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

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of STEWART DOLIN, Deceased,	)	
Plaintiff,	)	
-vs-	)	Case No. 12 CV 6403
SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, a Pennsylvania corporation,	)	Chicago, Illinois March 22, 2017
Defendant.	)	1:30 p.m.

VOLUME 6-B
TRANSCRIPT OF PROCEEDINGS - Trial
BEFORE THE HONORABLE WILLIAM T. HART, and a Jury

APPEARANCES:

For the Plaintiff:

BAUM HEDLUND, ARISTEI & GOLDMAN, P.C.
BY: Mr. R. Brent Wisner
Mr. Michael L. Baum
12100 Wilshire Boulevard
Suite 950
Los Angeles, California 90025
(310) 207-3233

RAPOPORT LAW OFFICES, P.C.
BY: Mr. David E. Rapoport
Ms. Melanie Joy VanOverloop
Mr. Matthew S. Sims
20 North Clark Street
Suite 3500
Chicago, Illinois 60602
(312) 327-9880

Court Reporter:

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

APPEARANCES: (Continued)

For the Defendant:

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

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

SNR DENTON US, LLP
BY: Mr. Alan Scott Gilbert
233 South Wacker Drive
Suite 7800
Chicago, Illinois 60606
(312) 876-8000

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

[redacted]

(Jury enters courtroom.)

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

You may proceed, sir.

MR. BAYMAN: Thank you, your Honor.

DAVID ROSS, PLAINTIFF'S WITNESS, PREVIOUSLY SWORN.

CROSS-EXAMINATION

BY MR. BAYMAN:

Q. Good afternoon, Dr. Ross.

A. Good afternoon.

Q. I just want to establish something at the outset. While you've worked for the FDA in the past, you're not speaking here today on behalf of the FDA, correct?

A. Correct.
Q. And you don't have authority to speak on behalf of the FDA, correct?
A. No.
Q. So, that's correct, you do not?
A. Correct.
Q. And while you work currently at the U.S. Department of Veterans Affairs, you're not speaking today on behalf of the V.A., are you?
A. Correct.
Q. Or on behalf of the U.S. government at all, are you?
A. Correct.
Q. Now, when you worked at the FDA, you worked in the group responsible for anti-infective drugs, is that right?
A. That was one of the groups that I worked in.
Q. And that -- there's a separate group at the FDA, though, isn't there, called the neuropharmacology division?
A. Yes.
Q. And you never worked in the neuropharmacology division, correct?
A. Correct.
Q. And that neuropharmacology division is the group responsible for the review and analysis of psychiatric medications like Paxil, correct?
A. The review and analysis of clinical trials on drugs such

as Paxil.
Q. And also for reviewing and approving NDAs, New Drug Applications, for drugs such as Paxil, correct?
A. Correct.
Q. And even though you never worked in that division, you also never received any assignments from the neuropharmacology division while you were at FDA, correct?
A. Not that I can recall.
Q. And while you were at FDA, you never reviewed any safety data for any SSRI or any psychiatric medication, correct?
A. Not that I can recall.
Q. You did not work at the FDA, in fact, on any issue concerning an SSRI or a psychiatric medication and suicidality, correct?
A. Correct.
THE COURT: Doctor, move that microphone closer to you.
THE WITNESS: Sorry, your Honor.
THE COURT: There's another one there on the stand.
THE WITNESS: Yes, sir.
BY MR. BAYMAN:
Q. For instance, while at the FDA, you never analyzed any data with respect to any SSRI or psychiatric medication to assess whether they increased the risk of suicidality, correct?

A. That specific issue, no.
Q. And during your time at the FDA, you never worked on the labeling for any SSRI or antidepressant, correct?
A. Correct.
Q. You were familiar with something that the FDA calls an advisory committee, correct?
A. Yes. If I may, I apologize. I need to clarify my answer to your previous question. For at least one of the products that I worked on during the time that I was in anti-infectives, there may have been work that involved simultaneous labeling considerations for an antidepressant.
Q. But that wasn't an SSRI, correct?
A. You know, I'd actually have to look at that label for that product to be sure, so I don't know.
Q. Do you have your deposition with you, Doctor?
A. I'm not sure if it's in this binder.
Q. What is that binder?
A. This is the exhibits for direct examination.
Q. Let me hand you your deposition.
A. Thank you, sir.
MR. BAYMAN: Your Honor, may I approach?
THE COURT: Yes.
MR. BAYMAN: That's his deposition.
BY MR. BAYMAN:
Q. Dr. Ross, turn, if you would, to your deposition, which

was taken April 5 -- April 2nd, 2015, to page 77, lines 1 to 4.

MR. WISNER: Objection, your Honor. If I could get a copy of whatever he's showing the witness.

MR. BAYMAN: It's his deposition. I'm happy to give you one.

MR. WISNER: Thank you.

THE COURT: Page?

MR. BAYMAN: 77, line 1 to 4.

BY THE WITNESS:

A. Yes, sir.

BY MR. BAYMAN:

Q. The question was, "While you were at FDA, you never worked on the labeling for any SSRI or any psychiatric medication, is that true?"

And your answer was, "That is true."

Did I read that correctly?

A. Yes.

MR. WISNER: Objection. Move to strike as improper impeachment. He testified that he may have worked on labeling in the anti-infective area that there was overlap. This is just reading testimony in from the transcript.

THE COURT: All right. Let's proceed.

BY MR. BAYMAN:

Q. You talked on direct a little bit with Mr. Wisner about an

FDA advisory committee. Do you recall that?
A. Yes.
Q. And FDA often consults advisory committees for independent expert advice on scientific matters, correct?
A. Correct.
Q. And advisory committees are composed of, at least in the FDA's view, authorities in the field?
A. Can you clarify -- when you say authorities in the field, I just want to make sure I understand what field you're talking about.
Q. Well, whatever field the particular advisory committees impanel. Let's say, for example, psychiatric medications. The FDA considers those people on the advisory committees to be experts in that field, correct?
A. Well, because there are by -- I don't know if it's regulation or law on FDA advisory committees, individuals such as consumer or patient representatives, I want to make sure I understand what you mean by expert. They may not be clinical expert, but they bring the different perspective to that.

So, I think it would be fair to say that the members of an advisory committee are consulted by FDA to provide input based on their perspective and experience.
Q. Fair enough. There are -- there may be consumer representatives, but there also may be medical doctors, too, correct, on the advisory committee?

A. And there's, I think, almost without exception a statistical consultant on the committee.
Q. You anticipated my next question. In any event, FDA invites experts outside of FDA to participate in advisory committees, correct?
A. Yes.
Q. And you've never served on an FDA advisory committee that assessed whether an SSRI or psychiatric medication was safe and effective, correct?
A. Correct. Excuse me.
Q. You have never served on an FDA advisory committee that assessed whether an SSRI or any psychiatric medication increased the risk or was associated with suicidality, correct?
A. Correct.
Q. And while you were at FDA, you certainly had no responsibility for reviewing any data concerning Paxil, correct?
A. Correct.
Q. And you never had any responsibility for reviewing Paxil's labeling, correct -- while you were at FDA, correct?
A. Correct.
Q. And you never had responsibility at FDA for reviewing any post-marketing data on Paxil, correct?
A. Let me qualify my answer, because again, I want to try to

make sure I'm giving you clear answers. You know, for example, you had previously said that I -- you know, during the deposition, I said I did -- I'm going to answer your question -- that I worked on the labeling. At the time of the deposition, my interpretation was you meant directly on the labeling, and that is correct.

