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

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of STEWART DOLIN, deceased,	)	
Plaintiffs,	)	
vs.	)	No. 12 CV 6403
SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation,	)	Chicago, Illinois
Defendant.	)	March 16, 2017 1:30 p.m.

VOLUME 3-B

TRANSCRIPT OF PROCEEDINGS

BEFORE THE HONORABLE WILLIAM T. HART, and a Jury

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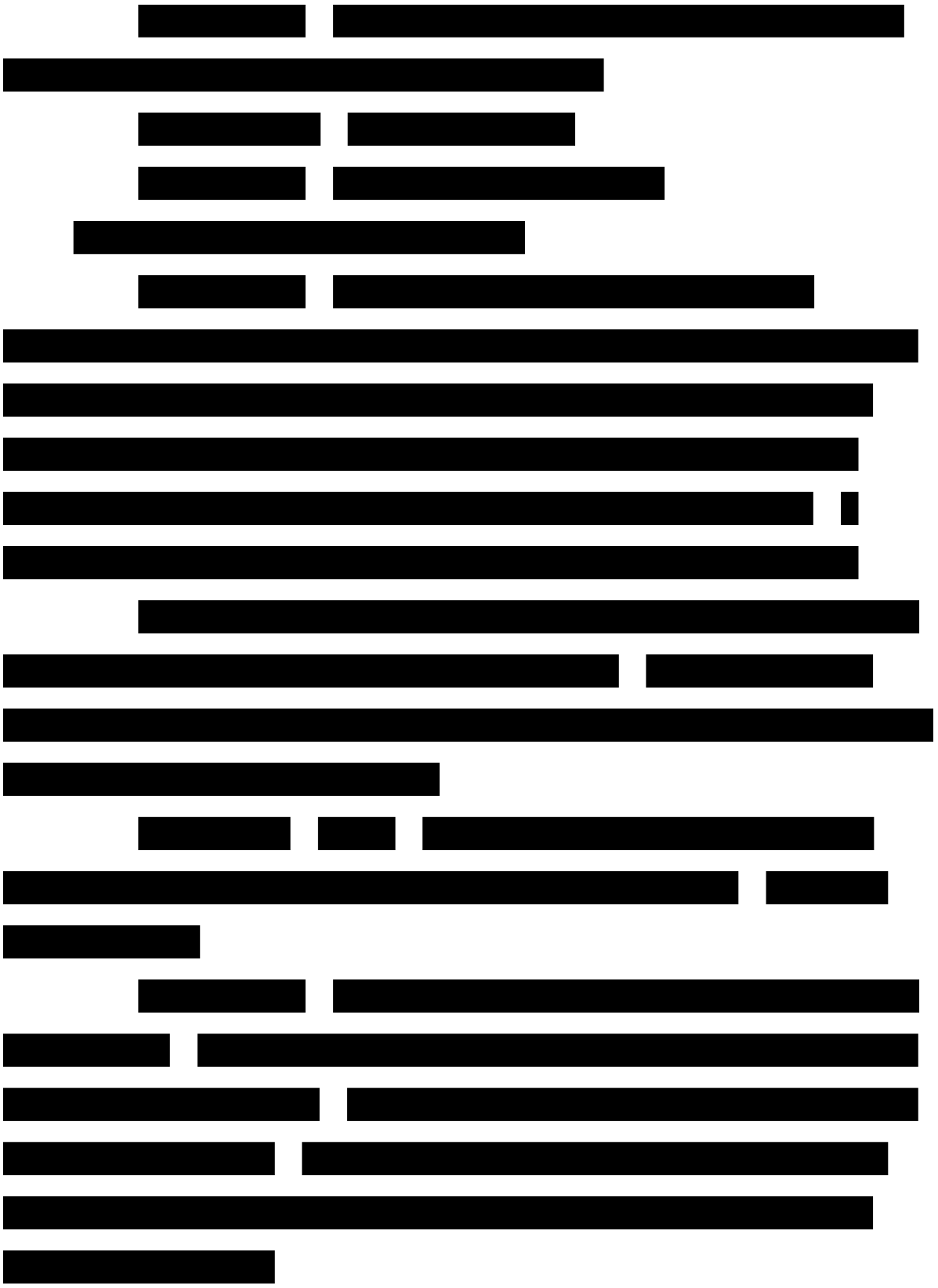
(Proceedings heard in open court. Jury out.)



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(Proceedings heard in open court. Jury in.)

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

You may proceed, sir.

MR. WISNER: Thank you, your Honor.

DAVID HEALY, M.D., PLAINTIFF'S WITNESS, PREVIOUSLY SWORN

DIRECT EXAMINATION (Resumed)

BY MR. WISNER:

Q. All right. Doctor, we were just talking about Table, it looks like it's 21.7 in this report that had these run-in suicides. Let's go to the suicide attempts which I have actually right here. So what is this, Doctor?
A. That's a table. Again, this would be a fairly standard table certainly for antidepressant trials which includes attempted suicides and overdoses. "Worldwide data" means trials that happened in both the United States and outside the United States.
Q. All right. And we have here that there were how many attempts on paroxetine?
MR. BAYMAN: Your Honor, once again, can I ask that he show the whole thing with the asterisk?
MR. WISNER: Your Honor, we'll get there.
THE COURT: All right.
MR. WISNER: I'm not hiding it.
BY MR. WISNER:
Q. Doctor?
A. Well, just all we need really to focus on is the group of columns, the worldwide columns over on the right because they include both U.S. and non-U.S. data.
Q. Is it appropriate in analyzing a risk to exclude data from non-U.S. sites?
A. No. Arguably, you would include all. There may be reasons to exclude some, but for the most part, unless there's

a good case made, you would include all.
Q. And it says here that there are how many paroxetine suicide attempts?
A. 42 here.
Q. And how many does it say there were for placebo?
A. It says there were 3.
Q. Now, we actually have a number under N. What is that, Doctor?
A. That's showing that there's 554 people who were entered into the placebo arm of trials.
Q. Now, those three people right there where it says "suicides" --
A. Yes.
Q. -- were those three people in that N of 554?
A. Well, they weren't. As it turns out, someone like me reading the document in the first instance would assume that they were but as it turns out, in fact, no, they weren't.
Q. All right. And you see there's an asterisk on there. Let's call out the asterisk here. And it says -- what does it say, Doctor?
A. It says two overdoses occurred during the placebo run-in period.
Q. So that 3 right there should be what?
A. It should be 1.
Q. And so 1 versus 42, what does that tell you?

A. Well, you have to take into account that there's more patients go on Paxil than on placebo. This is a very big difference.
Q. In your opinion, does it suggest that there's an association between Paxil and suicide attempts?
A. If we're using the 1, then it does. If we're using 3, then it's less clear.
Q. Okay. And then it says here, can you read that to the jury?
A. "The rates for attempted suicide and drug overdose, the most common subpopulation of attempted suicides, are not dissimilar when Paxil is compared to other antidepressants. The data in this table is not adjusted for dose exposure."
Q. Is that sentence accurate?
A. Well, as the data stands, if you assume that the three figures are generally from the placebo arm of the trial, it's -- even then it's not quite accurate in that the figures for Paxil are higher, but it's definitely not accurate if the figures should be 1.
Q. Well, should the figure be 1, Doctor?
A. The figure should be 1.
Q. So is that sentence accurate under any circumstances factually?
A. The figure -- this isn't the claim that should have been made about this data, in my opinion.

Q. Is this a misrepresentation of what the data shows?
A. I wouldn't have represented the data this way.
Q. Okay. All right. Let's -- so this was submitted in 1989. Did anything happen in the area of SSRIs and suicide after 1989 to bring any attention to the issue of SSRI-induced suicide?
A. Yes. There was -- concerns about the issue became much more of a public issue in the context of Prozac. There were reports -- you've seen the Rothschild and Locke paper. There was a paper by Martin Teicher which talked about six cases, and that was focused principally on Prozac because at this stage, at that stage, Prozac was on the U.S. market. It had been on it a year before the UK. Paxil wasn't on the U.S. market.
Q. All right. Turn to Exhibit 14 in your binder there, Plaintiff's Exhibit 14.
A. Yes. I think I've got it.
Q. What is this document, Doctor?
A. This is the article by Martin Teicher that for a lot of people kicked the issue off -- I mean, the issue about can SSRI drugs, can a drug like Prozac make people suicidal.
Q. Okay. Great. Is this a fair and accurate copy of that?
A. It appears to be.
MR. WISNER: Your Honor, at this time, this document has already been admitted into evidence. Permission to

publish it to the jury.

THE COURT: All right. You may proceed.

BY MR. WISNER:

Q. Who is Dr. Teicher?

A. Dr. Teicher was a doctor that was working in Boston at the time. I think he was associated with McLean Hospital at that time.

Q. And who are these other people on the --

A. Carol Glod was one of the senior nursing staff. Jonathan Cole was one of the senior figures in the field. In terms we've -- I outlined yesterday that the field begins in the mid-1950s.

Probably the single -- the person who coordinated most research about all the antidepressants and antipsychotics was Jonathan Cole. He was the person who was entrusted by Congress to coordinate research. Other people had applied to him for grants to study things, so he was a very senior figure in the field.

Q. All right. Let's look at one of the paragraphs in this article that came out. What year was this, Doctor?

A. This is actually March 1990 -- or February 1990.

Q. Okay. Great. All right. This paragraph here says:

"A great deal has been written on the possible role of serotonin in violence, suicide, and obsessive behavior, and fluoxetine is known to be a potent and

selective serotogenic uptake inhibitor."

What does that mean, Doctor?

A. That, what they're referring to here is that there had been issues from the point where there was a serotonin hypothesis. Some people were saying in the 1960s that serotonin was linked to people being depressed. That got thrown out, but what happened during the 1970s in particular is a few researchers with interest in this began to say that low serotonin might be linked in particular to people being impulsive and violent and going on to commit suicide and becoming alcoholic, for instance.

Q. So it goes on, it says:

"Given this background, we were especially surprised to witness the emergence of intense, obsessive, and violent suicidal thoughts in these patients. Their suicidal thoughts appear to have been obsessive as they were recurrent, persistent, and intrusive. They emerged without reason but were the patients' own thoughts. It was also remarkable how violent these thoughts were. Two patients fantasized, for the first time, about killing themselves with a gun, and one patient actually placed a loaded gun to her head. One patient needed to be physically restrained to prevent self-mutilation. Patient 2, who had no prior suicidal thoughts, fantasized about killing himself in a gas explosion or a car crash."

