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

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of STEWART DOLIN, deceased,	)	
Plaintiffs,	)	
vs.	)	No. 12 CV 6403
SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation,	)	Chicago, Illinois
Defendant.	)	April 10, 2017 1:30 p.m.

VOLUME 16-B

TRANSCRIPT OF PROCEEDINGS - Trial

BEFORE THE HONORABLE WILLIAM T. HART, and a Jury

APPEARANCES:

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

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

Court reporters:
JUDITH A. WALSH, CSR, RDR, F/CRR
CHARLES R. ZANDI, CSR, RPR, CRR
219 South Dearborn Street, Room 2504
Chicago, Illinois 60604
(312) 435-5895
judith_walsh@ilnd.uscourts.gov

APPEARANCES (continued:)

For Defendant GlaxoSmithKline:

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

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

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

(Proceedings heard in open court. Jury out.)

[redacted]

(Proceedings heard in open court. Jury in.)

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

We will when the witness gets here.

JOHN KRAUS, DEFENDANT'S WITNESS, PREVIOUSLY SWORN

DIRECT EXAMINATION (Resumed)

BY MR. BAYMAN:

Q. Dr. Kraus, I've handed you what's been marked as defense Exhibit 38 and ask you if you're familiar with that document.

A. Yes, I am.

Q. I had asked you prior to the break whether GSK submitted the 2002 reanalysis of the NDA Paxil suicide data to the FDA.

A. Yes.

Q. And I asked you about completed suicides. Did GSK also submit in May of 2002 the reanalysis of the suicide data regarding suicide attempts in the Paxil NDA?

A. Yes. We submitted a report looking at the placebo-controlled portions of those studies for suicide attempts.

Q. And is defense Exhibit 38 that submission to the FDA along with a cover letter from Mr. Kline in regulatory affairs at GSK?

A. Yes, it is.

Q. And are you familiar with this submission based on your review of the Paxil regulatory file as you were taking -- when you were taking on your responsibilities as responsible for the --

A. Yes, I reviewed this early on.

Q. And is this document kept in the ordinary course of

business by GSK?
A. Yes, it is.
MR. BAYMAN: Your Honor, I would move for admission of defense Exhibit 38 at this time.
MR. WISNER: The same objection as before. It's the same document, just a different submission. This is hearsay, and there's no dispute that it was submitted to the FDA. I don't know why we're covering this ground yet again.
THE COURT: All right.
MR. BAYMAN: This is the suicide attempts, your Honor. It's not the suicide --
THE COURT: You may proceed.
MR. BAYMAN: Thank you. I would move it into evidence, your Honor.
THE COURT: All right. It may be received.
(Defendant's Exhibit 38 received in evidence.)
BY MR. BAYMAN:
Q. And is this the cover letter of the --
A. Yes, it is.
Q. And turn, if you would, to Page, I guess it's got, 821. It starts, "Results for review of data about suicide attempts." I think it's --
A. In the letter or in the report?
Q. The fourth or fifth page in the document.
A. Yes, the report itself, yes.

Q. That's the report that was prepared by John Davies that -- that reanalyzed the suicide attempt data that we discussed on Thursday?
A. Yes, it is.
Q. Thank you. Now, I asked you some questions before the break about does anything in the Paxil clinical trial data show an increased risk of suicidal thinking and behavior in adult patients. You recall that line of questioning?
A. Yes, I do.
Q. When I was asking -- and you responded to those questions?
A. That's correct.
Q. What I -- in your response when you were referring to the clinical trial data, what clinical trial data were you referring to?
A. As we've discussed, we're looking at the placebo-controlled portion, drug versus placebo such that you can make an ascertainment as to whether drug treatment versus no treatment may have an association with the adverse effect, so the placebo-controlled portion.
Q. So your answers referred to the placebo-controlled clinical trial data?
A. That's correct.
Q. Now, this death analysis, the death report that we were talking about before the break, did that include just placebo-controlled trials?

A. No, it did not.
Q. What else were included?
A. It also included for that question active-controlled studies.
Q. What was different about the 1999 analysis that warranted the inclusion of the active-controlled studies?
A. The question was different. It was looking at whether or not there might be a risk in placebo groups of adverse events in diseases where lethal outcomes can occur like depression in suicidality. So in that instance, to compare a group of individuals going on to treatment, so active comparator or to drug versus individuals going on to treatment versus a placebo. So the question was about, does placebo increase risk relative to if you give medicine to everybody.
Q. And is that question because when taking placebo, you're taking a sugar pill, you're not getting treatment?
A. That's right. For diseases where some of the symptoms of the disease can have a profound outcome like suicidality, that can be a concern.
Q. Did this analysis have to do with whether paroxetine or Paxil induced suicide?
A. No.
Q. Did GSK provide data from both central studies and local studies to the FDA in 1999 as part of this report?
A. Yes.

Q. Did GSK specify to FDA which deaths came from central studies and which came from local studies?
A. Yes.
Q. Did GSK include in this report or response to this request investigator-initiated studies?
A. No.
Q. Why not?
A. Again, the investigator-initiated or sponsored studies, the investigator owns those data, and GSK does not have those data.
Q. Did FDA ask GSK for data from investigator-initiated studies?
A. No.
Q. Has FDA ever asked GSK for data on Paxil investigator-initiated studies?
A. No, just our sponsored studies.
Q. What does the term "sponsor" mean in the pharmaceutical industry?
A. Or sponsor in general in clinical trials is the entity or individual who's responsible for conducting that trial under the appropriate regulations and in compliance with good clinical practice. So for an investigator-initiated study, that's the investigator's responsibility. For our central studies that we talked about that we use for registration, that's GSK's responsibility as sponsor.

Q. In the pharmaceutical industry's -- pharmaceutical industry, are investigator-initiated studies considered studies done by the pharmaceutical company who provides the pills or the medicine?
A. No.
Q. Do these investigators sometimes publish the results of these investigator-initiated studies?
A. Yes.
Q. So do you have some information about the results of Paxil investigator-initiated studies?
A. Yes. When the studies are published, we typically receive the manuscript. We also sometimes will receive a study summary from the investigator.
Q. Based on everything you know about the results of investigator-initiated studies done on Paxil or paroxetine like 513 and 559, do you believe that including those studies in any of the suicide analyses that GSK or the FDA did on adult suicidality in 2006 would have had any impact on the results?
A. No.
Q. After GSK submitted information about deaths in central and local studies to FDA in 1999 in the deaths report, did FDA make any follow-up requests?
A. No.
Q. Did FDA request a change to the Paxil label following that

death submission?
A. No.
Q. Did FDA, based on your review of the regulatory file, did it say anything at all to GSK about the deaths including suicides that GSK reported in those trials?
A. No.
Q. Since GSK's and FDA's analyses of adult suicidality in 2006, have there been any new randomized double-blind placebo-controlled trials of Paxil or paroxetine that have addressed the question of whether paroxetine is associated with suicidality in adult patients?
A. No.
Q. Since 2006, has FDA or GSK conducted any analysis of the paroxetine clinical trial data that reflected an increased risk of suicidality for patients older than age 24?
A. No.
Q. Since 2006, has FDA notified GSK of a determination that there is reasonable evidence of an association between suicidality and the use of paroxetine or Paxil in adults over age 24?
A. No.
Q. Since 2006, has FDA ever requested that the Paxil labeling be changed to add any warning or precaution about a risk of suicidality for adult patients older than age 24?
MR. WISNER: Objection, asked and answered,

cumulative.

THE COURT: I think it's covered, but you may answer.

BY THE WITNESS:

A. No.

BY MR. BAYMAN:

Q. Doctor, I have one final question for you. Have you ever testified at a jury trial before?

A. No. This is the first time.

MR. BAYMAN: Thank you. I have no further questions.

THE WITNESS: May I ask a question? Can -- this notebook, can I remove this from my desk or do I need to --

MR. WISNER: You can put it on the floor for now, Doctor.

THE WITNESS: Okay.

MR. WISNER: I'm trying to get up and running, your Honor. One second.

(Pause.)

CROSS-EXAMINATION

BY MR. WISNER:

Q. Good afternoon, Doctor.

A. Good afternoon.

Q. My name is Brent Wisner. I understand we've never met before in any formal proceeding; is that correct?

A. No, just Thursday here.

Q. Briefly Thursday. I -- to let you know that I'm a bit

under the weather, so I apologize if I'm coughing or drinking water. It's just because I'm trying to fight off this cold. Okay?

A. Okay.

Q. I want to clarify something that you just discussed actually just before I got up here. And you said studies 519 and 559 were investigator-initiated studies; is that right?

A. Yes.

Q. But you also testified that the suicides that were listed in the 1999 death report didn't include investigator-initiated studies, didn't you?

A. Yes.

Q. You are aware that on Defendant's Exhibit 25, those two suicides are listed?

A. I'm not aware of that.

MR. WISNER: Let me show you.

Permission to publish Defendant's Exhibit 25, your Honor?

THE COURT: You may proceed.

BY MR. WISNER:

Q. Looking at your screen here, Doctor, this is Defendant's Exhibit 25. Do you see that?

A. I do.

Q. Okay. If we go down here to the attachments, the second page, you see the section right here, it says non -- "cases

from non-centrally databased paroxetine IR depression studies." Do you see that?
A. I do.
Q. And then if you look right here, I see studies 559 and 513, don't you?
A. I see that listed. I don't see the other context, though.
Q. Sure. Let's look at the whole context. Suicide, Paxil IR, female 31, male 46. Do you see that?
A. Yes, I do.
Q. So I'm just curious, was this an investigator-initiated study, or was it locally funded because it seems to be a contradiction here.
A. My understanding is this an investigator-initiated study.
Q. So then in 1999, the report did actually include investigator-initiated studies; is that right?
A. It would appear based on this that the suicides were reported as part of their report, yes.
Q. Now, Doctor, you said that GSK doesn't control the data, right, for these locally funded studies?
A. We -- for investigator-initiated studies, we don't own the data.
Q. Did you ever ask for it?
A. We ask for any serious adverse events that occur in the study be reported to us.
Q. That wasn't my question, Doctor. My question is: Did you

ask for all the data from these investigators?
A. We have not asked for all the data for the reasons I described earlier.
Q. Wait. To be clear, you didn't ask for the data from these investigator-initiated studies; is that right?
A. That's correct, as they weren't a part of our suicidality analyses or the request from the FDA at that time.
Q. So at least what we're looking at right here, you have two suicides on Paxil in a placebo-controlled trial, and you didn't bother to ask for the data; is that right?
A. We do have the data. Otherwise, it wouldn't have been reported. We have the serious adverse events that occur in the study.
Q. But you don't have the other data from the study, do you?
A. We don't have the full efficacy and safety data, but we do have the serious adverse events.
Q. And because you didn't collect all that data from them, you then couldn't give it to the FDA in 2006, right?
A. The FDA didn't ask for this data in 2006. They asked for sponsored studies, so GSK was the sponsor of the central studies. That was the request from FDA.
Q. I'm sorry, Doctor. GS -- the FDA asked for all placebo-controlled trials, correct?
A. By the company, sponsored by the company, that's right.
Q. You got -- are you familiar with a man named Dr. Duff in

your company?
A. Dave Duff, yes.
Q. He, in fact, pointed out that the FDA was specifically asking for placebo-controlled trials and that these locally funded studies were not being submitted to the FDA, didn't he?
MR. BAYMAN: Your Honor, that's best evidence. We've never heard about Dr. Duff in this case.
THE COURT: Overruled.
BY THE WITNESS:
A. I would need to see the documentation, please.
MR. WISNER: Permission to approach, your Honor?
THE COURT: You may.
BY MR. WISNER:
Q. I'm handing you what has been marked as Plaintiff's Exhibit 345, Doctor. You, in fact, have seen this document in a prior deposition, haven't you?
A. May I take a look?
Q. Please.
A. Thank you.
(Pause.)
Okay.
Q. You've seen this document before, right, Doctor?
A. I believe so.
Q. In March of 2009 during your deposition?
A. Referring to study 442, yes, I'll take your word on that.

Q. And this appears to be a fair and accurate copy of that email, Doctor?
A. Yes.
Q. If you look down at the bottom right, it says "Exhibit 8" next to it. Do you see that?
A. I do.
Q. That's Exhibit 8 to your deposition, isn't it?
A. Again, I'll take your word on that.
MR. BAYMAN: Okay. Permission to publish, your Honor.
THE COURT: Proceed.
BY MR. BAYMAN:
Q. All right. Doctor, this is the email we were discussing, and as we mentioned earlier, this is from David Duff. Do you see that?
A. Yes.
Q. Okay. Great. I'm going to read these two paragraphs:
"For some time, the company has been putting together a data set of information requested by the FDA who are conducting their own investigation into suicidality in adults."
Doctor, I'll stop right there. This is in 2005, right?
A. Yes, it is.
Q. And Dr. Duff here is specifically referring to the 2006 analysis that was sent to the FDA, right?

A. He's referring to the request from FDA. The data hadn't been sent yet, I don't believe.

Q. "They have requested data from manufacturers of all antidepressants as far as I am aware. Initially, they had tight rules for the studies they were interested in, for example, placebo-controlled, depression, max duration of 16 weeks, minimum N of 30. Since the initial request, they have broadened their request to now include any psychiatric disorder, not only 'true' depression and removed the duration limit. We supplied the data and descriptions of these cases of possible suicidality to a third party based in Columbia University who categorized the cases for the FDA."

It goes on:

"We have initially provided data from studies that were included in our central aggregated R & D database for paroxetine. However, during the recent exercise of producing CTR summaries for all completed studies, it has become apparent that GSK have data from additional studies, locally run, that are not on our central database but meet the FDA's criteria for studies that qualify for the suicidality analysis."

Did I read that right, Doctor?

A. Yes.

Q. It goes on to say, "Obviously, if the" -- I'm going to

stop right there. The CTR summaries, that's referring to the clinical trial registry on GSK's website?
A. Yes, it is.
Q. It goes on to read:
"Obviously, if the FDA were to find the CTR summaries of such studies on our website, they want to know why we had not included them in the data we supplied for their analysis of suicidality."
Do you see that, Doctor?
A. I do.
Q. So would it be fair to say that at least Dr. Duff believed that these locally funded studies, some of which were, in fact, placebo controls should have been submitted to the FDA as part of its analysis, correct?
MR. BAYMAN: Objection, calls for speculation about what Dr. Duff --
THE COURT: Overruled.
BY THE WITNESS:
A. I don't know. I think he's raising the issue that it could be.
BY MR. WISNER:
Q. And to be clear, Doctor, one of the reasons why GSK never did submit that additional data from locally funded studies is because GSK didn't have the data, the complete data set, right?
A. The data from locally funded studies could be in different

formats such that it couldn't be aggregated with the centrally funded studies, which could also include local countries like Japan, etcetera, but they ran the same data sets.