It occurred to me, and this is probably because of the example I used earlier, that there was labeling that I worked on for anti-infectives that had implications for antidepressant labeling.

But to answer your question, while there may have been adverse event reports involving patients who were receiving Paxil along with other drugs, I was not responsible primarily for assessment of those reports with respect to Paxil.

Q. Thank you. Now, as I understand, you left the FDA in 2006 and began practicing at the Veterans Administration or V.A., is that right?

A. Well, actually, no. I had already been on staff practicing at the Washington, D.C., V.A. from 1998 onwards. In 2006 -- and I continued that activity while I was at the FDA up through the present day.

In 2006, I left the FDA to assume the -- direct the V.A.'s HIV, hepatitis C, and what's now called related conditions program.

Q. So, the V.A. became your employer in 2006?
A. Correct.
Q. And your role at the V.A. is that of a general practice doctor, is that right?
A. I'm sorry. I'm not trying to be difficult, but when you say general practice, tell me what you mean.
Q. You're an internist, correct?
A. Among other things, yes.
Q. Okay. And you have a specialty in infectious disease, correct?
A. Correct.
Q. But you treat patients at the V.A., correct?
A. Yes.
Q. And adult patients, correct?
A. Yes.
Q. And you testified yesterday that in your practice, you do not prescribe SSRIs, including Paxil, correct?
A. Let me clarify that in the sense that other providers, particularly in mental health, may initiate therapy with an SSRI, and I may order a new prescription or refill for a patient. And in doing so, even though it's another physician who initiated it, I take the legal and ethical responsibility for renewing it.

So, maybe that's -- I'm just trying to clarify that point, that I've not initiated treatment of patients with

Paxil.
Q. You've not written the first prescription for Paxil for a patient, correct?
A. Correct.
Q. And when you talked about medicines that you prescribed yesterday, you were talking about antidepressant medications that are in a different class than Paxil, correct?
A. Correct.
Q. Those would be benzodiazepines, is that right?
A. Well, benzodiazepines are generally not antidepressants.
Q. Okay. But you prescribe benzodiazepines, correct?
A. If they are clinically indicated, yes.
Q. Okay. Now, correct me if I'm wrong, but I think you testified yesterday that you don't prescribe Paxil or other SSRIs because you believe they cause people who take the medication to commit suicide in some cases, correct?
A. No, that is not what I said.
Q. Okay. I believe you said based on the information you learned in this case, you don't prescribe Paxil to patients, didn't you?
A. Correct.
Q. Okay. But when you see a patient who's taking Paxil prescribed by another doctor, you have a conversation with that patient about your opinion regarding the relationship between Paxil and suicide, correct?

A. To be honest with you, I cannot recall the last time I saw a patient of mine who was on Paxil.
Q. What about other SSRIs?
A. If there are other SSRIs that they're on, as a matter of course, I do what's called a medication reconciliation, which means that I go through their medications, and I say, "Are you taking this? Are you taking this?"

One of the challenges in my patient population is I frequently will have patients who are on literally 25 different medications. And one thing I'm always looking to do is say, "Is this medication really needed, or is it the right medication?"

So, I do go through them, and that's part of -- as part of that, I'm also assessing what is going on with the patient, including things such as depressive symptoms and the like.

Q. I think you said this morning that your healthcare organization manages patients and informs them about the risk of suicide, correct?

MR. WISNER: Objection. Vague.

THE COURT: Overruled. You can answer it if you can.

BY THE WITNESS:

A. When you say the risk of suicide, in what context?

BY MR. BAYMAN:

Q. Well, I think -- again, correct me if I'm wrong, but my

notes show you testified that suicide is an enormous problem with veterans, correct?
A. Yes.
Q. And that you work with a high-risk population, I think was the word you used this morning?
A. Yes.
Q. You know, though, don't you, that other doctors at the V.A. prescribe Paxil and other SSRIs to veterans, correct?
MR. WISNER: Objection, your Honor. You stopped me from going down this inquiry about his work with V.A. and SSRIs, and now he's doing it. So, he objected. I think it should cut both ways.
MR. BAYMAN: He talked this morning about how he counsels veterans who he sees about the risk of --
THE COURT: Well, very limited, and I'll allow very limited cross. It was very limited.
BY MR. BAYMAN:
Q. Okay. You know that other doctors at the V.A. prescribe Paxil and other SSRIs to veterans, correct?
A. I believe it's available to them. I actually would have no idea of how often it's used compared -- or how infrequently it's used compared to other drugs.
Q. You know that the V.A.'s formulary permits physicians to prescribe generic paroxetine, correct?
MR. WISNER: Your Honor, we're going into formularies

now? Objection. This is irrelevant.

THE COURT: Sustained. I think we ought to stay on track, sir.

BY MR. BAYMAN:

Q. You're familiar with the -- well, you were with the Veterans Administration in 2010, correct?

A. Yes.

Excuse me. If I could, I apologize, your Honor. It's actually Department of Veterans Affairs. Veterans Administration was the name about probably 20, 30 years ago. So, just in the interest of clarity.

Q. Okay. Why don't we just say V.A. Would that --

A. That would be even better.

Q. And then given your expertise in treating patients and in counseling them on the risk of suicide, you know that the deputy chief officer at the V.A. has testified that antidepressants lower the risk --

MR. WISNER: Objection. Move to strike. This is hearsay and irrelevant.

THE COURT: Well --

MR. WISNER: He's about to quote someone who's not even a witness in the case, and I had to interrupt him before he got the hearsay out, your Honor.

MR. BAYMAN: I'm just asking if he knows that the deputy chief officer at the V.A. testified that

antidepressants lower the risk of suicide among veterans when he testified in front of Congress.

BY MR. BAYMAN:

Q. Do you know that?

THE COURT: Objection?

MR. WISNER: Objection, your Honor. Hearsay. Move to strike.

THE COURT: It's sustained. The testimony is stricken -- question is stricken.

BY MR. BAYMAN:

Q. You're not a psychiatrist, correct?

A. No.

Q. You're not a member of any professional organization that focuses on psychiatry, such as the American Psychiatric Association, American College of Neuropsychopharmacology?

A. Correct.

Q. The focus of your career has not been on suicide or suicidality, correct?

A. That is correct.

Q. You don't consider yourself an expert in suicidality, correct?

A. I haven't claimed to be.

Q. I want to make sure that the record's clear. You've never had any conversations with any of your patients about the risk of suicidality and the use of SSRIs, correct?

A. You know, I'm -- and again, I'm not trying to be difficult. It doesn't stand out in my mind. Let me put it like that.
Q. You -- and you testified a minute ago that you treat patients at the V.A. who may be taking SSRIs prescribed by other doctors, right?
A. Yes.
Q. But you don't stop their prescriptions of SSRIs based on what you know from this case, correct?
A. That's -- I'm sorry. I've got to again give some context to this. You -- that's not the way things work in an organization where you've got teams of physicians. We're not in these little silos.

We have a record where I can see what's going on with the patients, what other prescribers are saying. I don't just say, "Well, I'm going to stop this," unless it's a clinical emergency.