This description by Dr. Teicher and Dr. Cole about this manifestation of suicidality, does that comport with your understanding?

A. It does. And there's two things, two or three things here to quickly draw out. They're saying they came at this with no expectation that this drug would cause these problems. Quite the contrary, the expectation from prior research was maybe these drugs were going to be particularly helpful in people who were suicidal.

So that's why this was a big surprise to them, and they were struck by the fact that it's not classic depressive thinking. It seems to be different. It's -- they felt they were witnessing a new phenomenon, and they also report a bunch of this in the paper, but certainly the kinds of things Jonathan Cole said when you talk to him, which is the patients came back and said, "Gee, Doc, I've been depressed before, but this was very different."

Q. Did this article cause a reaction from the Food and Drug Administration?

A. Well, it ultimately led to an FDA hearing in 1991. The FDA were clearly -- anyone would be concerned about this. These authors weren't saying these drugs should be banned. Reporting what they were reporting, they were saying, look, this is a thing that can happen to some patients. And the expectation was, if we agree that it can happen, we can

explore why it's happening and work out who it's safe to give the drugs to and who might be at risk.

Q. Following the publication of the Teicher article, were any of the manufacturers such as the defendant asked to submit a suicide report?

A. I believe they were all asked to submit reports, yes.

Q. Draw your attention to Exhibit, Plaintiff's Exhibit 79, Doctor. Let me know when you get there.

A. I'm here.

Q. All right. What is this document, Doctor?

A. This is what appears to be an email or a -- well, no, it's actually a conversation record. I guess we didn't have email in quite the same way back then. This is October 3rd, 1990, it appears, and it's conversation with Martin Brecher, Dr. Martin Brecher who is working in the FDA at that time.

Q. Who is Dr. Brecher in the context of the suicide issue?

A. He was one of the persons that was -- one of the people who was reviewing, perhaps one of the authors, one of the main reviews of the Paxil application that have gone into FDA, looking at, does the drug work and what are the issues linked to it.

Q. Would he have been someone who looked at the document a second ago with the asterisks?

A. Yes. He -- I've seen that are comparable documents.

Q. Okay. And this document, Plaintiff's Exhibit 79, is it a

document that you have reviewed in preparation for your testimony?
A. Yes, it is.
Q. Is it something you relied on?
A. Yes.
Q. And would discussing its contents aid you in explaining the suicide story to the jury?
A. Hopefully, yes.
MR. WISNER: Okay. At this time, your Honor, permission to publish Exhibit 79 to the jury.
THE COURT: You may proceed.
BY MR. WISNER:
Q. All right. You mentioned this was a record of conversation. Who is it a record of conversation between?
A. Well, it's a record of conversation between GSK and Martin Brecher. The document gets signed at the bottom by Thomas Donnelly, but clearly there may have been more people on the conversation than just him.
Q. And what is your understanding of the purpose of these documents?
A. Well, there's people -- there's a lot of back and forth between companies and the FDA during the course of an application. And that would lead to a lot of phone calls. It may even lead to personal meetings. And the company will keep a log of all these so that, you know, afterwards, people, if

there are issues, can review what was actually said.
Q. So in this summary, who actually prepared or at least -- did the FDA or did GSK prepare this summary?
A. This is the GSK summary. I don't know if anyone on FDA's side would have been doing the same thing.
Q. Okay. Let's look at what it says. So in the first paragraph under "Summary of conversation" -- let me get the whole thing in there.

It says:

"Dr. Brecher called and initially mentioned that the last submission was fine, and he looked forward to receiving the weight gain response. He next said he was calling to inform us of a concern that has arisen about fluoxetine, and he is formally requesting that we prepare a response to the same issues. He said that the public press has been widely discussing the relationship between fluoxetine and violence ideation and suicide thoughts. Although the Division" -- I'll stop right there.

At this point, is Paxil on the market?

A. No, it's not.
Q. So what is he referring to when he talks about the public press?
A. Well, it's about the Teicher article which seems to be highlighting an issue that a lot of people around the place, a lot of people who have been taking Prozac seem to be agreeing

this happens to them. You've got a lot of patient groups beginning to form saying, "Look, we think the Teicher article is real."

Q. And who manufactures Prozac?

A. Lilly.

Q. Okay. It says here:

"Although the Division does not see it as a real issue but rather a public relations problem, Lilly has been asked to submit a detailed response to the public's concern. He is, therefore, requesting that we do the same since we have a drug with a similar mechanism of action."

What does that refer to, "mechanism of action"?

A. He's saying that both these drugs are serotonin reuptake inhibitors.

Q. Okay. He goes on to say:

"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?

A. I do.

Q. Now, this reference here to it not being a real issue but a public relations problem, is that true?

A. Well, I -- a bit hard to comment on it. It's --

Dr. Brecher is not clearly saying that it's FDA's view. It's very unfortunate phrasing. If it is FDA's view as opposed to Dr. Brecher's view, then it's terribly, terribly unfortunate.

Q. Do you think suicide is a real issue, Doctor?

A. I think suicide and treatment-induced suicide is a real issue and was since the 1950s, and to regard it as just a public relations issue would be unfortunate.

Q. He goes on to say, "Dr. Brecher said that he is working full-time on the review of efficacy and expects to finish by the end of the year."

What does that refer to?

A. He -- well, as I repeated, to just repeat, the NDA, when it goes in, it's about whether the drug works or not, so he's looking in particular at the issue of, has the drug been shown to work.

Q. All right. It goes on to say, he is not -- "He does not expect to have his time divided by any other drugs. Therefore, he would like us to submit this report by the end of November."

Do you know what report he's referring to?

A. Well, it's the updated report on, is there a suicide risk from Paxil.

Q. Okay. Do you know if GSK ever did submit a report?

A. They do.

Q. All right. Let's turn to Exhibit, Plaintiff's Exhibit 82.

Do you have it?
A. Yes, I do.
Q. All right. What is Exhibit 82?
A. This is a letter from Thomas Donnelly who's written the previous note we've just seen. In this case, he's writing to Dr. Paul Leber who was the person who was the head of the CNS division within FDA at that time, as I understand it. So he was the person who was coordinating the input of all these data. He was the person who would have been at this stage Dr. Laughren's boss.
Q. Is there anything attached to the letter?
A. There is, yes.
Q. What is attached?
A. There is confidential proprietary material and the review of suicidal ideation and behavior.
Q. Is this the report that we were just talking about that was to be submitted?
A. Well, it's a report, and it looks like it was a report to be submitted, yes.
Q. Is this a document that you relied upon in rendering your opinions?
A. Yes, it is.
Q. And would talking about this document aid you in your testimony today?
A. It would, yes.

MR. WISNER: Your Honor, permission to publish.

THE COURT: You may proceed.

BY MR. WISNER:

Q. All right. So again, we have here, I just want to call this out for reference. Who is SmithKline Beecham?

A. SmithKline Beecham is one of the forerunner companies of GlaxoSmithKline. GlaxoSmithKline is a merger of Glaxo Wellcome and SmithKline Beecham. That's where we get the name GlaxoSmithKline from.

Q. And at this time, was SmithKline Beecham, the predecessor to GSK, the ones controlling Paxil?

A. They were the company, yes, that had been handling Paxil. Paxil comes from the SmithKline side of the company rather than the Glaxo side.

Q. Got you. All right. Now, it says here in the letter -- wrong paragraph. Do you see that paragraph right there, Doctor? Can you read that to the jury?

A. I do, yes.

"To summarize in brief, this analysis of data from prospective clinical trials in depressed patients clearly demonstrates that patients randomized to paroxetine therapy were at no greater risk for suicidal ideation or behavior than patients who were randomized to placebo or other active medication."

Q. What does that mean in regular terms?

A. What that's saying, the brief message from this report is that there's no risk from Paxil.
Q. Okay. So let's go into the actual report itself. What date was this submitted?
A. April 1991.
Q. Okay. Great. And this is titled what, Doctor?
A. It's looking at suicidal ideation and behavior, an analysis of the paroxetine worldwide clinical database.
Q. All right. Let's go to the first table in the -- in the document, but I want to make sure that I don't miss any asterisks here. Okay. So I'm going to -- I'm going to do a pretty big one. Can you still read it?
A. Yes, I can.
Q. Okay. I don't see any asterisks here. What is this showing?
A. Right. Well, you'll see that most of the numbers are just, I was saying, the active control numbers. There's more patients from active control drugs here, but the Paxil number of patients and the placebo number of patients are just the same. And this is the people who have committed suicide.

Now, you didn't see -- you saw deaths before, and there were 12 on Paxil. Now you're looking at suicides only. Five of the 12 deaths were patients who committed suicide. The same two deaths you saw on placebo before are now here under the heading of patients who have committed suicide.

You're also seeing a new -- a new thing introduced which is PEY. That stands for patient exposure years.
Q. We'll get into the PEY in a minute, but let's focus on that 2. Did those two patients commit suicide in the placebo arm as indicated by the N 554?
A. No. We've been through this before. This didn't happen in the placebo arm. This happened in the run-in phase.
Q. What's the difference between this table and the one we saw before?
A. Well, one of the big differences is the missing asterisk. The other difference is the placebo number are in. And the third difference is we have a reference to PEY.
Q. All right. It goes on to say --
MR. BAYMAN: Your Honor, I'd ask, for the rule of completeness, that the jury be shown the paragraph, two paragraphs up where it says, these occurred -- suicides occurred during --
MR. WISNER: Your Honor, he's testifying. He can cross-examine. This is ridiculous.
MR. BAYMAN: I think the jury ought to be entitled to see the page.
THE COURT: Well, it's subject to cross-examination. I'm sure you'll call it to their attention.
Proceed.
BY MR. WISNER:

Q. All right. So the asterisk has disappeared. And then it says here what, Doctor?
A. You mean --
Q. I have highlighted the sentence.
A. "There were no substantive differences in the number or incidence of suicides among treatment groups."
Q. Now, this 2 is supposed to be zero, right?
A. Yes.
Q. Okay. Is there a substantive difference between 5 and zero?
A. Yes.
Q. Is that sentence true?
A. I don't believe it is.
Q. Okay.
THE COURT: Well, let's go back there. I'm not clear as to what you're saying.
MR. WISNER: I'm sorry.
THE COURT: The 2 -- put it up again. The 2 should be zero or 1?
THE WITNESS: Zero.
THE COURT: It should be zero. Okay. And if it's zero, then that changes the number on the other side?
THE WITNESS: It will change -- after the 2, your Honor, you've got a percentage, so it's 0.36 percent, which gives you the impression that, in fact, there's more suicides

happening on placebo than on Paxil but, of course, if the number is zero, then it's zero percent. So there's less suicides happening on placebo than Paxil.