Q. I noticed you used the word "could" there, Doctor. It's "could" because you don't know because you never looked at it, right?

A. Again, we limited it to the centrally funded studies for the reasons I described earlier including the ability to synthesize the data together.

Q. So to be clear, when we're talking about this 2006 analysis, we are talking about the sliver of data that is placebo controlled only and happens to be in GSK's central database, correct?

A. It's much more than a sliver. It's 15,000 subjects. But it is limited to the placebo-controlled studies that were in the database such that we could aggregate the data together.

Q. How many patients have been studied in all of GSK's Paxil clinical trials?

A. I can't answer that offhand.

Q. Over 100,000; is that fair?

A. I don't know the answer to that.

Q. Over 80,000?

A. I don't know.

Q. So you don't even know how many people have been studied on Paxil in GSK's clinical trials?

A. Right now offhand, I do not know.
Q. Okay. Would it be fair to say it's a lot more than 15,000, Doctor?
A. It's more than 15,000, and there have been millions treated in the community as well.
Q. In fact, in the NDA submission -- you recall that, right?
A. Yes.
Q. You guys had a nifty diagram of all the numbers of people in each type of trial, do you remember that?
MR. BAYMAN: Object to the characterization "nifty," your Honor.
THE COURT: Yes.
THE WITNESS: I don't know what you're referencing so --
MR. WISNER: Okay. I'll show it to you.
THE COURT: That may go out.
BY MR. WISNER:
Q. Do you remember this diagram, Doctor?
A. Yes, I do.
Q. Okay. So this is an example of different clinical trials that were submitted in the original NDA to the FDA?
A. That's correct.
Q. All right. And I've marked it as Plaintiff's Exhibit 339 so I can mark it up if I want to. The data that you're referring to that was submitted to the FDA is this type of

data right here, Paxil and placebo comparator trials, that portion of them, right?
A. That's correct, per the FDA's request.
Q. Okay. That adds up to about 1400, right?
A. Yes. This is supporting first approval, so it's less than in the 2006 --
Q. Oh, sure.
A. -- when we had many more subjects.
Q. Sure. I'm just trying to give a context of how much data is just placebo controlled here.
A. Yes.
Q. Based on the NDA, the thousand patients on Paxil and active controlled, you're not including that kind of data, right?
A. That's correct. As I explained, in order to assess whether there may be an association with drug versus no drug treatment, the scientifically valid area is to look in the placebo control.
Q. Okay. We're talking about whether or not you looked at a sliver here, so let's focus on my questions. Active, 1,151 patients excluded as well, right?
A. Yes. Again --
Q. Okay.
A. -- they did not meet the criteria.
Q. Extension phase, excluded?

A. That's correct.
Q. And then these uncontrolled studies up here, these 946 patients, do you see that?
A. Yes.
Q. Also excluded?
A. From the 2006 analysis, that's correct.
Q. So about a quarter of the data from the NDA at least would have qualified for this analysis, right?
A. I'd have to add the numbers, but the 921 plus 554 would have qualified.
Q. That's a sliver, right?
A. No -- well, whether you want to characterize it as a sliver, it's a significant number of subjects.
Q. Most of the data was not considered, correct?
A. Most of the data did not meet criteria for placebo control, so it wouldn't contribute to addressing that scientific question, that's right.
Q. All right. Now -- all right. I want to go back to some of this stuff -- well, let me just make sure we have a record on this part. You are actually an employee of GSK, right?
A. Yes, I am.
Q. So how many boxes do you have?
A. What do you mean?
Q. Well, who is above you?
A. I have a manager.

Q. Who is that?
A. David Gordon.
Q. Okay. Who is above David Gordon?
A. Paul-Peter Tak.
Q. And who is above him?
A. Patrick Vallance.
Q. Who is above him?
A. Emma Walmsley, the CEO.
Q. She's the CEO, right?
A. That's correct.
Q. Top of the food chain?
A. She's the CEO.
Q. Sorry. She's the top of the pyramid. I'm not suggesting that --
A. She's the CEO of the company. I think that's clear.
Q. So, Doctor, to be clear, you have to answer to a manager; is that right?
A. I have a manager that evaluates my performance and development. I don't know what you mean by "answer."
Q. Let me put it this way: You're testifying today as part of your job as an employee, right?
A. I'm here today because I was involved in -- directly in the issues that we're speaking to.
Q. And this is part of your job as an employee, right?
A. Yes, as were the original analyses, that's correct.

Q. And to be clear, you own stock in GSK, don't you?
A. Technically. I sell my stock as soon as it vests, but I have shares pending.
Q. So the welfare financially of the company directly affects your bottom line, right?
A. I mean, if I'm talking about the share price, that's true, but again, I sell my shares as soon as I can regardless of what the price is.
Q. And it's possible that once you get off this stand, if you said the wrong thing, you'd get fired, right?
A. No, I don't think that's possible because all I need to do is speak to the facts as I understand them.
Q. So you're telling this jury that there's no way you could get fired if they don't like the story you tell?
A. No, I'd be astounded if that were to occur.
Q. All right. Doctor, let's get into some of the stuff you discussed. Now, one of the issues you brought up was GSK attempting to put in the 2006 Paxil-specific language into the label. Do you recall that?
A. Yes, we discussed that.
Q. In fact, you and Mr. Bayman spent a considerable amount of time discussing that issue, do you recall that?
A. Yes, we did.
Q. We looked at correspondence to and from the FDA, right?
A. Yes, we did.

Q. Now, you understand that the plaintiff in this case has argued that that 2006 information is incorrect? You understand that, right?
A. I have heard that. I don't understand the validity of it, but I've heard it.
Q. So to be clear that when we're talking about the 2006 information about whether or not it was included in the label or not, we are talking about information that the plaintiffs have alleged is itself misleading, right?
A. Again, alleged, but I disagree.
Q. I understand that. It's your analysis, right?
A. It's my analysis as a scientist and a clinician. I think I'm well placed to interpret the data.
Q. Now, at the end of the examination, you discussed --
MR. WISNER: Permission to publish Plaintiff's -- I'm sorry, Defendant's Exhibit 129, your Honor. It's in evidence already.
THE COURT: You may proceed.
BY MR. WISNER:
Q. All right. Doctor, this is that email exchange that you discussed with Mr. Bayman. Do you recall that?
A. I'd need to see it. I don't have exhibit numbers memorized.
Q. It should be on your screen.
A. It's blank.

Q. Oh, it's the head cold. I'm missing stuff. It should be on the screen now. Do you see that, Doctor?
A. Yes, I see it.
Q. Okay. And this is dated June 22nd. Do you see that?
A. Yes.
Q. All right. And in this -- in this email it says, "If you'd like to discuss this matter further, please submit a formal meeting request." Do you see that, Doctor?
A. I do. And we discussed that earlier today.
Q. You guys didn't request that meeting, did you?
A. We did not request that meeting, correct.
Q. And you didn't so because I believe you testified that you thought it was futile; is that right?
A. It would not have changed the outcome so, therefore, yes we believed it would be futile.
Q. One of the things that I was curious about, Doctor, is what GSK had proposed was to put the Paxil-specific information in the middle of the class labeling. Do you recall that?
A. Right, in the appropriate area of the warnings and precaution, that's right.
Q. And to be clear, GSK never proposed putting it at the beginning part of the warnings, did it?
A. No. We proposed putting it where it fit appropriately with the flow of data from FDA.

Q. You never proposed putting it at the end of the class warning, did you?
A. No. We proposed putting it exactly where the jury saw it today.
Q. And the exact place where you proposed it, that's where the FDA said, "We don't want it in the middle of the class labeling," right?
A. No. They said they did not want product-specific language in the label.
Q. Actually, Doctor, if you look at the exhibit right in front of you, it says, "your product-specific analysis -- we do not believe that your product-specific analysis should be included in the class labeling revisions." That's what they said, right?
A. Right, and --
Q. Nowhere have you pointed to this jury a document that says you are prohibited from putting any Paxil-specific information anywhere in the label? The FDA never said that, did they?
A. They didn't say that, but as we talked this morning, the appropriate section of the label is in the warnings and precautions around suicidality and risk. That is entirely class labeling per FDA's label. So that's where we put the Paxil-specific language, and this is why FDA did not accept because the whole section is class-specific.
Q. Doctor, you told this jury that proposing Paxil-specific

language is futile, but you never even once tried to put it anywhere but in the middle of the class labeling; isn't that true?
A. That's true, but --
Q. Okay.
A. -- I dispute that putting it in the middle, beginning, or end would have made a difference in how FDA interpreted it given their feeling about the importance of class labeling and the consistency among drugs, so we do use our knowledge and experience as we assess these things as well.
Q. You talk a lot about what the FDA wanted and what they didn't. Did you ever actually speak to the FDA about this issue?
A. We spoke to them as you see here --
Q. I'm not asking --
A. -- with electronic communication.
Q. I'm asking if you did personally.
A. I spoke to them personally at the original teleconference, and again, I was project leader leading the team at this time. And our regulatory lead would handle the communications.
Q. "I received your voicemail as well as earlier -- email earlier this morning," do you see that?
A. I do.
Q. That wasn't your voicemail, right?
A. That was not my voicemail --

Q. Okay.
A. -- that's correct.
Q. Where is this email, Doctor?
A. Can you ask that again?
Q. Yes. It says right here, "We received your voicemail as well as email earlier this morning." I haven't seen that email. Where is it, Doctor?
A. I can't answer that question.
Q. Do you know what it said?
A. I can't answer that question, no.
Q. Because you didn't send it, right?
A. I don't know. It may have been a mistyping on Rimmy's part. I don't know if we sent an email or not.
Q. Okay. Now, let's back up here. Now, after this email, GSK sent back another email about three days later, right?
A. I don't know the timing, but we went through this sequence earlier today.
Q. Okay. Do you recall that that exhibit was May 25th -- I'm sorry, June 25th?
A. I'll take your word again.
Q. Okay.
A. I don't memorize the dates for all these documents.
Q. So when you, I assume Ms. -- is it Dr. Arning?
A. Yes, Dr. Arning.
Q. I'm assuming Dr. Arning shared this email with you at some

point, right, the one that we're looking at here?
A. The one we're looking at right here?
Q. Yes.
A. Correct.
Q. Did you guys have a meeting afterwards about whether or not you'd take up the FDA's proposal for formal meeting request?
A. I'm sure I discussed this with her on the phone.
Q. Okay. It was just a phone call then?
A. That's my recollection, that's correct.
Q. Was there a meeting with anybody else involved?
A. I can't recall. I know I spoke with her directly about it, though.
Q. Okay. So you had a phone call. Was there a formal meeting like in a conference room at any point?
A. Not at this stage, no.
Q. Okay. And on that phone call, did you tell her what to say in response to the FDA, or did she come up with the response herself?
A. We agreed that we would allow the class labeling to stay, stand, and she drafted the response.
Q. I'm sorry, Doctor. What conversation did you have with Dr. Arning about taking this meeting or not?
A. Again, I said we spoke about it and decided for the reasons I said that taking a meeting would not be useful.

Q. So was it Dr. Arning or yourself who proposed not taking that proposed meeting?
A. It was us in collaboration.
Q. Okay. So whose idea was it, do you recall?
A. Whose idea was what?
Q. Whose idea was it not to please submit a formal meeting request? Whose idea was it?
A. I suspect we both came to the conclusion independently given the chain of events, but I can't definitively say if one of us or the other raised this initially.
Q. Did you consult with any of your bosses before you made that decision?
A. At this time, probably not.
Q. So basically, the decision not to take the meeting came from either yourself or Dr. Arning; is that fair?
A. I would have been responsible for it as the project leader, so technically, the decision would be owned by me.
Q. Okay. So then it's fair to say then the decision not to take that meeting, that was your call?
A. Ultimately, yes.
Q. Okay. As a person who works at GSK, are you familiar with a periodical publication submitted within the company called *Monthly Highlights, U.S. Regulatory Affairs?* Are you familiar with that document?
A. I've seen those, but I couldn't tell you much about them.

Q. And of course, they --

MR. WISNER: Permission to approach, your Honor.

THE COURT: Yes.

BY MR. WISNER:

Q. Well, before I do, are these -- these monthly highlights, this was something that was traditionally created in the regular course of GSK's business, right?

A. Let's take a look at it and I can tell you.

MR. WISNER: Okay. Permission to approach, your Honor?

THE COURT: Yes.

BY MR. WISNER:

Q. I'm handing you what has been marked as Plaintiff's Exhibit 344.

A. Okay.

Q. Is that a copy of the monthly highlights for June 2007?

A. Yes.

Q. And this is, the date on this one is July 2nd, 2007, do you see that?

A. I do.

Q. All right. This is a fair and accurate copy -- I mean, minus all the redactions, obviously?

A. Right, which are probably other products and things of that nature.

MR. WISNER: Exactly. All right. At this time, your

Honor, we'd move this Plaintiff's Exhibit 344 into evidence.

THE COURT: It may be received.

(Plaintiff's Exhibit 344 received in evidence.)

BY MR. WISNER:

Q. Okay. I'm going to publish it. Let me get it up one second. All right. Doctor, this is the document we're talking about here. Do you see that? It says, "U.S. regulatory affairs: Psychiatry/neurology." Do you see that?

A. Yes, I do.

Q. Monthly highlights for June 2007, right?

A. Yes.

Q. And this is right around the period of time when you're dealing with the class labeling issues with the FDA, right?

A. Yes, that's right.

Q. This is actually the period of time when you made the decision not to take that meeting, right?

A. Yes, coincident with that time, yes.

Q. All right. Now, it's all redacted except for there's one little section that I want to focus on right here. Do you see that section that says "Paxil"? It's on your screen.

A. Yes.

Q. It reads, "On June 21, 2007, FDA responded to our CBE submission for Paxil, Paxil CR, and paroxetine submitted on May 23rd, 2007." That's the CBE submission that you discussed, right, with the jury?

A. Correct. That's the version that had the language in it still within the class labeling, I think.
Q. That's the one we were confused about the coloring and the strike-throughs, remember?
A. Yeah. It was actually yellow highlighting which is why it didn't show up --
Q. Got you.
A. -- right on the copy.
Q. It goes on to say:

"They requested additional changes in the wording of the class labeling from all sponsors and other GSK drugs as well and asked for response via email within one week."

Then it goes on to state, Doctor:

"GSK's request of maintaining the Paxil-specific language within the class labeling was not addressed. FDA requested that those additions or changes should be addressed with a separate supplement. In addition, FDA confirmed that we would have to ask for a meeting to discuss the option of including Paxil-specific language in the label."

There's that meeting you never took, right, Doctor?
A. That's referencing the same meeting, that's correct.
Q. So based on this document, the FDA did not even address the Paxil-specific language, correct?