So, before doing anything, where I said, "Boy, I really don't think this patient should be on this drug" -- and that has happened with psychiatric drugs, where they can interact with some of the HIV drugs -- I'm going to have a conversation with their prescriber.
Q. So, I guess the answer to my question is if a patient presents and they're taking an SSRI, you don't automatically stop that SSRI because of what you've learned in your work as

an expert in this case, correct?
A. I don't think there's any -- as a physician, there's no one-size-fits-all rule. If somebody came in and they were taking cyanide, yes, that, I would stop. But for a drug that they're on, you know, you assess the situation.
Q. You don't -- you don't address any issues concerning the safety or efficacy of SSRIs, antidepressants, or any psychiatric medications as part of your work at the V.A., correct?
A. I apologize. Can you -- I just want to make sure I'm answering this.
THE COURT: Read it back.
THE WITNESS: Thank you.
(Record read.)
BY THE WITNESS:
A. I, as part of my work, address approaches and treatments for depression, but I do not work on SSRIs directly.
BY MR. BAYMAN:
Q. You don't have a degree in epidemiology, correct?
A. I have training through the FDA in epidemiology, but not a Ph.D. in epidemiology.
Q. You don't have a degree in statistics, correct?
A. Again, training, not only through the FDA but also as part of my biomedical informatics training, but not a Ph.D. in statistics.

Q. You're not an expert in psychopharmacology, correct?
A. No.
Q. You're not an expert in neurology, correct?
A. No.
Q. You've never done any clinical research regarding Paxil or any other SSRI or any psychiatric medication, correct?
A. That is correct.
Q. And you've never done any clinical research on whether any medication increases the risk of suicidality, correct?
A. There are hepatitis C drugs that are known to induce suicide or suicidal behavior, and I believe I've looked at that issue.
Q. Do you have your deposition there in front of you?
A. Yes, sir.
Q. Could you look at page 62, line 22?
A. Um-hum.
Q. Have you got that?
A. Yes.
Q. The question was, "Have you ever done any clinical research on suicidality for any medication?"

And your answer was, "No."

Did I read that correctly?
A. Yes. At that time, that was a correct answer. That was two years ago.
Q. You've never designed any clinical trial intended to

determine whether a medication increases the risk of suicidality, correct?
A. Correct.
Q. And you've never been involved in any clinical trials where the trials were designed to determine whether any medication causes or increases the risk of suicidality?
A. Correct.
Q. You've never conducted any research on the subject of the effects of psychiatric medications, correct?
A. Not that I can recall.
Q. You've never lectured on the subject of the effects of antidepressants, anti-anxiety medications, or psychiatric medications, correct?
A. Correct.
Q. And you've never conducted any scientific research of any kind involving an SSRI, correct?
A. Not to the best of my recollection.
Q. You've never lectured on the subject of the effects of psychiatric medications, correct?
A. Not that I can recall.
Q. You've never published any articles in the professional literature about Paxil, correct?
A. No.
Q. Or any other SSRI or psychiatric medication for that matter, correct?

A. Correct.
Q. You've never published anything in the scientific literature about suicidality and Paxil or other SSRIs, correct?
A. Correct.
Q. You've not authored any publications concerning when or how to change a prescription drug labeling, correct?
A. No.
Q. You've not authored any publications concerning industry standards for prescription drug labeling, correct?
A. I'm sorry. Could you read the question back.
(Record read.)
BY THE WITNESS:
A. I believe that guidance documents that I've worked on -- worked on when I was at FDA may have addressed some aspects of drug labeling.
BY MR. BAYMAN:
Q. You've never published any article that specifically discusses the regulatory standards for when an adverse event should be included in labeling or how it should be included in labeling, correct?
A. Not that I can recall.
Q. And you've never published any articles that specifically discuss -- strike that.
You've never published any article in which you form

an opinion about the adequacy of a medication's labeling, correct?
A. I'm not sure I would agree with that statement.
Q. Which article do you have in mind?
A. So, I published an article in *New England Journal of Medicine* in -- boy, it's been a long time, I believe it was either 2007 or 2008, that at least indirectly addressed that by discussing the integrity of data in the trials and the safety and efficacy of a drug.
Q. It indirectly addressed it?
A. Well, that's the basis for labeling, so yes.
Q. You've never worked at a pharmaceutical company, correct?
A. No.
Q. You've never been retained as a consultant of any kind by either a generic or a brand name pharmaceutical manufacturer of any psychiatric medicine, correct?
A. I'm not sure.
Q. You don't recall?
A. I've been retained once by a pharmaceutical company, but I don't know if they're a manufacturer of pharmaceutical medications.
Q. Of psychiatric medications?
A. I'm sorry, I apologize, of psychiatric medications. They both begin with a P.
Q. Well, let's narrow it down. You've never been retained as

a consultant by any generic or brand name SSRI manufacturer, correct?
A. Again, I -- in the one instance, I don't know if that entity manufactures SSRIs, either as a generic or as a brand name.
Q. Can you turn in your deposition to page 62.
A. Yes.
Q. Starting at line 1.
A. 62, line 1. Yes.
Q. The question was, "Have you ever been retained as a consultant of any kind by a generic or brand name manufacturer of any psychiatric medication?"
Your answer was, "No."
Did I read that correctly?
A. The -- my retention occurred after this deposition.
Q. Okay. Now, you're here testifying as an FDA regulatory expert, correct?
A. Correct.
Q. And so you claim to understand the laws and regulations that control between the FDA and pharmaceutical manufacturers, correct?
A. I'm not sure I completely -- when you say control between the FDA and manufacturers, can you be a little more specific?
Q. The laws that impact the relationship between the FDA and pharmaceutical manufacturers.

A. With respect to the focus of my testimony, the laws and regulations concerning labeling of drugs and the standard for including information in the label.
Q. You testified about it a little more broadly yesterday. In fact, you testified that the FDA was privately funded by drug companies under what's called user fees, correct?
A. Yes.
Q. The user fees that you're talking about are derived from the Prescription Drug User Fee Act, correct?
A. Well, there's other user fee acts besides that, the Generic Drug User Fee Act, for example.
Q. Well, the one you were referring to yesterday was what we call PDUFA, P-D-U-F-A, correct?
A. Correct.
Q. And that's an act of Congress, right? It's passed by Congress?
A. That's correct.
Q. The user fees are not optional payments by the drug companies, are they, Doctor?
A. They can be waived by the FDA under certain circumstances.
Q. The user fees, Doctor, that the FDA collects from the drug manufacturers are mandated by law in that statute, correct?
A. Actually, no. They are -- part of what are called PDUFA agreements, there's what are called side letters. The actual legislation is fairly broad. So, on the one hand, the agency

sets the fees; and on the other hand, there's an agreement about how fast the FDA will review the drugs -- or the applications, I should say.

Q. Okay. But when a company wants to get a new drug approved, they have to file an application fee, correct?

A. Correct.

Q. And that application is -- application fee can be as high as $2 million, correct?

A. Actually, I think for FY '16, it may be more like 2.3 million.

Q. Okay.

MR. WISNER: Your Honor, they objected when I asked questions about this. You sustained the objection. I feel we're again in a goose-gander situation. I'd move to stop this line of inquiry because it's not fair.

MR. BAYMAN: He was asked a number of questions before my objection was sustained.

THE COURT: I do recall testimony about user fees, so I'll allow some liberality.

BY MR. BAYMAN:

Q. Okay. A user fee is just -- for example, it's like getting your driver's license; you pay an application fee, correct?