BY MR. WISNER:

Q. Let's go to the next table, Table 2. All right. What's this table, Doctor?

A. This is again very similar, and just to stress, this is the kind of stuff that the jury can be as expert on reading as anyone like me. You've got the same numbers we've seen before. You've got the missing asterisk although there is text as Mr. Bayman has referred to.

And again, you've got the same figures we had before. You've got the 40 and the 6. And again, there's a percentage introduced which you saw in the previous table, and also there's this PEY bit which for most jurors coming into this not being used to it, they think, "What the hell is that?" These days, you can Google these things, and you'll find it's patient exposure years.

Q. And we will get into patient exposure years. Just stick to the wash-outs for now. All right. So it says here that there were six attempts of suicide in the placebo arms. Do you see that, Doctor?

A. I do.

Q. Is that a factually true statement?

A. No. We've seen before from the previous document a year

or two before that that 6 should really be 1.
Q. Okay. And if that 6 goes to a 1, how does that change the relationship between placebo and paroxetine?
A. Well, again, it looks from the figures you're seeing that there's no big difference between the two. You'd expect actually that the Paxil data should be less than the placebo data. That's what most people would have expected.

So to see anything even slightly bigger, 1.3 versus 1, is a little bit of a surprise, but if it drops down to just 1 and the figure of 1.1 drops down to 0.2, then we're into a very big surprise.
Q. And it goes on to say again here, "No substantive differences in the number or incidence of attempted suicides were found among the paroxetine placebo or active control groups." Is that true?
A. That's not true, no. And one of the other ways things could have been handled would be to say that there were four -- as I said, that there were over 4,000 patients in the placebo group, and that would adjust the figures. And, you know, and it would be interesting to see what the company would have said then, but the best way to handle it is to just stick strictly to the 554 patients who, after they were randomized and after randomized, how many acts were there, and that was 1. And if it's 1, then the statement below is incorrect.

Q. All right. Well, Mr. Bayman started reading into the record other stuff. Let's actually look at it. Do you see this paragraph right here, it says, "Of the three suicides committed by patients randomized to the active control requirements" -- actually, hold on. It's the paragraph before that one.

A. Yes.

Q. Why don't you read it to me, Doctor, since you're the expert.

A. Well, it's the kind of thing that the jury will be as expert on reading as I am but:

> "Of the two suicides committed by patients randomized to placebo, the method by which they took their lives was unknown. Although these patients were actually participating in an active control study, the acts of suicide were committed during the participation in the placebo run-in phase. The specific points in time at which these individuals took their lives were two days and seven days prior to the baseline evaluation."

Q. Why do they have negative 2 and negative 7 in there?

A. Well, that's saying, you know, what would happen is, on the trial, once you go on the active treatment, they'd be looking at day one or day two or day ten. You'd see it, day ten without a plus before it. Minus before it means this happens before the trial proper begins.

Q. All right. So this is discussing the actual two completed suicides, right?
A. Yes.
Q. The zero to five, right?
A. Uh-huh.
Q. I'm looking at the next page under "Attempted suicides." Does it mention anything about the run-ins there?
A. Well, I can't see it there.
Q. Read through that paragraph and tell me if you see anything.
A. No, I can't.
Q. So there's no asterisk and there's no discussion at all about the five or the six suicide attempts being in the run-in --
A. Well, it isn't just in that.
Q. Where else is it?
A. I'm unsure. I'm not saying it is.
Q. Okay.
A. It's just both the jury and I can see that it's not in this.
Q. Okay. So it's not in this section called "Attempted suicides." I'll go to the next page. It goes on to suicide attempts by overdose in patients randomly -- do you see that, Doctor?
A. I do, yes.

Q. That's not what we're talking about here. The next section is suicide attempts other than overdose in patients randomized. Do you see that?
A. I do, yes.
Q. All right. Is there anything in there about that?
A. Not that I'm aware of it.
Q. It says -- well, let's take a look at these. It's sort of interesting. It says, 12 patients who had received paroxetine therapy attempted suicide by methods other than overdose. The following methods were reported: Lacerations. What's a laceration?
A. When you cut your wrists or throat or whatever.
Q. Poisoning, what's that -- I mean, we know what that is. Defenestration, what's that?
A. It involves usually jumping out through windows.
Q. There's a word for jumping out of a window?
A. Yes.
Q. All right. Hanging?
A. Well --
Q. And one method unknown. Do you see that?
A. Yes.
Q. All right. I've gone through several pages here. We're now in the Hamilton Depression Scale section, and I haven't seen any mention of the run-ins. Have you seen any?
A. Well, I've seen loads and loads of documents. I'm going

to trust you that it's not here. I amn't aware of it being here, but just as I sit here right at the moment, I can't absolutely swear to the jury that it's not, but I think it's not.

Q. How would you have to go about figuring out whether or not those five of six suicide attempts ascribed to placebo actually happened in the run-in? What would you have to do?

A. You would have had to see the previous document. That would have had -- that would have alerted you to what was going on. It's not clear from just this document, but the one we looked at previously where they listed six and it turns out actually to be one, you'd have to know about that.

Q. And if someone was just cursorily reading this like it wasn't a real issue, would it be easy to miss the data?

MR. BAYMAN: Objection. It calls for speculation, your Honor.

THE COURT: Sustained.

BY MR. WISNER:

Q. Based on your experience as a person who's dealt with people --

A. Well --

Q. Let me ask the question. Let me ask the question. Based on your experience, do you believe it would be easy for you to miss that?

A. Well, I think even people like Michael Teicher who came

out, most people came from a background --

MR. BAYMAN: Your Honor, it is not Martin Teicher and how he would react. The question was asked to Dr. Healy.

THE COURT: Confine yourself to your thoughts.

THE WITNESS: Yes. Sure.

At that time, the expectation was that these drugs wouldn't cause a problem. So people without expectation, that would included me back then, would have -- would have missed it. If there wasn't anything there, we wouldn't have had any reason to doubt the 6. We would have thought, that's probably the right number.

BY MR. WISNER:

Q. All right. All right. I want to go back to the suicide language. I just want to review this where it says, do you see this sentence right here, Doctor, "There were no substantive differences in the number of incidence of suicides among treatment groups." Do you see that?

A. Yes.

Q. And then we have almost identical language right here. Do you see that?

A. Yes.

Q. All right. Why don't you turn to Exhibit 28.

A. Yes. I'm here.

Q. All right. What is document 28?

A. This is a summary basis of approval document.

Q. What is that document?
A. Well, that's a document again looking at the FDA review of the data that has come in to them from GSK.
Q. Okay. And is this the document that precedes a drug's approval?
A. Yes. The FDA will write out to the company, "We approve, you'll be able to claim your drug works as an antidepressant," and this will be the background document to the letter that FDA writes.
MR. WISNER: Your Honor, this document has already been admitted into evidence. Permission to publish.
THE COURT: Yes. You may proceed.
BY MR. WISNER:
Q. Okay. Now, Doctor, we have here the screen shot from the prior exhibit. Okay?
A. Yes.
Q. All right. I want you to turn to Page 29 in Exhibit -- in Exhibit 28. Turn to Page 29 in Exhibit 28.
A. I think I have that, yes.
Q. Are you there on Page 29?
A. Yes, I think so.
Q. All right. I'm going to show the jury in a second, but I just want you to read it. Read the last paragraph there. Read the second sentence.
A. This is where I'm going to have to put on my glasses

because it's reasonably small print here.

"The incidence is expressed as cases per patient exposure year, brackets, PEY, where total PEYs are equal to the sum of the duration of treatment for each patient, brackets, in days, divided by 365."

Q. I actually gave you the wrong sentence to read.

A. Sorry.

Q. That was a pretty complicated one. Why don't you read the next sentence.

THE COURT: Why don't you put it up on the board.

BY MR. WISNER:

Q. Sure. Read the next sentence, Doctor.

A. "There were no substantive differences in the number or incidence of suicides or suicide attempts among treatment groups."

Q. That is nearly verbatim from what's in the suicide report?

A. It is, yes.

Q. Okay. And this is the FDA's report?

A. Yes.

Q. All right. After GSK submitted the suicide report in 1991, did it actually try to make the data available or publish it?

A. The data appeared in a range of different articles, yes.

Q. Are you familiar with Dr. Dunbar?

A. Yes, I am familiar with Dr. Dunbar.

Q. Are you aware that his deposition has already been played in this case?
A. I am aware that part of his deposition has been played, yes.
Q. Okay. And are you aware of whether or not he published data based upon this suicidality report?
MR. BAYMAN: Your Honor, this is cumulative. They've heard from Dr. Dunbar.
MR. WISNER: I'm just laying foundation.
THE COURT: I haven't heard the question, sir.
BY MR. WISNER:
Q. I said, are you aware if he published data relating to it?
A. Yes, he did. It was more than one article.
Q. Okay. Please turn to Exhibit 34 in your -- I'm sorry, Doctor. I think I went ahead too quickly. Can you turn to Table 55 in -- I'll get it up on the screen, 55 in the FDA summary basis of approval. So it's the exhibit we were just looking at. It's No. 28.
A. Yes. And you want me to look at?
Q. Turn to the second-to-last -- third-to-last page, Table 55.
MR. BAYMAN: Your Honor, this is cumulative. The jury has heard Dr. Dunbar read from the article and be asked the very same questions by videotape yesterday. This is entirely cumulative.

MR. WISNER: We're talking about the FDA report, not about Dunbar right now. I went back. Sorry.

MR. RAPOPORT: They haven't seen 55 yet.

THE COURT: Table 55?

MR. WISNER: In the summary basis of approval. This is not about Dunbar.

MR. RAPOPORT: Yes, your Honor. This is the FDA's version.

