing to do with SSRIs; and they show a very similar pattern.
Q. Does this confidence interval get above 1 when you decrease this to 80 percent?
A. I haven't done that computation. I imagine it would.
Q. So, I mean, when you decide the confidence interval that you care about, you use the convention of 95 percent, right?
A. Well, the convention of 95 percent was prespecified in all of these studies. In the statistical analysis plan, a 5 percent type 1 error rate, 5 percent, or 95 percent confidence, was prespecified in these studies.
Again, this confidence interval is the result of

multiple comparisons that we would have to adjust for. If we were doing a genetic study and we wanted to find out whether or not a gene was related to the likelihood of suicide and we looked at 10,000 genes, geneticists would adjust for the fact that they looked at 10,000 genes and not just declare that this one gene was responsible for suicide.

The same thing applies here. This is one of about 15 different diagnostic subgroups that have been evaluated for three different time points for two different end points, one of which is primary and one of which is secondary; and you're focusing on the secondary end point in one of those 14 or 15 subgroups. So, I don't know how else to say it.

MR. WISNER: Would you please read back my question.

(Record read.)

BY THE WITNESS:

A. So, the answer is you use that for the primary end point of a particular study. In --

BY MR. WISNER:

Q. Is that a yes, Doctor?

MR. DAVIS: Your Honor, can we take down the volume and the argument?

MR. WISNER: Could he answer the question, your Honor?

THE COURT: Proceed.

BY MR. WISNER:

Q. Is that a yes, Doctor?
A. Repeat the question.
(Record read.)
BY THE WITNESS:
A. You use the convention of 95 percent for the primary end point for a single analysis, yes.
BY MR. WISNER:
Q. Okay. Great. Now, you could have used -- if you wanted to, you could have constructed an 80 percent confidence interval, right?
A. That would be very non-standard.
Q. But you could, right?
A. You could have computed any confidence interval.
Q. You could have computed a confidence interval of 51 percent, just a little bit over 50 percent, couldn't you?
A. The statistical computation could be done. It's not something that I would have done.
Q. And it would be fair to say that even if you used the 51 percent, right, you'd say that it would probably be statistically significant under a 50 percent confidence interval, right?
A. Well, it would certainly not include 1.
Q. All right.
MR. WISNER: Court's indulgence, your Honor?
BY MR. WISNER:

Q. Doctor, the 2006 analysis, the three placebo-controlled suicides that we talked about on Paxil weren't included in that, right?

MR. DAVIS: Objection, your Honor. I believe this has already been covered.

THE COURT: You may proceed.

BY THE WITNESS:

A. No.

BY MR. WISNER:

Q. And, in fact, the FDA specifically requested that GSK submit every suicide event from its placebo-controlled trials, right?

A. The FDA worked with GSK to review all of the trials that were used to extract suicidal events and didn't simply rely on what GSK submitted to them.

Q. All right. Doctor, I'm going to try to see if we can do a simple calculation because you're a statistician. You keep talking about placebo-controlled trials. Let's see if we can look at everything for one second. Okay?

So, I'd like you to tell me the total number of suicides that occurred in every single Paxil clinical trial, period, by people taking Paxil, sorry.

A. By people taking Paxil as a part of the database? I think -- isn't that the number, the 42 number that you were showing me before? Is that the number?

Q. No, Doctor. I'll ask you the question again.

As we stand here today, do you know the total number of patients in all of GSK's clinical trials, the open label, the placebo-controlled, the active-controlled, who got Paxil and killed themselves?

A. I don't know that exact number sitting here right now.

Q. What are the total number of suicide attempts by people taking Paxil in all of the Paxil clinical trials? The total number, what's the number?

A. I don't recall sitting here right now.

Q. Did you ever know, Doctor?

A. At some point, I probably reviewed all of these. I wouldn't have looked at the uncontrolled trials, but they -- where those data were available, I reviewed them.

Q. This should be an easy one, then. What are the total number of patients studied with Paxil by GSK?

A. I'd have to go back and take a look at the tables to do that. That involves tables that included uncontrolled studies that I would not have used in forming my opinions.

Q. So, to be clear, you came to an opinion and told this jury about whether or not Paxil's associated with suicide; and you've never looked at all the total suicides, the total suicide attempts, or even the total number of patients studied, is that right?

A. No, that's wrong. I told you I don't remember those

numbers sitting here right now. I've looked at all of the data.

Q. Doctor, nowhere do you mention it in your report, do you?

A. Again, it's not relevant to my conclusion from placebo-controlled randomized clinical trials.

Q. That's the point, Doctor, isn't it? These people who killed themselves in GSK's clinical trials, committed suicide, suicide attempts, they're not relevant, right?

MR. DAVIS: Objection, your Honor. That's argumentative, and it's also irrelevant.

THE COURT: Proceed.

BY THE WITNESS:

A. Everyone who dies by suicide is relevant to me.

MR. WISNER: No further questions at this time.