A. I disagree with that characterization in here. As we've --
Q. Let's read it.
A. -- testified this morning -- no, no. I mean, I don't agree with how that's written. As we talked about this morning, the FDA was clear in their wanting to have their class language and not the language for specific drugs including paroxetine.
Q. That's not what it says right here, right, Doctor?
A. It says, "GSK's request to maintain the Paxil-specific language within the class labeling was not addressed." And again, I don't think that's an accurate way of writing that.
Q. Now, this -- this periodical publication, "U.S. Regulatory Affairs," I assume this would have gone to your bosses, right?
A. The audience for this may be regulatory affairs still, not necessarily my bosses.
Q. So within the regulatory affairs umbrella, they believed that the Paxil-specific label -- language was not addressed and that if we wanted to include it, we'd have to request that meeting; isn't that true?
A. I don't know if that's how they would perceive it or not.
Q. So we just read that, Doctor, didn't we?
A. Yes, we did, but I know individuals who worked on the project wouldn't have perceived it that way.
Q. Now, in 2006, the analysis that you did, you would agree

with me that it did show an elevated risk of adult suicidal behavior in adults beyond the age of 24 in the condition of major depressive disorder, right?
A. I wouldn't agree with that characterization as you stated it. There's caveats to that.
Q. I'm sorry, Doctor. You agreed with that statement in your deposition in this case, didn't you?
A. If you pull out the deposition language, we can look at that.
MR. WISNER: All right. Well, it's time for your binder.
Your Honor, I have one on standby should you need it.
THE COURT: Give it to my law clerk, please.
BY MR. WISNER:
Q. Here you go, Doctor.
A. Thank you.
Q. All right. So let's -- before we get to your deposition, let's just make sure we're on the same page here. Isn't it true, Doctor, that in your opinion, the 2006 analysis showed there was, quote, a statistically significant increase in the frequency of adult suicidal behavior; yes or no?
A. Can you repeat that question again, please?
MR. WISNER: Sure.
THE COURT: Read it back.
THE WITNESS: Yes, please read it back.

(Record read.)
BY THE WITNESS:
A. I'd have to answer that "no" because it was in a specific subpopulation.
BY MR. WISNER:
Q. So let me rephrase the question then. You'd agree with me there was a statistically significant increase in the frequency of adult suicidal behavior in the major depressive subgroup?
A. Right.
Q. Okay.
A. That's correct.
Q. Okay. And you'd agree with me that that analysis was accurate, correct?
A. Yes.
Q. It was accurate at that time, correct?
A. Yes, and it continues to be.
Q. It's accurate today, correct?
A. Yes.
Q. And isn't it true that nowhere in the Paxil label as it existed in 2010 did it state that?
A. Right. The Paxil-specific analyses were not listed in the label for the various reasons we described earlier --
Q. Now --
A. -- so that's correct.

Q. Doctor, I want to make sure I understand something about GSK's position. You understand that there's a difference between authority and responsibility, right?
A. Describe for me your thoughts on this so I know exactly what you're talking about.
Q. Well, a police officer has the authority to give me a ticket for speeding, right?
MR. BAYMAN: Your Honor, this is argumentative. I object.
MR. WISNER: He asked me to explain.
THE COURT: All right. Don't argue, though.
MR. WISNER: I'm not arguing. I'm just trying to make sure we're on the same page, that's all, defining my terms.
BY MR. WISNER:
Q. So a police officer, they have the authority to give me a speeding ticket, right?
A. Assuming the data supports that, yes.
Q. Okay. And I have the responsibility as a person driving on the road to obey the speed limit, right?
A. Yeah.
Q. And you'd agree that if I was speeding recklessly and I plowed into a car and killed a family, I couldn't blame the police for not giving me that ticket, right?
MR. BAYMAN: Argumentative, your Honor. Objection.

THE COURT: Yes, you're getting a little bit beyond. I think the jury understands your sophisticated approach.

THE WITNESS: It's good someone understands it.

BY MR. WISNER:

Q. Well, let me be clear here. The FDA has the ultimate authority to make final labeling decisions, correct?

A. Right. Our label has to be consistent with FDA's judgment. Otherwise, it can be considered misbranding.

Q. But the responsibility of the label, its accuracy and content, that rests with the manufacturer, correct?

A. Yes. And again, we've exercised that responsibility in this case as we've discussed.

Q. Sure. So when we talk about a label, that label is GSK's responsibility, right?

A. Not any more, it's not. In the United States today --

Q. Doctor --

A. -- it's someone else.

Q. Doctor, we're not going to get there.

A. Well --

Q. We're talking about the label as it exists in 2010.

A. Okay.

Q. That's GSK's responsibility, right?

MR. BAYMAN: Objection, asks for a legal conclusion, your Honor.

MR. WISNER: He already said yes. He just went on --

THE COURT: Proceed.

MR. WISNER: -- to a non-responsive area.

THE COURT: Proceed.

BY MR. WISNER:

Q. Yes, Doctor.

A. It's our responsibility to maintain the label again, in collaboration and review with FDA such that the factual basis is supported such that the drug is not misbranded.

Q. And you'd agree, you don't hide behind the FDA, do you? You take responsibility for your label, right?

A. Yes, but as you understand, in the United States, the FDA must agree with what's in your label for it to be valid and to allow you to continue marketing the medicine.

Q. And you'd agree that if people get hurt because of that label, GSK is the responsible party, not the FDA, right?

MR. BAYMAN: Objection. Argumentative, your Honor.

THE COURT: Yes. Sustained.

BY MR. WISNER:

Q. Now, Doctor, I want to turn your attention to another exhibit you used on direct, if I can find it. All right. Doctor, do you recall on direct examination a chart that you showed the jury that related to all the approvals for the various supplements that were made?

A. Yes, I do.

Q. And you testified that each time that -- let me find it.

One second. You testified each time that GSK submitted an application, it had to be approved, right?
A. Right. A new drug or supplemental new drug application has to be reviewed to show evidence of the safety and efficacy for approval, so yes, each time there was a new indication, that had to occur.
Q. Okay. And each time that you submit a request for a new -- oh, here we go. Here it is. Okay. This is the document, right, Doctor?
A. That's correct.
Q. Okay. And so we have like panic disorder, obsessive-compulsive disorder. Do you see that?
A. I do, sir.
Q. Submitted May 1996, right?
A. Or approved in May '96.
Q. Fair enough. Approved in May of 1996. Now, to be clear, Doctor, every time GSK submitted this and it got approved, they were allowed to then market Paxil to treat those conditions, right?
A. Right. Once a drug is approved, you get something called marketing authorization where the drug can be sold for those conditions.
Q. And so as more approvals happened, the ability to sell Paxil for a variety of conditions, that opportunity increased, right?

A. Right. Based on the evidence showing it was effective for these disorders, that's correct.
Q. Now, isn't it also true, Doctor, that every time you, GSK or you yourself, submitted one of these applications, you had to submit proposed labeling, correct?
A. Yes. You submit proposed labeling to the FDA, that's correct.
Q. And so my question, Doctor -- and I want to go through each one of these -- is: Did GSK propose a Paxil-specific suicide warning? Okay. So in 1996, part of the application, did it submit a Paxil-specific suicide warning?
A. No, because there was no evidence to support that.
Q. '97, did they submit a warning?
A. The same answer, no, because there was no evidence to support that.
Q. '99, February 1999?
A. It's -- it would be the same answer for all of these. There was not evidence at the time to support until 2006.
Q. So to be clear, every time GSK filed a submission to increase the amount of Paxil it could sell and market, it never once in any of those times proposed a label that said Paxil itself could induce suicide, correct?
MR. BAYMAN: Objection, argumentative, Judge. He's saying that it could sell and market.
THE COURT: Overruled. Proceed. Let's get on with

it.
BY THE WITNESS:
A. Basically, that wasn't done because there was no data to indicate adding that to the label, so it would not have been factually correct.
BY MR. WISNER:
Q. You said there was no data. In the original NDA that was submitted to the FDA, wasn't there, in fact, an elevated risk of suicidal behavior versus placebo?
A. No, that's not evident in the NDA.
Q. All right. Doctor, what I'd like to do now is I'd like to actually go through the chronology of Paxil that you sort of went through. I want to fill in some of the gaps. Okay? So let's start at the beginning. The original NDA for Paxil was submitted in 1989, right?
A. Yes, I believe that was the submission date.
Q. And at that point, Prozac had been on the market for two years, correct?
A. I -- actually, I think that's right. I think Prozac was approved in '97.
Q. And it was a raging success, wasn't it?
A. It was an effective medicine with a good side effect profile, so it was successful, yes.
Q. It was making Lilly a lot of money, right?
A. I have no idea how much money Lilly made.

Q. Are you telling this jury you don't know how much money Lilly made off of Prozac?

MR. BAYMAN: Objection, your Honor.

BY THE WITNESS:

A. Yes, that's just what I said.

BY MR. WISNER:

Q. So you have no idea if it was a blockbuster drug, Doctor?

MR. BAYMAN: He's not an Eli Lilly witness, your Honor. Now we're getting into Eli Lilly's sales.

MR. WISNER: I'm just confirming that he's stating that. I was sort of surprised.

THE COURT: He said he doesn't know.

MR. WISNER: Okay.

THE WITNESS: I don't follow the market shares of the medicine. I follow the scientific clinical aspects of the medicine.

BY MR. WISNER:

Q. So when GSK submitted its NDA in 1989, it was going to be a competitor SSRI, correct?

A. It would be a medicine of same class, so yes, theoretically, those would potentially compete with each other for new patients.

Q. I don't mean to be crass, Doctor, but it's not theoretically; Paxil was a competitor to Prozac, right?

A. Yes, essentially, but again, based on the evidence of

safety and efficacy before it could ever be approved.
Q. So they submitted the NDA in 1989, and then in 1990, Dr. Teicher published an article about Prozac-induced suicidal events, correct?
A. Yes, a case series.
Q. And Dr. Teicher, he was also accompanied by Dr. Cole, correct?
A. His coauthor.
Q. Yes. And that raised concerns within the medical community, specifically within the regulatory community, that this might be a class-wide effect, correct?
A. I think that was one of the first pieces of evidence that raised that question, yes.
MR. WISNER: All right. Permission to publish Plaintiff's Exhibit 79, your Honor.
THE COURT: All right. You may proceed.
MR. WISNER: It's in evidence.
BY MR. WISNER:
Q. Now, what we have in front of us, Doctor, is a memo of conversation -- the jury has seen it, I won't spend too much time on it -- between Dr. Brecher and a person within GSK, correct?
A. Again, it's not on the screen.
Q. Okay. Thomas Donnelly, do you see that?
A. It's not on the screen.

THE COURT: It's not on the screen, Mr. Wisner.

BY MR. WISNER:

Q. Sorry. There it is. Do you see it, Doctor?

A. Yes, I see the -- kind of the beginning of it and the signatory page, yes.

Q. Okay. Great. And you've seen this document before, I assume, right?

A. Yes, I have.

Q. And this is the part where Dr. Brecher is telling GSK that they want them to submit a suicide report, right?

A. Asking us to assess the suicidal ideation and behavior, that's right.

Q. And this ultimately --

A. It wasn't just suicides.

Q. Fair enough. And this led to the suicidality report submitted in 1991, correct?

A. That's correct.

Q. All right. And in here, it says:

"Although the division does not see it as a real issue but rather as a public relations problem, Lilly has been asked to submit a detailed response to the public's concern. He, therefore, is requesting that we do the same since we have a drug with a similar mechanism of action. He said his request is not based on any concern that has developed from his review of paroxetine but

simply that it is an issue that must be addressed with this group of drugs."

Do you see that, Doctor?

A. I do.

Q. Now, to be clear, this memo of conversation wasn't written by Dr. Brecher, it was actually written by a GSK employee, correct?

A. That's right. It's a GSK employee's representation of the discussion that was had.

Q. So it would be fair to say then that GSK believed at this time that the issue -- that the FDA did not consider it to be a real issue but more of a public relations issue; is that fair?

A. As expressed in this note, that is the impression that they received from Dr. Brecher. Whether Brecher represented everyone in FDA, I don't know the answer to that, but for Dr. Brecher, yes.

Q. So GSK is getting ready to prepare a suicide report, and it's fair to say that GSK, when it's submitting the suicide report, believes that the agency does not think it's a real issue, right?

A. Well, clearly they think it's an issue as they're doing the analyses, but the way it was phrased, the evidence that the -- that Brecher had seen to date didn't suggest that there was evidence of an association.

MR. WISNER: All right. Let's take a look at the suicide report. This is Plaintiff's Exhibit 82. It's already in evidence, your Honor.

BY MR. WISNER:

Q. This is the suicide report that was ultimately submitted, do you see that, Doctor, on May 10th, 1991?

A. Yes, I do.

Q. And this is the cover letter that is in front of the suicide report, right?

A. Yes.

Q. Okay. And just so you know, we have a paper copy in that binder I've handed you, so if you want --

A. Do you have the tab? It's a little easier because sometimes this is --

Q. Sure. This is Plaintiff's Exhibit 82. And so it should say Plaintiff's Exhibit 82 on the tab.

A. PTX 82?

Q. That's right.

A. All right.

Q. So if you want to follow along on paper, you're welcome to, Doctor. All right. So we go on to the document, and we have here this report. Do you see that, Doctor?

A. Yes.

Q. Dated April 29th, 1991, right?

A. Yes.

Q. This is in response to Dr. Brecher's conversation, correct?
A. Yes, it is.
Q. All right. And then we go into the report, and I want to start off with the section right here, the sentence that reads, "Rather than introducing any selection bias, the data from all trials has been pooled." Do you see that?
A. Yes, I do.
Q. And that's referring to the fact that data in placebo-controlled trials will involve patients that may be slightly different than patients in active control or even patients in open label, correct?
A. Yes. I think we discussed a bit on that on Thursday that depending on the study design, the severity of the patients can be different.
Q. So if you have a person who's particularly severely depressed or maybe even suicidal, they probably wouldn't get put into the placebo-controlled trial, they'd probably get put into an open-label trial; is that fair?
A. What I would say is it would be more likely for an investigator if they had concerns about the safety of the patient to ensure that they were in a study that may have active treatment.
Q. So in the 1991 report, GSK decided to include all the data from all the studies to avoid any bias, right?
A. That's what we did in the study, that's correct.

Q. And to be clear, you stated on your direct examination that the placebo group in a placebo-controlled trial most represents what would happen if a person didn't receive treatment; is that right?
A. Let me represent what I said.
Q. Sure. Please. I don't want to put words in your mouth.
A. The best way to assess whether or not there is a relationship between a given treatment versus observing a contemporaneous group across the time is to have the drug versus the absence of drug be studied, so the placebo-controlled portions of the trial --
Q. But you would --
A. -- if you're going and try make assessments about an association to treatment.
Q. But you'd agree that circumstances in which people actually take a drug and undergo treatment in a placebo-controlled trial don't mirror what people experience in the real world, right?
A. Are you asking if clinical trial populations can differ from real world populations?
Q. Let me put it this way. In the real world, if I go fill a prescription for Paxil, I know I'm taking Paxil, right?
A. As long as it's the branded drug.
Q. Yes. You know you're taking the drug. It's not a blind, right?