MR. WISNER: Yes. This is the FDA document.

BY MR. WISNER:

Q. All right. Doctor, do you have Table 55?

A. I do, yes.

MR. RAPOPORT: Wait.

MR. WISNER: Oh, I'm sorry. May I proceed, your Honor?

THE COURT: Yes.

BY MR. WISNER:

Q. Okay. All right. What is Table 55, Doctor?

A. Well, this again gives you the data on the suicides and the suicidal acts which we have seen before. It's pretty much the figures that we've seen earlier.

Q. Well, Doctor, you said "pretty much." Let's actually look at them. It has placebo. Do you see that?

A. Yes, I do.

Q. And under "suicide," it has how many suicides in the

placebo arm?
A. Two.
Q. Is that true?
A. No.
Q. Is that a copy and paste from the suicide report?
MR. BAYMAN: Objection, your Honor. That calls for speculation. This is an FDA document.
THE COURT: Yes. Sustained.
MR. WISNER: Fair enough. I just meant, is that a copy, a verbatim --
THE COURT: "Is it the same."
BY MR. WISNER:
Q. Thank you. Is it the same?
A. It is, yes.
Q. All right. Sorry. It's been a long couple of days. Okay. Attempted suicides, the data there, do you see that?
A. Yes.
Q. And then you have attempted, total attempted suicides. You have a number here. I actually have it highlighted incorrectly. Do you see that, 6?
A. Yes.
Q. Were those all in the placebo group?
A. Well, they weren't actually. They've been represented as being in -- at the placebo group, but they weren't.
Q. And that's the same as the '91 suicide report?

A. Yes.
Q. Doctor, I -- are there any asterisks on this page?
A. No.
Q. Is there any statement about these suicides being from the wash-out periods?
A. No.
Q. Any statement that they didn't occur in the placebo arm?
A. No.
Q. Thank you. All right. Let's move on to Exhibit 34 like I had asked you about. Now, I asked you earlier if GSK ever published any literature conveying the data we were just looking at, right?
A. Yes.
Q. Look at Exhibit 34. What is that?
A. Well, this is -- this is a brief abstract of an article by Dunner and Dunbar. And it says, "Reduced suicidal thoughts and behavior, brackets, suicidality, with paroxetine" presented at the American College of --
Q. We don't have it up yet, Doctor. I just want you to tell me what the document is.
A. It's an abstract of a presentation that was made, and the abstracts usually give the key features.
MR. WISNER: Okay. Your Honor, permission to publish Exhibit 34 to the jury. It's already been admitted into evidence.

THE COURT: You may proceed.

MR. BAYMAN: Your Honor, I don't object to it, but it's cumulative. The jury has heard the very author of the article by videotape yesterday get asked these very same questions.

THE COURT: We didn't have the article yesterday. That was the problem. Remember, there were some objections about the exhibits and, therefore, I said go ahead since we hadn't had that aspect resolved. So I'll let him go back to it and clear it up just as I'll let you do that as well.

MR. BAYMAN: Okay. Thank you.

BY MR. WISNER:

Q. All right. Doctor, so this is a packet. On the first page, it has -- it's hard to read, but do you see it says "Paxil"?

A. Yes.

Q. And it says, "annotated bibliography."

A. Yes.

Q. What does that refer to?

A. Well, again, this is a bunch of articles or other published material on Paxil. It's the kind of documents that a company like GSK might give to doctors who might be thinking about prescribing Paxil, or they might give them to their sales representatives to hand out to doctors.

Q. And so who prepared this compilation? Was it --

A. This would have been prepared by SmithKline Beecham as they were then.
Q. Okay. All right. So then we have an annotated bibliography. On Page 27 of this document, there's a reference to Dunner and Dunbar. Do you see that?
A. I do, yes.
Q. And the title, you already read the title to the jury, it says, "Reduced suicidal thoughts and behavior, suicidality, with paroxetine." And it goes on to read, "Presented at the American College of Neuropsychopharmacology, December 1991, San Juan, Puerto Rico."

What is the American College of Neuropsychopharmacology?
A. The American College of Neuropsychopharmacology is the premiere body in the United States for looking at issues to do with psychotropic drugs, the antidepressants, the antipsychotics, issues ranging from brain research through to clinical research.

The British corresponding group would be the British Association for Psychopharmacology, of which I was the secretary at one point.
Q. Now, is the -- is it also known as the ACNP?
A. Yes.
Q. Is the ACNP a prestigious organization?
A. Very, yes. In terms of the use of drugs, ACNP would be

regarded as the people who know about these things as opposed to the American Psychiatric Association. They're doctors but they include therapists and people who do all sorts of other things or have expertise in other things than just drugs. These are the people who identify as being the experts on the drugs.

Q. Now, it says it was presented. What does that mean?

A. Well, it means that it could have been either presented as an oral presentation, or it could be presented as what's called a poster where the materials, the kinds of tables you're seeing, would be presented to an audience, and someone like Dr. Dunbar or Dunner would be there to talk to anyone who came up and was interested to ask about the issues.

Q. All right. Let's read what it says here -- well, it talks about what happens, but I want to actually get to the punch line. It says here:

> "Suicides and suicide attempts occurred less frequently with paroxetine than either placebo or active controls. Paroxetine was also significantly superior to placebo and active controls on most measures of emergence of suicidal thought. This analysis shows that suicidality is inherent in depressive illness and that antidepressant therapy with paroxetine is appropriate for the integrity of depressed patients."

In non-doctor terms, what is that saying?

A. That's saying that, "Our drugs don't cause the problem, the illness causes the problem, and the key thing is to make sure you get people who are depressed on antidepressants like Paxil."
Q. Wait a second, Doctor. I understand it's one thing to say we don't know if it causes suicidality, but this is saying that it actually reduces suicidality?
A. That's what it's saying and --
MR. BAYMAN: Objection to leading.
THE WITNESS: -- that's --
THE COURT: Yes, you're leading.
BY MR. WISNER:
Q. Fair enough. Do you have an opinion about what this is telling doctors?
A. Yes, I do, which is that whatever you've heard about the fuss that's been happening out there about these drugs causing a problem, you should be reassured, our view is the drug isn't causing a problem and that actually you're going to do more harm than good if you stop using the drug.
Q. Now, if you're a practicing physician and you get handed an article from a prestigious organization like ACNP, how does that affect the way you treat a patient who you're treating with Paxil?
A. Yes, it will make you more likely to use the drug and dismiss the concerns that may be out there as coming from a

fringe group or whatever.
Q. Well, let's say your patient starts having a reaction, an akathisia-type reaction. Seeing this, what does a physician do?
A. Doubled --
MR. BAYMAN: Objection, calls for speculation.
BY MR. WISNER:
Q. I'll rephrase, your Honor. Seeing this, what would you do?
A. Well, seeing this, if I believed this at that time, I would have doubled the dose of the pills.
Q. And what would doubling the dose to a person who's already taking the drug and is having a reaction do?
A. It may kill them.
Q. Do you know if Dr. Dunbar has ever sought to retract his publication?
A. Not that I'm aware of. I've seen a range of different points where he says, our drug actually reduces the risk. I'm not aware of him ever saying anything to the contrary, not even coming back to the point where, you know, that the drugs may be neutral as regards to risk.
Q. Now, Doctor, was it appropriate for GSK to have used that run-in data in assessing the suicide risk?
MR. BAYMAN: Objection, company conduct, your Honor.
THE COURT: Overruled.

BY THE WITNESS:
A. It's not appropriate. It breaches regulations. The regulations say you should be counting from baseline, not from entry, from baseline.
MR. BAYMAN: Your Honor, he's now testifying as an FDA regulatory witness. This is beyond the scope of his expertise. Move to strike.
THE COURT: Well, you can inquire as to, when you use the word -- you haven't established the use of the word "regulations."
MR. WISNER: Yeah. Let's not --
THE COURT: In that sense, I sustain your objection.
MR. BAYMAN: Thank you, your Honor.
BY MR. WISNER:
Q. Dr. Healy, let me ask you this question: Based on, you know, basic scientific principles, was it scientifically legitimate to count the pre-baseline suicide attempts?
A. No, it's not. It would be scientifically legitimate to explore what happens during the baseline period, but it's not legitimate to include it in the placebo figures.
Q. Now, Doctor, have you seen any documents from within GSK itself acknowledging that fact?
A. I have.
Q. Okay. Please turn your attention to Exhibit 17, Doctor. It's in your binder.

A. I was about to say that I can't find it, all your efforts to keep me on track here had failed, but I have found it.
Q. You found it?
A. Yes.
Q. Okay. Great. What is this document, Doctor?
A. Now, this is a note from Daniel Burnham to a number of colleagues within GSK.
Q. Is this a document that you reviewed in preparing your testimony today?
A. Yes, it is.
Q. Is this a document that you believe discussing would help your testimony today?
A. I believe it would.
MR. WISNER: Okay. Can we switch -- it's actually already here. It's actually already here. Your Honor, permission to publish. This has already been admitted into evidence.
THE COURT: All right.
MR. WISNER: Unfortunately, it's not in my iPad because it got corrupted, so I'm going to have to use the old-fashioned method.
THE WITNESS: I'm pleased that it's not in your iPad. I prefer the old style of doing things.
BY MR. WISNER:
Q. Okay. All right. So, Doctor -- all right. Doctor, who

is Daniel Burnham?
A. Well, he's a person who works in GSK at that point in time. I'm sure at one point, I'll have known just what he did, but as I sit here today, I can't tell the court just exactly what his role was.
Q. Okay. But he was a physician within GSK; is that right?
A. That's my understanding.
Q. All right. And he has an email here that he sent to a couple of different people. Do you see that?
A. I do.
Q. And the subject is what?
A. It's, "Incidence of death and suicide in paroxetine randomized controlled trials in depression, FDA request."
Q. And what is the date of this email, Doctor?
A. November 1998 -- '9. Sorry, '9.
Q. So that Dunham article we were talking about, that was published when?
A. That was 1991.
Q. Okay. So now we're, what, how many years later?
A. Two years later.
Q. This is 1999, Doctor.
A. Yes.
Q. Two years later?
A. Is the Dunbar one -- let's go back.
Q. Yes. Let's take a look at that.