THE COURT: All right. Redirect, sir.

MR. DAVIS: Yes.

MR. WISNER: Oh, your Honor, this was Exhibit -- Plaintiff's Exhibit 336.

MR. DAVIS: Can I have Plaintiff's Exhibit 336, please. Thank you.

MR. WISNER: If you're going to mark it, I'm going to make a new exhibit, sir.

BY MR. DAVIS:

Q. Dr. Gibbons, I want to start where you just left off. If one were to go and take the number of either total suicides,

total suicide attempts, or total patients that were in uncontrolled studies or active-controlled studies, could that information even have been submitted to FDA for analysis?
A. They wouldn't have accepted it.
Q. Was the -- what was FDA's criteria for looking at whether or not there was, in fact, an association between paroxetine and suicidal thoughts or behavior in patients, in adult patients?
MR. WISNER: Objection. Move to strike the witness's opinion about what the FDA would or would not do in a hypothetical. He does not represent the FDA.
MR. DAVIS: I didn't ask him that. I asked him simply what was the FDA's criteria.
MR. WISNER: The previous question, your Honor. I rose to object; but he already started questioning, so I didn't want to interrupt him.
MR. DAVIS: Let me ask it again. Would that be all right, your Honor?
BY MR. DAVIS:
Q. What was the FDA's criteria for assessing whether or not paroxetine and other SSRIs increased the risk of suicidal thoughts and behavior or suicidal behavior or completed suicide in adult patients?
A. The active double-blinded phases of placebo-controlled randomized clinical trials.

Q. So, would it have been inappropriate to look at, under that set of criteria, total suicides or total suicide attempts or total patients in order to really get to the key issue, which is: Is this medication -- are these other medications actually increasing the risk of suicidal thoughts or behavior, suicidal behavior, or completed suicides?
A. It would be completely irrelevant to that question.
Q. Is that what you meant when you were trying to explain to Mr. Wisner about why that data, in terms of trying to get to that key issue, would not be appropriate?
MR. WISNER: Objection. Leading, feeding answers.
THE COURT: Overruled. Let's get on with it.
BY THE WITNESS:
A. Yes.
BY MR. DAVIS:
Q. If you -- if this -- if uncontrolled data were included, could it reasonably be used by -- would it be a reasonable and appropriate way to get to the core and key issue that was being investigated?
A. Of course not. It would be misleading.
Q. Let's talk a little bit -- I'll swing this around.
Your examination started off with 45 minutes of asking you questions about the observational studies and the authors of those studies, and you went through a whole litany of whether or not those authors had some conflict of interest

when they made those publications.

I want you to take a few minutes and tell the jury what contributions that Dr. Olfson and Dr. Simon and Dr. Wong have made to the -- the issue of assessing suicidality risk in the scientific community.

MR. WISNER: Objection. Irrelevant.

THE COURT: Sustained.

BY MR. DAVIS:

Q. Doctor, are you familiar with Dr. Olfson, Dr. Wong, and Dr. Simon?

A. Yes.

Q. And in terms of who those people are, what do they do? What do they do in terms of their research commitments?

MR. WISNER: Objection. Irrelevance.

THE COURT: Sustained. Let's go on with it. The question was conflicts. That's all.

BY MR. DAVIS:

Q. Did Mr. -- did Mr. Wisner -- in the 45 minutes that he asked you about those authors and those studies that you relied upon, did he point to a single place in those studies where the authors got the numbers wrong?

A. No.

Q. Did he point to a single place where the number -- where the authors actually misrepresented or twisted around data or didn't present the data in an accurate and reliable way?

A. No.

MR. WISNER: Objection. Lacks foundation.

BY MR. DAVIS:

Q. Did Mr. Wisner point to a single place in any of those studies where he said, "You know what, because of these conflicts of interest -- or possible conflicts of interest that were identified, that ended up affecting the outcome of how the data was presented or whether it was presented accurately"?

MR. WISNER: Objection. Lacks foundation as to the mental --

THE COURT: This is argument now, sir. You can point that out to the jury at some later time, but we're in an area of argument now.

BY MR. DAVIS:

Q. For each of those articles, those studies that you relied upon that Mr. Wisner asked you about, did each of those studies go through a peer review process?

A. Yes.

Q. What is that process?

A. It's a rigorous process where the manuscript is submitted to the journal. It's reviewed by three to five leading people in the field. They can request additional information, and then there are comments, criticisms. And then the paper is either published, rejected. In these cases, the papers were

published.

There may have been issues that the authors had to respond to the reviewers indicating points where it was unclear from the study. And ultimately, all of the reviewers have to be satisfied that the results are appropriate and the study is worthy of publication in those cases in the leading psychiatric journals.