A. Oh, I see what you're saying. That's correct. You know you're receiving a treatment.
Q. And in a placebo-controlled trial, the people in the placebo group as well as the people in the drug group, they don't know if the pills that they're taking are drug or placebo, right?
A. In a double-blind study, that's correct.
Q. And in the double-blind placebo-controlled trials, they go back and see investigators weekly or pretty frequently, correct?
A. Right, depending on the study design.
Q. And they get assessed a whole bunch of questions, the HAM-D scale, for example, right?
A. Right. They get measurements of their disease's severity and assess for adverse events, that's right.
Q. And these are mostly efficacy trials, right?
A. Well, the primary end points are typically efficacy. The key secondary is always safety as well.
Q. Sure. So the primary end point is to see if these drugs are actually working in people, right, that's the plan?
A. To treat the disease under study, that's right, to see if they're effective in reducing symptoms.
Q. So these people in a placebo-controlled trial, you would agree with me, their experiences, whether you're in the Paxil group or in the placebo group, they're not really experiencing

what regular people would experience when they take a drug, right?
A. I'm not clear what you're asking about.
Q. Okay. Well, if I go to fill a prescription, I don't go weekly to my doctor and get asked a series of questions, right?
A. So you're asking is what occurs in a clinical trial the standard of care?
Q. Yes. It's a different standard than what happens in real life, right?
A. Right. For good reasons, but yes.
Q. Sure. And so when you try to use placebo-controlled trial data to make an estimation of what's happening in the real world, there's -- there's some obvious limits, right?
A. There are some limitations, but as we described earlier, when assessing whether there's an association of treatment with an adverse event, it is the best way and definitive way of doing that.
Q. And so in this suicide report, GSK isn't just looking at placebo-controlled trials, they're looking at open-label trials, right?
A. In this report, all the data from all sections of the trials was captured, that's correct.
Q. And open-label trials, that's where people know that they're being given Paxil, right?
A. Yes. It's open label.

Q. Okay. Now, if we go into the report, the first paragraph, you actually addressed this on direct. Do you recall that?
A. If you ask a question, I'll see if I can recall it.
Q. Do you recall talking about this paragraph and it got highlighted and all that stuff on direct examination?
A. Yes.
Q. Okay. And then it says, "Five suicides were committed by patients who were randomized to paroxetine." Do you see that?
A. Yes, I do.
Q. And then it goes on to say, "Two were committed by patients randomized to placebo." Do you see that?
A. I do.
Q. We know that that placebo statement is factually incorrect, right?
A. They were not necessarily randomized to placebo. They were on placebo. So as expressed, "randomized to placebo," that's not accurate.
Q. That's a lie, isn't it, Doctor?
A. I would not call it a lie, no.
Q. It's a statement that's false, correct?
A. When I think of a lie, it's intentionally trying to deceive. This is just inaccurately written.
Q. Okay. Did you talk to the author of this report?
A. I don't think I ever spoke to the author of the report directly, no.

Q. Did you ever ask them, "Hey, did you lie?" Did you ever ask them?
A. No.
Q. So you're speculating about the intent behind that sentence, correct?
MR. BAYMAN: Objection, argumentative, your Honor.
THE COURT: Overruled.
BY THE WITNESS:
A. Informed speculation as I have worked with the people in the company for years.
BY MR. WISNER:
Q. All right. Now, if we go to the first paragraph, we've all seen this before, you see this representation here, this is the suicides?
A. Yes, I do.
Q. And actually, you referenced this in your direct examination, didn't you?
A. Yes, we reviewed this.
Q. You told the jury specifically that this shows that there was no association with completed suicides, right?
A. That's correct.
Q. But this chart's inaccurate, isn't it?
A. In terms of the randomization aspect, yes.
Q. Let's just talk about the numbers. This number right here, 2, open paren, 0.36, that's an inaccurate number,

correct?
A. The placebos that contribute to that, we don't have the, what's called the denominator to calculate the rate, so the rate of .36 is inaccurate.
Q. That 2 -- that .36 is actually 2 divided by 554, isn't it?
A. That's right.
Q. And that's completely inaccurate, correct?
A. It wouldn't reflect the total number exposed to placebo in the run-in phase.
Q. You told this jury that the PEY, which is .028, was higher than Paxil. Do you see that?
A. Yes, it is.
Q. Okay. But again, that .028, that's based on the run-ins, isn't it?
A. Right. I think we addressed that as well earlier on direct.
Q. So that actually should be zero, shouldn't it be, Doctor?
A. Well, if you exclude the placebo run-ins from there, yes, that would be a zero.
Q. If you view the numbers that it says N 554, those should both be zero, right?
A. Right. And they're uncontrolled. And if you remove the paroxetine uncontrolled, you would reduce it to zero as well.
Q. I know you want to eliminate the Paxil suicides, Doctor, but I'm focusing on the placebo here.
MR. BAYMAN: Objection, your Honor --

BY MR. WISNER:
Q. That should be zero, correct?
THE COURT: Proceed.
BY THE WITNESS:
A. It should be zero if you're excluding placebo run-in phase, that's right.
BY MR. WISNER:
Q. It goes, "There were no substantive differences in the number or incidence of suicides among treatment groups." Do you see that?
A. I do.
Q. Five to zero, that's substantively different, right, Doctor?
A. Again, based on exposure year in comparison with the active controls in here, I don't think you can say it's substantially different. And again, if you were to apply that standard of looking at the controlled phases or removing uncontrolled phases, we would have to do that for paroxetine as well. And that's why the reanalysis of this data was done by John Davies looking at the placebo-controlled portions. And we have spoken about that today as well --
Q. All right.
A. -- or Thursday. I can't remember.
Q. I'm sorry. Are you done, Doctor?
A. I'm done, yes.

Q. Okay. So 5 versus zero, that's a substantive difference, correct; yes or no?
A. Again, you're looking at the thousand patient exposure years versus 72, so possibly not given that suicidality is part of the disease as we've discussed before.
Q. So it's not yes or no, it's you don't know; is that right?
A. I would say even if it was 5 and zero, it would not be substantially different, that's correct.
Q. Okay. Let's go to the -- let's go to the next chart. We've all seen this as well. It's the first time we've had a GSK employee to talk to about it, so that's why I'm bothering you with it, Doctor --
MR. BAYMAN: Move to strike the commentary --
MR. WISNER: -- do you see that?
MR. BAYMAN: -- your Honor.
THE COURT: Yes. That may go out, sir.
BY MR. WISNER:
Q. This is Table 2, Doctor, right?
A. I'm sorry. What's your question?
Q. This is Table 2, right, Doctor?
A. Yes, it's Table 2.
Q. Okay. Great. This is attempted suicides, yes?
A. Yes.
Q. All right. And again, we have the N here of 554, right?
A. Yes.

Q. Then we have 6. Do you see that?
A. Yes, I do.
Q. It's calculated at 1.1 percent. Do you see that?
A. Yes, I do.
Q. That actually is an incorrect calculation, correct, Doctor?
A. Describe why you say it's incorrect.
Q. Because that 6 -- that 1.1 was calculated when you divide 6 by 554, right?
A. Yes.
Q. And that is inaccurate in your own words, right, Doctor?
A. As the denominator doesn't include all the patients at the run-in phase, yes.
Q. So back to the question I asked you: 1.1 is inaccurate, correct?
A. In terms of how you're asking it, yes.
Q. All right. And that .083, do you see that?
A. Yes.
Q. Also inaccurate, correct?
A. If you remove the run-ins, yes.
Q. If you remove the run-ins, you're left with 1 out of 554, right?
A. That's correct, I believe.
Q. Now, this attempted suicide section of the report doesn't actually include completed suicides, right?
A. Can you read that back, please?

THE COURT: Read it back.

(Record read.)

BY THE WITNESS:

A. That's correct.

BY MR. WISNER:

Q. But you would agree with me that before one can complete a suicide, they have to attempt one, right?

A. They're different things. So there's an action that one performs if they have a successful suicide, but it's not called a suicide attempt. It's completed, so it's called a suicide.

Q. All right. So let's focus on my question. Before you can complete a suicide, you have to attempt it, right?

A. You have to do something to affect your own death, that's correct.

Q. So what would have been fair, as least based on the Columbia standards as we talk about them today, to include completed suicides in this chart as attempts, right?

A. No. They're completely different.

Q. So if someone jumps out of a window and happens to live, that's completely different than if they happen to die?

A. Yes. They're counted differently. One is an attempt. One is a completed suicide. So yes, they're looked at differently.

Q. It says here, "no substantive differences." Do you see

that?
A. Yes, I do.
Q. That's not true, is it, Doctor?
A. Related to the numbers we talked about earlier, it would -- you know, it would not represent the placebo group appropriately, but as we stated before, if we take out the run-ins, you would need to take out the uncontrolled portions of the Paxil to do the apples-to-apples. So even today when the analysis was redone, it proved in the apples-to-apples comparison that there was no substantive differences.
Q. Come on, Doctor. 40-to-1, that's a substantive difference, right?
A. But what I'm saying to you, I think that's an improper comparison. If you are removing the run-ins, the uncontrolled portions of the placebo, you need to remove the uncontrolled portions of paroxetine.

As we've said frequently throughout this testimony, suicidality is part of the disease of depression. You're watching patients for 1,000 patient exposure years. Even under treatment, these events can occur. So if we want to understand what is the possibility of an association with drug versus non-drug and you want to do a comparison fairly between two groups, you can't just take away one controlled side and leave the other. So I dispute that you would end up with 40 versus 1 unless you did an improper analysis.

Q. Okay. Would you dispute that you would have the numbers 1.3 percent versus 1.1 percent even under your version, if you say you had to keep all the data included, it wouldn't be that, would it?
A. Correct, because the 554, it doesn't represent all the run-in patients.
Q. So this is an incorrect analysis then?
A. In the placebo phase, the denominator is incorrect, that's right.
Q. Nowhere in this suicide report did GSK tell the FDA that those suicide attempts, the five of them, were in the run-ins, right?
A. Not in this report, no. In other correspondence, yes.
Q. And that's because in GSK's view, the FDA didn't consider it to be a real issue, right?
A. No, I wouldn't say that.
Q. You're telling me that GSK submitted an inaccurate report, they didn't submit an inaccurate report because they didn't think it was a real issue?
A. No. I would say that this was an honest error and was not intentionally inaccurate in any way, shape, or form.
Q. An honest error that GSK didn't correct for ten years, right?
A. We corrected the analysis with the apples-to-apples in 2001, I believe.

Q. 2002, actually, right, Doctor?
A. With the submission, that's right.
Q. All right. So ten years later. This is 1991, right?
A. Right. And it had no material effect on the assessment of safety or efficacy of the drug.
Q. Ten years is sort of an important number when it comes to the drug industry, isn't it?
A. I don't know what you're getting at.
Q. Well, I'll get very specific. When you submit an application and it gets approved by the FDA, the drug manufacturer, the sponsor, gets to sell that drug exclusively for ten years, right?
MR. BAYMAN: Judge, now we're getting into patent issues. This --
MR. WISNER: It goes straight to motive, your Honor.
MR. BAYMAN: Mr. Dolin took a generic version of the drug. GSK didn't profit from it, and now he's getting into patents and trying to get into sales and profit information.
THE COURT: We're not going to get into patents, I assure you.
MR. WISNER: We're not going to get into patents. We're talking about exclusivity. It's not related to the patent. It's related to the NDA, your Honor.
THE COURT: Proceed.
BY MR. WISNER:

Q. You get ten years of exclusivity based on the NDA submission, correct?
A. I don't know the answer to that. I think data exclusivity is different than patent exclusivity in the U.S., but again, I'm not a patent expert, so I have no idea what the patent life was when this was submitted.
Q. I'm not talking about the patent, Doctor. I'm talking about, once the FDA approves the drug for sale in the United States, that sponsor gets to sell it by itself in a monopoly for ten years, right?
A. I don't know if that is true at the time. Today, if you don't have patent protection, it's only five years.
Q. Okay. At this time, they had it for ten years, correct?
A. Again, I'm saying I don't know. I'm not a patent expert.
Q. Okay. Fine. But you would agree with me that ten years after the drug gets approved, GSK suddenly submits the report to the FDA --
MR. BAYMAN: Objection --
MR. WISNER: -- correct?
MR. BAYMAN: -- calls for speculation. He said he didn't even know how long the patent exclusivity period was.
THE COURT: Overruled. Proceed.
BY THE WITNESS:
A. It was submitted in 2002.
BY MR. WISNER:

Q. Now, Doctor, isn't it true that the reason why GSK submitted that new analysis ten years after the NDA was approved was because of ongoing Paxil litigation?
A. Right. I think we saw documentation of that where it was highlighted, this issue of the run-ins which you have been discussing, so we wanted to look in the controlled portions of the trial, and we did that. And there was no evidence of any increased risk for paroxetine in the NDA data.
Q. So it took lawyers like myself and my colleagues suing GSK for them to finally fix it; is that right?
MR. BAYMAN: Objection, your Honor. Now we're getting --
THE COURT: Sustained.
MR. BAYMAN: -- into --
THE COURT: Sustained.
MR. BAYMAN: I'd ask the jury to disregard that comment.
THE COURT: The jury may disregard it.
MR. WISNER: Well, permission to publish, your Honor, admitted Exhibit 124.
THE COURT: Proceed.
THE WITNESS: Is this PTX 124?
BY MR. WISNER:
Q. Yes, sir. This is already in evidence. This is the record of conversation that you showed the jury -- sorry, that

you and Mr. Bayman showed the jury on your direct examination. Do you recall that?

A. Yes.

Q. All right. So this is dated -- let's get to the date -- April 10th, 2002. Do you see that?

A. Yes, I do.

Q. And if we go into it, it reads:

> "I spoke with Dr. Tom Laughren of the FDA neuropsychopharmacology division last Wednesday, April 10th, concerning the updated Paxil analyses on suicide attempts. I explained to Dr. Laughren that subsequent to ongoing defense of Paxil cases, the issue of attempts in patients on placebo during placebo run-in had been debated, and a decision had been made to reanalyze the original NDA data on suicide attempts doing the apples-to-apples comparison."

Do you recall -- do you see that, Doctor?

A. I do see that, yes.

Q. You showed that to the jury on your direct, didn't you?

A. Right, and I just mentioned it earlier to a question you asked me.

Q. Now, here is the thing that I'm sort of interested in. If you read down here, it says:

> "Dr. Laughren quickly recognized the conundrum of accounting for placebo run-in attempts in terms of how

you would adjust the denominator in calculating incidence and agreed that this was an acceptable way of addressing the issue."

That denominator issue is what we were just talking about a second ago, right?