A. No, it is not just like a driver's license. There is a guaranteed standard of service that FDA agrees to provide in

exchange for that fee.
Q. But the people who pay the fees are the people who are getting the service; that's why it's called a user fee, correct?
A. Correct.
Q. Have you ever informed the FDA about the opinions that you're offering in this case?
A. I don't believe so.
Q. You've never informed the FDA that you believe there's an association between the use of paroxetine or Paxil by adults older than 24 and a risk of suicidality, correct?
A. Correct.
Q. You've never told the FDA that you think the FDA-approved labeling for Paxil is inadequate or false or misleading, correct?
A. Well, with the qualification that it's actually GSK's responsibility to do that, no.
Q. We'll get into that later. You've never submitted the opinions that you offered yesterday and today in response to Mr. Wisner's questions for review by your peers in the medical community, have you?
A. I'm not actually sure, given the fact that some documents are, I believe, under seal, that I would be able to do that.
Q. You've never published your opinions in any peer -- about Paxil and suicidality in any peer-reviewed publication,

correct?
A. I would give you the same caveat that I would have to back those up, and I'm not sure if I would be able to do that given the sealing of documents.
Q. No professional or scientific medical organization has ever sought out your opinion about Paxil's labeling, correct?
A. Not that I'm aware of.
Q. You generated your opinions about the adequacy of Paxil's labeling regarding suicidality solely for the purposes of this litigation, correct?
A. Hum. With the caveat that the principles that I based it on are in data analysis, which is the same science that was used at the FDA, is something that I did not discover for purposes of this litigation, I would say that I provided the opinions on the basis of the data that I was provided as well as data that I requested.
Q. Well, you provided them in the context of this litigation, this case, rather than in some other scientific context, correct?
A. If you mean that I didn't go looking for this, you're correct.
Q. Well, maybe I can make this easier.

Other than this lawsuit, has there been any time anyone else other than the plaintiff's lawyers have asked you to determine if there's reasonable evidence of association for

suicidality for any SSRI, antidepressant medication, or psychiatric medication?
A. I've not been in a position before where someone would ask me to do that.
Q. So, the answer is no?
A. Correct.
Q. And you're paid for your testimony in this case, correct, an hourly rate?
A. Yes.
Q. And how much do you charge?
A. I am being compensated -- I currently charge $550 an hour, but for this litigation, I'm charging $480 an hour.
Q. I want to turn now to the FDA approval process.
A. Okay.
Q. You know that when it -- or you agree that when it comes to prescription medications such as an SSRI, that the FDA has the sole and exclusive authority to approve that medication for use in the United States?
A. Could you reread back the last line.
THE COURT: Read it back.
(Record read.)
BY THE WITNESS:
A. With the caveat that other government entities, excuse me, and I think the example I mentioned in my deposition was the Drug Enforcement Administration, may have authority over some

aspects of that, I would say -- I would say the FDA has authority over that.

BY MR. BAYMAN:

Q. Could you look in your deposition at page 79, line 24. And it carries over to page 80, line 4.

Are you there?

A. Yes.

Q. Are you there?

A. Yes.

Q. Okay. The question was, "But you agree that when it comes to prescription medications such as an SSRI, that the FDA has the sole and exclusive authority to approve that medication for use in the United States?"

And your answer was, "Yes," correct?

A. Well, the qualification that I gave immediately before that was that this has gotten a little confused because of the advent of medical marijuana. So, that's where I indicated that that statement may not be completely accurate.

Q. And that would be the DEA with respect to medical marijuana would be the other organization; is that what you're saying?

A. Well, I'm saying it would be both.

Q. Both.

A. And also -- I mean, the issue here, as I understand it, is: Is it going across a state line? So, when you say the

United States, I think -- what you're saying, I guess, is interstate commerce I guess is the legal phrase. Is that fair?

Q. But you agree when it comes to an SSRI --

A. Yes.

Q. -- that the FDA has the sole and exclusive authority to approve an SSRI for use in the United States?

A. Yes.

Q. And to obtain FDA approval, manufacturers are required to prove that the drug is both safe and effective for its proposed indication, correct?

A. That's, in basis -- there's more qualifications to that, but yes.

Q. And it's the FDA that makes that determination whether a drug is safe and effective, correct?

A. Based on the information provided by the manufacturer, yes.

Q. And the FDA has to approve all prescription drug labeling, correct?

A. Eventually, yes.

Q. Do you agree that the Federal Regulations provide that the FDA has the final say on what should be included in prescription drug labeling?

A. So, I would say that leaving aside issues about the jurisdiction of the courts in this, I would say the sponsor

has the ultimate responsibility. The FDA is the ultimate authority in that context.

Q. You agree that the FDA makes the determination that the labeling and information evaluated with respect to a drug is sufficient so that in the FDA's judgment, it provides adequate directions for safe use to the prescriber, correct?

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

THE COURT: Yes, read it back.

(Record read.)

BY THE WITNESS:

A. Again, based on the information available to the FDA from the manufacturer at that point in time, yes.

BY MR. BAYMAN:

Q. And would you agree that the FDA's mandate is to ensure that the manufacturer's label contains relevant information regarding effectiveness -- accurate and relevant information regarding effectiveness and safety, correct?

A. Among many other things, yes.

Q. But it's the FDA that makes that determination, correct?

A. Again, based on the information provided to it, yes.

Q. You agree with me that the FDA has been charged by Congress with ensuring that drugs are safe and effective and that their labeling adequately informs users of the risks and benefits of the product and that it is truthful and not

misleading?
A. One non-trivial correction. The Congress, the last time I looked at the Prescription Drug User Fee Act, said that it wants the FDA to get safe and effective drugs to the market. And that was a revision back in, I think, the FDA Modernization Act.
But substantially, yes.
Q. And you would agree with me that Paxil could not remain on the market if the FDA was of the view that it was not safe and effective for use in accordance with the approved labeling, correct?
A. When you say, "could not remain on the market," could you clarify?
Q. That the manufacturer of either Paxil or generic paroxetine could not sell it in this country if the FDA were not of the continuing view that it was safe and effective for use in accordance with the approved label, correct?
A. That's one possible outcome.
Q. Now, we talked about GSK's New Drug Application. You talked about that with Mr. Wisner on direct, correct?
A. Yes.
Q. And that was submitted to the FDA in November of 1989, correct?
A. I believe so.
Q. And the applicant for an NDA -- I'm sorry, the company who

files an NDA is legally obligated to provide full reports of investigations which have been made to show whether the medication is safe and effective, correct?
A. It is -- I would say it is required to do so, yes.
Q. And those reports include safety data and other information about the medication from the clinical trials, correct?
A. Yes.
Q. And the Paxil NDA included data from the clinical trials conducted to that point, correct?
A. Yes.
Q. You talked yesterday about how much data is included in an NDA submission. You're not suggesting that a manufacturer should not provide all the data that the FDA requires or requests, are you?
A. I don't believe I was saying that.
Q. And along with the data, the New Drug Application, the NDA, must include proposed labeling for the medication, correct?
A. Yes.
Q. In addition, the manufacturer must furnish substantial evidence of adequate and well-controlled studies, correct?
A. I apologize. I would say it's substantial evidence from adequate and well-controlled studies.
Q. Thank you. And once the FDA -- or the NDA is filed, the

FDA's doctors and scientists review that submission to determine whether the drug is safe and effective for its intended uses, correct?

A. Based on the information provided by the company, yes.

Q. And you'd agree with me that the FDA's process for a New Drug Application is rigorous, correct?

A. When you say rigorous, I just want to make sure we're using -- on the same page. Please tell me what you mean.

Q. Rigorous. Thorough.

A. Well, okay. So, I think that with the understanding that there's different levels of rigor. There's rigor looking at the summary tables. There's rigor looking at -- going further and looking at individual what we call case report listings, looking at case report forms, and then finally, going back to the raw data.