Q. And that's my next question. Were those studies published in some of the leading psychiatric journals?

A. Yes.

Q. Okay. Now, Dr. Healy, does Dr. Healy testify in litigation?

A. Yes.

Q. And does Dr. Healy also publish his findings about his views about SSRIs in the peer-review literature?

A. There may be some publications, but very few.

Q. Yeah. And there's one article that we've talked about, which is the Healy-Fergusson article, right?

A. Yes.

Q. So, the mere fact that Dr. Healy has a potential conflict of interest, he's allowed to publish articles, is that right?

A. Absolutely.

Q. Okay. Now, you got asked some questions about the propensity score issues in the Juurlink article. Does anything about those propensity score analyses address the

issue of the fact that there was no analysis of paroxetine data in the Juurlink article?
A. No, no.
Q. Does that particular -- does the fact that -- did Mr. Wisner show you any study that would replicate a finding in Juurlink that dealt with all SSRIs in patients above the age of 66?
A. No.
Q. Doctor, do you have your deposition in front of you? It's in the notebook. If you could turn to page 285.
A. Yes, I'm there.
Q. My question is simply in your deposition, did you explain what you meant when you got asked the question about whether you considered yourself an expert in a particular area?
A. Yes, I did.
Q. And what did you explain at your deposition?
A. I explained that I am an expert in suicide research design analysis --
MR. WISNER: I'm going to object to showing him his deposition. I don't know if he's reading it or what's going on here.
MR. DAVIS: I'm just asking him what he testified to.
MR. WISNER: Why does he have it in front of him?
MR. DAVIS: It's rule of completeness, your Honor.
MR. WISNER: No, it's hearsay.

THE COURT: It has nothing to do -- his deposition has nothing to do with his testimony here at this point.

MR. DAVIS: I'll rephrase the question.

THE COURT: You can ask the question, not with reference to his deposition.

MR. DAVIS: I'll rephrase it.

BY MR. DAVIS:

Q. Did you explain before you took that witness stand, when you had an opportunity -- the plaintiff's lawyers had a chance to ask you questions, did you explain to them your areas of expertise?

A. Yes, I did.

Q. And did you explain to them that your areas of expertise were in statistical analyses about suicidality and suicide-related events, including with antidepressant medications such as SSRIs?

MR. WISNER: Objection. Leading.

THE COURT: Yes, well, I think that's all been covered. The doctor's given us a very good explanation of his background. Let's go on to something else.

BY MR. DAVIS:

Q. With respect to the black box warning in pediatric patients, was the scientific analysis that FDA did to reach the determination of putting a black box warning in all antidepressant medications, was that based just on data

concerning pediatric patients and paroxetine?
A. Yes.
Q. I'm sorry?
A. Yes, it was.
Q. It was based upon -- what drugs were looked at, Dr. Gibbons?
A. All of the SSRIs.
Q. Okay. And so my -- were there other drugs besides SSRIs that were analyzed?
A. There may have been.
Q. And so my question is: For the paroxetine data that was analyzed by FDA, did that show a statistically significant increased risk when you just looked for suicidal thoughts or behavior when you looked at pediatric patients for paroxetine?
A. I don't believe so.
Q. Would it help you refresh your recollection if you looked at your expert report?
A. Yes.
Q. If you could turn to your expert report that's up there that I believe is behind --
MR. WISNER: It's behind the tab that says, "Report."
THE WITNESS: I have this.
BY MR. DAVIS:
Q. And go all the way to the very end. There's an appendix that you put together.

THE COURT: Page?
MR. DAVIS: I'm sorry, your Honor. It's the very last page -- second-to-last page, your Honor.
MR. WISNER: Your Honor, I'm going to object to all this. This is about the pediatric data. This is well beyond my cross-examination. I just asked what he voted.
THE COURT: This is page 42?
MR. WISNER: No, your Honor, it's appendix -- the last two pages of the report, all the way at the back, after the appendices.
THE COURT: I guess I don't have that. Go ahead. What's the question?
BY MR. DAVIS:
Q. Doctor, does that refresh your recollection about the results of the pediatric data for suicidal thoughts or behavior for paroxetine?
A. Yes, it does.
MR. WISNER: Renew my objection, your Honor.
MR. DAVIS: Was --
THE COURT: Well --
MR. WISNER: We never got into the pediatric results.
THE COURT: You've both opened the door from time to time on pediatrics, so I'll let him answer.
BY MR. DAVIS:
Q. Was there a -- based upon FDA's analysis, was there a

statistically significant increased risk of suicidal thoughts or behavior in pediatric patients who took paroxetine?
A. No.
Q. Okay. And so when the -- when the black box warning went into effect, was that based upon pooled data looking at all SSRIs as well as other antidepressants?
A. Yes.
Q. Was it based just upon paroxetine data that that black box warning went into effect?
A. No.
Q. Okay. So, were your concerns that you expressed at the advisory committee -- did those concerns that you had about the black box warning come to fruition based upon scientific data?
A. Yes.
Q. What happened?
A. What we found was that the data that FDA analyzed -- these are now the pediatric data -- showed for the spontaneous reports an overall increased risk, 2 percent versus 4 percent, largely suicidal ideation; but the prospective clinician ratings showed actually a protective effect of antidepressant treatment in children.