A. That's right.

Q. Okay.

"I assured him that this was only an issue in terms of attempts and that the other analyses stood as submitted in the FDA in '91 report based on the NDA."

Do you see that?

A. Yes.

Q. That's not true, is it, Doctor?

A. When we reanalyzed the data, we also assessed the apples-to-apples for suicides as well.

Q. So when he says he assured him that this was only an issue in terms of attempts, that was a lie, correct, Doctor?

A. Again, I characterize a lie as intentionally trying to mislead. I think this was just an error in representing what we were doing in the analysis because the analysis, plain and clearly, we did suicides as well.

Q. So to be clear then, in your opinion, this wasn't an intentional misrepresentation, this was just an accidental one; is that right?

MR. BAYMAN: Objection, your Honor.

THE COURT: Overruled.
BY THE WITNESS:
A. Right, because we reanalyzed suicides and suicide attempts for the FDA submission here.
BY MR. WISNER:
Q. Well, on this conversation, it goes, "I indicated that similar analyses had been done," for completeness sake, "on the more recent 2000 database for all Paxil studies and the conclusions were the same: No signal for Paxil versus the comparator groups. He indicated that the agency would not need to see these data, but thank you for the update."
Do you see that?
A. Right. So here we had --
Q. I'm sorry. I just asked you if I read that correctly, Doctor.
A. Yes, you read that correctly.
Q. Okay. So to be clear, in a document, documented conversation that contained an accidental misrepresentation, the FDA said, "Oh, we don't need to see the data;" isn't that true?
MR. BAYMAN: It's argumentative, your Honor. He didn't say it was an accidental misrepresentation.
BY THE WITNESS:
A. We -- what it says here is for the updated database which includes many more subjects, Tom Laughren didn't ask to see

these data.
BY MR. WISNER:
Q. Now, you said this wasn't intentional. Did you speak to the author of this memo?
A. I did not.
Q. So you don't know what Dr. Wheadon actually was thinking?
A. No, but again, the analyses we did and submitted included suicides and suicide attempts --
Q. Now, Doctor --
A. -- and highlighted where the run-in was an issue in each instance.
Q. Now, Doctor, I apologize. I know you didn't actually join GSK until 2005, right?
A. That's correct.
Q. So you got involved in this whole thing, what, 13 years after the drug had been on the market, right?
A. Yeah, about that.
Q. So you weren't involved in these apples-to-apples discussions or the run-ins or any of that stuff, were you?
A. I was not directly involved, no.
Q. And if you were, you wouldn't have done that, would you?
A. Have done what?
Q. Made accidental misrepresentations, would you?
MR. BAYMAN: Same objection, your Honor.
THE COURT: It's sustained.

BY MR. WISNER:
Q. Okay. Now, the data from the 2- -- I'm sorry, from the 1989 NDA and the 1991 suicide report, in that period of ten years before this stuff was disclosed to the FDA, GSK actually promoted that data to physicians, didn't it?
A. Which data?
Q. The incorrect run-in data, Doctor.
A. Explain to me how you say "promoted." What was done? What are you referring to specifically to?
MR. BAYMAN: Your Honor, this is outside the scope of direct now.
MR. WISNER: GSK --
MR. BAYMAN: He's not a marketing witness.
MR. WISNER: We didn't call him in our case in chief specifically because they said they would call him now. This is my time to get the testimony out.
THE COURT: Proceed.
BY MR. WISNER:
Q. What do I mean by "promotion," I mean GSK went into doctors office, handed them research saying, "This is the data on suicides," and that included the run-in data, correct?
A. I'm not certain of that.
Q. You're not?
A. No. Again, I wasn't involved in reviewing marketing practices. I may have seen documents in the past, but I don't

necessarily memorize them.
Q. Okay. Well, let's show you the documents that you looked at in the past. Okay?
A. Okay.
Q. All right. Let's turn to Plaintiff's Exhibits 34, Doctor. This is already in evidence. Are you there, Doctor?
A. Yes. I've got it.
Q. All right. The first page it says, "annotated bibliography." Do you see this?
A. Yes, I do.
Q. And actually, if there was any doubt here, you can see that's your name on a deposition exhibit number, isn't it?
A. No, I'm not doubting I've seen this before.
Q. Okay.
A. I just don't memorize every document I've seen.
Q. Sure. So we turn the page. There's a section here that reads, Dunner and Dunbar, "Reduced suicidal thoughts and behavior, suicidality, with paroxetine." Do you see that, Doctor?
A. Yes, I do.
Q. It states that it was presented at the American College of Neuropsychopharmacology on -- in December of 1991 in San Juan, Puerto Rico, right?
A. Yes, I see that.
Q. Now, to be clear, Doctor, December 1991, Paxil is not even

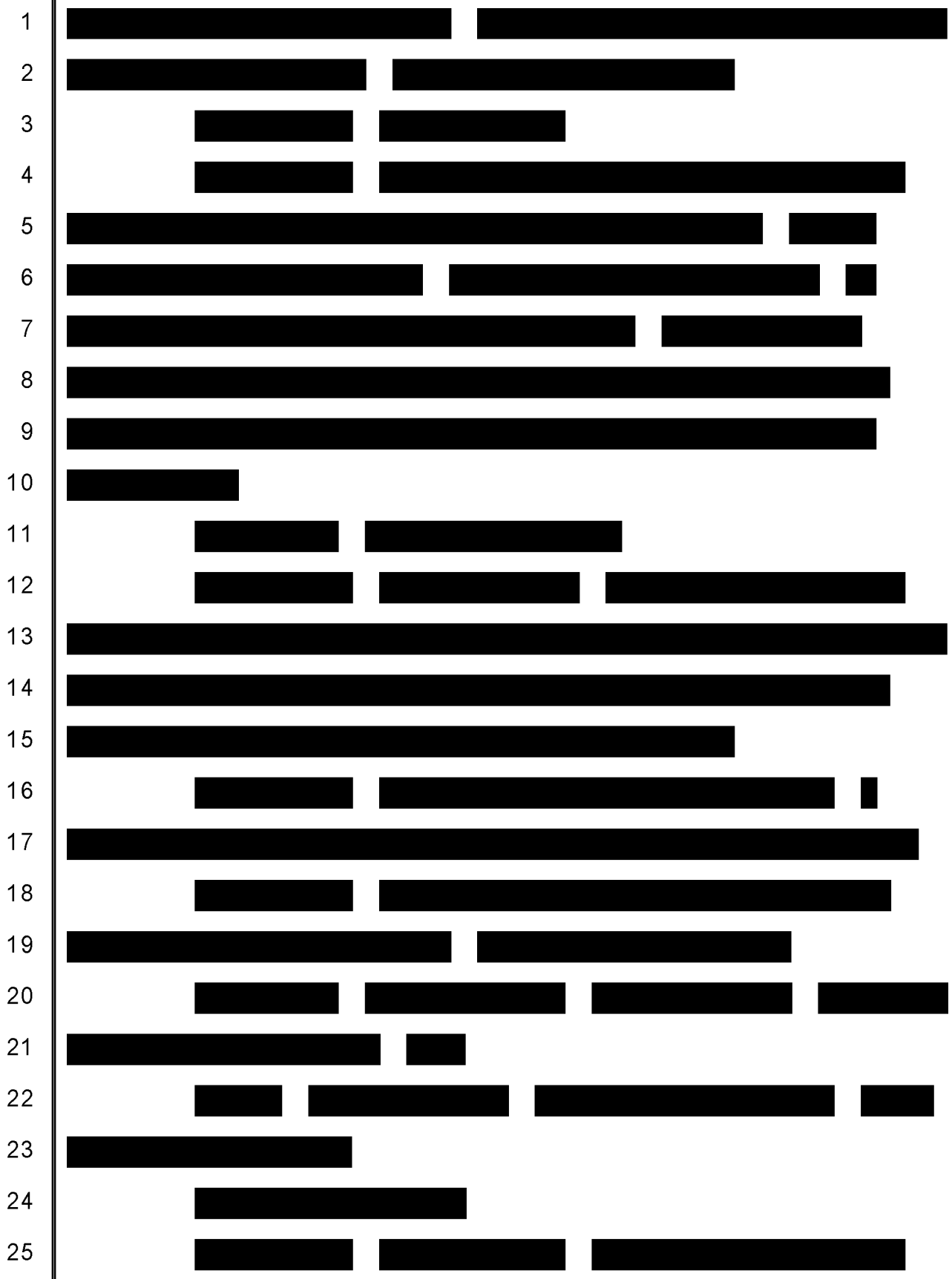
approved yet, is it?
A. No. I believe it was approved in 1992.
Q. And Dr. Dunbar, he was a GSK employee?
A. I believe that's correct, yes.
Q. So here he is presenting to physicians data about the reduced suicidal thoughts before Paxil was even on the market; is that right?
A. It's not unusual to present data for drugs in development, that that's actually --
Q. I'm not --
A. -- how the scientific literature is shared, so yes, he did do that.
Q. I didn't ask you if it was unusual, Doctor. I said he was telling doctors that it reduced suicidality before the drug was even on the market, correct?
A. He presented the results of this analysis before the drug was on the market, yes.
Q. All right. If you look in the analysis, it states right here: "Suicide and suicide attempts occurred less frequently with paroxetine than with either placebo or active controls." Do you see that?
A. Yes, I do.
Q. That's reflecting the data that we looked at that used the incorrect denominator, correct?
A. Yes, it's reflecting that data.

Q. Okay. So at this point, at least prior to Paxil's approval, Dr. Dunbar and Dr. Dunner are out in -- in Puerto Rico telling physicians about this data, correct?
A. Well, they're informing the results of the analysis including the rating scales measured, so yes, they're sharing the information with other clinicians.
Q. And that table that we talked about, that table was duplicated verbatim in Dr. Brecher's report, right?
A. I know the numbers are similar. I don't know if it's verbatim exactly the same.
Q. Do you want to look at it?
A. Yes, if you want to pull it up.
Q. All right. Publishing Defendant's Exhibit 305, which is already in evidence.
A. I'll look at it on the screen.
Q. Okay. Let me get it up. Oh, here we go. Okay. All right, Doctor. This is Exhibit 305. Do you see that? This is the Dr. Brecher report.
A. Yes. It's the clinical review.
Q. All right. Let's go to Page 30. You recall during your direct examination, I objected and said, "show the table above," remember?
A. I don't remember. You object a lot.
Q. All right.
THE COURT: Good for you, Doctor.

THE WITNESS: Yes, I didn't mean it that way.
BY MR. WISNER:
Q. This is the table, right?
A. Suicidality in paroxetine -- I don't know. Again, I'll take your word that this is a table you either objected to or didn't.
Q. Forget that question. This is the table in Dr. Brecher's report, it says "Suicidality in paroxetine clinical trials," right?
A. That's correct.
Q. All right. If you look at the data, it has the 2 and the 6. Do you see that?
A. Yes, I see that.
Q. So it's verbatim with what's in the suicidality report, right?
A. Yes. Dr. Brecher accepted the same numbers, that's correct.
Q. Okay. Do you know if he copied and pasted it or if he accepted them?
A. I don't know which was which.
Q. All right. And these exact numbers also made it into the summary basis of approval, didn't it?
A. That's what this is part of, that's correct.
Q. This is Dr. Brecher's report. I'm talking about the summary basis of approval issued by the FDA. These exact

numbers entered -- appeared there, correct?
A. I'm not certain of that, but they would be because they come from his report.
Q. All right. I'll show it to you in one second. Before I move on from this, you've seen the asterisks stating that these 2 and 6 include run-ins?
A. That's not in this report, no.
Q. Okay. So let's go to Plaintiff's Exhibit 28, also admitted. I'll pop it up on the screen. This is the summary basis of approval, right, Doctor? I'll call it out so you can see it.
A. It is --
THE COURT: I think we'll take our recess.
MR. WISNER: Okay.
THE WITNESS: This is one of the times --
THE COURT: We're off the record.
(Recess from 2:59 p.m. to 3:15 p.m.)

(Change of reporters, Volume 16-C.)



[redacted]

(Jury enters courtroom.)

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

You may proceed, sir.

BY MR. WISNER:

Q. Doctor, the document in front of you is a call-out from the NDA, summary basis of approval. Do you see that?

A. Yes. Does this have a -- it's PX 028?

Q. It is Plaintiff's Exhibit 28, that's correct.

A. Okay. I've got it.

Q. Okay. Great. Now, if we turn to page 46 in the document, I've called it out for you right here, Doctor. It's table -- I'll call out the whole thing. It's table 55. Do you see that, Doctor?

A. What page again, sir?

Q. Page 46 in the document, so the second-to-last -- third-to-last page of the document.

A. Yes, table 55, I've got it.

Q. Okay. Great. And that again is the same table that we saw on Dr. Brecher's report as well as in the 1991 suicide analysis?
A. Yes, these utilized the same numbers.
Q. This is with the -- with the percentages as well as the PEY numbers being calculated with placebo run-ins, correct?
A. Yes, all the data, yes.
Q. Okay. All right, Doctor. Now, we mentioned that this data was presented in 1991 previously. It was also published in an article by Dr. Montgomery and Dunbar, correct?
A. I believe that's correct. Some aspects of this were published in that article, yes.
Q. Okay. And if you look at Plaintiff's Exhibit 98 in your binder, this is not in evidence, so I have to make sure it's authenticated. Do you see it, Doctor?
A. I do.
Q. That is a copy of that article?
A. Yes, it is.
Q. Have you seen this document before?
A. Yes, I have.
Q. You've been deposed about it before?
A. I'm sure I have, yes.
MR. WISNER: Permission to publish, your Honor.
THE COURT: You may proceed.
MR. BAYMAN: I would object to admission of this

article through this witness.

THE COURT: Yes. I haven't admitted it. It's simply available for inquiry of an expert witness.

MR. WISNER: I have no intention of admitting it, your Honor.

BY MR. WISNER:

Q. All right. Doctor, I'm showing you on the screen, that is a copy of Plaintiff's Exhibit 98. Do you see that?

A. Yes, I see it.

Q. Just so we're all on the same page, we have here Drs. Montgomery, Dunner, and Dunbar. Do you see that?

A. Yes, sir.

Q. And Dunbar at this time was, in fact, an employee of GSK?

A. Yes.

Q. All right. Now, if we go in to the document, if you go to page 6 of the document, you see there table 8 on the bottom left corner? I've popped it up on the screen, too, for you.

A. Table 8?

Q. Yes.

A. Yes.

Q. And again, this table includes the placebo run-in data, correct?

A. Yes, includes all the data, placebo run-in, extension, open label, placebo-controlled, yes.

Q. It includes the incorrect calculations that were in the

1991 report, Dr. Brecher's report, the summary basis of approval, correct?

A. It doesn't control for the denominator aspect that we talked about, so it's the same numbers from each of those reports.

Q. Okay. And if we look at the conclusion that's written here, just above it, it says, "Calculated per patient year of exposure, there were 2.8 times fewer suicides in the paroxetine-treated group compared to active control and 5.6 times fewer compared to the placebo." Do you see that?