A. The Dunbar one is 2001.
Q. So that would be how many years later, this email?
A. Two years later.
MR. BAYMAN: No, that's wrong.
THE COURT: '91.
MR. WISNER: 1999, 1991.
THE WITNESS: Oh, sorry.
THE COURT: '91.
THE WITNESS: Sorry. Well, hang on a second. No. Dunner is 1991. This isn't later. This is later than the Dunner one, so this is eight years later. This is eight years after the Dunner and Dunbar. Sorry about that.
BY MR. WISNER:
Q. You might have thought I said '89. I apologize.
A. No, no, no. Actually, all the problems were at my end. I haven't had quite enough coffee.
Q. All right. So what's Dr. Burnham talking about? What's his concern that he's raising here?
MR. BAYMAN: Your Honor, it's not -- objection. I let it go before, but he's not a physician.
MR. WISNER: Oh, I'm sorry.
THE COURT: Who isn't a physician?
THE WITNESS: Dr. Burnham.
MR. BAYMAN: Burnham is not a physician, your Honor. And Mr. Wisner said that earlier and I let it go but now --

MR. WISNER: I thought he was a Ph.D.

THE COURT: Oh, Burnham is not.

MR. BAYMAN: He's not a physician.

MR. WISNER: I though he is a Ph.D., though.

MS. HENNINGER: That's not in evidence.

BY MR. WISNER:

Q. All right. Mr. Burnham is at GSK?

A. Well, if he's a Ph.D., then he is Dr. Burnham, but he wouldn't be a medical doctor.

Q. Okay. Well, let's just move through this. We'll call him Mr. Burnham so we don't mess -- create any problems.

THE COURT: We'll call them all doctors.

BY MR. WISNER:

Q. All right. So it says here:

"The two suicides among the 544 placebo patients in Montgomery and Dunbar's 1995 publication actually occurred during the placebo, the 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 Mr. Burnham lists these three reasons why that was

inappropriate?
A. He does.
Q. And then he goes:
"Bottom line, we must mention the placebo run-in deaths to reconcile the overall incidence 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 .1 percent suicide rate on paroxetine IR and a zero percent rate on placebo."
A. Yes.
Q. What does that mean, Doctor?
A. Well, it means that there's a recognition here that the way things were presented earlier isn't appropriate and we need to reorganize how we're going to present the material.
Q. Now, did GSK, following this email, immediately publish a retraction of the Dunbar material?
A. Not that I'm aware of.
Q. Do you know if GSK continued to hand out the Dunbar article?
A. They may well have done, but I'm not sure.
Q. Okay. All right. Doctor, just so to remind you, we're still talking about the wash-out problem. We've got 13 things to cover. They'll get much faster after this.
A. Yes.
Q. But do you know if following the realization of this

error, GSK ever went back and reanalyzed the data?
A. They did.
Q. Do you know what year that was?
A. I believe the next iteration of the data is around 2002.
Q. Okay. Do you know what they were doing in the time in between?
A. Well, there was -- again, there's a lot of back and forth between the regulators and companies, not just GSK, on these issues. And there was a view that maybe the data shouldn't be handled the way they had been handled and that it might be appropriate to just consider placebo-controlled data.
Q. Now, at this point prior to 2002, were you out speaking out about whether or not Paxil could cause suicide?
A. I was saying that the SSRIs can come with a problem. I didn't specifically single out Paxil.
Q. Prior to 2002, you never specifically addressed Paxil, Doctor?
A. Well, I've said the problem can come from these drugs generally, Paxil included.
MR. WISNER: Okay. Please turn to Exhibit 16.
This also, your Honor, has been admitted into evidence. Permission to publish.
THE COURT: Proceed.
BY MR. WISNER:
Q. Do you have Exhibit 16 in front of you, Doctor?

A. I do, yes.
Q. All right. This is an email we've discovered in litigation.
What year is it dated?
A. This is dated 2001.
Q. And what year in 2001?
A. Sorry. What month?
MR. BAYMAN: Your Honor, can I ask that that comment be stricken, he discovered in litigation?
THE COURT: Yeah. That may go out.
MR. WISNER: Oh, I'm sorry.
MR. BAYMAN: Thank you.
MR. WISNER: This document -- sorry, your Honor.
BY MR. WISNER:
Q. So it reads -- well, it's from Bonaventure Agata. Do you see that?
A. Yes, I do.
Q. Do you recognize any of the people on this?
A. Well, yes. There's some senior GSK people here.
Q. Can you point one out for me?
A. Barry Brand is one, for instance.
Q. Do you know what department Barry Brand worked in?
A. No. As I sit here today, I'm tempted to say marketing, but I'm not sure.
Q. Okay. It goes on:

"Paul/David, these suicide reports seem to be appearing too often for comfort. Would it be possible to do -- possible to do identify through meta analysis the incidence of suicide/homicide when patients have been on Paxil versus general population versus patients on other antidepressants versus depressed patients in general? This is a potentially -- this is potentially an area in which competitors are likely to capitalize on once the lawyers have finished their work in the courts."

What does it mean to -- what is it talking about competitors capitalizing on?

A. Well, the worry being expressed here is that a perception may be generated that Paxil is worst in class so that other SSRI companies would perhaps say --

MR. BAYMAN: Your Honor, this is now calling for speculation. He's --

THE COURT: Sustained.

MR. BAYMAN: Thank you.

THE COURT: Sustained.

MR. BAYMAN: And I move to strike his prior --

THE COURT: It may go out.

MR. BAYMAN: Thank you.

BY MR. WISNER:

Q. Well, the next sentence reads, "It would, therefore, be prudent to have a publication ready." Do you see that,

Doctor?
A. I do.
Q. Following this email in 2001, did GSK go ahead and prepare a document to respond to the suicide data?
A. They did.
Q. Is that the data that reanalyzed the data from 20' -- from 1989?
A. Yes.
MR. BAYMAN: Objection. That's just not demonstrated by the evidence, your Honor. I move to strike.
THE COURT: That may stand. Proceed. Subject to cross-examination.
BY MR. WISNER:
Q. All right. Doctor, we're going to move on to, we were talking about these 13 ways GSK hid the signals. We've talked about the wash-out data. Let's move on to the next one. Do you want to -- do you want the list in front of you? I know you created it.
A. What is the exhibit number again? 34, something, wasn't it?
Q. Sounds about right. It was -- I believe it was 34 -- or 36.
THE COURT: 36.
THE WITNESS: 36.
MR. WISNER: Yes.

THE COURT: This is not in evidence, counsel.

MR. WISNER: They're not in evidence, and I'm not showing it to the jury.

THE COURT: All right.

THE WITNESS: Yes. Okay.

BY MR. WISNER:

Q. Okay. So we covered the wash-out data. What's the next way GSK hid the signal?

A. This is the PEY you've seen, the patient exposure years.

Q. All right. What is patient exposure years? How is that used in a suicide risk analysis?

A. Okay. Let me explain this to the court quickly. The easiest way to explain it is perhaps this. I'm sure all of you and certainly I can remember when the space shuttle blew up leaving the earth and also when one blew up coming back to earth.

You can count the risk of the space shuttle by the number of astronauts that have gone up into orbit and the number that have ended up dead. That's just the number of deaths per trip. Or you can count the number of deaths per mile.

Now, if you count the number of deaths per mile -- I mean, if you look at the number of deaths per trip, the space shuttle is a very dangerous way to travel. If you look at the number of deaths per mile, it may be the safest form of travel

on earth or in the universe because there are hundreds of thousands of miles that they actually cover, and the number of deaths per mile is actually extremely low.

So from that point of view, there's two different ways. The standard way to look at adverse events is the number of deaths per trip. And in particular, the space shuttle is very good for this one because everybody had always felt that the risks of an antidepressant are when you go on the drug -- when you're leaving the earth's atmosphere -- and when you come back in, when you come off the drug. They're the two risky periods.

When you're on the drug, if the drug suits you, you could be there for years on the drug circling around quite happy and at no risk at all. So if you count in all the years where the people who are the selected group who are happy on the drug get mixed in with the people who are the ones at risk, you can dilute the risk to make the drug look terribly safe.

FDA usually -- the usual way to count adverse events was the number of events per trip. FDA has said -- I mean, they said later that you can also use exposure years, but it shouldn't be the main thing you use. There are certain adverse events that it may be important for. There are certain adverse events that only start happening when you've been on a drug for a few years. That's where it may be

important. But it's not a useful technique for problems that happen going on the drug and coming off it.

Q. All right. Let's go back to Exhibit 82 which is the -- which is the suicides report from 1991.

A. Yes.

Q. All right. Let's look at the attempted suicide rate here on Table 2. Have you got it?

A. Yes, I have.

Q. All right. Show us where the -- and you can actually touch the screen, Doctor, and it should show up.

A. Yes.

Q. Where is the PEY in here?

A. Okay. It's just -- ah, this is new to me. This is the first time I've played with this machine.

Q. Okay.

A. Anyway.

Q. And then where is the PEY for paroxetine?

A. It's over here.

Q. Okay. Great. And I see that there's 1008 PEY for paroxetine and 72 for placebo.

A. Yes.

Q. What does that mean?

A. What happens here is nobody in these trials stays on -- well, very few people stay on placebo for a long time. They're just in for a six-week trials, so they don't

accumulate a lot of years safely on placebo.

But in some of the paroxetine trials, it's not just the six-week period. Some of them have an extension arm, so the patient can remain on treatment for months or years afterwards. And this is appropriate. I mean, that's not a bad thing to be doing if you want to look at the safety of the drug.

But counting all of those patients who only remain on treatment because they're doing quite well, counting every single week they're on treatment can be inappropriate when you're adding it in to a problem like this.

Q. So we have here the placebo number, and we have the PEY number. Do you see that?

A. Yes.

Q. And what's the difference between those numbers?

A. Well, there's a much bigger difference between the patient exposure years on Paxil compared with the patient exposure years on placebo than there is between the number of patients on Paxil and the number of patients on placebo.

Q. It's double for placebo; is that right?

A. How do you mean?

Q. Well, it's .0 --

A. Oh, you mean the actual figures?

Q. Yes.

A. Down the -- you're asking me to look at the actual -- yes.

When you get when this happens, you transform the picture. And if you see on the bottom line here, when you do this, if you're doing the figures by patient exposure years, it looks like Paxil only poses half the risk placebo poses. That is, not only is it not causing a problem but it's actually preventing a problem.

