



1 Appearances (continued:)

2

3 For Defendant GlaxoSmithKline:

4

KING & SPALDING  
5 BY: Todd P. Davis  
Andrew T Bayman  
6 Heather Howard  
1180 Peachtree St Ne  
7 Atlanta, Georgia 30309  
(404) 572-4600

8

KING & SPALDING LLP  
9 BY: Ursula M. Henninger  
Suite 3900  
10 100 N Tryon Street  
Charlotte, NC 28202  
11 (704) 503-2631

12

13

14

SNR DENTON US, LLP  
15 BY: Alan Scott Gilbert  
233 South Wacker Drive  
16 Suite 7800  
Chicago, Illinois 60606  
17 (312) 876-8000

18

19

20

21

22

23

24

25

26

27

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

(The following proceedings were had out of the presence of the jury in open court:)

09:20:26

09:20:46

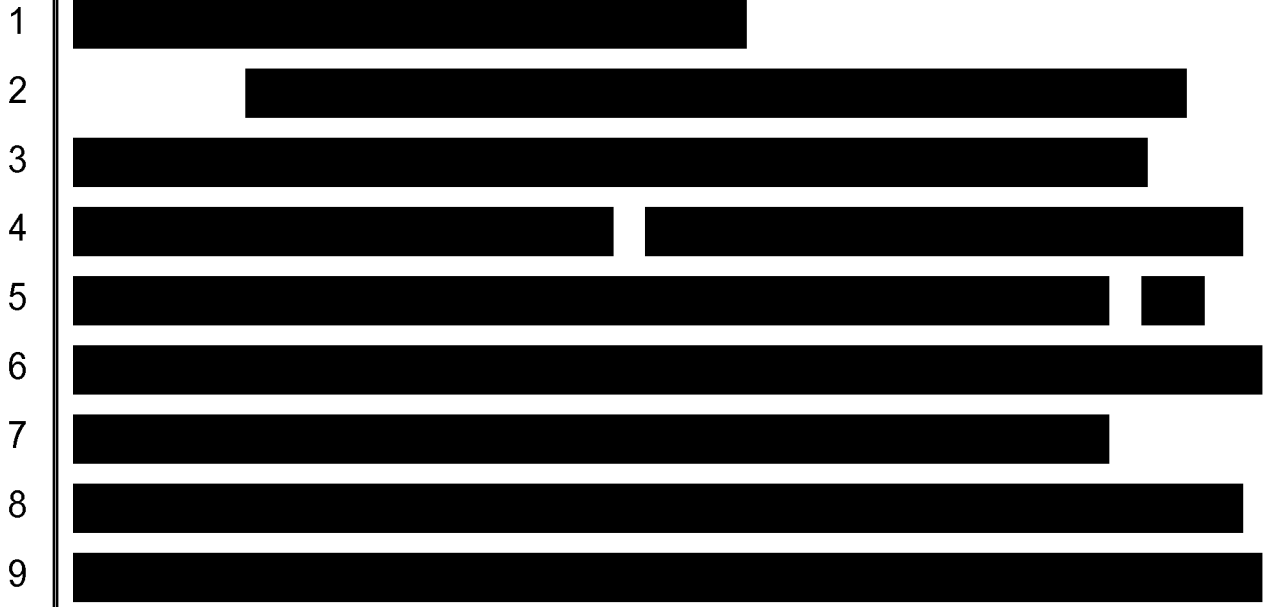
09:21:10

09:21:22

09:21:50

[Redacted text blocks]

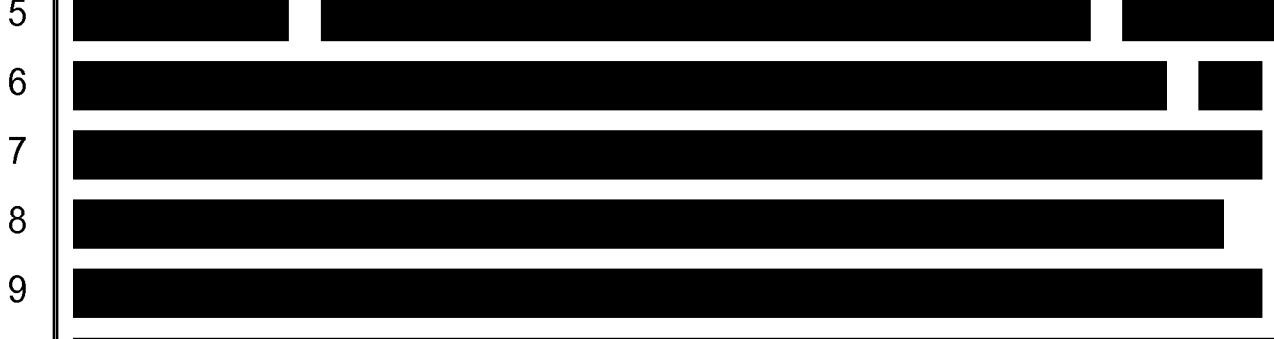
09:22:11



09:22:34



09:22:55



09:23:13



09:23:32

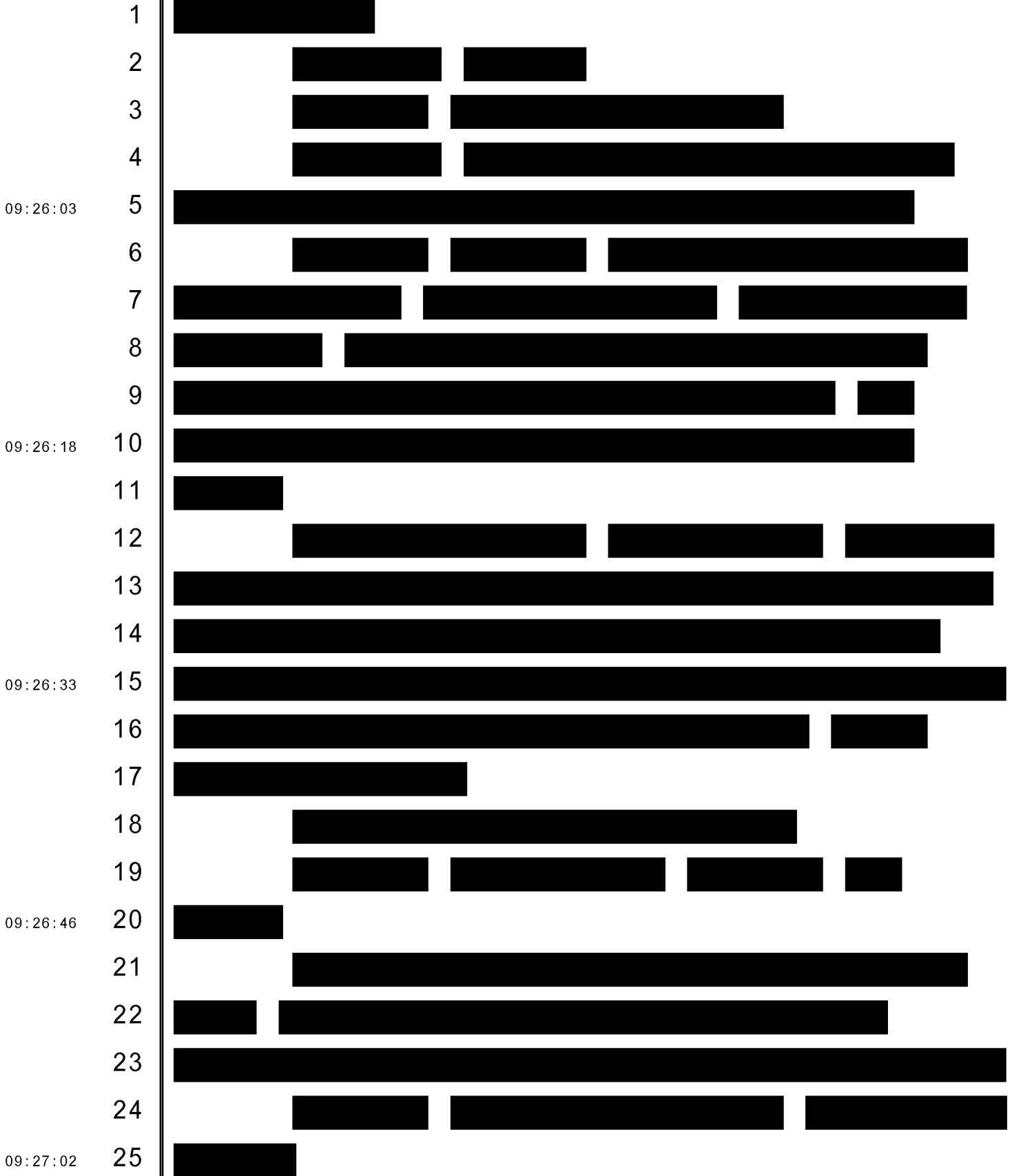


1  
2  
3  
4  
09:23:49 5  
6  
7  
8  
9  
09:24:06 10  
11  
12  
13  
14  
09:24:17 15  
16  
17  
18  
19  
09:24:27 20  
21  
22  
23  
24  
09:24:36 25