The FDA's process is rigorous with the data it receives, but it does not get the raw data.

Q. But it can request that if it wants it, correct?

A. If it knows to request it, yes.

Q. You mean to tell the jury that the FDA doesn't know there's raw data behind the summary reports that are done?

A. Well, there's too much for the FDA to get all of it. You have to focus. And so if, for example, to take a hypothetical example, you don't know that emotional lability really means attempted suicide, then you won't know --

MR. BAYMAN: Your Honor, this is beyond the scope of my question. I move to strike it.

MR. WISNER: Your Honor, he was asking his question. He asked an open-ended, vague question. He can answer it.

THE COURT: You may finish your answer.

BY MR. BAYMAN:

Q. You would agree with me that the FDA is comprised of hundreds of scientific experts, correct?

A. I would actually go further and say it's composed of hundreds of scientific experts who have to review thousands of submissions a year.

Q. And that includes medical doctors, correct?

A. Yes.

Q. It includes chemists, correct?

A. Yes.

Q. It includes biostatisticians, correct?

A. Yes.

Q. Toxicologists, correct?

A. Yes.

Q. Pharmacologists, correct?

A. Clinical pharmacologists.

Q. Epidemiologists, correct?

A. Yes.

Q. And many of those people have advanced degrees, do they not?

A. Yes.
Q. And you agree with me that the reviewers at FDA, based on your experience at FDA, bring scientific and technical expertise and a strong commitment to public health to the issues which they address, correct?
A. The ones who I've worked with, yes.
Q. Are you aware of anybody who worked in the neuropharmacology division at FDA during the time that Paxil and the other SSRIs were approved as safe and effective who did not have the necessary expertise to evaluate the safety and efficacy or effectiveness of those medications?
A. Well, I guess the way I would answer that is looking at the reviews and other documents that I've seen, it's not only a question of expertise. It's a question of execution.

So, I would say do they have -- you know, expertise is one thing, but being able to actually put it into practice and use it effectively is another.
Q. Well, let's get back to my question. Do you know anybody during the time period that Paxil and SSRIs were approved as safe and effective that did not have the expertise to evaluate the safety and effectiveness of those medications?
A. Not directly.
Q. You would agree with me that the FDA reviews the safety data of a medication that is part of an NDA in order to satisfy itself that the drug is safe and effective, correct?

A. I don't think it's a matter of the FDA satisfying itself. I think it's a matter of complying with its responsibilities under the law.
Q. And you would agree with me that the experts at the FDA will do their own analysis on the information and data that is supplied by the drug manufacturer in an NDA, correct?
A. Well, it varies. I mean, there's some things where they do their own analyses, and there's some where they simply accept what the sponsor said.
Q. Well, let's talk about safety and adverse events. You would agree with me that's one of the areas that the FDA will specifically look at and review on its own, correct?
A. Well, when you say review on its own, I mean, to the extent that they are doing things beyond what the sponsor gives them, I would say yes.

If they are simply taking tables and graphs that a sponsor -- text that the sponsor's provided and cutting and pasting it into a document without adding substantive additional commentary, it's hard to say if that's independent or not.
Q. You know from your own experience that FDA does independent reviews of the data provided by a sponsor, correct?
A. In some instances, there -- and again, we're talking -- you're saying FDA. FDA is a huge organization. I know what

people in my office and my division do, and certainly, there's some things where you go -- divisions, because there were multiple offices that you worked in.

But, you know, if somebody's got an adverse event -- table of adverse events, there are some instances in which the FDA reviewer will seek to independently verify that; and there's others in which they'll say, "Well, I don't see any reason to do that. I'm just going to accept what the sponsor has said."

Q. And you don't know what the FDA did when they reviewed the NDA for Paxil in this case, do you?

A. Actually, I can make a pretty good guess.

Q. I don't want you to guess.

A. Okay. So, the --

Q. There's no question. I just said, "I don't want you to guess."

A. No, I understand.

MR. BAYMAN: Your Honor, I don't have a question.

THE COURT: Wait for a question.

THE WITNESS: I'm sorry, your Honor.

BY MR. BAYMAN:

Q. You would agree with me that the FDA is not limited solely to information submitted by the manufacturer, but can rely on other information that exists in the world of science when deciding whether to approve an NDA or drug labeling, correct?

A. It can.
Q. One of those things might be scientific literature, correct?
A. Yes.
Q. And, in fact, when you were at the FDA, you considered it part of your responsibility to keep up with the medical literature and scientific advancements in your field of infectious diseases, correct?
A. Well, I think this actually is a good illustration that answers a question you asked previously about independent review. So, in one of the Paxil applications, I believe --
Q. Can I get an answer to my question first?
A. Yes, I'm going to answer it, but I want to qualify it because you've been talking about the FDA and you've been talking about me. I want to clarify the distinction.

In that application, the sponsor told the FDA review division that there was no relevant literature. The reviewer simply said, "Okay. We're going to accept that." They did not -- even though they could have, they did not make an independent effort to verify that.

Now, I would not have done that. If I had verified it, I would have said, "The sponsor said this. I did a literature search on Pub Med," and that would be independent. But that did not happen in this instance.
Q. Doctor, you weren't at the division of neuropharmacology

when this NDA for Paxil was submitted, correct?
A. I'm actually talking about a supplemental NDA, and the sponsor did not -- just said, "The sponsor said there wasn't any new information in the literature," without any -- didn't say, "I reverified it." They said, "Therefore, there will be no review of the literature."
Q. You don't know what the reviewer did, do you?
A. No, I do actually. The reviewer wrote it down. It's available on the Internet for anyone to look at.
Q. You haven't talked to that reviewer, have you?
A. I don't have to. It's on the Web. There's one thing that FDA is very focused on through what are called good review practices is documenting what you do and providing -- we're scientists. You want to be able to tell another scientist what you did in such a way that they can replicate and verify or find issues with what you did. So, if it's not there, it wasn't done.
Q. We're going to get to what was done with respect to the NDA in a minute, but I want to make sure that I understand that -- I didn't really get an answer to my question, which is --
A. Yes, I would do my own independent analysis, correct.
Q. And when the FDA reviews a proposed label as part of a New Drug Application, it can edit and propose revisions to that labeling, correct?

A. The FDA review division can do that based on the information that it has available to it.
Q. And that happens frequently, doesn't it? A manufacturer submits labeling, and the FDA makes comments and revisions and sends it back, correct?
A. Based on the information provided by the manufacturer, yes.
Q. But the FDA makes its own comments; it doesn't just accept what the manufacturer submits, correct?
A. It may accept some things and not others.
Q. And sometimes the FDA, as we learned earlier, will call for an advisory committee to discuss the medication at issue, correct?
A. Sometimes.
Q. And you know there was an advisory committee impaneled in conjunction with the Paxil New Drug Application submission, correct?
A. For the original one. Is that what you're -- okay. Because they did not call one for other indications in supplemental NDAs.
Q. But the original one for major depressive disorder, right?
A. That's correct.
Q. And you agree with me that the FDA will not approve an NDA that fails to satisfy the standard of demonstrating the medication at issue is safe and effective when used in

accordance with the label, correct?
A. What I would say is the FDA, based on the information that's submitted to it by the manufacturer, can approve it, will approve it if the information that it sees from the manufacturer demonstrates safety and efficacy.
Q. But it's the FDA who makes that decision, correct?
A. Based on the information that it's provided, yes.
Q. And the FDA doesn't approve all NDAs that are submitted, does it?
A. No.
Q. And, in fact, if the FDA doesn't think it has enough information to make a decision on the drug's safety or effectiveness, it must reject the application, correct?
A. No, not necessarily. It really is: What does the labeling -- what does the labeling say, and what is the data?