And I saw that disconnect between the clinician ratings and the spontaneous reports as raising serious questions about the integrity of the statistical analyses

performed and the conclusions drawn in that advisory.
Q. And was there any scientific data that came out after the black box warning went into effect for pediatric patients about the effect that that had with respect to suicide?
A. There were numerous effects that happened after the black box warning.
MR. WISNER: Objection, your Honor. I believe this is going towards ecological data on suicide rates. I never once got into the pediatric data with this analysis. I simply asked how he voted.
MR. DAVIS: I think he opened the door by the witness's answer.
THE COURT: I think we've heard enough. He explained his answer at some length before.
BY MR. DAVIS:
Q. With respect to study 369 that Mr. Wisner asked you about, is that a pediatric study?
A. I'd have to see the specific study.
Q. Okay. You don't recall it being an adult study, do you?
A. No, I don't recall.
Q. Okay. Now, did Mr. Wisner show you any evidence of -- one shred of evidence that showed that the information in the case report forms that were used to put together the narratives that went to Columbia University for adult patients was somehow compromised or not done in the appropriate way?

A. No.
Q. You mentioned -- there was a discussion about studies 057 and 106 in your examination by Mr. Wisner. Please tell the jury what kind of studies 057 and 106 were about.
A. These were long-term studies in patients who were at very high risk for suicide, being that they'd made a suicide attempt quite recently. I don't remember. It was like the last week or two.
Q. So, were the patients that were enrolled in those studies high-risk patients for suicide?
A. Yes, they were.
Q. And when -- and did GSK do a placebo-controlled study looking at those high-risk patients on paroxetine and those high-risk patients on placebo?
A. Yes.
Q. And when they did that analysis, what was the result?
A. No association with paroxetine and these high-risk patients for future suicidal thoughts or behavior.
Q. So, for high-risk patients who had prior existing suicidal thoughts, was there any evidence that paroxetine was increasing the risk in those patients?
A. No evidence.
Q. What's your takeaway from that, based upon this analysis of high-risk patients, Dr. Gibbons?
A. It's extremely important, because in many cases,

randomized controlled trials designed for the purpose of efficacy excluded patients with suicidality. And so one of the objections to some of the randomized controlled trials that had been conducted in this area are that the -- they excluded just those patients that should be a part of those studies.

These two studies actually included those subjects to determine whether or not the effects of paroxetine might be exacerbated in terms of increasing suicidal risk in people with a high risk of having suicidality, people who had suicidality at high risk for suicide, and no effect was seen.

Q. You got asked some questions about Defendant's Exhibit 25. Okay? And I want to go back to this discussion about table 1 and ask you, is this analysis on table 1, is that dealing with only double-blind randomized -- excuse me, randomized double-blind placebo-controlled trials?

MR. WISNER: Objection. Cumulative. This has already been covered.

THE COURT: Yeah, we've been over this before.

MR. DAVIS: I didn't cover it in direct, your Honor. It was covered by Mr. Wisner. I haven't touched upon it.

MR. WISNER: I believe the question he asked was said by him about five times. I mean, this is really getting to be a waste of our time, your Honor.

MR. DAVIS: I'll make it shorter, your Honor.

BY MR. DAVIS:
Q. Let me ask you this, Doctor. With respect to patient 083 -- the patient in study 083 who was taking paroxetine and committed suicide, if that patient actually committed suicide before randomization, would that patient be part of the controlled portion of the placebo-controlled trial?
A. No.
Q. Mr. Wisner asked you a bunch of questions about Defendant's Exhibit 735, and he made a bunch of markings on it.

For starters, is what -- did what Mr. Wisner did in terms of using those --

MR. WISNER: Your Honor, I object right now. This says it's Plaintiff's Exhibit 334-A. That is not my exhibit or Plaintiff's Exhibit. If they're going to mark it up, which they're allowed to do, it's Defendant's Exhibit, not Plaintiff's.

MR. DAVIS: Sure. I'll identify it better for the record. I have placed -- it's Defendant's Exhibit 7035, which Mr. Wisner marked on, and he made it 334. I now have a new one called 334-A, which is an exact copy of what he did.

MR. WISNER: That says Plaintiff's Exhibit 334-A. He is not allowed to create a Plaintiff's Exhibit, your Honor.

MR. DAVIS: I'm just using the same thing he's used, your Honor.

MR. WISNER: Yeah. Call it a Defendant's Exhibit.

MR. DAVIS: If I could turn our attention to --

THE COURT: Originally, it was Defendant's Exhibit 7035-FF.

MR. WISNER: So, why don't we call it Defendant's Exhibit 7035-FF-A.

MR. DAVIS: I like that. Thank you. We'll get to the end of the alphabet, I'm sure, by the end of the day.

THE COURT: And then with that lovely emendation, we will take our recess.

(Jury exits courtroom.)