A. Yes, in terms of the PEY.

Q. And that is an incorrect calculation because it uses an improper denominator, right, Doctor?

A. That's correct. The denominator couldn't provide the rate for which the PE -- EPEY would be calculated.

Q. Do you recall the first time someone showed you this article and this table, Doctor?

A. No, I don't recall that.

Q. It would be before 2009, right?

A. Yeah, probably.

Q. Okay. Since then, have you done anything to encourage Dr. Dunbar to correct this article?

A. I have not, no.

Q. Okay. Now, if you go to the conclusion section, Doctor, on page 8 of the article or page 12 in the top left, if you're

looking for it, do you see in the conclusion section, it reads, "An important finding in this analysis is the reduction in the number of suicides expressed per patient year of exposure in the paroxetine-treated patients compared with placebo, 5.6 times, and active control, 2.8 times, and a twofold reduction in the rate of attempted suicide compared with placebo." Do you see that?

A. I do see that.

Q. "This result is consistent with the advantage shown for paroxetine in ameliorating suicidal thoughts compared with placebo and active control." Do you see that?

A. Right, which is referencing the change in rating scales and improvement on suicidality items.

Q. It goes on to say, "Although it is not possible to directly link suicidal acts, complete or unsuccessful, with suicide thoughts, this consistent reduction in suicides, attempted suicides, and suicidal thoughts, and protection against emergent suicidal thoughts suggest that paroxetine has advantages in treating the potentially suicidal patient."

Do you see that?

A. Yes.

Q. That conclusion is based on those improper calculations, correct?

A. In part. It's also based on the rating scale and the comparison to active comparator.

Q. Well, the point it references before it gets to that section is specifically the improper calculations of 5.6 and 2.8, correct?
A. That's summarized in the paragraph above.
Q. Now, Doctor, you would agree with me that based on the fact that there were some incorrect calculations, it would be inappropriate for GSK to give this study to physicians to alleviate their concerns about suicide risk in Paxil, correct?
A. The authors who wrote this at the time believed this was correct information, so it's only later that the issue of the run-ins became evident. So, at the time, this represented the authors' views of the data.
Q. Another accidental misstatement, Doctor?
A. No. It occurred in the original report, and that was repeated by FDA and in this manuscript.
Q. That original report, it got included everywhere, including this article, didn't it?
A. You've asked that, yes.
Q. In fact, shortly after this article was published, GSK's marketing department specifically instructed its sales representatives to use this article to ameliorate physicians' concerns with Paxil and suicide, isn't that true?
MR. BAYMAN: Objection. It goes to marketing. Your Honor has ruled that out.
THE COURT: If he knows, he may testify.

BY THE WITNESS:
A. I don't recall. I may have seen a document in the past. If you have that document, I'm happy to review it.
BY MR. WISNER:
Q. Sure. Let's go to Plaintiff's Exhibit 100. It's in evidence. I'll put it up here on the screen.
Do you see this memo here, Doctor?
A. Yes.
Q. July 5th, 1995?
A. Yes. Let me -- this is something I have not either seen in a while or recall, so let me take a look.
Q. Sure.
A. Yes, I've reviewed it. I've seen this before.
Q. Okay. And it's addressed -- it's written by Barry Brand, correct?
A. Yes.
Q. Product manager for Paxil, correct?
A. Assistant product manager for Paxil, yes.
Q. Fair enough. He was -- fair enough. He later became the product manager, correct?
A. I believe he became the brand manager, yes.
Q. And then you have, "To," and it has, "SK&F Consultants." Do you see that?
A. Yes.
Q. All these people it's referencing are the sales force of

GSK, isn't that true?
A. That would be my guess, but I don't -- I don't recall the word "consultants" used for sales specialists, but maybe that was used back then.
Q. Okay. All right. It says, "In the analysis from controlled studies and open extension studies of Paxil calculated by patient year of exposure, there were 2.8 fewer suicides in the Paxil-treated group compared with active control and 5.6 times fewer compared with placebo. Clearly, very positive results."
Do you see that?
A. Yes.
Q. Again, it's repeating the same data that we've been talking about, right?
A. Right. It also includes tables on the rating scale showing the effects of paroxetine as well in this letter.
Q. It reads, "This paper has been approved for use with physicians to alleviate any concerns they may have regarding suicidal ideation." Do you see that?
A. I see that.
Q. If you go to the second page, it again repeats the data about the 2.8 times and the 5.8. Do you see that?
A. I do see that.
Q. And again, this is actually quoted out of directly the article. It even says the page and column line number.

A. I see that.
Q. Do you see that?
A. Yes.
Q. Okay. And then the bottom paragraph says, "This paper adds to the burden of proof that Paxil is a safe and effective antidepressant and may be used with physicians to alleviate any concerns they may have regarding suicidal ideation. Although reprints are not currently available, you may use this paper with physicians, but may not leave behind. A copy of this paper is included in this week's field mail."

Do you see that, doctor?

A. I see that.
Q. And you understand based on this document that GSK sales representatives were, in fact, instructed to use the Montgomery and Dunbar publication to alleviate concerns with the physicians as it relates to Paxil and suicide, correct?

MR. BAYMAN: Objection, your Honor. This witness is not a marketing witness, and there's no evidence that these articles were ever given or shown to Dr. Sachman in this case.

THE COURT: Overruled. He may answer if he knows.

BY THE WITNESS:
A. You're stating what's written in the letter, sir.
BY MR. WISNER:
Q. All right. So, that's 1995. Again, the issue wasn't disclosed to the FDA until 2002, right?

A. The reanalysis to look and see if there was a potential for association of drug versus placebo did occur in 2001 into 2002 for the submission.
Q. And that was that conversation memo we looked at a minute ago, Dr. Laughren and Dr. Wheadon, do you remember that?
A. Oh, yes, that one, yes.
Q. Okay. Good. Now, in 1999, somebody raised concerns -- strike that.

In 1999, Mr. Burnham raised concerns that this information was inaccurate, isn't that true?
A. I would need to see the document, but I have recollection of that.
Q. All right. Look to Plaintiff's Exhibit 114. It's also in evidence.
A. Okay.
Q. Now, there's an e-mail in the front, but just turn to the second page, because we're going to start there.
A. Okay.
Q. All right. Do you see that this is the e-mail from Mr. Burnham, and if you look at the second -- the bottom of the first page, it has who it's from, Daniel Burnham, to a bunch of different individuals. Do you see that? Bottom of the first page.
A. Oh, yes.
Q. And you see one of those individuals was, in fact, Barry

Brand, the guy who wrote the memo that we talked about a second ago?
A. Yes, it looks that way.
Q. Okay. Great. So, on the second page, this is what we've called the Burnham e-mail. Do you see that?
A. I see it, yes.
Q. And he states right here, "The two suicides among the 544 placebo patients in Montgomery and Dunbar's 1995 publication actually occurred during single-blind placebo run-in, not double-blind placebo. Because patients undergo usually one week of single-blind run-in before randomization, these two suicides on placebo are not comparable to deaths occurring after randomization for three reasons."
Do you see that, doctor?
A. I do.
Q. And he goes on to list three different reasons in bullet point fashion. Do you see that?
A. Yes, I do.
Q. Now, the context of this e-mail is in July of 1999, that's when the FDA had asked for the death report, correct?
A. Yes, '99 was when the death report was requested, that's correct.
Q. And GSK submitted a preliminary death report in July 1999, but was getting ready to submit the final one in December of 1999, correct?

A. I believe that time period is correct.
Q. All right. And if you look at the first page, it actually talks about -- the subject, it says, "Incidents of death/suicide in paroxetine randomized control trials in depression, FDA request." Do you see that?
A. Yes, I do.
Q. And this was in November of 1999. Do you see that?
A. Yes.
Q. So, this is right before they submit that final death report, correct?
A. Approximately, proximal to that, yes.
Q. Okay. Now, if you look at the bottom part, it says, "Bottom line, we must mention the placebo run-in deaths to reconcile the overall incident figures with the Montgomery and Dunbar publication; however, we cannot combine these placebo run-in deaths with the randomized placebo death rate for the three reasons above. Thus we are left with a .01 percent suicide rate on paroxetine IR and a 0 percent rate on placebo."

Do you see that?

A. I do.
Q. And in fact, in the ultimate death report that was submitted in 1999, there were six completed suicides in the active and placebo-controlled clinical trials for paroxetine and 0 in the placebo arm, correct?

A. I would need to look back at the report, but I think -- I think that is correct from my recollection. Again, that's the Paxil suicides from all stages of clinical trials.
Q. I'm sorry, Doctor. The death report only included deaths, suicides --
A. In the controlled phase. I meant active comparator in addition to placebo control.
Q. To be clear, an active-controlled clinical trial, that is different than an open label file, right?
A. Yes, it is.
Q. And in fact, a placebo-controlled clinical trial and an active-controlled clinical trial, the only difference is in one of the trials they get placebo, and in the active-controlled trial they get an active comparator, right?
A. That's not the only difference. That's one difference.
Q. What other differences are there?
A. The scientific question being addressed is often different.
Q. Sure. In the placebo-controlled it's, "Is this drug more effective than placebo," and in the active-controlled trial, it's, "Is this better than what's already on the market." Fair?
A. And also safety profiles, things of that nature.
Q. Okay. So, for purposes of randomization, blinding, reliability, elimination of bias, they are essentially the

same type of controlled clinical trial, right?
A. They're operationalized and executed similarly. It doesn't mean you can draw the same conclusions from each study.
Q. Now, so this is in 1999 that Mr. Burnham is raising this issue, and then we have a response. Do you see this? It's on the first page, Doctor. Do you see that, Doctor?
A. Yes.
Q. And it's from Barry Brand, the guy who wrote that memo that we discussed in 1995, right?
A. That's what it looks like, yes.
Q. He says, "This response to FDA seems to be setting us up for potential problems, suggesting that Paxil is associated with a higher rate of suicide versus placebo. A very comprehensive meta-analysis published by S. Montgomery clearly showed a higher incidence of placebo-related suicides, and a 1998 study published in the American Journal of Psychiatry in non-depressed patients suggested that Paxil offered a protective effect in patients with less than three previous suicide attempts. Can we use the Montgomery meta-analysis as the baseline for our analysis and reference to American Journal of Psychiatry study in our response back to the FDA? I have provided copies of those studies to Dan Burnham. Let me know your thoughts. Regards, Barry."
Do you see that?

A. I see that.
Q. So, it would appear that Mr. Brand has recognized that this response is exposing the problem with the Montgomery and Dunbar article, correct?
MR. BAYMAN: Objection. It's speculation, your Honor, as to what Mr. Dunbar recognizes.
THE COURT: Overruled. He may answer if he knows.
BY THE WITNESS:
A. I don't know other than what's written here.
BY MR. WISNER:
Q. He is suggesting that Paxil is associated with a higher rate of suicide versus placebo. That's what he says, right?
A. He wrote that in the first sentence.
Q. Okay. Now, at this time, Doctor, when GSK is figuring out what they're going to be submitting to the FDA in December of 1999, there was an instruction that anything submitted to the FDA had to first get cleared by GSK's lawyers, right?
A. I'm not --
MR. BAYMAN: Objection, your Honor.
THE COURT: Overruled.
BY THE WITNESS:
A. I'm not aware of that, no.
BY MR. WISNER:
Q. Oh, okay. Well, let's look at Plaintiff's Exhibit 110. It's also in evidence.

Have you ever seen this document before, Doctor?
A. Yes, I did see this document.
Q. Okay. If you look at the bottom, "Subject: FDA conversation Paxil request for data on deaths." Do you see that? That's the subject at the bottom?
A. Yes.
Q. And we're talking here about this issue. And if you look in here, there's Mr. Brand. Do you see him?
A. Amongst dozens of others, yes.
Q. Okay. So, we go to the top. It says, "Tom, please allow some time for legal to review this prior to submission to FDA. Per my earlier e-mail on this one, I think Andrea Perry and I will need to be involved in light of the litigation in this area. I want to ensure our positions are not inadvertently compromised as a result of anything we share with FDA."
MR. BAYMAN: Your Honor, I object to this.
MR. WISNER: It's in evidence, your Honor.
MR. BAYMAN: Ask for a sidebar.
THE COURT: It's in evidence?
MR. WISNER: Yes.
THE COURT: Proceed.
BY MR. WISNER:
Q. That's what it says, right, Doctor?
A. You just read what it says, yes.
Q. So, isn't it true that at this time, there was an

instruction that anything submitted to the FDA regarding deaths or suicides had to first go through the lawyers to make sure it didn't compromise ongoing litigation?

MR. BAYMAN: Your Honor, I object to him turning and pointing at us and saying, "the lawyers."

THE COURT: Sustained.

MR. BAYMAN: Thank you.

THE COURT: Sustained.

BY MR. WISNER:

Q. Isn't it true that at this time, there was an instruction that any information submitted to the FDA about suicides or suicide attempts had to be first run by the lawyers before it got sent to the FDA?

A. Whoever Mary is requested that. Whether that was done or not, I don't know.

Q. Okay. Do you know who Mary Kohler is?

A. I don't.

Q. Do you know who Andrea Perry is?

A. Yes.

Q. Who is she?

A. She used to work at GSK in -- I forget the name of the department, but she was a lawyer.

Q. She was an attorney?

A. Yes.

Q. She worked on the Paxil suicide issue, right?

A. She supported that at the time, yes.
Q. Now, look at the date -- if we go back to the previous exhibit, Doctor, Exhibit 114, this is the Brand e-mail, and if you look at the date, it says December 7th, 1999. It's right on your screen, but if you want to look at the paper, that's your choice.
A. I actually like to see the context of what's around it as you're zooming in, just in case.
Q. I would as well. I totally understand.
A. Okay.
Q. So, do you see that, December 7th, 1999?
A. I do see that.
Q. Okay. Now, the next day, GSK actually calls the FDA to discuss the run-in issue, doesn't it?
MR. BAYMAN: Your Honor, can the witness be given a full copy of the document, as he requested?
THE COURT: Oh, surely. Does he have a full copy?
MR. WISNER: He's staring at it right now.
MR. BAYMAN: Can you tell him what tab?
THE WITNESS: It's --
MR. WISNER: He knows. I don't think there's any concern here.
THE WITNESS: It's 114?
BY MR. WISNER:
Q. Yeah. Are you good, Doctor? Do you have the document?