Q. Well, Doctor, that patient exposure years, is that actually including the run-ins as well?

A. In this case -- well, what's happening, it's not including the run-in we can do. They aren't added in here. But what's happening is, you have two things going on at the same time. One is including the run-in suicidal acts and using patient exposure years.

So there are two different things here that are making the problem seem less, not only making the problem seem less but actually turning it into an issue about the drug being protective rather than risky.

Q. Okay. I've got to clear it up here.

All right. Doctor, that was the second one that was used in the PEY, or patient exposure years. What's the third way you can hide the signal?

A. I'm sure the jury are pleased and I'm pleased that we're moving through these things a bit quicker now.

Q. You should just pull it out and set it aside.

A. Yes. Using Studies 057 and 106.

Q. Okay. What does it mean when a study has a number? What is that?
A. That -- well, all of the trials that are done by all of the companies will have a protocol number. So it's a way for people to be able to identify the trial afterwards.
Q. And what is Study -- you said two studies. What are they?
A. 057 and 106.
Q. Were these studies somehow different than the other types of studies that GSK did?
A. Very different.
Q. How so?
A. Well, they were done in a different patient population, and they have a completely different profile of adverse events as regards patients being suicidal than the major depressive disorder trials did.
Q. And what's the difference?
A. Well, what you're looking at is 056 and -- 057 and 106 were done on patients that GSK call intermittent brief depressive disorders, other people have called recurrent brief depressive orders, and other people have called borderline personality patients.

And these are patients who have multiple suicide attempts regularly. I mean, long before treatment, this is nothing to do with treatment, they just have multiple suicide attempts.

And this is the kind of patient group that, you know, you might have thought an SSRI, if they were anti-suicidal, could help, you know. So it's not illegitimate to do a trial in this patient group necessarily. Okay.

But when I said they have a lot of suicidal acts compared to major depressive disorder patients, for instance, in 3,000-odd major depressive disorder patients, GSK reported 11 suicidal acts. In roughly 170 or maybe that's 150 patients with intermittent brief depressive disorders, GSK report 34 suicidal acts. So you can see there's a vast difference here. This is a group of patients who are regularly committing suicidal acts. Almost every one of them nearly do.

Q. Well, how is using that data somehow able to hide a suicide risk for regularly depressed patients?

A. Well, as the term "intermittent brief depressive disorder" suggests, you can view this condition as a mood disorder. You can even view it as a kind of depression. Now, if you mix -- I mean, one of the things that I could have told people, and I've written articles on this, and it doesn't just apply for depression. It applies for back pain and things like that.

If you mix patients with a back pain of different sources in together, then a treatment that might be helpful for one kind of back pain won't show up when you mix a bunch of different kinds of back pain together. Like, antibiotics can be good for some back pains, but if you just take all back

pain patients, it won't show.

In the same kind of way, you can hide a problem that a drug causes by using a problem the drug causes. And that's what's happening in this case. If you drown out -- you can drown out the signal from 11 suicidal acts versus one by adding in 34 to the 11 and 34 to the 1. All of a sudden, the problem vanishes.

Q. Because the numbers are then 36 to 47; is that right?

A. Something like that, yes.

Q. Okay. This approach of trying to add in these data from these studies, did GSK attempt to do that when they came to the suicide issue?

A. Well, GSK certainly did the studies that would do -- that would have that kind of effect. And their view was, people looking at this issue should mix the two. They should mix major depressive disorder with intermittent brief depressive disorder if you want to get a true picture of what was going on.

Q. And if you do mix them, what happens to the suicide signal?

A. Well, if you mix them, the suicide signal goes away, and this -- this is something that GSK have done ordinarily.

Q. Now, these studies, these 056 -- there's a buzzing noise. These studies, did they -- 057 and 106, did they -- did the FDA consider them in their FDA analysis?

A. In the 2006 one, no, they didn't. GSK asked -- thought, made representations to the FDA that they should be included in. FDA said no.
Q. All right. Let's move on to the next way GSK hid the data. What's the next one, Doctor?
A. The next one I've got here is discounting run-out suicides.
Q. What's a run-out, Doctor?
A. Well, as opposed to the run-in, this is the wash-out phase. Before you randomize, there's a run-out period. When the trial ends after, say, six weeks, there's a 30-day period where people should monitor the patients who have been in both arms, the active treatment arm and the placebo arm. So this is often called the run-out phase.
Q. And I understand, Doctor, in your expert report, you prepared a diagram that helps you explain this?
A. I did, yes.
Q. Would using that diagram today help you in explaining how that works?
A. Yes.
MR. WISNER: Your Honor, permission to publish Exhibit -- Plaintiff's Exhibit 42 for demonstrative purposes only.
BY MR. WISNER:
Q. All right. This is from your expert report, Doctor. What

is this?
A. This is Figure 3. It may be helpful to show Figure 1 and 2 briefly so people can see what's going on.
Q. Sure. Let me pull it up.
A. Just the previous page.
MR. WISNER: Your Honor, can I show the previous figure?
THE COURT: Yes.
BY MR. WISNER:
Q. Okay. All right. So walk us through this, Doctor. This is from your report.
A. What you see here is what I have been trying to explain. You can leave that as it is. Hold on so the jury can see. You don't need to blow anything up.
You see the three dots up at the top, that's the placebo -- that's the suicide attempts happening during the wash-in -- wash-out or run-in phase. And you see in Figure 2 down below, they've migrated down to -- they appear to be in the placebo arm, and that makes the --
Q. I'm listening, Doctor. Sorry.
A. That makes the difference between Paxil and placebo look less. Now, if we go on to the next slide.
Q. Okay. Just for the record, that was exhibit -- Plaintiff's Exhibit 42.
A. Okay.

Q. Sorry.
A. Okay.
Q. Yes.
A. And on the next --
Q. Sorry. That was Plaintiff's Exhibit 43. Now we're on Exhibit 42. Okay. Sorry, Doctor.
A. Okay. On the next slide, there have been concerns about this. And you've seen the documents even within GSK. There were concerns that people weren't happy with the way this was being done. So this document reverses that --
MR. BAYMAN: Your Honor, that is just -- he is now just --
THE COURT: Yes, it may go out. Sustained.
MR. BAYMAN: I move to strike.
THE COURT: Yes. Your motion is granted.
BY MR. WISNER:
Q. All right, Doctor.
A. Okay.
Q. Please don't talk about concerns.
A. Sorry.
Q. Just talk about what the data is.
A. Okay. In GSK, they thought it would be more appropriate not to include the wash-outs in the placebo arm, and this document reverses that. The wash-out suicides have gone back up to the wash-out phase. But what you see down below is, a

further way to change things is to add suicides or suicide acts, and these are two completed suicides, into the placebo arm.

One -- the first little bullet you see there happening shortly after the dotted line where it's migrating up to the placebo arm is a person who is on placebo in the trial, and then in the wash-out period, they end up in hospital, being given Prozac, and they commit suicide on Prozac but they're being regarded as a placebo suicide.

The bullet you see down below the closed line completely is a person who falls -- whose death happens outside the 30-day period. And again, that's being counted in the placebo arm.

Q. So to be clear, Doctor, these are patients who are in the placebo arm, left the study, and then had a suicide event, and that was counted as though it happened in the study --

A. No, they hadn't actually left the study. Monitoring should happen, so they're still being observed, but it's terribly difficult to regard a person who commits suicide after going on Prozac as a placebo suicide. This just doesn't make a great deal of sense.

Q. I understand. So this was a Paxil trial, but the placebo patient was put on Prozac at the hospital --

A. After the trial was over --

Q. I see.

A. -- during that 30-day period.
Q. And -- okay.
A. The suicide happens during a period when the patient should be monitored, but it only happens after they go on Prozac.
Q. And so what does that essentially do to the placebo count?
A. Well, this gives you the impression that there was only one suicide on Paxil, and you're given the impression actually overall when this takes place that there were three suicides on placebo when there weren't.
Q. Okay.
A. At least you can debate whether that should be counted that way or not.
Q. What do you think it should be?
A. Well, I don't think it should be counted that way.
Q. Okay. All right. Doctor, what's the next way GSK hid the data? What number are we up to, five?
A. We're getting through them all right. Coding maneuvers.
Q. What is coding maneuvers?
A. Well, these days, almost all people use a coding dictionary called MedDRA. If I'm trying to code things, the team I work with will be using the MedDRA coding dictionary. And that's the one that FDA recognizes, also.

Before that, the main dictionary used by FDA was a dictionary called COSTART, but when it came to these trials

during this period, GSK was using a dictionary called ADEX. And using ADEX, they had an option to code suicides, completed suicides, and suicidal acts and suicidal ideation under the heading of "emotional lability."

And when that happened, people like me reading an article where this term appears in 2001, as it turned out, missed the fact that what's happening here is something awfully serious. We just think emotional lability is no big deal. We don't realize it's been used not -- it's -- I think English has been used. In fact, what's been used is coding language. And in coding language, it means a completely different thing to what the average doctor or person who may be on the pill thinks.

MR. BAYMAN: Objection, your Honor. He's speculating about what the average doctor thinks or knows.

THE COURT: Overruled at this point.

THE WITNESS: Okay. So there's a range of different things, and I've got an article on this which goes through the range of different coding maneuvers that GSK used in the Paxil trials. It's not confined to just emotional lability, but that was clearly the key one.

And just, this is -- let's put it this way. My view on it has been a doctor like me reading the article would be fooled. A layperson like the jury would be more likely to look at this article and say --

MR. BAYMAN: Objection, your Honor.

THE COURT: Overruled.

THE WITNESS: It was, in fact, laypeople that spotted the problem, not experts like me. So we have to be thankful for laypeople like the jury. You don't want to depend just on experts to get this right.

BY MR. WISNER:

Q. Are you aware of whether or not the FDA ever caught GSK doing this?

A. Well --

MR. BAYMAN: Objection, your Honor.

THE COURT: Yes, sustained as to whether they caught them.

BY MR. WISNER:

Q. Fair enough. Are you aware of whether or not the FDA ever expressed concern over GSK's coding maneuvers?

A. They did. They wrote to GSK and asked them to clarify where this term came from and to break out the data by suicides and suicide attempts rather than emotional lability.