[redacted]

(Recess had.)

(Proceedings heard in open court. Jury in.)

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

You may proceed, sir.

MR. DAVIS: Thank you, your Honor.

BY MR. DAVIS:

Q. Dr. Gibbons, I want to ask you about the declaration that you submitted in the Neurontin litigation that Mr. Wisner asked you about. Do you have that in front of you?

Would you like my copy?

A. Please.

THE COURT: They'll bury you pretty soon with the documents.

BY MR. DAVIS:

Q. All right. Having read that, can you read both -- the first two paragraphs to yourself and let me know when you're finished?

A. Yes.

Q. Can you explain to the jury why it is you said what you said in the Neurontin litigation?

A. The Neurontin litigation, there were very, very few events, one, two, three events per 10,000 people even for suicidal ideation. It was extremely rare. And there was a part of that litigation trying to express that suicidal ideation and completion were exchangeable, which clearly isn't

the case. Suicidal ideation is important in the sense that it is a precursor of suicidal behavior, and suicidal behavior is a precursor of suicide.

MR. WISNER: Objection. Move to strike, improper opinion. He is not a medical doctor. A precursor is a medical statement.

MR. DAVIS: He's simply --

THE COURT: Well, he's explaining his response, and to that extent, I'll permit him to testify.

Go ahead, Doctor.

BY THE WITNESS:

A. My opinion on this is based on published literature that shows national -- not national, but epidemiologic data looking at people over time in terms of the relationship between these kinds of events. So they're all important to look at but to -- the issue in this case was using suicidal ideation as a pure proxy of suicide completion.

BY MR. DAVIS:

Q. And with respect to the analysis at issue in that litigation, was that -- was that analysis that you're speaking about have to -- had to do with suicidal ideation and behavior as a proper primary end point?

A. No, it did not.

Q. I need you to help me with something because I'm not a biostatistician, but I want to show you Plaintiff's Exhibit

35. And we have here the zero on the left and the 50 on the right. And my question is: Is that the proper way to present a logarithmic scale where you look at confidence intervals?
A. When we produce things like this, confidence intervals are forced plots which we've seen in this litigation, series of confidence level intervals that are about the value 1. We do it on a logarithmic scale. Otherwise, it has this, you know, impression that the risk goes off to infinity.
Q. So, for example, what would be on the left-hand side of the logarithmic scale?
A. Well, we would have -- we'd either do this in natural logarithms or in logarithms, so it would be a negative value.
MR. DAVIS: So, for example -- I'm going to publish Defendant's Exhibit 737. I'll show it to Mr. Wisner.
Do you have an objection?
MR. WISNER: Well, a little bit.
MR. DAVIS: I'll do it another way.
MR. WISNER: Okay. Why don't you make it again. Do you want some white paper?
BY MR. DAVIS:
Q. No. I want -- this will be 737. If we did a logarithmic scale for this kind of -- can I have you black pen -- would we start with 0.1 on the left?
A. Yes.
Q. So you'd have 0.1, and then on the right, what would we

put?
A. It might be 100 or --
Q. Okay. Let's do 100. And then we'd have our -- we'd have our forced plot right there, we'd have our logarithmic scale, and we'd have 1.0 in the middle?
A. Yes.
Q. And if we were plotting out .8 versus 48.95, where would we start; about right there?
A. Yes.
Q. And then for 48.95, we would be right here?
A. About that.
Q. And this is what we'd look at?
A. Yes.
Q. Okay. So that's a more -- is that a more accurate representation of how to present the findings on the -- of your analysis dealing with the NDD reanalysis that you did?
A. Yes.
Q. All right. Another help that I need for you on biostatistics which is, you got asked questions about whether you could calculate a confidence interval for 51 percent, and my question to you is: Is it scientifically reliable to use that versus the 95 percent confidence level?
A. Not at all.
MR. DAVIS: Can we please call up JX 13-035, Mr. Holtzen?

BY MR. DAVIS:
Q. For Table 24 which we're looking at here, the FDA analysis, adult suicidality analysis, what age group is reflected in this data table?
A. 18 to 24.
Q. And what, for Table 25 -- which is the next one, two pages later, Mr. Holtzen -- what age group is being reflected in that data table?
A. 18 to 24.
Q. Okay. So for purposes of assessing whether or not paroxetine increases the risk of suicidal thoughts or behavior or behavior alone in adult patients over the age of 25, do these two tables answer that question?
A. No, they don't.
Q. And in terms of your view of what's reflected in Tables 24 and Table 25 with respect to paroxetine, can you explain to the jury your views on the significance of any of those findings?
A. They're not relevant to a -- inferences about suicide later in life.
Q. And in terms of what the numbers are that are driving those results, which numbers do you believe are driving those results in terms of the age category?
A. The -- all of the results are driven really by the younger aged subjects in these studies.

Q. Is it appropriate to take the findings in Tables 24 and 25 and say, aha, this is a consistency of result that we've seen based upon also the major depressive disorder finding by GSK in its NDD subgroup analysis?