So, for example, if an NDA, and this has happened, requests two indications, and the FDA says, "Well, we're going to grant this one, or we think there's enough information for this indication but not for another," it will approve the NDA but only for that indication.

Or to take it more broadly, if it has information saying that the use of a product is associated with an increased risk in a particular population, it will say, "We'll approve this if you change the label," if it knows about it.
Q. I think I understand. But you would agree with me that

approval of an NDA indicates that the FDA has concluded that the medication is safe and effective when used in accordance with the approved labeling, correct?
A. Based on the data it has at that time, yes.
Q. And for Paxil, the first approval for major depressive disorder was in December of 1992, correct?
A. That's correct.
Q. And at the time it approved that NDA, it -- the FDA also had to approve the Paxil prescription drug labeling that goes to the doctor, correct?
A. Well, yes. I'm sorry. I'm just trying to parse out the distinction between the drug and the label, but I agree.
Q. And the labeling approved by the FDA is an assessment by the FDA that it has determined that the label contains adequate information for the drug's use, including any relevant hazards?
A. Based on information given to it by the manufacturer, yes.
Q. And you talked some in your direct about misbranding. You would agree with me that a drug is misbranded when, among other things, its labeling is false or misleading in any particular way?
A. That's the verbatim language.
Q. And that the Food, Drug, and Cosmetic Act prohibits the misbranding of drugs, correct?
A. Correct.

Q. And if the labeling for a drug fails to include all necessary warnings, contraindications, adverse reactions, side effects, the drug is misbranded and in violation of the FDA statute, correct?
A. It can be found to be misbranded. I mean, it's not like throwing a switch.
Q. Can you turn in your deposition to page 93.
A. Yes.
Q. Line 18.
A. Yes.
Q. The question was, "And if the labeling of a drug fails to include all necessary warnings, contraindications, hazards or side effects, the drug is misbranded and in violation of the FDA statute" --
A. I see what you're saying. I guess what I would say is it's a little bit like if I take one step over the Canadian border, have I -- is there an invasion? Technically, but it doesn't mean we're necessarily going to war. I guess I should have clarified that back in 2000- -- whenever this was, two years ago.

I think -- what I'm saying is that the FDA has to reach the -- it's not like it's some physical law is, I guess, what I'm saying. The FDA has to go through a process where it says it's misbranded. It has to make that determination, and then it usually will offer to work with the company to get it

to correct the problem.
Q. Back to -- the question was, "If the labeling of a drug fails to include all necessary warnings, contraindications, hazards, or side effects, the drug is misbranded and in violation of the FDA statute," and your response was, "That is absolutely correct."
A. Yeah. I'll stick with that response. I'll just say there's a few intermediary steps. How's that?
Q. And if the labeling is also misbranded -- labeling is also misbranded if its labeling doesn't provide adequate directions for use, correct?
A. Correct.
Q. And violators can be subject to regulatory and enforcement actions, including injunction, seizure, and criminal prosecution, correct?
A. That is all possible.
Q. And if the FDA determines that the medication's labeling is false or misleading, the medication is subject to removal from the marketplace, correct?
A. It could be, sure.
Q. And you agree with me that the FDA may not knowingly approve any labeling that it knows to be false or misleading, correct?
A. Technically yes.
Q. After a drug is approved in a New Drug Application and

comes on the market, if a drug manufacturer wants to change the content of the labeling for an approved drug, it's required to work with the FDA regulatory process and file what's called a supplement to its approved NDA, correct?

A. That is correct.

Q. And if the manufacturer decides to change the labeling that's been previously approved, it has to submit those proposed changes to the FDA, correct?

A. Correct.

Q. And you also agree that there are situations where the FDA, in fact, drafts and proposes language itself and submits that language to manufacturers and says, "You need to implement these changes," correct?

A. Prior to about 2009, actually, FDA in general did not have that authority to order manufacturers to do that. It could request changes. From a practical point of view, if the manufacturer refused, the only option FDA had was to say, "Well, then we're going to declare you misbranded," which was not something that was practical to do on a large scale.

So, just to be clear, prior to that point, the FDA did not have the authority to order manufacturers to do it. It would have to go to court and attempt to do so. It's changed since then.

Q. All right. I'll come back to that.

You would agree with me that after a label has been

approved by the FDA, a drug's labeling must be revised when there's what's called newly acquired information, correct?
A. Are you talking about safety-related information?
Q. Yes.
A. Yes, that's correct.
Q. And newly required information is defined under the Federal Regulations, correct?
A. Yes.
Q. And it's defined as data, analyses, or other information not previously submitted to the agency, correct?
A. Correct.
Q. And the newly acquired information in the safety context must reveal a risk of a different type or a greater severity than previously submitted in submissions to the FDA, correct?
A. With the caveat that -- or the qualification, if you will, that it may be something that's closely related to something that's already in the label. The new information might be if the liver -- if the label says, for example, "elevated liver enzymes," and the new analysis shows liver inflammation, that would be an example of new information.
Q. But that's the language from the regulation, right, that I just asked you?
A. Yes. Yeah, I wanted to put that context in there. It's not like it has to be from a new organ system or something. But I agree with you.

Q. Fair enough. But a manufacturer is supposed to take those newly identified risks to the FDA and discuss whether and how the medication's labeling should be changed, correct?
A. Well, what the regulations provide for, as I said in the previous testimony, if a manufacturer wants to add or strengthen a regulation, it can do so without the FDA approving it.

It doesn't have to come in and discuss it. It can submit a -- what I mentioned is changes being effected supplement. But actually, generally, these things sort of landed on our doorstep. There was not any previous discussion.

Q. But ultimately, the FDA has to approve that change as being effective, correct, that change, correct?
A. It has to review it, and most of the time, those get approved.
Q. Well, turn in your deposition to page 107, line 10.
A. Okay.
Q. The question was, "And a manufacturer is supposed to take those newly identified risks to FDA and discuss whether and how the medication's labeling should be changed?"

And your answer was, "Yes," correct?

A. Yes. I don't think it's a -- what I'm trying to say here is the word "supposed to" I did not interpret as meaning a regulatory requirement. So, I'm just clarifying that ideally,

they would do that. They don't have to.
Q. But it's ultimately the FDA's decision to decide whether the newly acquired information submitted by the manufacturer will be included in the medication's labeling, when it will be included, where it will be included, and what will be said about the risk at issue, correct?
A. So, I think that, you know, basically, it's the sponsor's -- I'm sorry, manufacturer's responsibility to keep it updated. It's the FDA's -- has the authority to enforce that. So, the answer would be essentially yes to what you're saying.
Q. And part of the enforcement of that is, you would agree, determining where it will be included in the label, correct?
A. Yes. I'm sorry.
Q. What will be said about the risk, correct?
A. Yes, with -- again, with the caveat that it's not a yes-no thing. It's not like buying a lottery ticket.

The FDA may say, "You know, we're not sure why you're doing this. Can you come back and explain it?"

The manufacturer may say, "X, here's what we want to do."

The FDA says, "Oh, we understand now." Or they say, "Well, how about if we change this?"