A. I've got 114.
Q. Sure. And if there's some document you want to see the paper copy, let me know and I'll make sure you have it in front of you. All right?
A. Yeah, I've asked before.
Q. Yeah, no problem. So, you've got 114 in front of you. This is dated December 7th, 1999, right?
A. It is.
Q. Okay.
THE COURT: Excuse me. Who is Mr. Kumar? Doctor, do you know?
THE WITNESS: I think he was a medical director at the time, but I can't remember definitively.
THE COURT: Okay. Thank you.
BY MR. WISNER:
Q. All right, Doctor, so this is December 7th, 1999, right?
A. That's the date on the e-mail, yes.
Q. Okay. The next day, GSK had a conversation with the FDA to discuss the run-in issue, doesn't it?
A. I don't know, so we need to look at the document.
Q. All right. Turn the page, 115, Plaintiff's Exhibit 115. Have you got it, Doctor? It's also in evidence.
A. Yes, I have it.
Q. December 8th, 1999, the next day, right?
A. Yes, that's the next day.

Q. And this is a conversation between Michael Seika and Thomas Kline. Do you see that?
A. Yes.
Q. And it says, "FDA request for deaths and suicide rates." Do you see that?
A. That's the topic, yes.
Q. Oh, and if we go down to the summary of conversation, in the middle of it, I'll highlight it. He says, "In addition, I raised a hypothetical example for his consideration. I inquired about his interpretation of classifying placebo run deaths. Specifically, I asked if a patient" -- well, I'll just stop right there.

That hypothetical placebo run-in death, this wasn't hypothetical. They'd actually done that in the 1991 report, right?
A. Again, as represented here, he raised a hypothetical example. I don't know if he spoke to the '91 report or not.
Q. Sorry, Doctor. I guess my question is: We know standing here today that this issue with the run-ins was not hypothetical; it's actually what GSK did in the 1991 report, right?
A. It was an issue in the report, that's correct.
Q. Okay. It goes on to read, "Specifically I asked if a patient were to die during placebo run-in, i.e., prior to randomization, should that patient be included in the

calculation for placebo deaths. He clearly stated that such a patient should not be counted in our analysis since such a patient would not comprise the 'controlled' portion of a trial."

Do you see that, Doctor?

A. Yes, I see that.

Q. This is December of 1999, right?

A. Yes, it is.

Q. So, it would be a year-and-a-half before GSK actually told the FDA about the run-in issue, right?

A. Well, as we've seen in some of these documents, we've disclosed run-ins depending on the document shown. But the analysis where we looked at the placebo-controlled portions of the files and highlighted where the run-in issue subjects were not in there, that was the John Davies analysis of the original NDA data.

Q. Okay. Doctor, we'll take a pause here in the chronology and ask you to step back for a quick second. Now, you testified on direct examination that the information contained in the original 1992 label for Paxil included a warning about disease management, correct?

A. Yes.

Q. You testified that the warning did not specify that the drug itself --

THE COURT: Take this off the screen unless it's

being dealt with.

MR. WISNER: Oh, sorry, your Honor. Yes, your Honor.

BY MR. WISNER:

Q. The 1992 label, in your opinion, did not warn that the drug itself could induce suicidal behavior, correct?

A. There was no data to support such an assertion, so it was not in the label.

Q. So, it wasn't in the label; you agree, right?

A. It was not in the label.

Q. All right. You agree that the information that was contained was disease management, right?

A. In terms of treating patients with depression, yes.

Q. All right. Now, I'm going to draw your attention to Plaintiff's Exhibit 48. Now, you can look at the paper copy, but it's almost entirely illegible because it's so small; but you can tell me?

A. I'll look at it here.

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

BY MR. WISNER:

Q. This is the Paxil label from 1992. I'll wait until you get there.

A. There you go. I can actually still read this.

Q. Okay.

THE COURT: Good for you.

BY MR. WISNER:
Q. So, this is the '92 label, right?
A. Yes, December 1992.
Q. Okay. And on the front page here, there is a section here that says, "Suicide." I'm going to call it out so that those of us without super eyes can read it.
It's on the screen. Do you see that, Doctor?
A. Yes, I do.
Q. Okay. Great. And it reads, "The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs." Do you see that?
A. Yes, I do.
Q. So, that's the risk of suicide associated with depression, right?
A. Yes.
Q. It says, "Close supervision of high-risk patients should accompany initial drug therapy." Do you see that?
A. Yes.
Q. So, in the original 1992 label, it's saying you should closely observe patients when they start drug therapy, doesn't it?
A. For high-risk patients, those with a risk of suicidality.
Q. That's disease management, right?
A. Yes.
Q. It's disease management even though it says, "Accompany

initial drug therapy," right?
A. Yes.
Q. It goes on to talk about how prescriptions for Paxil should be written for the smallest quantity, right?
A. Right, to avoid overdose. That is true with other drugs as well.
Q. And that's standard practice for any physician prescribing a drug, right?
A. In general, if there's a risk of overdose for that medicine.
Q. Okay. Great. Now, on the second page of this label, Doctor, is a section that's called, "Other Events Observed During the Premarketing Evaluation of Paxil." Do you see that, Doctor? I've blown it up for you, but you can use the paper if you need it.
A. I see it.
Q. Okay. And this is the section where it's discussing data from every single clinical trial for Paxil that GSK possessed, right?
A. During the premarketing phase, yes.
Q. Yeah. This is actually the NDA data. You have the same number of patients, 4,126, right?
A. Right.
Q. Okay. And it goes on to talk about -- on the next page, it says, "The tabulations that follow reporting adverse events

were classified using a standard," and then I'll call out the next paragraph, "COSTART-based dictionary terminology."

Do you see that?

A. Yes.

Q. Now, on direct examination, the issue of coding suicide attempts as emotional lability came up. Do you recall that?

A. Yes, we discussed that.

Q. And you told this jury that because the dictionary didn't have suicide attempt in it, you had to use emotional lability, is that right?

A. The company chose to use emotional lability, as it seemed the most reasonable preferred term in the absence of suicide attempt.

Q. Okay. We're going to get back to the dictionary in one second, but let's just quickly go down the thing and just point out where it says here in the nervous system, do you see that, "Frequent," Doctor?

A. Yes.

Q. "Amnesia, CNS stimulation." That means central nervous system stimulation, right?

A. Yes.

Q. And then it says, "Concentration impaired, depression, and then emotional lability." Do you see that?

A. Yes, I do.

Q. And you would agree that that emotional lability is

primarily suicide attempts?
A. I don't know if that's the case because other things could be coded to that preferred term, but I do know suicide attempts were part of that preferred term.
Q. Well, let's not guess here, so we'll go look at it in one second. But before we do, Doctor, in the original integrated summary of safety, there was 42 attempts, right?
A. That's right. That's what was -- wait, yes, in the U.S.. And then in the '90 and '1 report, it was 40.
Q. Okay. Let's look -- unfortunately, you don't have it in your binder because I didn't think we would need it, but I'm going to show you on the screen what is Plaintiff's Exhibit 75. It's already in evidence. This is the integrated summary of safety.
MR. WISNER: Permission to publish, your Honor?
THE COURT: You may proceed.
BY MR. WISNER:
Q. See, this is the integrated summary of safety, Doctor?
A. No.
Q. It's not on the screen.
There it is. Have you got it?
A. Yes.
Q. All right. And if we turn the page, a couple of pages in, there's a table right here where it lists out comparison of adverse experience listed by preferred term within body

system. Do you see that, Doctor?
A. Yes, I do.
Q. And if we go down to emotional lability, we see 42, right?
A. Yes.
Q. And we know there was 42 suicide attempts, at least as it's disclosed in this document, right?
A.
Q. So, it does appear that emotional lability was primarily driven by suicide attempts, if not entirely?
A. It seems that way, yes.
Q. Now, you told this jury that suicide attempt was not in the COSTART dictionary, is that right?
A. The dictionary used at the time of these studies, which may have been COSTART.
Q. Okay. Turn to Plaintiff's Exhibit 27.
A. Yes.
Q. Are you there, Doctor?
MR. WISNER: This is a document that's in evidence. Permission to publish, your Honor?
THE COURT: Yes, proceed.
MR. BAYMAN: Your Honor, there's no foundation for this document. You've ruled it out previously with Dr. Healy.
THE COURT: I ruled it out, you say?
MR. WISNER: No, it's been admitted into evidence, your Honor.

THE COURT: I'll assume it has. You may proceed.
MR. BAYMAN: He has no foundation to use it with this witness, your Honor.
MR. WISNER: Your Honor, I have every right to use admitted evidence with a witness.
THE COURT: You may proceed.
MR. WISNER: If I could get this to work. One second, your Honor. It will be right up.
BY MR. WISNER:
Q. Okay. So, Doctor, we're looking at Plaintiff's Exhibit 27. This is in evidence. This is in a series of e-mail exchanges that we've seen already and the jury has seen. Okay, doctor?
A. May I take a look through it?
Q. Yeah, sure.
A. Is this an e-mail chain that I should read backwards or what?
Q. It's a series of e-mail exchanges. I just draw your attention to page 8. That's the only one we're going to look at for now.
A. Page 8 as listed in the document? I go from page 5 to --
Q. Page 47 on the bottom, the second-to-last page.
A. Page 47 on the bottom? Okay.
Q. There's an e-mail from Carol Palmer to a bunch of individuals. It reads, "Good morning. A question has come up

about the way suicides/suicide attempts were coded in the recent NDA supplement. Apparently, the company chose a term like 'emotional lability' when in actuality, most were suicide attempts. They used WHOART and COSTART as their dictionaries, see below, and a dictionary I'm not familiar with, ADECS. We are talking about GSK and Paxil pediatric supplement, FYI. How can we verify whether WHOART has a specific term for suicide/attempts. I don't have a copy of a WHOART reference if there's one around here. It would also be helpful to have someone to verify for me that COSTART has suicide attempts and perhaps others are the same. Too many brain cells have come and gone for me since the era of COSTART."

Do you see that, Doctor? Did I read that mostly correctly?

A. Well, you just read it verbatim, and ADECS was the dictionary used by SmithKline Beacham at the time of these studies.

Q. It says right here, "Hi, Carol. I have an old COSTART manual. Suicide attempt did exist. The manual has a COSTART to WHOART translation table which states that suicide attempt also existed in WHOART. Sally." Do you see that?

A. Right, but we were using the ADECS dictionary.

Q. Well, Doctor, let's go back to the exhibit we were just looking at, Plaintiff's Exhibit 48. It says right here in this exact part of the label, "COSTART-based dictionary

terminology." Do you see that, Doctor?
A. I do see that.
Q. So, isn't it true, Doctor, suicide attempt did exist in the COSTART dictionary at the time GSK put out this 1992 label?
MR. BAYMAN: Your Honor, objection. That's misleading. This says, "COSTART-based." It doesn't say, "COSTART dictionary."
THE COURT: Overruled.
BY THE WITNESS:
A. Right. What we used was the ADECS, which did not contain that term.
BY MR. WISNER:
Q. Now, these e-mails with the FDA were actually released publicly in 2004, correct, Doctor?
A. I don't know the answer to that.
Q. All right. At some point, there existed a dictionary that had suicide attempt in it, right?
A. That's correct.
Q. And isn't it true that as of 2010, emotional lability still appears as a frequent adverse event for Paxil?
A. It remains in the label, yes.
Q. Never got changed to suicide attempt, correct?
A. No. It's the preferred term. It was continued to be used, as this was used since the inception of the drug.

Q. I see an e-mail from the FDA saying, "They should be coded as suicide attempt." How come GSK never went about fixing that, Doctor?

MR. BAYMAN: Objection. Mischaracterizes what that e-mail says.

BY THE WITNESS:

A. Which e-mail are you describing?

BY MR. WISNER:

Q. The one we were looking at a second ago. Let's go back to it, actually, because I think there's some more interesting stuff in here, Doctor.

A. Again, I don't know who these people are and where they worked.

Q. All right. Well, let's start off on the first page. Go to the first page, Doctor. This is in evidence.

We have an e-mail from Dr. Russell Katz. Do you see that?

A. Yes.

Q. You sure know who Dr. Katz is, right?

A. Dr. Katz was at FDA.

Q. He was the head of the psychopharmacological division at this point, isn't that true?

A. That may be correct.

Q. Okay. And if we read through this e-mail, he's writing an e-mail to Andrew Mosholder. Do you see that?

A. The first one.
Q. Yeah. From Russell Katz to Andrew Mosholder. If you want to look at the screen, it might be easier to see where I am. Do you see that, Doctor?
A. Yeah. I don't know who Andrew Mosholder is.
Q. You don't know who Dr. Mosholder is?
A. I don't think so, no.
Q. Okay. In 2002, GSK attempted to get a pediatric indication for Paxil, correct?
MR. BAYMAN: Judge, I object to this. We're now going down the pediatric road.
THE COURT: That door has been opened, sir, by both sides. Overruled.
MR. BAYMAN: There's no foundation, though, for this witness. He doesn't even know who some of the people are.
THE COURT: Overruled. Well, that -- you can bring that out, sir.
BY MR. WISNER:
Q. Sure. You know that GSK submitted a pediatric indication for Paxil, right?
A. I believe for OCD.
Q. Yeah. They wanted it to be used -- to be approved for use in children with OCD, right?
MR. BAYMAN: Your Honor, may I have a continuing objection to this line, since you ruled it out pretrial?

THE COURT: Yes, sir, absolutely.

THE CLERK: Can you read that question back, sir. I'm sorry.

(Record read.)

BY THE WITNESS:

A. The SNDA was for obsessive compulsive disorder, so -- for marketing authorization.

BY MR. WISNER:

Q. That ultimately got denied, didn't it?

A. No, it was never marketed.

Q. Sorry. Did it get denied, or did it get approved, the application, Doctor?

A. I think it was -- again, I haven't looked at this in preparation for this. I've worked in the adult suicidality. I think there may have been an approvable letter, but it wasn't pursued.

Q. Now, Doctor, I want to be clear here about something. When you came to GSK in 2005, you didn't review all the submissions related to the pediatric use of Paxil?

A. I did, and in particular around this question that we're talking about, suicidality, because it was relevant to my work.

Q. Yeah, because while adults --

THE COURT: Mr. Wisner, stay with the issue that you opened here.

MR. WISNER: Sure.

THE COURT: We have agreed that we're not going into pediatric suicidality. Although I agree the door has been opened by both sides --

MR. WISNER: Sure.

THE COURT: -- I still would like to keep that issue at a very low level. You were talking about something in this e-mail that related to emotional lability.

MR. WISNER: Yeah, I'll get to that. Sorry, your Honor.

THE COURT: Stay on the track, sir.

BY MR. WISNER:

Q. Just to be clear, Doctor, you don't know who Dr. Mosholder is?

A. That's what I said, yes.

Q. Okay. Well, if we go down to the second page here, in the third paragraph, it says, "We want to move quickly to evaluate this signal. We are planning to look at the NDAs for other SSRIs to see whether or not events are being hidden" -- "whether or not similar events are being hidden by various inappropriate coding maneuvers, but we'd also like to compare the drugs in other meaningful ways if we can. We also want to call the sponsor very soon and ask some questions about their methodology."

Do you see that, Doctor?