MR. WISNER: Objection, leading and argumentative as to "aha."

BY MR. DAVIS:

Q. I can rephrase it. Is it a fair characterization to look at Tables 24 and 25 and to say that this is a consistent -- this is a consistent finding -- I'll start again.

With respect to Tables 24 and 25, is it fair to say that these results show that there's a replication of findings that lines up with the 6.7 odds ratio finding in the NDD subgroup analysis that GSK did?

A. Not at all. The -- there is a consistent signal for young adults that the FDA believed was an extension of the signal that they saw in the pediatric trials. And the results for adults were either neutral, no increased risk, or protective depending on the two end points, or protective for people ages 65 and above both for the primary and secondary end point.

So in FDA's own conclusion based on these data, they would not attribute this increased risk to the adult data.

Q. Okay. Let me go back to what was marked as Plaintiff's Exhibit 334 and Defendant's Exhibit 735 FFA and ask you: With all of the marks that Mr. Wisner made on this particular

exhibit, did those marks include uncontrolled and active controlled data?

A. Yes.

Q. So is -- are these marks including pooling together active control and uncontrolled data with placebo controlled a valid and reliable way to assess the core issue of whether paroxetine increases the risk of suicidal thoughts or behavior or behavior alone in adult patients?

A. Not at all, but the real -- the real point here is the issue of the age distribution. It's not that suicidal behavior doesn't occur in the elderly in older people across the age distribution, the point here is that among the area where there was a difference between treated and control subjects, the -- that one area, that major depressive disorder, it was in those subjects that there was an imbalance in the age distribution.

Putting in these other ages that have nothing to do with that particular subgroup and came from uncontrolled studies doesn't inform the question about what is driving that NDD result.

Q. If we can go back to Defendant's Exhibit 1117, Mr. Holtzen -- oh, I'm sorry.

Using Mr. Wisner's analysis where he puts in all the adverse events from uncontrolled data and active control data, would that comply with the cautions expressed by these FDA

scientists that if you pool controlled and uncontrolled data, you may get misleading results?

THE COURT: We've been over this before. Redirect is limited to cross-examination, not to restating the initial direct. The jury has heard all this. I'm going to interrupt you if you continue to repeat.

MR. DAVIS: I'll shorten it, your Honor. I'll shorten it.

BY MR. DAVIS:

Q. With respect to this particular analysis, would this -- would -- this analysis that Mr. Wisner did, would that be accepted under the FDA's criteria to look at only placebo-controlled data to answer the core issue of whether or not paroxetine or other SSRIs increased the risk of suicidal thoughts or behavior or behavior alone or completed suicide in adult patients?

MR. WISNER: Objection, speculation as to what the FDA believes as well as improper opinion and asked and answered.

THE COURT: I think it's already been covered. Let's move on.

BY MR. DAVIS:

Q. One more question, and I'll move on. Dr. Gibbons, based upon your research, someone who's spent a career looking and analyzing these kinds of meta-analyses, if one of your

students came to you and presented this analysis that took uncontrolled data and active control data and mixed it with placebo-controlled data, what would you say to that student?

THE COURT: A student?

MR. DAVIS: A student.

BY THE WITNESS:

A. If one of my students came to me with this, I'd suggest they pursue another career, perhaps in the legal profession.

THE COURT: Pretty good answer.

MR. WISNER: Amen to that.

BY MR. DAVIS:

Q. All right. A couple wrap-up questions. Number one, did Mr. Wisner show you any randomized placebo-controlled trials or large-scale observational studies showing that paroxetine increases the risk of either suicidal thoughts, suicidal behavior, or completed suicide in adult patients above the age of 24?

A. No.

Q. Did Mr. Wisner in his questioning of you show you any randomized placebo-controlled trials or large-scale observational studies showing that treatment, emergent agitation, akathisia, or any other symptoms in adult patients taking paroxetine increased the risk of either suicidal thoughts or behavior or suicidal behavior alone or completed suicide?

A. No.
Q. Did Mr. Wisner show you any randomized placebo-controlled trials or large-scale observational studies showing that paroxetine at 10 milligrams per day increased the risk of either suicidal thoughts or behavior, suicidal behavior, or completed suicide in adult patients?
MR. WISNER: Objection, asked and answered.
MR. DAVIS: I was asking about dosage, your Honor.
THE COURT: Pardon me?
MR. DAVIS: I was asking about dosage.
THE COURT: I don't know that we got into dosage on cross, did we?
MR. WISNER: No. We also didn't get into the color of the pill either.
THE COURT: All right.
BY MR. DAVIS:
Q. On his questions -- my last question. With Mr. Wisner, did he ever show you any statistical textbook, article that in any way challenged the methods that you used to arrive at your opinions in this case?
A. No, sir.
MR. DAVIS: Thank you, Dr. Gibbons.
THE WITNESS: Thank you.
MR. WISNER: You can leave that there.