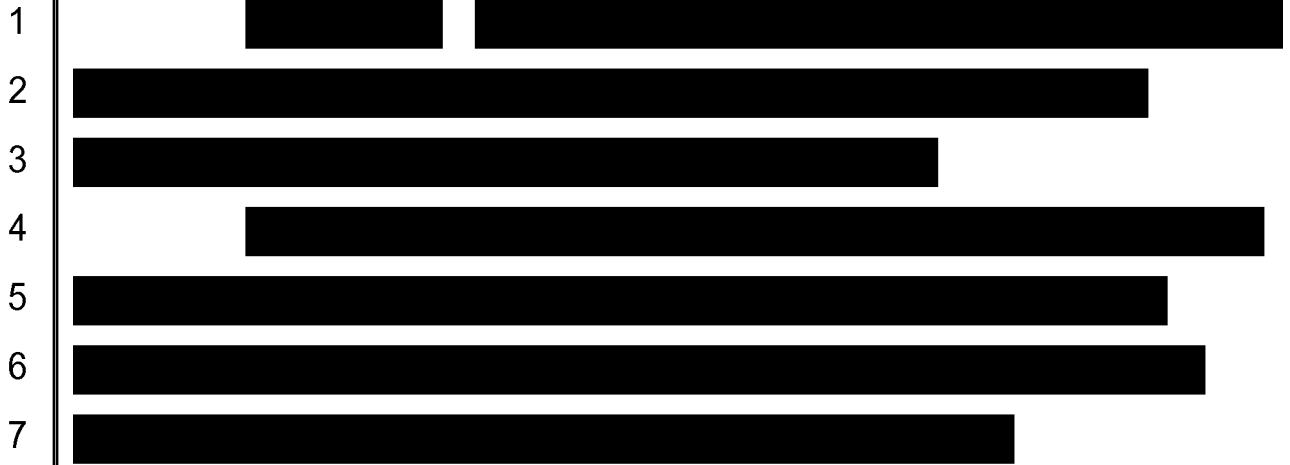


1  
2  
3  
4  
09:24:56 5  
6  
7  
8  
9  
09:25:09 10  
11  
12  
13  
14  
09:25:23 15  
16  
17  
18  
19  
09:25:39 20  
21  
22  
23  
24  
09:25:55 25