A. I do see that.
Q. And you know that the sponsor that they're referring to here is, in fact, GSK, correct?
MR. BAYMAN: Objection. I think that calls for speculation.
BY MR. WISNER:
Q. Look at the first paragraph. "Dr. Raines told us that the company (GSK) had submitted data that demonstrated that use of Paxil in kids was associated with increased suicidality compared to placebo and that the company proposed labeling changes. He also said that it was" --
MR. BAYMAN: Your Honor, objection. That's a different e-mail chain.
MR. WISNER: It's the same e-mail. It's complete nonsense. It's the same e-mail.
THE COURT: I thought the reference was to the second paragraph.
MR. WISNER: Yeah. I said this paragraph right here on page 136, right here, from Rusty, also Russell Katz, is a continuation of the e-mail from the prior page. You can even look at the words. It says, "OCD and social anxiety are," "pooled for possible suicide-related events occurring." This is the same e-mail. I don't think there's any dispute here about that.
BY MR. WISNER:

Q. So, Doctor, my point was, this issue about the coding maneuvers, that's relating to GSK and Paxil, correct?
A. He's referencing the GSK submission, but he's also querying about other companies as well.
Q. Yeah. In fact, this is what prompted the FDA to look into the suicide issue for children and then adults in 2006, isn't that right?
A. Not the coding, sir. The data that was submitted by GSK on the adverse events.
Q. Okay. So, the issue of coding, you're telling this jury, didn't play in to the FDA's decision to re-evaluate all of the data and have it reanalyzed by Columbia University? Is that right, Doctor?
A. They say here, specifically, "We asked them -- we received this partial response, and these events are related to suicidality. The bottom line is the data from the control trials from depression including social anxiety" --
THE COURT: Doctor, if you want this in the record, you've got to go a little slower.
BY THE WITNESS:
A. I'm sorry. I guess what I'm saying is they pooled the adverse events of suicidality across the different pediatric studies, and that's what showed a possible signal. So, it was clear that these were related to possible suicide attempts.
BY MR. WISNER:

Q. Doctor, the FDA decided to hire Columbia University to review the narratives by drug sponsors because they were concerned that there were inappropriate coding maneuvers used to hide this thing; isn't that true, Doctor?

MR. BAYMAN: Objection. Asked and answered, your Honor.

THE COURT: Overruled.

BY THE WITNESS:

A. I believe they had Columbia adjudicate these cases because there could have been differences in how suicide attempts were classified by investigators and by different companies. And on some suicide attempts --

BY MR. WISNER:

Q. How they were coded?

THE COURT: Wait. Let the doctor --

Go ahead, Doctor.

BY THE WITNESS:

A. And also some attempts which may have been coded as a suicide attempt may actually not have represented one, and vice-versa. So, it was an independent way of actually reviewing these that really didn't have to do with the coding, *per se*, but consistency across companies.

BY MR. WISNER:

Q. All right, Doctor. Following the pediatric issue, then we move in to the adult issue, and that's an analysis that really

began -- FDA began collecting the data in 2005, right?
A. The request, I believe, was in 2005, and they began receiving data from sponsors at that time.
Q. And in that process of collecting data, GSK was negotiating with the FDA about what data the FDA would consider and data it would not consider, right?
A. I wouldn't call it negotiations. It was clarifications. In the original letter, they outlined what they wanted. They listed a series of studies that they thought met that criteria, and we had correspondence about those studies and additional ones.
Q. And, in fact, you specifically -- I'm sorry. Strike that.
GSK specifically tried to incorporate studies from the intermittent brief depression into the FDA's analysis; isn't that true?
A. I don't know if that's true because we did not submit those to the FDA.
Q. Because the FDA said they didn't want it; isn't that true?
A. I think that's because they were long-term studies, yes.
Q. So, to be clear, the analysis that GSK did in 2006 under the umbrella, "all depression," it included the IBD studies, right?
A. Yes. We included those studies as well.
Q. But the FDA didn't, didn't want to look at them, correct?
A. We didn't submit them to the FDA, so they did not look at

them.
Q. Okay. And when you talk about all depression -- well, let's just actually go to the document itself.
You published and, in fact, showed the jury your analysis from the -- what we call the Carpenter paper, right, Doctor?
A. Yes, that's correct.
MR. WISNER: Permission to publish Plaintiff's Exhibit 285? It's been shown with this witness already.
THE COURT: Yes.
BY MR. WISNER:
Q. All right, Doctor. This is the Carpenter paper. Do you see it?
A. Yes, I see it.
Q. And if we go down into the paper, there's a table that this jury has seen a couple of times. It has the infinity in it. Do you recall? I've blown it up there for you, table 6.
A. Yes.
Q. All right. Now, we spent a lot of time discussing this infinity risk here, but I actually want to focus in on something else for a minute. Now, what we have here is age 25 to 64, right?
A. That's correct.
Q. And then underneath there, we have, "All indications," "All depression," "MDD," and, "IBD." Do you see that?

A. Yes, I do.
Q. All right. And if we scroll over to the right here, we have, "Definitive Suicidal Behavior Alone." Do you see that, Doctor?
A. I do.
Q. And then underneath there, we have the IBD numbers and the major depressive numbers. Do you see that?
A. Yes.
Q. So, this is -- there's 22 out of 112 and 8 out of 2,713. Do you see that?
A. Yes, I do.
Q. All right. And if you look at the all-depression number, it says 30. Do you see that?
A. Yes.
Q. Okay. So, in the two IBD trials, of the 30 suicide attempts between 25 and 64, 22 of them occurred in these two clinical trials, right?
A. Yes.
Q. And if we look at MDD by itself, that's where we get that statistically significant odds ratio higher than 1. Do you see that?
A. Well, again, we didn't describe it as statistically significant because it was a subanalysis of the secondary end point, but I see where you're pointing.
Q. The confidence interval is above 1, right?

A. It is, but it's a subgroup of a subgroup, so we did not highlight that in that regard.
Q. Okay. But if we go up and look at all depression, so if you go up and look at all depression, all of a sudden, the confidence interval goes below 1. Do you see that?
A. Yes, I do.
Q. So, the .06. Do you see that -- I'm sorry. The .6. Do you see that?
A. Yes, I do.
Q. In fact, you told the jury that that's suggestive of a protective effect, didn't you?
A. I don't know if it was that data or whether it was all indications or whatever. I said a confidence interval less than 1 could be subjective of a protective effect; but in this instance, the confidence interval also includes 1, so I didn't say that this provided definitive evidence of that.
Q. Very good. I believe the Court asked you a question about that. Remember?
A. Right. And I said because the confidence interval includes 1 that you couldn't state that.
Q. Now, isn't it true, though, that when you add in the incidents from the IBD, the placebo number goes from 0 in MDD to 30 when you add in the IBD in all depression?
A. Yes, that's clear, yes.
Q. So, you would agree with me, then, that when you look at

the IBD clinical -- there was only two IBD trials, right?
A. Yes.
Q. And there was like 19 MDD trials?
A. Something like that. I'd have to look at the list.
Q. So, when you add in the IBD data into the MDD data, it washes out any signal, doesn't it?
A. You're saying that incorrectly. So, what the analysis is doing is looking by indication, so you see MDD and IBD. So, you can look at those individually, but the question also was: If we add all depression together, what would that look like? And that's the result. So, it's not necessarily washing out. That's just the result of that analysis.
Q. IBD is not an actual clinical diagnosis, correct?
A. That's correct. It was a proposed diagnosis.
Q. So, to be clear, the IBD clinical trials were done on a diagnosis that's not recognized, and that data makes it so the all depression analysis has 30 suicide attempts in the placebo arm instead of 0, correct?
A. Right. But we also included dysthymia studies, bipolar depressions in there that contribute to the denominators as well.
Q. Now, when we talk about the IBD studies, isn't it true, Doctor, that GSK specifically conducted those trials so it could get a bunch of suicide attempts in the placebo arm to drown out the all depression signal?

MR. BAYMAN: Objection. It's argumentative, your Honor.

THE COURT: Overruled.

BY THE WITNESS:

A. No, that's not true at all. If you actually believed that your medicine could perhaps result in an increase in suicidality, you really probably wouldn't study it in a high-risk population.

As I said Thursday, the proposal here was paroxetine improves depression. The evidence from rating scales and some of the data we looked at, it reduces suicidality. The hope was to demonstrate a reduction in suicide attempts in treated patients, so that's completely wrong what you said.

BY MR. WISNER:

Q. The purpose of those IBD trials was to prove that they were effective in that clinical population, correct, the primary end point?

A. That was the hope, yes.

Q. Prior to initiating either of those clinical trials, Lilly had done one for Prozac and had shown no effect, correct?

A. I'm not aware of that.

Q. Is your testimony to this jury that GSK didn't know about the failed Lilly trial on IBD?

A. I'm saying I don't know about that.

Q. Oh, okay. But GSK knew about it back when they did the

trial in the '90s, right?
A. I can't speak to that.
Q. So, you don't know?
A. That's what I said.
Q. All right. So, after they did the first IBD trial and it showed no efficacy, right?
A. Who are you referring to now?
Q. GSK.
A. Okay. You were just talking about Lilly, so be very clear.
Q. Okay. We're back to GSK. The first IBD trial did not show any efficacy in that population, right?
A. Neither study showed efficacy.
Q. Were they established and final?
A. I can't recall. I'd have to look at the dates of the recruitment.
Q. So, it's possible that one was completed and then another one was done?
A. It's possible. But just because one study doesn't show a positive result doesn't mean that's a definitive answer. That's why FDA requires for an indication two control studies minimum.
Q. Isn't it true that you published that you cannot consider the IBD population in the context of suicidality for major depressive disorder because they're very different

populations?
A. Yes, they are very different populations. And I mentioned that in the methods of that -- of my manuscript.
Q. And you also testified that one of the reasons why you discounted or disregarded this risk here for over 25 through 64 was because it wasn't consistent, is that right, in the other data?
A. Can you please read that back.
THE COURT: Read it back.
(Record read.)
BY THE WITNESS:
A. I can't remember saying that specifically. What struck us was that the age distribution, as we looked at yesterday, all clustered at the lower age groups, so it wasn't consistent with what we had seen in the overall data sets.
I did speak to the fact that the MDD finding of the 11 versus 1 was not supported by any of the other end points.
BY MR. WISNER:
Q. In 2006, GSK consulted with experts to decide whether or not -- one of the questions was to decide whether or not they should include the IBD studies in their analysis, isn't that true?
A. I think it was earlier than 2006.
Q. 2005, 200- --
A. It was before the analysis was done. That's when you get

advice from scientific experts.
Q. And the scientific experts said not to include it because it would skew the results, isn't that true?
A. No, I would not characterize it that way.
Q. Do you know Dr. Barrett from GSK?
A. Yes, Pam Barrett.
Q. She worked with you, right?
A. Yes.
Q. And she believed that including that data would skew the results, didn't she?
MR. BAYMAN: Objection to hearsay, your Honor.
THE COURT: Overruled.
MR. WISNER: Admission by a party opponent.
BY THE WITNESS:
A. She never expressed that to me.
BY MR. WISNER:
Q. Did you ever see her notes from that meeting, Doctor?
A. What meeting are you referring to?
Q. The meeting with the experts that GSK hired. She had notes, and she said it would skew the data, didn't she?
A. I don't know. You'd have to refresh my recollection with the notes.
My recollection is we asked the experts their opinion as to categorizing depression as a whole because depression is a risk of suicide, or whether each indication should be

assessed individually; and their recommendation was to go by indication alone.

Q. All right. Doctor, if you'd turn in the binder to Plaintiff's Exhibit 284, this is a document that was shown to you in your deposition. Do you recall?

MR. BAYMAN: Your Honor, I object to this. There's been no foundation laid that Miss Barrett is authorized to speak on behalf of GSK, so there's no foundation for this as an admission.

THE COURT: At this point, it's an inquiry. Overruled.

MR. WISNER: Yeah, I'm going to lay the foundation if I can.

BY MR. WISNER:

Q. Do you recall this document, Doctor?

A. I've seen this before, yes.

Q. This was shown to you at your deposition, correct?

A. Yes, it was.

Q. And this reflects the notes of Ms. Barrett from the presentation made by GSK's experts?

A. By GSK's experts? Can you ask that question differently? I'm not sure what you're asking.

Q. Okay. That meeting that the experts for GSK made, they presented a Power Point, correct?

A. I don't know if they presented a Power Point to Drs. Mann

and Thase, so I don't know if this was something that was shown to them as opposed to internal GSK.

Q. Okay. This document you testified to in your deposition were the notes of Pamela Barrett from that meeting, correct?

A. The meeting with the -- with Mann and Thase?

Q. Yes.

A. I think it's a summary of some of that, but I don't think it was used to meet with them. That's what you had asked.

Q. Fair enough. And you understand that in this meeting, the handwritten notes on this are from Pamela Barrett, correct?

A. If this was derived from her documentation, this was her property, it's likely true, yes.

Q. Okay. And Pamela Barrett worked for you on the 2006 analysis that GSK did, right?

A. She worked with me. She didn't work for me.

Q. Sorry. She worked with you, correct?

A. That's correct.

Q. And she was helping with the scientific integrity of that analysis, correct?

A. She was, at the time, the project leader, so was ensuring that the analyses were conducted and complete. The statistical team, medical team, safety team were heavily involved in the analysis plan development, and she kind of oversaw the team.

Q. Now, if you turn to the page Bates stamped at the bottom

750, do you see that, Doctor?
A. Bates stamps at the bottom. Oh, okay. I see what you're saying.
Q. Do you see it?
A. Yes.
Q. Do you see that slide right there at the top?
A. Yes.
Q. That's Mrs. Barrett's -- Dr. Barrett's handwriting, correct?
A. Again, if these were her documents -- I don't remember what her handwriting looked like, to be frank, but I would assume.
Q. Okay. Why don't you read through that paragraph and let me know when you're done.
A. Which paragraph? Her handwriting?
MR. BAYMAN: Objection again. There's no foundation been laid, your Honor.
THE COURT: Overruled.
BY THE WITNESS:
A. Okay.
BY MR. WISNER:
Q. So, Doctor, I'll ask you the question again now. According to Pamela Barrett, the inclusion of studies 057 and 106 in the suicidality analysis would have skewed the data, correct?

MR. BAYMAN: Same objection.

THE COURT: Overruled.

BY THE WITNESS:

A. Again, that's what she wrote.

BY MR. WISNER:

Q. Okay.

THE COURT: All right. We'll break now, ladies and gentlemen, until tomorrow morning at 9:30. Thank you very much.

(Jury exits courtroom.)

[redacted]

(Court adjourned, to reconvene 4/11/17 at 9:30 a.m.)

CERTIFICATE

We certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/Judith A. Walsh — *April 10, 2017*

Judith A. Walsh
Official Court Reporter — Date

/s/Charles R. Zandi — *April 10, 2017*

Charles R. Zandi
Official Court Reporter — Date