Q. Have you seen any internal email correspondence from within the FDA about this point?

A. I have.

Q. And did it relate specifically to Paxil?

A. It did.

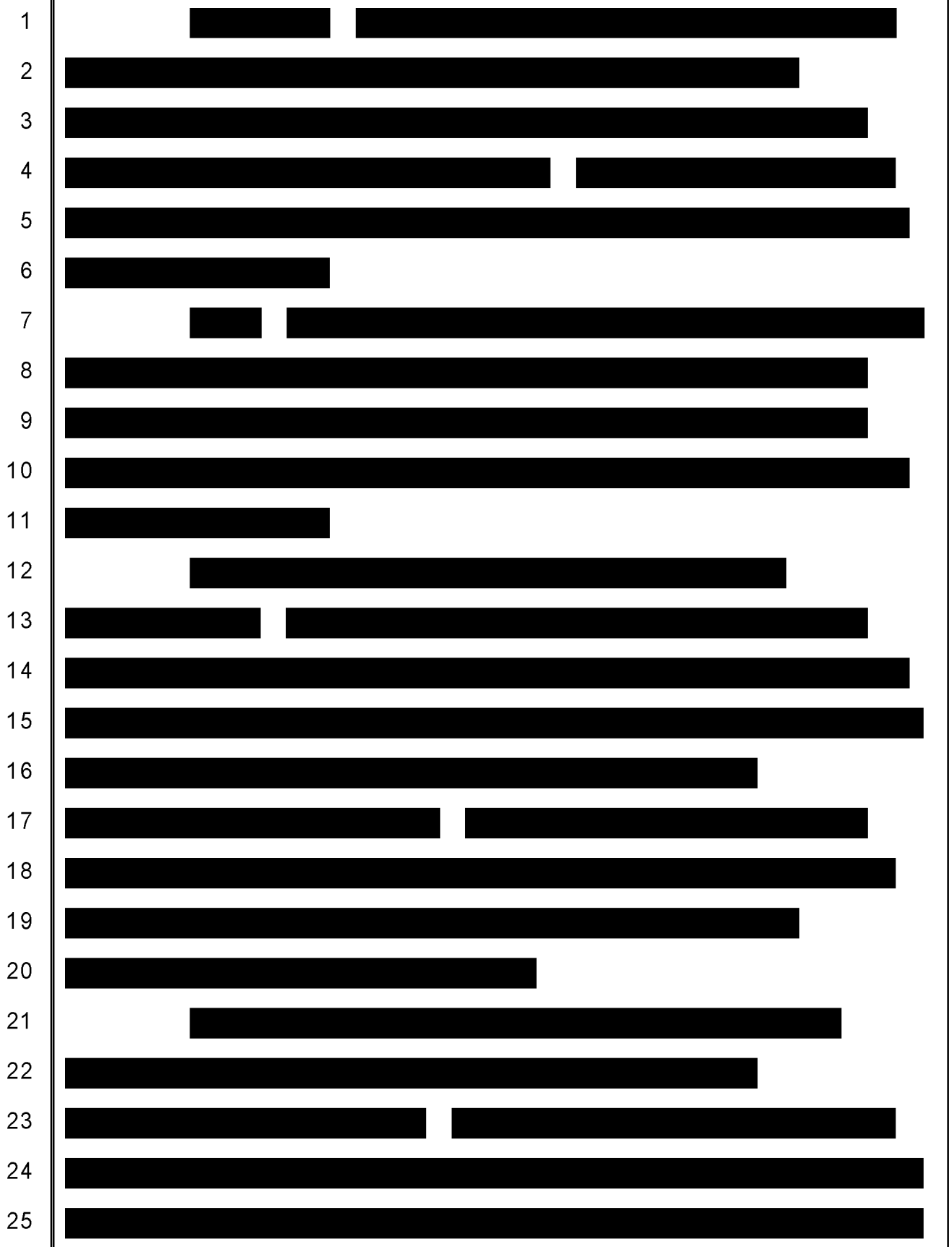
Q. All right. Please turn your binder to Exhibit 27. Are

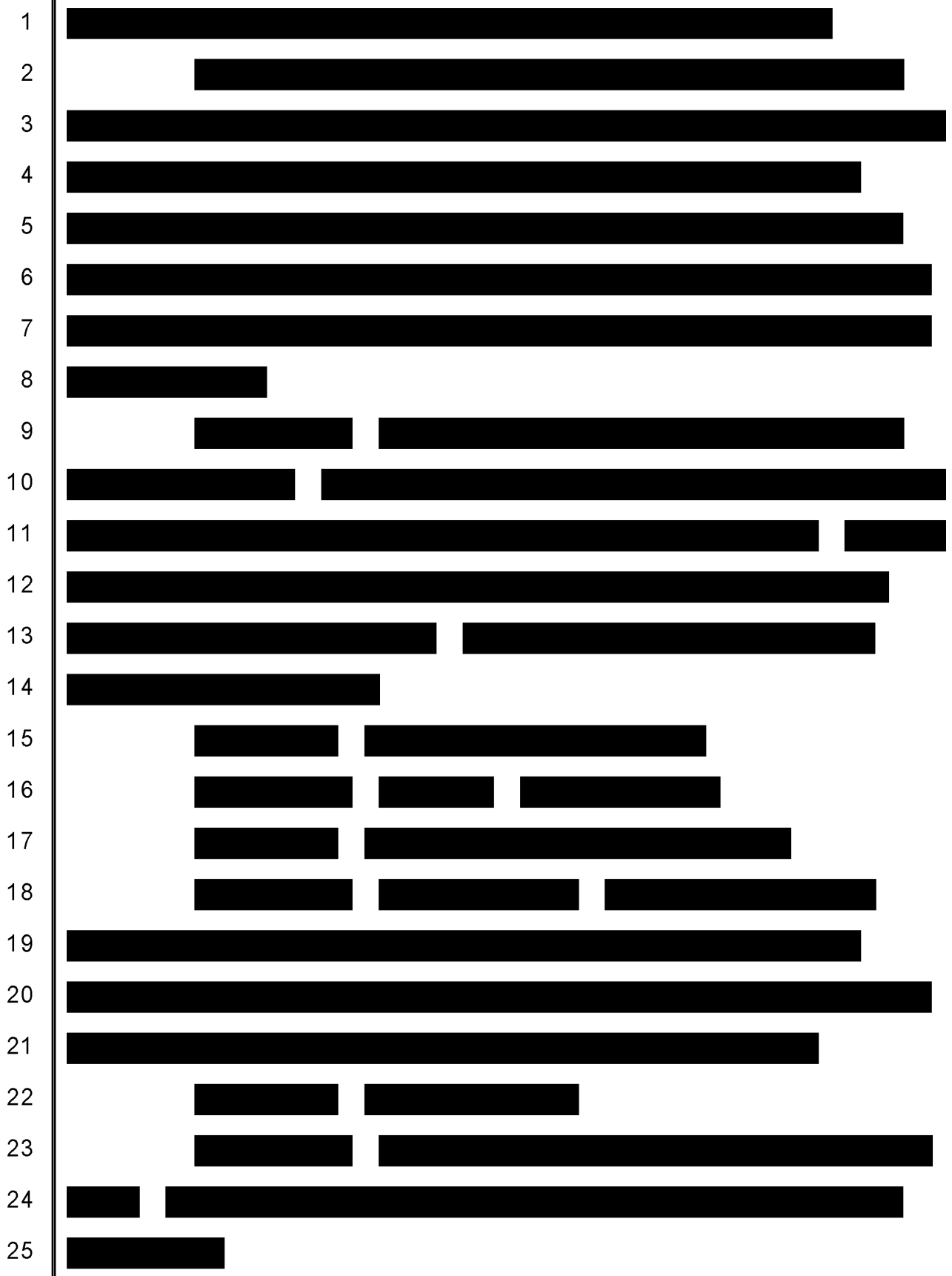
you there?
A. Yes, I am.
Q. All right. This is Plaintiff's Exhibit 27. And this is a series of -- what is this, Doctor?
A. This is a series of emails between individuals in FDA.
Q. Is this a document that you relied upon in coming to your opinions today?
A. Yes, it is.
Q. And is this to be a fair and truthful, accurate representation of a document that you reviewed?
A. It appears to be.
Q. Okay. Great. And does it discuss this coding issue?
A. It does, yes.
MR. WISNER: Permission to publish, your Honor.
THE COURT: You may proceed.
BY MR. WISNER:
Q. All right. Let's start off -- let's start off at the top. Let's look at this email exchange here. It's from who, Doctor?
A. Which -- right. Okay. This is from Russell --
MR. BAYMAN: Your Honor --
THE WITNESS: -- Katz.
MR. BAYMAN: Pediatrics.
THE COURT: Does this relate to the issue of coding?
MR. WISNER: It does, your Honor.