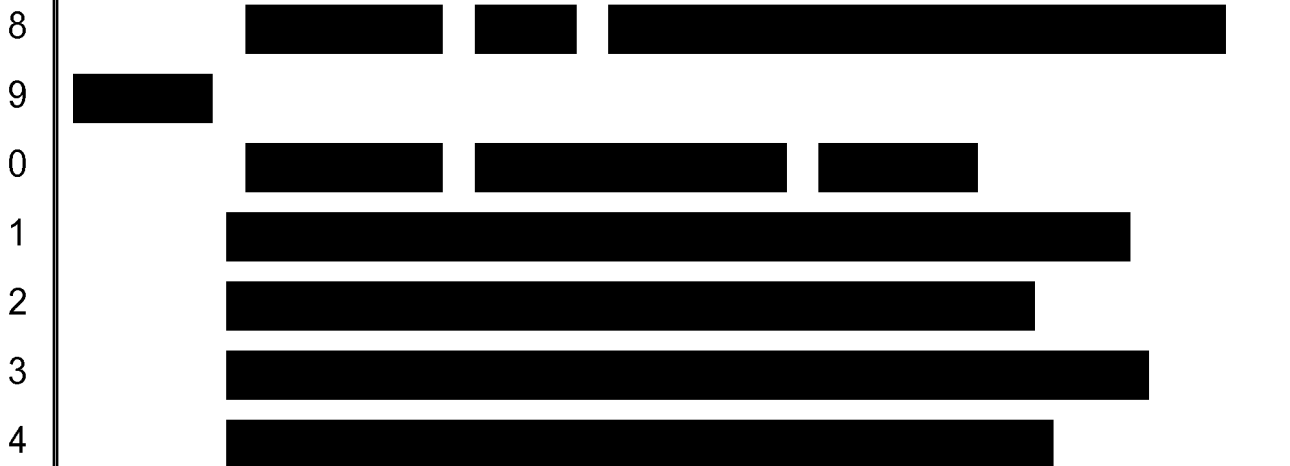




09:27:16



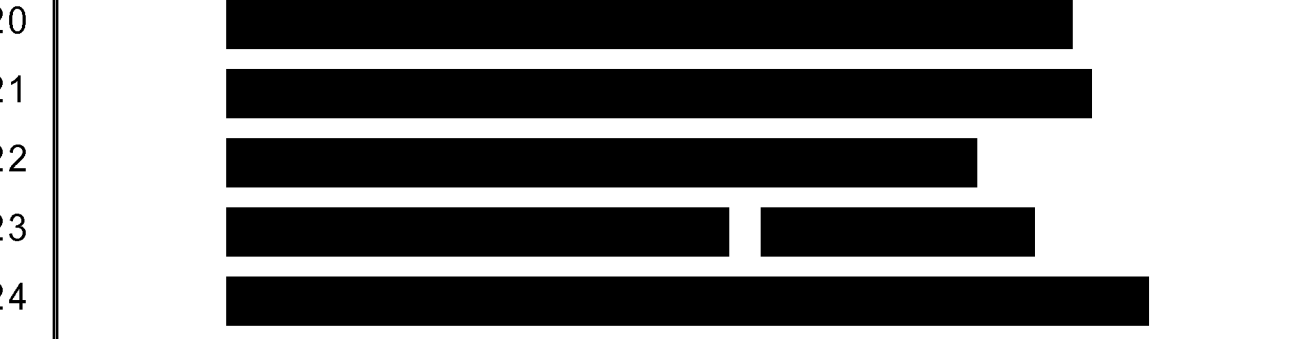
09:27:33



09:27:47



09:27:56

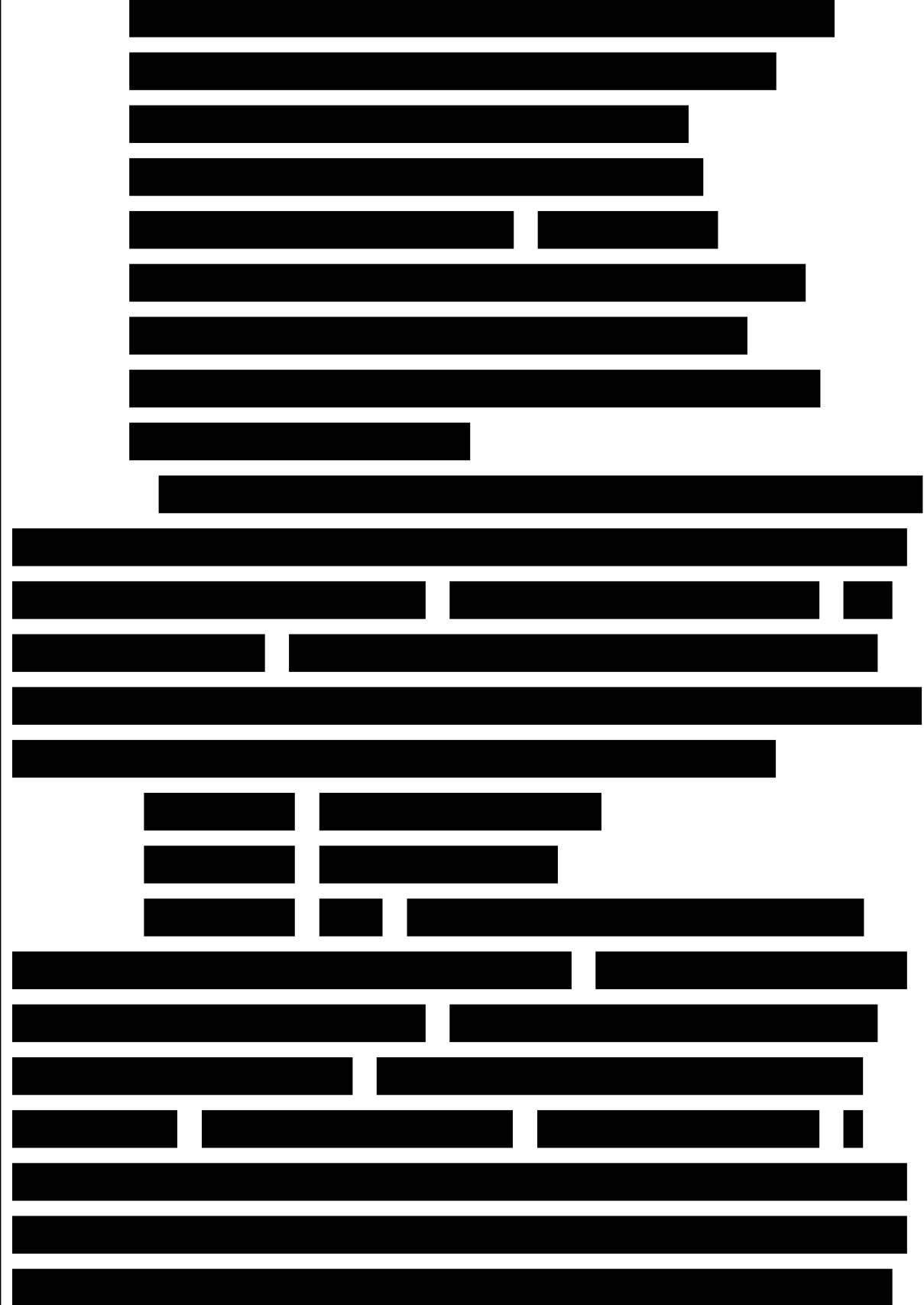


09:28:09

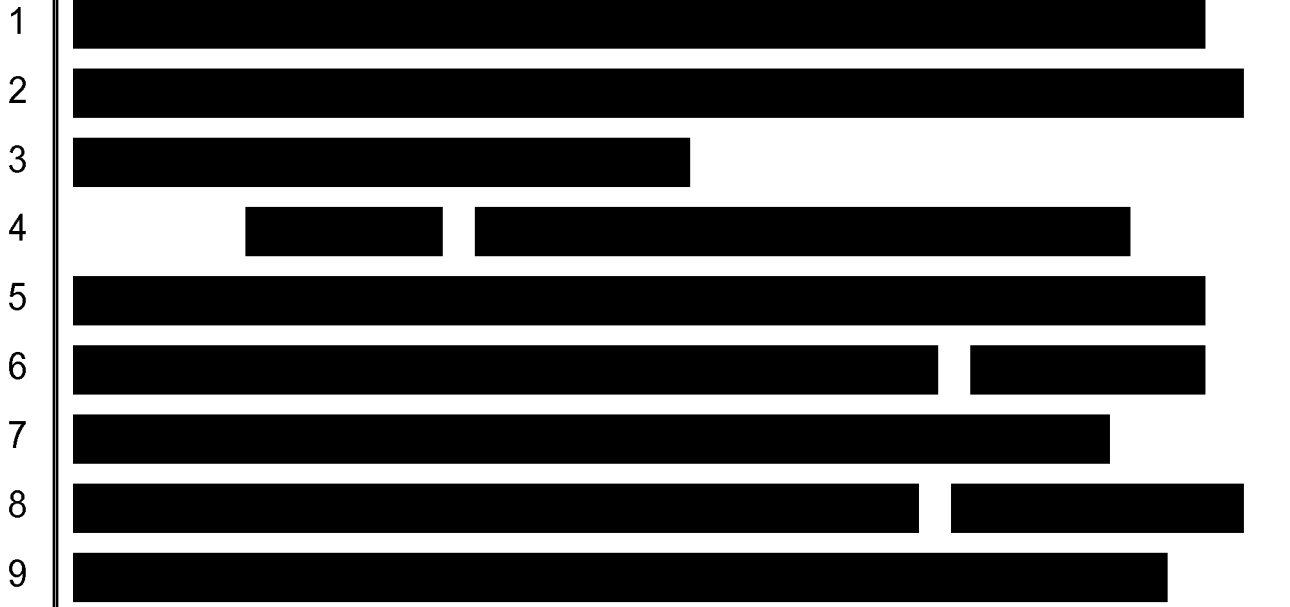




1  
2  
3  
4  
09:28:22 5  
6  
7  
8  
9  
09:28:40 10  
11  
12  
13  
14  
09:28:58 15  
16  
17  
18  
19  
09:29:09 20  
21  
22  
23  
24  
09:29:33 25



09:29:50



09:30:11



09:30:28



09:30:43

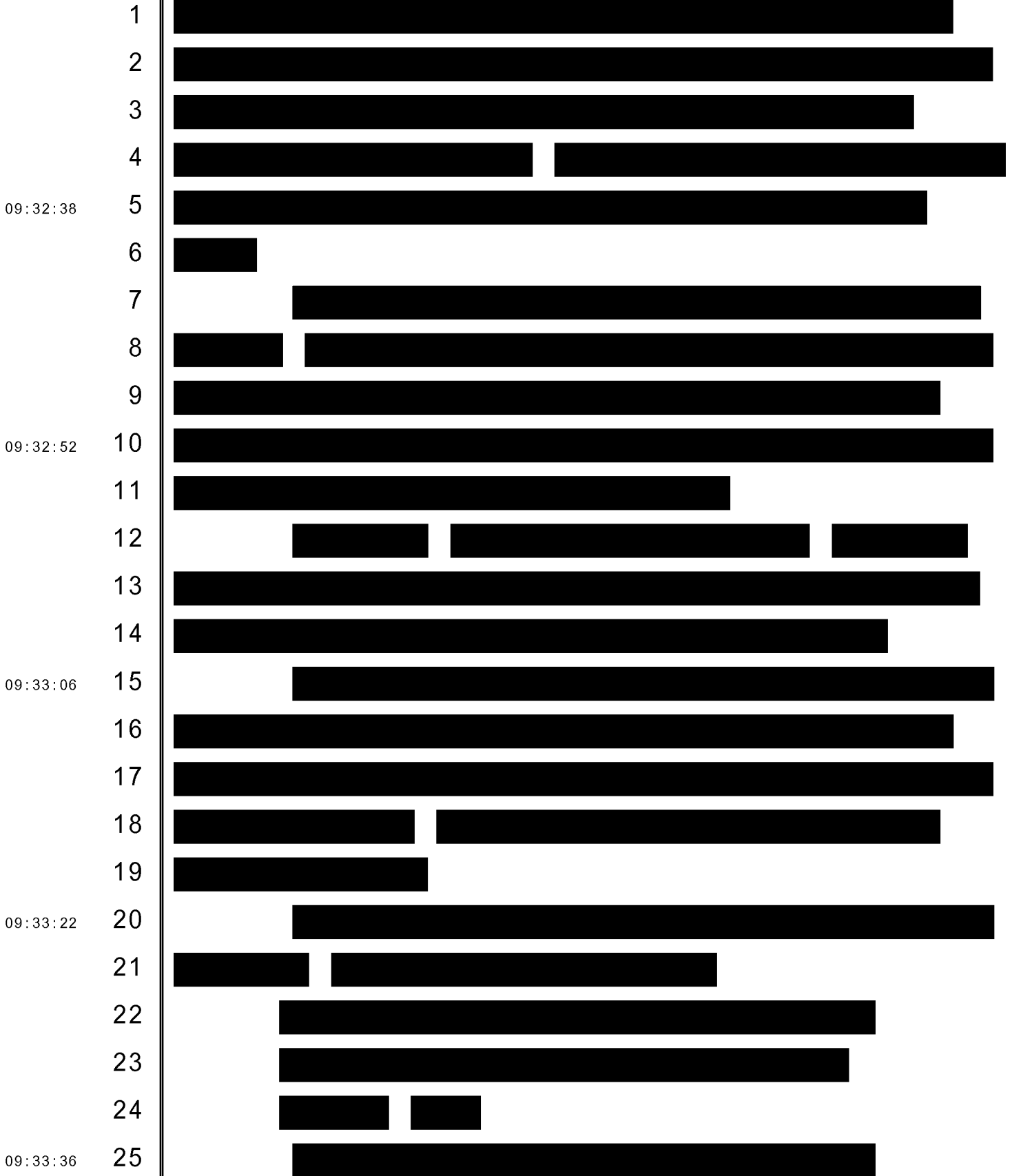


09:31:01



1  
2  
3  
4  
09:31:18 5  
6  
7  
8  
9  
09:31:34 10  
11  
12  
13  
14  
09:31:49 15  
16  
17  
18  
19  
09:32:05 20  
21  
22  
23  
24  
09:32:17 25