RECROSS-EXAMINATION

BY MR. WISNER:
Q. Doctor, you mentioned peer-reviewed journal articles, right?
A. Yes.
Q. And the peer review process?
A. Yes.
Q. And that those articles that you cited where the authors had connections to pharmaceutical industry, that they went through a peer review process, correct?
A. Yes.
Q. Isn't it true, Doctor, you don't know how many of those peer reviewers were also in the pockets of the drug companies?
A. I don't know --
MR. DAVIS: Objection, argumentative.
THE COURT: Sustained.
BY MR. WISNER:
Q. You just testified that I did not show you a single large-scale observational study that showed a statistically significant increased risk in suicidal behavior over the age of 24. Do you recall that?
A. Yes.
Q. What about Juurlink?
A. Juurlink was not a randomized control trial.
Q. I said observational, Doctor. That's an observational study, correct?

A. It is an observational study.
Q. And as an observational study, it showed a nearly fivefold increase, statistically significant, in people over 65, right?
A. Over 65 in the first month.
Q. So a second ago when he asked you that question, I guess it slipped your mind?
THE COURT: Go on. Proceed.
MR. WISNER: I'll proceed.
BY MR. WISNER:
Q. You also said I didn't show you any evidence of randomized control trials that showed a statistically significant increased risk. GSK's own 2006 analysis showed a 6.7 statistically significant increased risk, correct?
A. I don't view that as statistically significant.
Q. GSK does?
A. Okay.
Q. Finally, Doctor, I understand you'd fail the student who put this graph together for you, but here's my question, Doctor: I just marked the suicide attempts and completed suicides that were in the original new drug application, correct?
A. I believe so.
Q. I didn't mark how many other people killed themselves or attempted to kill themselves in all the clinical trials since 1989, did I?

A. No.
Q. And Doctor, the reason why I marked this graph wasn't to compare placebo-controlled trials but it was to address why you created the graph to begin with because you testified to this jury that this graph shows that it's a clustering of risk for people under 25, didn't you?
A. I testified that the NDD effect for suicidal behavior was a clustering of risk in the younger patients, not the rest and not that the risk of suicidal behavior in general is clustered in younger patients but that imbalance between paroxetine and placebo is produced in the younger patients and not in patients of the age relevant to this trial.
Q. So for all the clinical trial data that exists out there, you looked at the single sliver which had placebo-controlled data only, correct?
A. Correct.
MR. WISNER: No further questions.
MR. DAVIS: I just have one question, your Honor.
MR. WISNER: Actually, sorry, your Honor. I do have one more question.
BY MR. WISNER:
Q. You got into whether or not Paxil can increase the risk of pediatric suicide on your redirect. Do you remember that?
A. Yes.
Q. And you said that, in your opinion, it does not, right?

A. My opinion was that those results were not statistically significant.
Q. Doctor, you are aware --
MR. WISNER: Permission to approach, your Honor.
BY MR. WISNER:
Q. I'm handing you Plaintiff's Exhibit 283, Doctor. This is a peer-reviewed journal publication written by Alan Aptar and a whole host of other physicians. I'm sure you've seen this document before, right?
MR. DAVIS: You Honor, I believe the foundation has got to be laid for this document --
MR. WISNER: I'm asking the question.
MR. DAVIS: -- with respect to this witness.
BY MR. WISNER:
Q. I believe you've seen this document before, right, Doctor?
A. I may have. I don't remember sitting here right now.
Q. I'm sorry. You just told this jury that Paxil doesn't increase the risk of pediatric suicide, and you haven't even read this journal article about it?
MR. DAVIS: Your Honor, I object. That's a mischaracterization of what the question was and what the answer was.
THE COURT: Proceed.
MR. DAVIS: It had to do with FDA's analysis.
BY THE WITNESS:

A. I reviewed all of FDA's analyses, and my comments were about the FDA analysis.
BY MR. WISNER:
Q. So you haven't looked at this journal article?
A. I may have looked at this journal article. I don't remember sitting here right now.
Q. You agree that the journal *Child and Adolescent Psychopharmacology* is a reliable journal?
A. I think it's a peer-reviewed journal, I think so.
Q. It has Dr. Alan Apter on there, do you see that?
A. I do.
Q. Dr. Alan Lipschitz?
A. Yes.
Q. Those are all well-renowned M.D.s, right?
A. I don't know them personally.
Q. They're well renowned?
A. I don't know.
Q. Okay. And the title of it says, "Evaluation of suicidal thoughts and behaviors in children and adolescents taking paroxetine," correct?
MR. DAVIS: Your Honor, I don't believe he has established a foundation --
MR. WISNER: I asked him the title.
MR. DAVIS: I don't believe he can do that yet. He's got to lay the foundation to ask about substance.