There's, you know, that sort of discussion. It's not between two robots, far from it.

Q. There's a back-and-forth between the company and the FDA about what should be included, correct?
A. Correct.
Q. And where it should be included, correct?
A. If the sponsor proposes something, yes. And they can go to the FDA, you know, and say, "Well, we're not sure where it's supposed to go, but we think it needs to be in here. Can you tell us?"
Q. You would agree with me that the structure of the label is provided for by statute, the very sections in the label?
A. No, actually, it's provided by regulation.
Q. Excuse me. Regulation. But there is -- there are regulations that talk about the sections and what is to be included, correct?
A. That is correct.
Q. And it is -- I think you'll agree that in terms of the hierarchy of things, a warning is higher up on the hierarchy than, say, adverse reactions, correct?
A. All other things being equal, I would agree.
Q. Because the adverse reactions can include things that are serious and not serious, correct?
A. Well, again, I want to be careful because one of the -- and this is true -- much truer with a new format, more readable format. The Paxil label is in the old format.
But anyway, one of the things that people do try and

do and that labels are supposed to do in that laundry list adverse reactions section is capture things that aren't captured elsewhere.
Q. I think you said yesterday that the adverse reactions contains a listing of some side effects that are not as serious, as in the warnings, correct?
A. If it's not -- if it was serious enough to be in the warning, it should be in the warning section. And it can be in both places. I should clarify that.
Q. I don't mean to belabor this, but you would agree with me that the more serious risks, relatively speaking, are in the warnings section as compared to adverse reactions, correct?
A. Yes.
Q. So, in this debate between a manufacturer and the FDA, there might be some debate about where it should go in the label; and if the manufacturer says, "We think this should be in adverse reactions," and the FDA says, "No, this needs to be in warnings," it's the FDA's view that trumps that, correct?
MR. WISNER: Objection. Speculation.
THE COURT: Overruled.
BY THE WITNESS:
A. I think that really depends on the circumstances about -- I mean, there's no one-size-fits-all rule. But generally, when you're talking about fatal events, it's -- that are

occurring above some threshold -- and it may depend on the exact circumstances -- I've yet to hear a manufacturer argue, "Well, let's just bury it in the adverse event reaction and not mention it anywhere else."

BY MR. BAYMAN:

Q. Okay. Fair enough. But there -- you've seen in your experience times when the FDA and the manufacturer may disagree about where in the label an adverse event should go, correct?

A. Sure.

Q. And then if there's that disagreement, at the end of the day, it is the FDA's view that trumps or prevails, correct?

A. About where it should go?

Q. Yeah.

A. But both of them -- I just want to make sure I understand your question. This is on a circumstance where the manufacturer says, "Well, we think it should be in the label," and there's just a debate over where. Is that --

Q. Yes.

A. But the manufacturer wants it in the label somewhere?

Q. Right. In that hypothetical I gave you, the manufacturer says, "We think this adverse event should be in adverse reactions," and the FDA says, "No, this should be in warnings," it is the FDA's view that prevails, correct?

A. In that scenario, yes.

Q. And also, if there is a disagreement about what the language reporting on that adverse event should say, the manufacturer has one view of describing it, the FDA has another view of describing it, it's the FDA's view that trumps or prevails, correct?
A. Again, understanding that it is a negotiation and not -- a lot of times, FDA will take the manufacturer's arguments and say, "You know what, we agree with you." I agree with you on that.
Q. But it doesn't have to take the manufacturer's view, does it?
A. I think what I would say is it has to consider it. Perhaps that's the best way to put it.
Q. Okay. Consider it. But the FDA can consider it and say, "We disagree with you. We think it needs to go here," correct?
A. Yes.
Q. "And it needs to go here, and it needs to say this," correct?
A. Again -- and I'm just -- again, I -- it may be that the concept -- I mentioned before risk communication, and the issue may be less one of exact wording, although it can be. So, I just don't want to say -- when you say, "It has to say this," that's one event. It could be, "You have to express this concept, but we're flexible about the wording."

I'm just trying to indicate there's not always one thing. But in terms of the general concept that you're expressing, I would agree with you on that.

Q. And when that event needs to be reported in the label, again, if there's a disagreement between the manufacturer and the FDA, it again is the FDA's view that prevails or trumps, correct?

A. Yes.

Q. We talked about the standard when the manufacturer may revise its labeling. You remember that discussion with Mr. Wisner about when there is reasonable evidence of an association or of a serious hazard with a prescription medicine?

A. Yes.

Q. You agree with me that there's an important distinction between an association between a medication and a hazard and a causal relationship between the two, correct?

A. Yes.

Q. Reasonable evidence of an association does not equal causation, correct?

A. And the regulation recognizes that and says a causal relationship need not have been proven.

Q. An association, for you, represents reasonable suspicion that a drug may be related to a hazard from the drug, correct?

A. That's what I -- how I phrase it in my report, yes.

Q. You told the jury this morning in no uncertain terms that your opinion is that Paxil can induce suicide in adults of all ages, correct?
A. Yes.
Q. That opinion is not in your expert report, is it?
A. I believe that what I said is that the risk is not restricted to individuals under the age of 25, and what I said was there's -- it's not restricted to any one age group. So, that's in essence saying it can do it in all ages.
Q. Your opinion is that Paxil causes suicide in adults of all ages, correct?
A. Yes.
Q. Okay. Your opinion in your report says, "Paroxetine" -- which is the chemical name for Paxil, correct, and also the generic name, correct?
A. It's the -- what's called the United States -- well, never mind. Go ahead.
Q. Your report says, "Paroxetine is associated with an increased risk of suicidal behavior in adults relative to placebo, with the risk being higher than other antidepressants."
Did I read that correctly?
A. Yes.
Q. It doesn't say "cause," does it, Doctor?
A. I don't believe I -- I don't have the report right in

front of me, but --
Q. I'll be happy to get it for you.
A. Okay.
Q. Let me --
MR. BAYMAN: I have a notebook for you, your Honor, and for the doctor. May I approach?
THE COURT: Sure.
THE WITNESS: Thank you, sir.
MR. WISNER: Your Honor, while Dr. Ross is looking at that, can we have a short sidebar?
THE COURT: Do I need that?
MR. BAYMAN: This is going to be the exhibits that I was going to use with him, your Honor. We could take the other one away.
THE COURT: I've got the exhibit here.
MR. BAYMAN: I mean this is for the rest of the examination. So, I'll be happy to hold on to it until we get to another.
THE COURT: Hold on to it until I need it. I'm buried here.
MR. BAYMAN: Sure.
THE COURT: Give it to my law clerk.
MR. BAYMAN: Sure.
THE COURT: He doesn't have anything in front of him. All right. You have your report, Doctor?

THE WITNESS: I do.

THE COURT: Page, please, sir?

MR. WISNER: Your Honor --

MR. BAYMAN: Page 3.