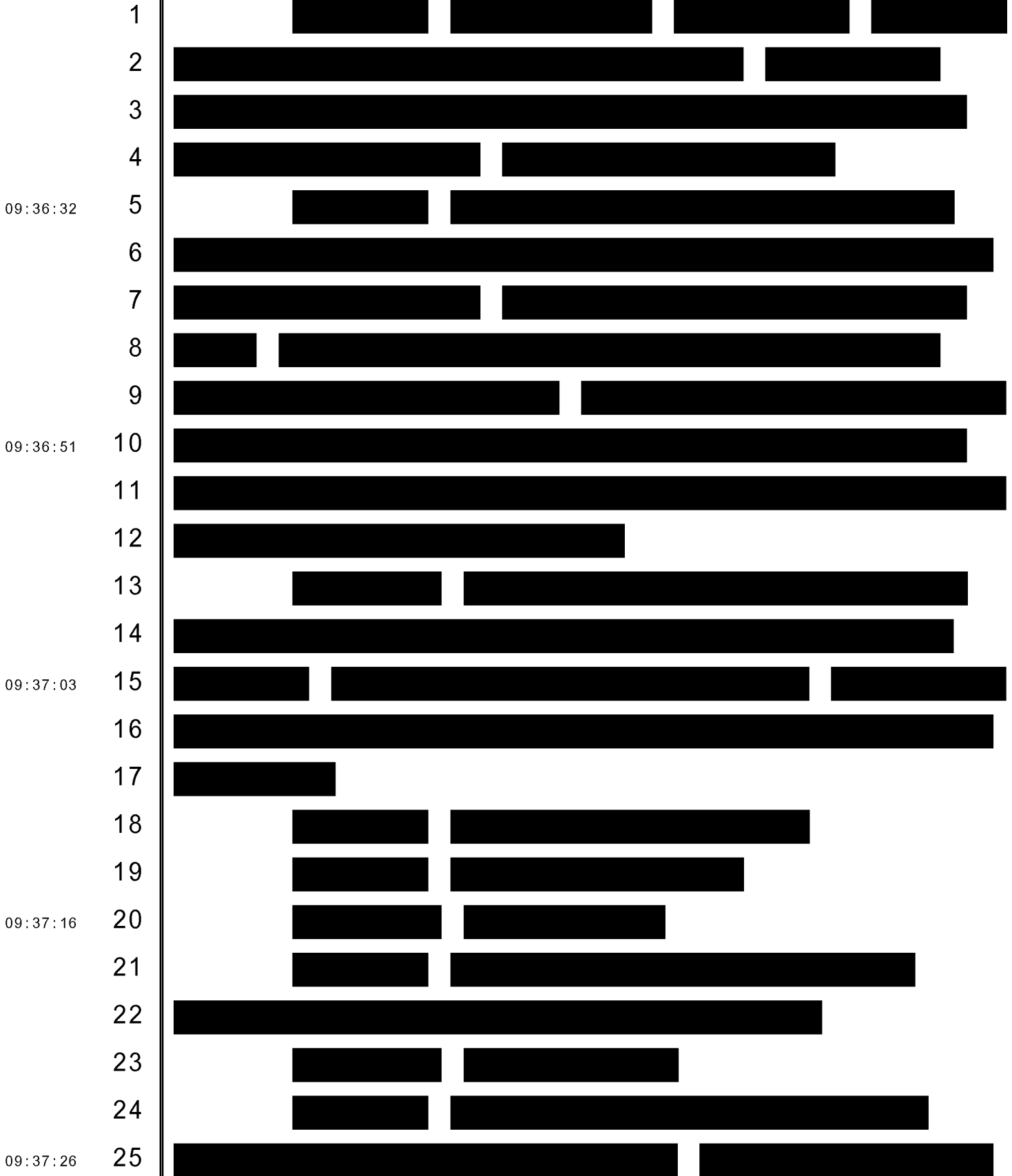
1  
2  
3  
4  
09:33:47 5  
6  
7  
8  
9  
09:34:07 10  
11  
12  
13  
14  
09:34:28 15  
16  
17  
18  
19  
09:34:43 20  
21  
22  
23  
24  
09:34:59 25



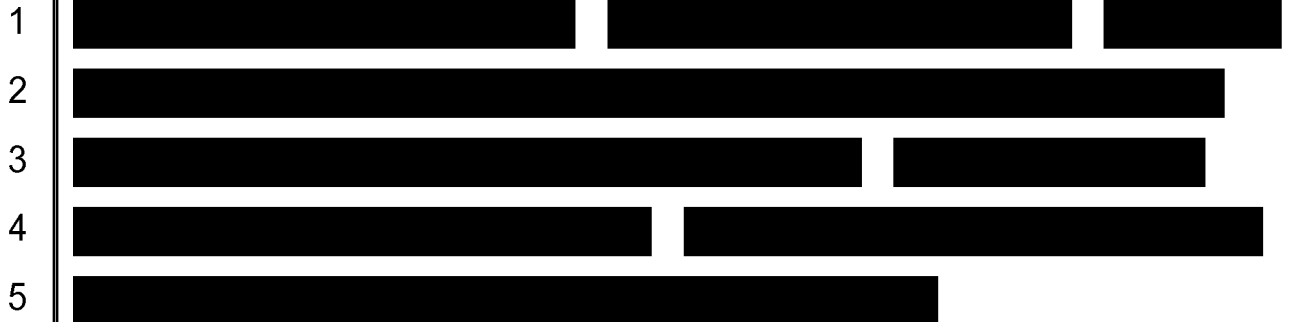
09:35:19  
09:35:39  
09:35:51  
09:36:03  
09:36:16