THE COURT: Proceed.
BY MR. WISNER:
Q. That's the title of it, Doctor?
A. Yes.
Q. And it sure sounds based on the title that this directly relates to the opinion you gave to this jury about Paxil and its relationship to pediatric suicide, right?
A. My opinion was based on the FDA analysis that led to the black box warning on the committee that I was a member.
Q. Doctor, I'm sorry. I asked you a separate question. This article relates to pediatric suicide, right?
A. All I can tell you is from the title, it sounds like it.
MR. WISNER: Okay. Permission to publish, your Honor?
MR. DAVIS: No foundation has been laid, your Honor. It's also outside the scope of --
THE COURT: He says it's peer reviewed, didn't he?
MR. WISNER: So Doctor --
THE COURT: Wait, wait.
MR. WISNER: Oh, sorry. I thought you said publish.
THE COURT: I do think that you have to ask a couple more questions to use the article.
BY MR. WISNER:
Q. So Doctor, you agree that a peer-reviewed publication published in this journal, that's a reliable source of

information?
A. Well, I don't think that every article that's peer reviewed is necessarily a reliable source of information. There are articles that have been retracted. There are articles that get published that don't necessarily -- you know, there's all kinds of different qualities of the scientific literature.
Q. All right. Doctor, isn't it true that independent scientists have looked at the correlation between Paxil and pediatric suicide and have found an over 3.86 --
MR. DAVIS: Objection, your Honor. The foundation has been not laid.
MR. WISNER: -- risk that is statistically significant --
THE COURT: Sir, he's not using the article. That was a freestanding question, as I understand it.
MR. DAVIS: He's reading the article. He's suggesting that -- he hasn't established a foundation.
MR. WISNER: I'm asking if he knows, your Honor.
THE COURT: He may answer if he knows.
MR. WISNER: Can I have the question -- should I just reask, your Honor?
THE COURT: If you're going to use the article, you have to ask him if he regards it as authoritative. If -- you don't have to use the article. You can ask a question without

regard to the article.

MR. WISNER: Yes, your Honor.

BY MR. WISNER:

Q. Put the article away, Doctor. Isn't it true that researchers and scientists that have looked at the issue of pediatric suicidality with regard to Paxil have published in peer review journal articles that the risk ratio is 3.86 and that it's statistically significant? You don't have to look at the article, Doctor. I'm just asking if you know that.

A. I don't know that.

Q. Okay. And really where we all started here was the PDAC meeting that you participated in, right?

A. I'm not sure that's where we started, but I certainly participated in it, yes.

Q. To be clear, you voted against the black box warning?

A. Based on the data.

MR. WISNER: No further questions.

MR. DAVIS: I just have two questions, your Honor.

MR. WISNER: We're still doing this, your Honor?

THE COURT: Well --

MR. DAVIS: I just have two.

THE COURT: It never ends, does it, ladies and gentlemen.

REDIRECT EXAMINATION

BY MR. DAVIS:

Q. Doctor, with respect to the Juurlink article, did that article have any data in it that was specific to paroxetine in adult patients?
A. No.
Q. Okay. The next -- second, last question: With respect to the amount of data that was analyzed as far as GSK's 2006 adult analysis and the FDA 2006 analysis, do you view that as having enough information to be able to answer and assess the question of suicidality risks with paroxetine?
MR. WISNER: Objection, beyond the scope.
THE COURT: That, we're finished now. Sustained.
MR. DAVIS: Thank you -- your Honor, he did ask about the sliver of information as he put it, and I'm just following up on that.
THE COURT: I know. We've had enough. Thanks.
MR. DAVIS: Very good, your Honor.
THE COURT: Thank you, Doctor. It was very interesting.
THE WITNESS: Thank you, your Honor.
THE COURT: You may step down.
(Witness excused.)
THE COURT: You may proceed.
MR. DAVIS: Our next witness will be by videotape, Mr. John Iino, your Honor.
THE COURT: All right.

MR. BAYMAN: And your Honor, this tape is 50 minutes, so we probably won't finish today.

THE COURT: Oh, it takes 15 minutes?

MR. BAYMAN: 50, 5-0.

THE COURT: Oh, 50.

MR. BAYMAN: Yes, sir.

THE COURT: All right. Let's get on with it.

(Videotaped deposition of John Iino played in open court.)

THE COURT: All right. Ladies and gentlemen, I'm sorry to tear you away, but we will recess now until tomorrow morning at 9:30. I promise, your coffee and rolls will be there.

(Proceedings heard in open court. Jury out.)

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

(Proceedings adjourned from 4:30 p.m. to 9:30 a.m.)

* * * * * * *

C E R T I F I C A T E

We, Charles R. Zandi and Judith A. Walsh, do hereby certify that the foregoing is a complete, true, and accurate transcript of the proceedings had in the above-entitled case before the Honorable WILLIAM T. HART, one of the judges of said Court, at Chicago, Illinois, on April 5, 2017.

/s/ *Charles R. Zandi, CSR, RPR, FCRR* April 5, 2017

/s/ *Judith A. Walsh, CSR, RDR, F/CRR* April 5, 2017

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