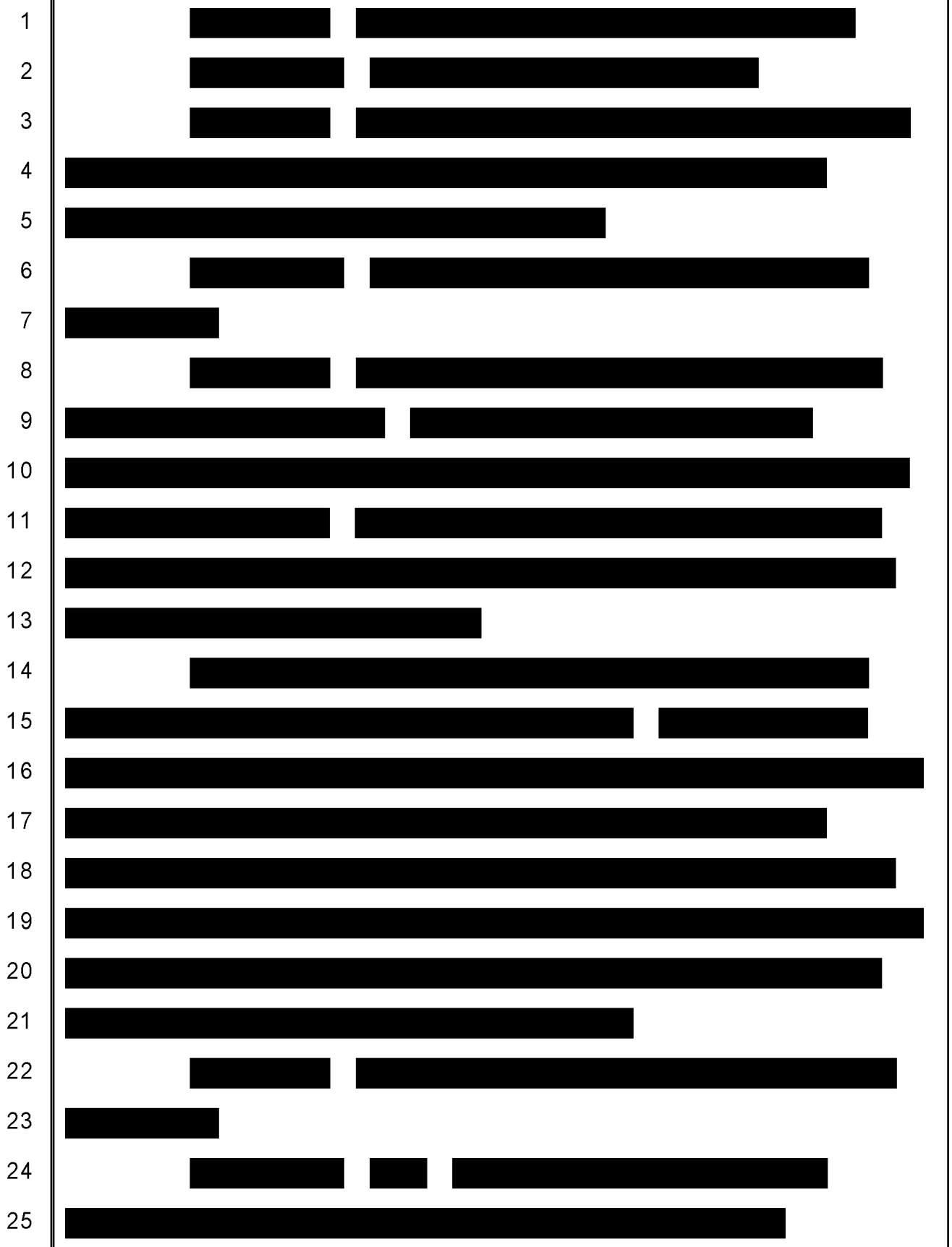
THE COURT: Although it also touches on the pediatric problem, is that your point?

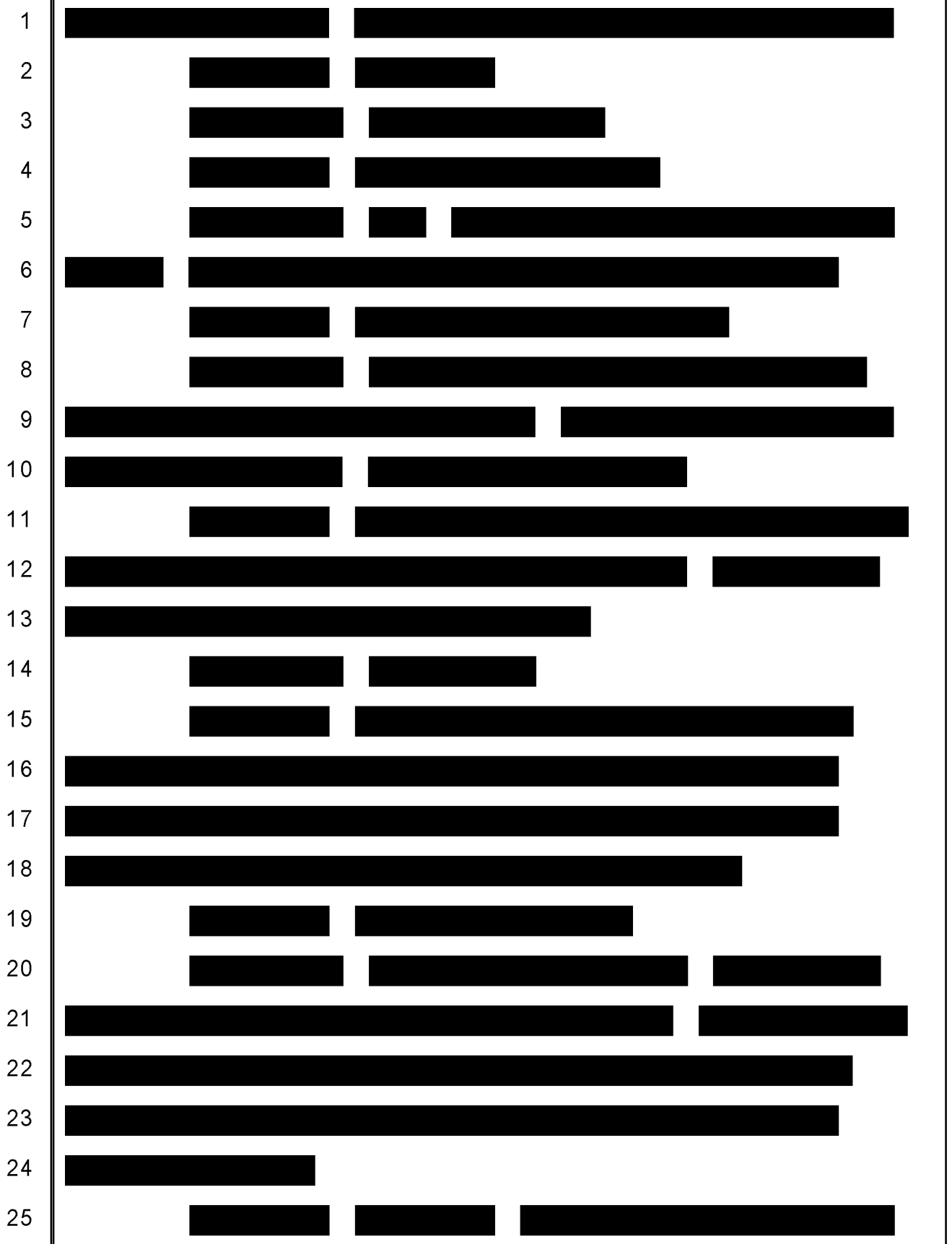
MR. WISNER: Your Honor, can we do a sidebar?

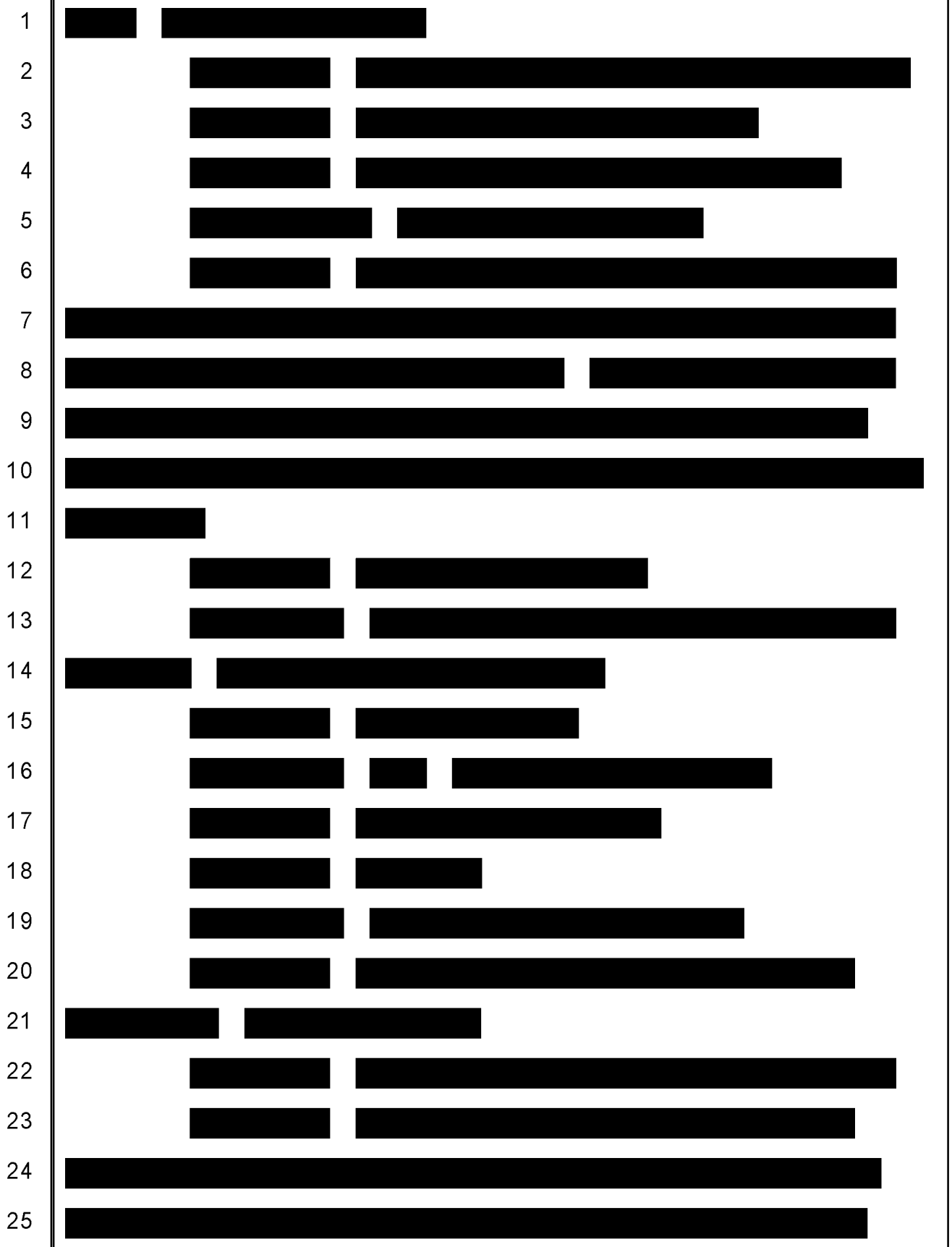
MR. BAYMAN: Sure.











[redacted]

(Proceedings heard in open court. Jury in.)

THE COURT: Okay. We'll take a 15-minute recess, ladies and gentlemen.

(Proceedings heard in open court. Jury out.)

(Witness exits the courtroom.)

[redacted]

[redacted]

[redacted]

[redacted]

(Recess from 3:05 p.m. to 3:15 p.m.)