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25





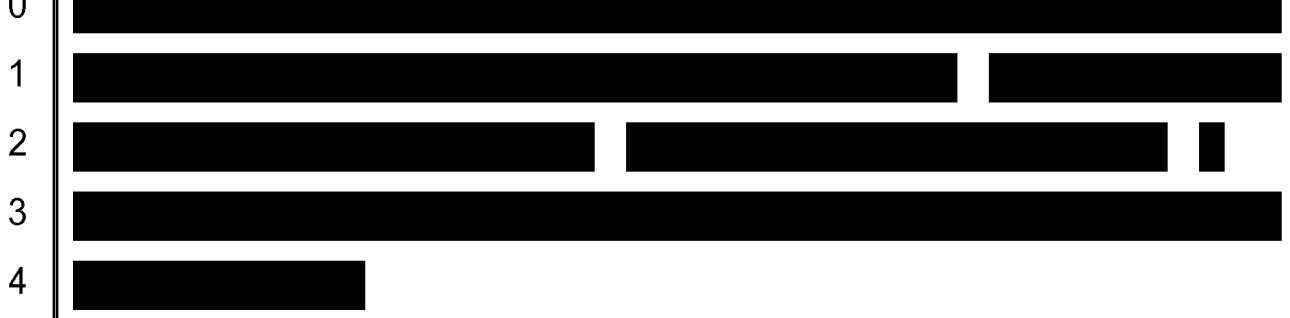
09:37:46



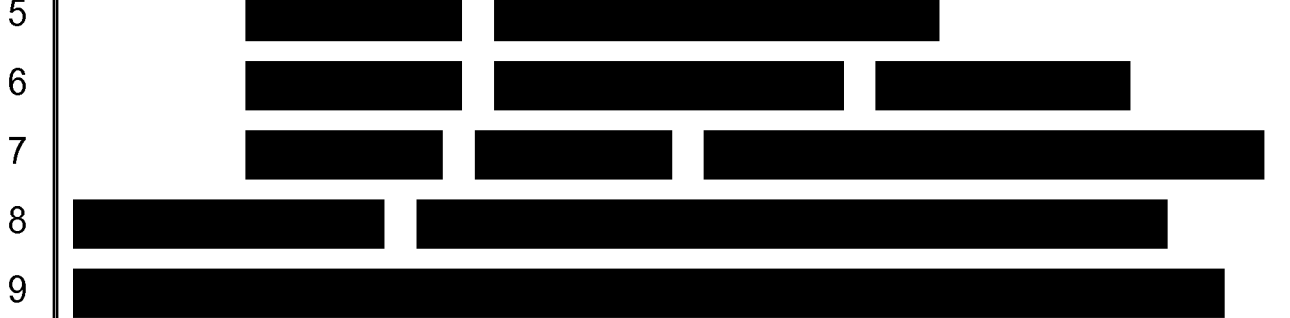
09:38:02



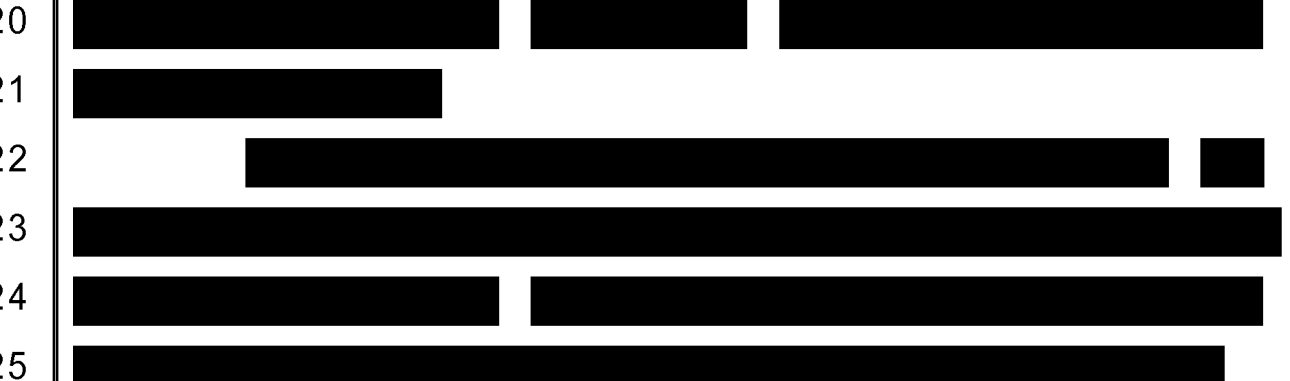
09:38:17



09:38:32



09:38:50

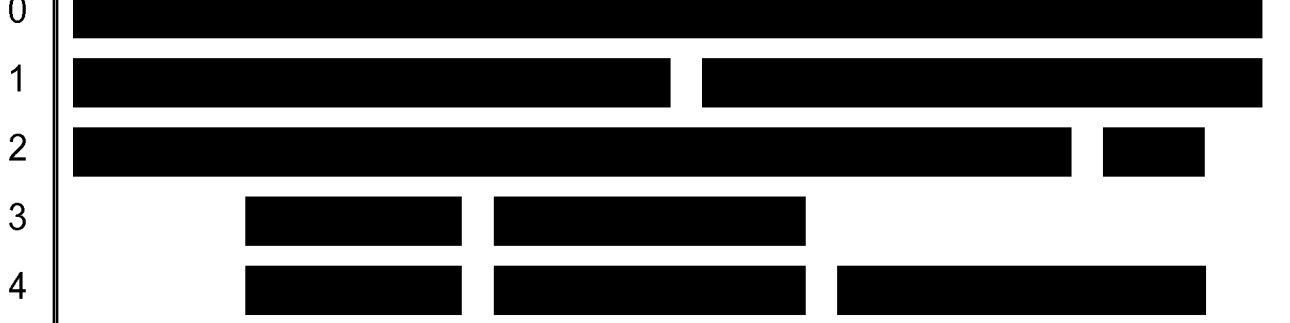




09:39:12



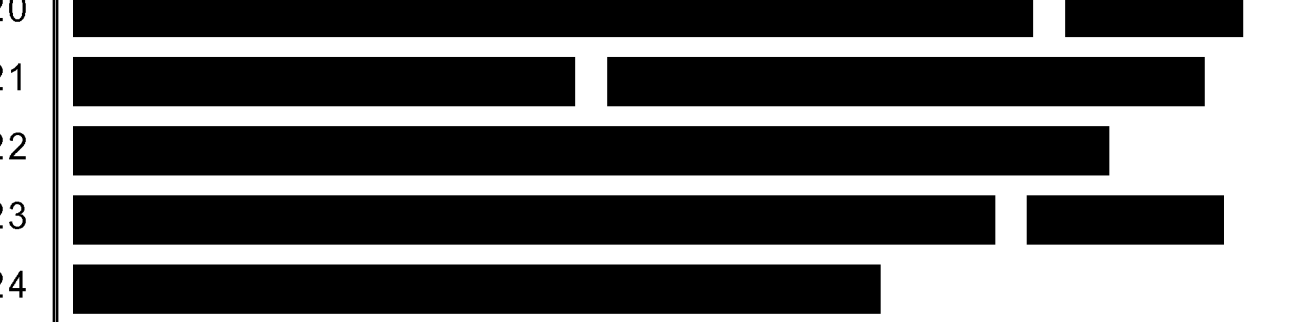
09:39:31



09:39:49



09:40:03



09:40:23



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

[REDACTED]  
[REDACTED]  
[REDACTED]

09:41:35

(The following proceedings were had in the presence of the jury in open court:)

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

You may call your witness.

Dr. Healy.

09:41:42

(Brief pause).

THE COURT: I think there's water and a cup there.

THE WITNESS: Hopefully there is.

THE COURT: All right. You may proceed, sir.

MR. BAYMAN: Thank you, Your Honor.

09:41:44

DAVID HEALY, PLAINTIFF'S WITNESS, SWORN (previously sworn)

CROSS EXAMINATION

BY MR. BAYMAN:

Q. Good morning, Doctor.

A. Hi, Mr. Bayman. How are you?

09:42:04

Q. I'm fine.

To avoid the issues we ran into last week with respect to documents, I've got a notebook for you with tabs.

A. Ah, yes. Thank you very much.

Q. You're welcome.

09:42:31

MR. BAYMAN: Your Honor, may I approach? I've got one

1 for you too.

2 THE COURT: All right, sir.

3 (Document tendered to the Court and witness.)

4 BY MR. BAYMAN:

09:42:44

5 Q. Ready to begin?

6 A. Yes. Hopefully.

7 Q. You told us last week that for hundreds of years the group  
8 of people who had been most likely to commit suicide had been  
9 middle-aged men, correct?

09:42:55

10 A. No, I said that over in the West that there tends to be  
11 middle-aged men. In the East it's different; it's often women.

12 Q. Okay. By "the West" you mean the western world, such as  
13 the United States, correct?

14 A. Yes. It has been usually three men to one -- one woman.

09:43:14

15 The at-risk group, the group thought of at the highest risk are  
16 older men. That doesn't mean necessarily that the number of  
17 suicides are greatest among older men. It can be younger men,  
18 but actually because there's more of them, are the ones who are  
19 -- who actually commit the most suicides.

09:43:36

20 Q. The greatest risk age group has been middle-aged men,  
21 correct?

22 A. The group who have been of particular concern in terms of  
23 people who are depressed have been middle-aged men, 40's, 50's,  
24 60's.

09:43:54

25 Q. You would agree that some people commit suicide who've

1 never been on Paxil or any other antidepressants, correct?

2 A. Absolutely correct.

3 Q. And you would agree that some people who do take Paxil or  
4 Paroxetine and commit suicide do it for reasons unrelated to  
5 the Paroxetine, correct?

09:44:08

6 A. Yes, I would.

7 Q. You agree that some people will have suicidal ideation or  
8 make a suicide attempt or commit suicide totally independent of  
9 whether they've ever taken an SSRI, correct?

09:44:21

10 A. Yes.

11 Q. In fact, you never assumed it's the drug that caused the  
12 suicide, correct?

13 A. No, just because I believe a drug can actually cause people  
14 to commit suicide, I look for the specific features in an  
15 individual case if I'm asked to give a view on that case.

09:44:34

16 Q. And just to be clear -- and you weren't asked to give a  
17 review on this case, correct?

18 A. That's true, but as I've indicated I have reviewed --

19 MR. BAYMAN: Your Honor --

09:44:48

20 BY THE WITNESS:

21 A. -- I have reviewed the case.

22 MR. BAYMAN: Your Honor, I object to that.

23 THE COURT: Yes. You may proceed.

24 MR. BAYMAN: Thank you.

09:44:53

25 And I move to strike that comment, "I've reviewed

1 the case."

2 THE COURT: He said he reviewed the file. That may  
3 stand.

4 BY MR. BAYMAN:

09:45:04

5 Q. Just to be clear, Paxil is not a drug that you said you're  
6 simply not going to prescribe, correct?

7 A. Well, I said the SSRIs are a group of drugs that I do use.  
8 I've indicated that in the hospital, where I work, it's not a  
9 drug that is on the formulary. And it was to me among the SSRIs

09:45:25

10 that I would be less likely to use.

11 Q. But you still -- you still do prescribe it, correct?

12 A. I haven't been routinely prescribing it, but I'm not, in  
13 principle, against using it, that's correct.

14 Q. You're not licensed to practice medicine in this country?

09:45:48

15 A. That's correct.

16 Q. And that means you're not allowed to write prescriptions in  
17 the United States, correct?

18 A. That's correct.

19 Q. You're not board certified as a physician in this country,  
20 correct?

09:45:54

21 A. That's correct.

22 Q. And you're not a member of the American Psychiatric  
23 Association, correct?

24 A. Correct.

09:45:58

25 Q. You're also not a statistician, correct?

1 A. Well, if you mean by that that my day job is just to purely  
2 do statistics, then that's correct.

3 Q. In fact, you're not awfully concerned about things being  
4 statistically significant, are you?

09:46:18

5 A. Oh, I am very concerned that we adhere to what Ronald  
6 Fisher thought what statistical significance meant when he  
7 introduced it.

8 Q. You've never used -- you never made the statement, "I'm not  
9 awfully concerned about things being statistically

09:46:37

10 significant"?

11 A. Because the way the terms are used at the moment, I think,  
12 is inappropriate. So when I hear people use it and say we  
13 should only pay heed results that are statistical significant,  
14 I don't think they're adhering to what the concept meant when  
15 it was introduced.