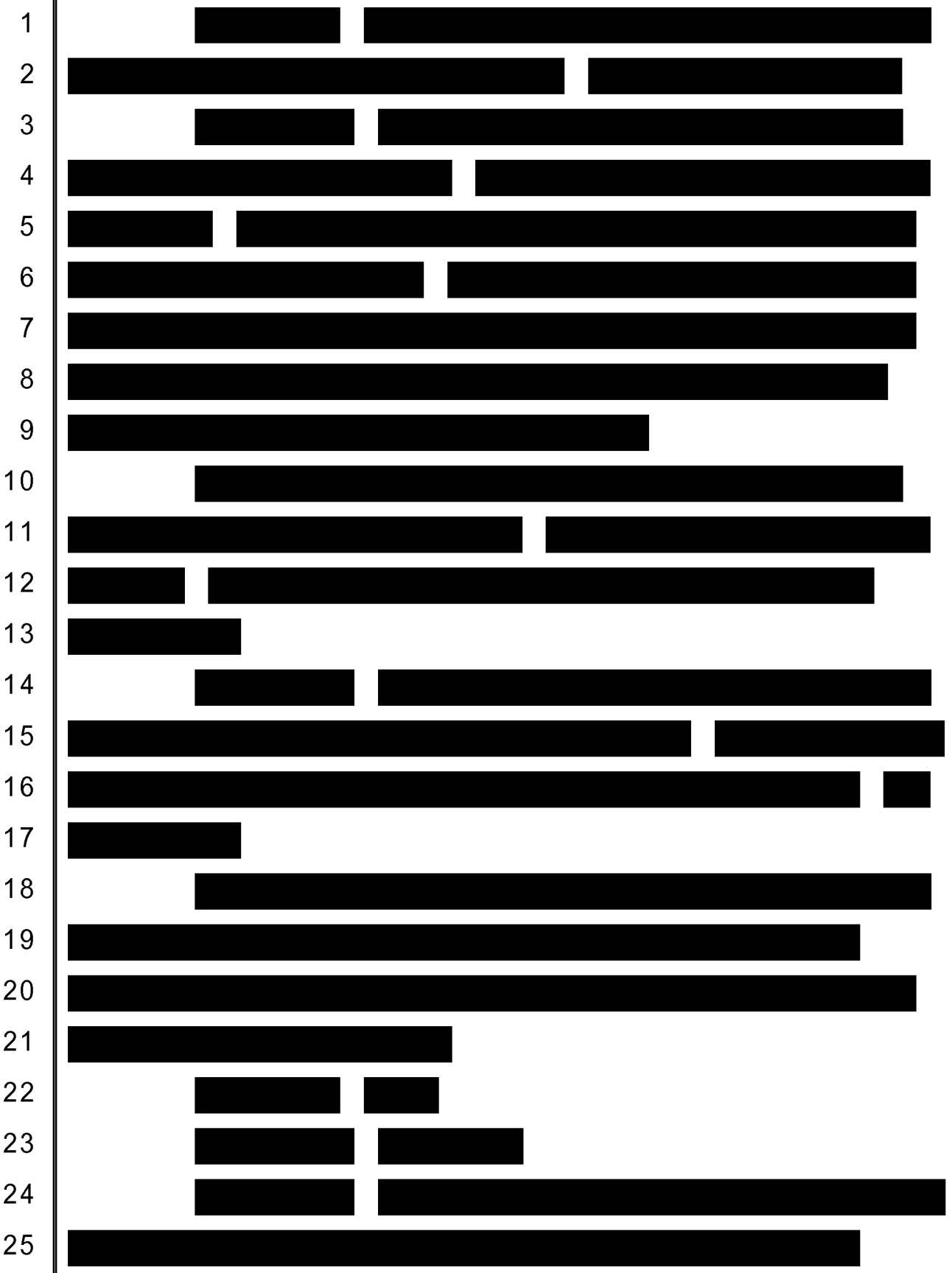
MR. WISNER: I had requested a brief sidebar.

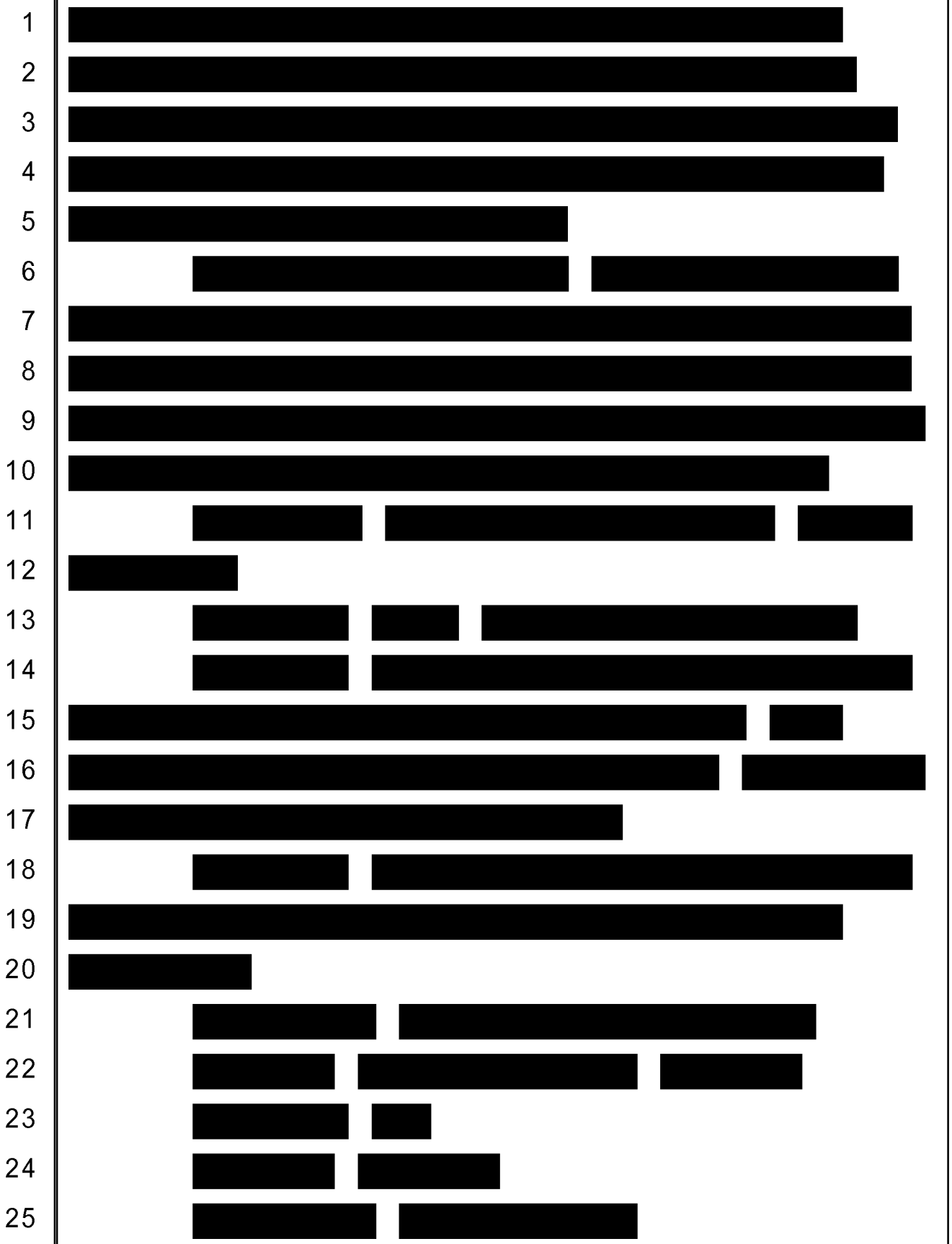
THE COURT: Oh, you want a sidebar. Okay. We'll go to sidebar while you're looking at that, Doctor. Give him the page number you want him to look at.

MR. BAYMAN: Page 3, summary of opinions, section B1, first one.

THE COURT: All right. We'll go to sidebar.

(Proceedings heard at sidebar:)





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(Recess had.)