09:46:52

16 Q. I mean, in that same vein, you said statistical  
17 significance actually provides no useful information at all,  
18 correct?

19 A. No, the point of context to that particular statement is, I  
20 haven't ever said that. I haven't never implied that it hasn't  
21 got a role. It certainly has a role, and, for instance,  
22 weeding out drugs that may be ineffective.

09:47:05

23 Q. Turn Tab E, if you would, in your notebook.

24 A. Yes, I have.

09:47:32

25 Q. You have it?

1 A. I do.

2 Q. You were asked on August 16, 2007 --

3 MR. WISNER: Objection, Your Honor. I haven't seen  
4 this. It's not in my notebook.

09:47:42

5 THE COURT: I don't seem to have it either. Tab E did  
6 you say, sir?

7 MR. BAYMAN: Yes, I did.

8 (Brief pause).

09:47:54

9 THE COURT: If you're going to cross-examine on a  
10 deposition, you have to show counsel first or inform him of the  
11 page and the line so that he has it in front of him when you  
12 proceed.

13 MR. BAYMAN: Yes.

14 THE COURT: You may not do it otherwise, sir.

09:48:05

15 MR. BAYMAN: Yes, sir.

16 BY MR. BAYMAN:

17 Q. Page 261, lines 1 through 12.

18 MR. WISNER: Thank you.

19 BY MR. BAYMAN:

09:48:15

20 Q. You were asked:

21 "... is it fair to say that statistical  
22 significance applied appropriately provides the  
23 measure of whether or not the findings that are  
24 being reported are by chance or not."

09:48:26

25 And your answer was:

1

2

3

4

09:48:36

5

6

7

8

9

09:48:51

10

11

12

13

14

09:49:02

15

16

17

18

19

09:49:09

20

21

22

23

24

09:49:22

25

"Answer: I could provide you and the Court in this case with a large series of quotes and references from quite a few of some of the most senior epidemiologists in the field to say that the invention of statistical significance was one of the worst things that ever happened to statistics within medicine, that it actually provides no useful information at all."

Did I read that correctly?

A. You did read it correctly except -- well, the words are read correctly, but you haven't probably caught the irony that was in my voice at that time.

In fact, this is part of a much larger discussion that was going on. That was --

MR. BAYMAN: Your Honor, that wasn't my question.

BY THE WITNESS:

A. That wasn't going on.

Can I please expand?

THE COURT: Yes, you may. Go ahead.

BY THE WITNESS:

A. I mean, I didn't say here that I didn't believe the concept could be useful. I said I can provide you with people like Ken Rothman who is a professor of epidemiology in Harvard saying it's one of the worst things that was every invented. Or Louie



1 Lasanya who introduced control trials to the 1962 FDA Act who  
2 said statistical significance has done more harm than good.

3 That's what I was saying. I didn't say that I didn't  
4 believe the concept could be useful even in the quote that you  
5 offered here. But, as I said, when you read the word  
6 correctly, I don't think you captured the spirit of what I was  
7 saying.

09:49:40

8 BY MR. BAYMAN:

9 Q. I didn't catch the irony in your voice, is that what you're  
10 saying?

09:49:49

11 A. I'm saying that, yes.

12 Q. Okay. Okay. Fair enough.

13 Let's look at your own work. You authored a book  
14 entitled Pharmageddon, correct?

09:49:58

15 A. I did. Correct.

16 Q. And you've written in this book Pharmageddon that:

17 "... statistical significance is a technique used  
18 to hypnotize doctors into focusing only on the  
19 figures that suit companies."

09:50:10

20 Correct?

21 A. Well, I have to see where it comes in the book. I have to  
22 see the context.

23 Q. Why don't we put that up on the screen.

24 MR. WISNER: Objection. There needs to be some

09:50:27

25 authentication, some showing to the opposing counsel what

1 they're doing before they put stuff in front of the jury.

2 THE COURT: Yeah, you got to do that, sir. You got to  
3 show it to counsel before you do that.

4 MR. WISNER: Just tell me what page. I've got the  
5 book here.

09:50:41

6 MR. BAYMAN: Page 75.

7 MR. WISNER: Thanks.

8 THE WITNESS: It would be keen to have the book, Your  
9 Honor, if I could.

09:50:46

10 MR. BAYMAN: Sure.

11 (Tendered to the witness).

12 THE COURT: This is your textbook (indicating)?

13 THE WITNESS: It is, yes.

14 THE COURT: Okay.

09:50:56

15 BY MR. BAYMAN:

16 Q. You see there on page 75?

17 A. Yes, I've got page 75.

18 Q. Okay. You wrote:

19 "... at the heart of these drug company  
20 interpretations lies their use of Fisher's  
21 second innovation, the idea of statistical  
22 significance, a technique used to hypnotize  
23 doctors into focusing only on the figures that  
24 suit companies."

09:51:23

09:51:36

25 You read that, correct?

1 A. Yes. What I was going to say, that comes back to the idea  
2 that was introduced by Fisher and I think companies have been  
3 using the idea incorrectly.

4 Q. Turn, if you would, same book to page 78.

09:51:59

5 (Brief pause)

6 THE COURT: What's your question?

7 MR. BAYMAN: I was going to ask him to look at a  
8 passage on page 78.

9 THE WITNESS: Yes.

09:52:08

10 BY MR. BAYMAN:

11 Q. You call statistical analysis a crack pipe, correct?

12 A. No, I haven't. I was taking that from a statistician that  
13 has done work for GSK and pointed out that the GSK birth defect  
14 data for Paxil showed that Paxil causes birth defects.

09:52:27

15 MR. BAYMAN: Your Honor, I move to strike that. We're  
16 now into birth defects.

17 BY THE WITNESS:

18 A. That's what the quote comes from. It comes from a man who  
19 has worked as a statistical consultant for GSK and said the  
20 data on Paxil and birth defects shows this problem.

09:52:37

21 MR. BAYMAN: Let's put that page up on the screen.

22 (Brief pause).

23 BY THE WITNESS:

24 A. You see the reference at the end. You'd have to go to the  
25 reference to check who it was who used those words. I'm not

09:52:48

1 using them.

2 BY MR. BAYMAN:

3 Q. So "crack pipe," those are not your words?

4 A. They're not, no. I'm not quoting from, as I said, an  
09:52:59 5 imminent statistician who has done a considerable amount of  
6 work for GSK.

7 Q. You don't have "crack pipe" in quotations though here,  
8 correct?

9 A. Well, I don't know why it's not in quotations, it probably  
09:53:09 10 should be, but there is a reference there which shows you where  
11 the phrase came from. And I would've thought, given the Paxil  
12 birth defect cases, you would've known that.

13 Q. Okay. Dr. Healy, you testified -- I mean, in fact, in your  
14 expert report in this case you say:

09:53:27 15 .. in fact, whether a risk is demonstrated  
16 through a statistically significant degree is  
17 simply irrelevant."

18 Correct?

19 A. Well, I'd like to have my expert report here to see the  
09:53:38 20 context in which --

21 Q. Tab 1 in your book.

22 A. -- to see if that's been said.

23 Okay.

24 (Brief pause).

09:53:45 25 BY THE WITNESS: Tab A, you mean?

1 BY MR. BAYMAN:

2 Q. Tab 1. I'm sorry.

3 A. Okay. Right. And the page -- oh, no, this is my  
4 deposition, I think, not the report. I can be wrong.

09:53:59

5 Oh, it's A deposition. It isn't the report, tab A, at  
6 least not --

7 THE COURT: Tab A, Mr. Bayman, that we're looking at?

8 MR. BAYMAN: It's Tab 1. Excuse me, Your Honor.

9 BY MR. BAYMAN:

09:54:12

10 Q. I'll bring it to you, doctor.

11 A. Fine.

12 (Brief pause).

13 MR. WISNER: It's Exhibit 1 under tab A, does that  
14 help, Dr. Healy?

09:54:23

15 MR. BAYMAN: That's right. I'm sorry. Excuse me.

16 BY THE WITNESS:

17 A. I don't have it. I've got a deposition transcript here,  
18 that appears to be all I have. In Tucker and Miller of GSK,  
19 that's what I've got.

09:54:37

20 MR. WISNER: I have two binders, one has the tab A1  
21 and then the other has tab A which is just depositions.

22 Dr. Healy, do you have deposition transcripts in front  
23 of you?

24 THE WITNESS: That's all I've got here in front of me.

09:54:48

25 BY MR. BAYMAN:

1 Q. I'm sorry. I handed you the wrong notebook. There should  
2 two notebooks, there's one with depositions and one with  
3 exhibits.

4 Do you have both of those books?

09:54:58

5 A. No, I've just got one here.

6 (Brief pause)

7 (Exhibit tendered to the witness).

8 BY THE WITNESS:

9 A. This is even bigger.

09:55:31

10 BY MR. BAYMAN:

11 Q. Yes, it is. Yes, it is.

12 (Brief pause).

13 BY MR. BAYMAN:

14 Q. Page 16 of your report. Sorry about that.

09:55:55

15 A. Okay.

16 Q. Third paragraph.

17 A. Yes.

18 Q. (Reading:)

19 "... whether risk is demonstrated through a

09:56:47

20 statistically significant degree is simply

21 irrelevant."

22 A. Can you actually show me.

23 Q. Sure.

24 A. I mean, I'm reading what I understand to be the third

09:56:57

25 paragraph.

1 Q. Third full paragraph.

2 A. Oh, yes. You just picked out a phrase of a paragraph which  
3 says, the point that I made to the jury the other day, which is  
4 if the trial is not prepared to look at a particular problem,  
5 then statistical significance doesn't apply.

09:57:11

6 Dr. Krall from GSK has said, on that basis, he is not  
7 aware of any evidence that Paxil causes any adverse event at  
8 all.

9 MR. BAYMAN: Your Honor, again, this is beyond my  
10 question.

09:57:25

11 May I publish this to the jury, Your Honor?

12 THE COURT: What is it you want to publish, sir?  
13 Something in the deposition?

14 MR. BAYMAN: The paragraph from his expert report.

09:57:34

15 THE COURT: Oh, from the report?

16 MR. BAYMAN: Yes, sir.

17 THE COURT: No objection?

18 MR. WISNER: No objection. Although, I think that if  
19 he's going to read something, he probably should read the whole  
20 sentence. But, yeah, that's fine.

09:57:43

21 THE COURT: Rule of completes.

22 BY MR. BAYMAN:

23 Q. This is the sentence we're talking about, right  
24 (indicating)?

09:57:50

25 A. Well, you've highlighted a particular phrase, and if you

1 would read that on its own without the rest of the paragraph,  
2 you might get a different view of what I was thinking or what I  
3 think compared to the view that I gave to the jury on Thursday.  
4 I think the view I gave to the jury is consistent with the  
5 entire paragraph. And it's consistent with what people in GSK  
6 think --

09:58:09

7 THE COURT: Doctor, let's just answer the question now  
8 so we don't take up too much of your time.

9 Proceed, sir.

09:58:22

10 BY MR. BAYMAN:

11 Q. Okay. Let's cut to the chase. I'm going to show you a  
12 statement about statistical significance and ask you if you  
13 agree or disagree. We'll just cut to the chase:

09:58:36

14 "... if there is no statistically significant  
15 difference in the incidents of the events on  
16 Paroxetine compared --"

09:58:51

17 MR. WISNER: Your Honor, at this time I have no  
18 particular objection to this, but they can't put stuff in front  
19 of the jury that they haven't given me. I handed them every  
20 single demonstrative before I put him on the stand. They have  
21 not done the same.

22 MR. BAYMAN: Your Honor, I'm just asking the wit  
23 witness if he agrees with this statement or not.

09:58:57

24 THE COURT: We don't know where the statement came  
25 from, so the objection is sustained. And you have to give



1 counsel copies of everything that you are going to use  
2 beforehand on either side.

3 MR. BAYMAN: It's just a statement, Your Honor.

09:59:08

4 THE COURT: Yes, sir, but if you want to ask the  
5 question yourself on your own, okay, but whose statement it is,  
6 we don't know, where it came from we don't know.

7 MR. BAYMAN: All right.

8 BY MR. BAYMAN:

9 Q. We'll come back to that.

09:59:34

10 You told the jury last week that one of the ways GSK  
11 supposedly hid the risk of suicide was by using significance  
12 testing, correct?

13 A. Well, yes, it is correct, and on that basis GSK have said  
14 that Paxil causes no adverse effects.

09:59:54

15 Q. When you talked to the jury about the 2006 FDA analysis and  
16 GSK's 2000 analysis, you did make sure to point out the finding  
17 that was statistical significant, correct?

10:00:11

18 A. No, I didn't. That was a thing that Mr. Wisner did. I  
19 didn't point it out. I said that statistical significance was  
20 not appropriate at that point. I've been fairly consistent all  
21 the way through it, I think.

22 Q. So the finding that the jury heard about the 6.7 and 2.76  
23 from the FDA analysis --

10:00:30

24 A. I said when it comes to numbers like that, that I would not  
25 apply statistical significance to the figure. I think the

10:00:48

1 jury, and anyone in the street, and anyone here in court would  
2 think a six-fold higher risk was pretty serious, and the fact  
3 that it's statistically significant or not, given that it comes  
4 from studies not designed to look at the problem, if it was  
5 coming from studies with a scientific problem, the odds are  
6 that it would be a much higher risk again. So I don't see  
7 where that idea of statistical significance comes in, that's  
8 the point that I was making.

10:01:15

9 Q. Okay. Would you turn also to your -- again, to your expert  
10 report, page 30.

11 THE COURT: I'm going to trouble you, Mr. Bayman. Do  
12 I have that and under what tab is that report in the book that  
13 you just handed to me?

14 MR. WISNER: Your Honor, do you have two?

10:01:30

15 MR. BAYMAN: Two notebooks, Your Honor.

16 THE COURT: It's under 2?

17 MR. BAYMAN: No, you should have two notebooks.

18 THE COURT: Well, I don't. I only have one notebook.  
19 I'm suffering from not having everything in front of me.

10:01:48

20 Or if you'd like, just give me his report. We can get  
21 a copy from chambers. I suspect you're going through his  
22 report several times.

23 MR. BAYMAN: Yes, sir.

24 THE COURT: If anyone has a loose copy of his  
25 report ...

10:02:08

1 MR. BAYMAN: I do.

2 MR. WISNER: I got one right here, Your Honor.

3 Oh, you got one?

4 MR. BAYMAN: Yes.

10:02:10 5 MR. WISNER: Okay.

6 THE COURT: All right. I'll work with this. Thank  
7 you very much.

8 Page now again?

9 MR. BAYMAN: Page 30, Your Honor.

10:02:31 10 THE COURT: And the question again?

11 MR. BAYMAN: I asked him to turn page 30.

12 THE COURT: Turn to page 30, okay.

13 MR. BAYMAN: Okay.

14 THE COURT: You've got page 30?

10:02:35 15 THE WITNESS: Yes, I do.

16 THE COURT: So do I, Doctor, so we'll proceed.

17 BY MR. BAYMAN:

18 Q. There's a table there, table 5?

19 A. Yes, there is.

10:02:43 20 MR. BAYMAN: If we could put up table 5.

21 (Brief pause).

22 BY MR. BAYMAN:

23 Q. And you recognize this on the screen, that's table 5 from  
24 your expert report?

10:02:53 25 A. Yes, I do.

1 Q. Okay. And you've also presented this same table in an  
2 article you published in the International Journal of Risk and  
3 Safety, correct?

4 A. That's right.

10:03:02

5 Q. And if you would, again in the exhibits notebook, Tab 3 --

6 MR. WISNER: Your Honor, can I raise an issue outside  
7 the presence of the jury? Sorry. It's it'll be quick.

8 THE COURT: All right.

9 (Proceedings heard at sidebar on the record.)

10:03:24

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

10:03:57

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

10:04:09

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

10:04:19

25 [REDACTED]

1 [REDACTED] [REDACTED] [REDACTED]

2 [REDACTED]

3 [REDACTED] [REDACTED] [REDACTED]

4 [REDACTED] [REDACTED] [REDACTED]

10:04:43

5 (Proceedings resumed within the hearing of the

6 jury).

7 BY MR. BAYMAN:

8 Q. Do you have Tab 3?

9 A. I do, yes.

10:04:52

10 Q. That's the article science rhetoric in the causality of  
11 adverse events International Journal of Risk and safety, 2011?

12 A. Yes, I have that.

13 Q. And you're the only author, correct?

14 A. Yes, I am.

10:05:06

15 Q. I'd like you to turn to page 159 of the article.

16 A. Yes, I'm here.

17 Q. And that exact same table that we showed a minute ago from  
18 your expert report is identified as table 4 in the article,  
19 correct?

10:05:32

20 A. Correct.

21 Q. Okay. This table, which you published in 2011, shows one  
22 suicide in 2943 Paroxetine major MDD, major depressive  
23 disorder, patients versus zero suicides in 1671 placebo MDD  
24 patients in placebo-controlled clinical trials, correct?

10:05:59

25 A. Yes.

1 Q. And that should be a zero in that first column for suicides  
2 in MDD patients on Paroxetine, correct?

10:06:17

3 A. Well, absolutely, correct. Probably, yes, if it was a  
4 faithful representation of the GSK press release about their  
5 briefing document, but it's not absolutely clear that it should  
6 be zero.

7 Q. Well, you've testified in the past that it should be zero  
8 and that was a mistake in your stable, correct?

10:06:32

9 A. Well, that's not exactly what I testified. It's a little  
10 bit more complex than that. It is possible that the correct  
11 figure should -- well, in a sense, I think most of the figures  
12 here are probably incorrect, not mine, GSK's in that you could  
13 make a good case that there was a completed suicide in the  
14 major depressive disorder trials.

10:06:47

15 When that table was composed first, it was composed  
16 before I had the benefit of the full GSK briefing document and  
17 I was having to work at, as lots of other people were, at what  
18 the likely distribution of the suicidal acts were, which were  
19 11 on Paxil.

10:07:02

20 Now, it seemed to me it's a good case knowing what I  
21 knew about the suicidal acts and the suicides in MDD trials  
22 that the distribution was one and 10. But I agree with you  
23 that based on the briefing documents GSK since released, that  
24 the figure should be zero and 11, and I've written to the  
25 journal to point this out to them.

10:07:23

1 Q. You've never retracted this article, have you?

2 A. I haven't retracted the article, but I've written to the  
3 journal to point out that it was a mistake and they're going to  
4 publish the fact that it should be zero and 11, which is more  
5 than GSK have done in the case of studies.

10:07:38

6 Q. As of February of this year you've not written to the  
7 journal, correct?

8 A. No, in fact, this year I have written to the journal.

9 Q. As of February 7th you had not written to the journal when  
10 your deposition was taken, correct?

10:07:54

11 A. That's correct, because I was unaware of the mistake as of  
12 that point, but it was pointed out to me on that day and just  
13 afterwards I wrote to the journal.

14 Q. This mistake has been pointed out to you prior to February  
15 7th, 2007, correct?

10:08:05

16 A. Not that it was in this article -- I mean, as I've  
17 indicated, I'm not sure it's a mistake, but in terms of what  
18 was published in that article that was pointed out to me at  
19 that point, so I have written to the journal since.

20 Q. When was the briefing document that you're talk about?  
21 When did that come out?

10:08:19

22 A. Well, as I've explained to Dr. Halprin, I was working from  
23 an 11 page GSK document that GSK seemed not to have been aware  
24 existed, and based on that, that's where I derived table 5  
25 from.

10:08:38

1 Q. When was that briefing document?

2 A. 2006.

3 Q. Okay. And this was published in 2011, 5 years later,  
4 correct?

10:08:45 5 A. That's correct.

6 Q. And you have said in prior testimony that you've made a  
7 mistake in that table, correct?

8 A. Well, as I've indicated, probably not as simply as that. I  
9 think there's a good case for saying there were a lot more  
10 suicidal acts and a lot more suicides in GSK placebo-controlled  
11 trials than appear in the briefing documents.

12 So it's not exactly clear that it was a mistake. What  
13 it is a mistake, as it turns out, is in terms of representing  
14 faithfully what the briefing document says, as opposed to what  
15 the clinical trial show, that you can regard that as a mistake,  
16 yes.

17 But it's not the same thing, and my point in this was  
18 to show the influence of the study 0576 and 106 was nothing --  
19 whether we had a completely different set of numbers, as I  
20 pointed out to the jury, you could greatly increase if you see  
21 -- if you see the line which says "studies," 057 and 106 and go  
22 to the third set of figures where it shows 32 suicidal acts out  
23 of 147 patients, you can increase that by 10 and GSK would  
24 still achieve the same effect by the document as they have from  
25 the group of figures you have there.

10:10:04



1 Q. Thank you, Doctor, appreciate that, but my question was  
2 just very simple, that you have said in the past that putting 1  
3 there instead of zero was a mistake, correct?

10:10:24

4 A. I told you, it's not a simple mistake in that there are  
5 suicides in GSK placebo-controlled trials which don't appear in  
6 figures GSK produced in the -- in the -- the briefing document.

7 Q. And that mistake was pointed out to you before February 7,  
8 2017, of this year, correct? That mistake in that table?

10:10:45

9 THE COURT: I think it's covered now, sir. Go on to  
10 something else.

11 BY MR. BAYMAN:

12 Q. I asked you about a quote that Mr. Wisner objected. I'm  
13 going to ask you if you agree or disagree with this statement,  
14 very simple:

10:11:01

15 "... if there is no statistically significant  
16 difference in the incidents of the events on  
17 Paroxetine compared to placebo, it is not even  
18 possible to say that there is an association,  
19 let alone a causal relationship between  
20 Paroxetine and those events."

10:11:16

21 Do you agree or disagree with that statement?

22 A. I would have to see the context in which that statement was  
23 being made and probably who it was being made by.

10:11:33

24 Q. It's just a statement, Doctor. Want to know if you agree  
25 or disagree. It's a basic statement.

1 A. I don't think I can give you a view without seeing the full  
2 context.

10:11:46

3 Q. You can't tell me whether you agree or disagree that if  
4 there's no statistically significant difference in the  
5 incidents of events on Paroxetine compared to placebo, it's not  
6 possible to say there's an association, let alone a causal  
7 relationship?

10:12:04

8 A. Well, if we back up, if there was going to be a  
9 statistically significant difference, that will be because the  
10 trial had been designed to look at that adverse event. I don't  
11 think that GSK have designed any trial to look at any adverse  
12 event. So from that point of view, to look at statistical  
13 significance would be inappropriate.

10:12:25

14 And on that basis, Dr. Krall from GSK said Paxil has  
15 no -- he hasn't aware of any evidence, good evidence, that  
16 Paxil causes any adverse event. It's an adverse-event free  
17 pill, according to Dr. Krall.

18 MR. BAYMAN: Your Honor, I'm going to move to strike  
19 that, about Dr. Krall.

10:12:43

20 THE COURT: That may stand.

21 Proceed.

22 BY MR. BAYMAN:

23 Q. So you disagree with the statement then?

10:12:48

24 A. Well, I haven't said that at all. I said to you I would  
25 like to see the context.

1 THE COURT: It's covered, sir. Please go on.

2 BY MR. BAYMAN:

3 Q. This is not the first time you've been hired by lawyers to  
4 offer the opinion that a medicine causes suicide, correct?

10:13:00

5 A. I am -- I don't know that it's correct to say I've been  
6 hired to offer the view that it does cause suicide. I've been  
7 hired to offer the view that medicine -- well, if you put it  
8 that way, I've been also hired to offer the view that medicines  
9 don't cause suicide or homicide, for instance.

10:13:18

10 Q. You've testified before, correct?

11 A. I have testified before on both sides, saying that the drug  
12 has caused a problem and that it hasn't.

13 Q. You charge an hourly rate for your work in cases like  
14 this?

10:13:29

15 A. I do.

16 Q. What is your hourly rate?

17 A. For looking through the details of various different  
18 materials, depositions \$400 per hour.

19 Q. And how about for testifying?

10:13:44

20 A. Well, until this trial it was \$600 per hour.

21 Q. And what is it in this trial?

22 A. \$750 per hour.

23 Q. And in this case when you invoiced for your time, you  
24 requested payment be made to Databased Medicine, correct?

10:14:03

25 A. Correct.

1 Q. And when we took your deposition in this case and we paid  
2 you for your time, the check was made out to Database Medicine,  
3 correct?

4 A. I don't know but I assume so.

10:14:14

5 Q. On direct examination you told the jury that you've been  
6 looking at the issue of SSRIs and suicide for more than  
7 20 years, correct?

8 A. Ah -- yes, that's true.

10:14:30

9 Q. And, in fact, you've been working with lawyers like Mr.  
10 Wisner and his partner, Michael Baum, who is back there in the  
11 second row, since at least 1997, correct?

12 A. That's correct.

13 Q. And you've been -- you've worked with their firm on other  
14 cases over those 20 years, correct?

10:14:49

15 A. That's correct.

16 Q. And, in fact, you're not only an expert witness for Mr.  
17 Baum, you're also his business partner, correct?

18 A. No, now I don't know that that's, correct, but I'm happy to  
19 try to explain to you and to the jury what's involved, if you  
20 want.

10:15:03

21 Q. Well, you're the founder and majority shareholder of a  
22 company called DMBG, correct?

23 A. Database Medicines Global, yes.

24 Q. Okay. And a related company called Database Medicines,  
25 Ltd.?

10:15:19

1 A. Americas probably, Ltd., yes.

2 Q. Okay. Mr. Baum is also an owner of Database Medicines  
3 Global, correct?

10:15:36

4 A. He put some funds into it, correct. Probably less than 1  
5 percent of the funds that have been put into it.

6 Q. And another lawyer in the United States who sues drug  
7 company, Andy Vickery, is also an owner of DMBG, Database  
8 Medicines Global, correct?

10:15:52

9 A. That's correct. But I've also approached, what's his name,  
10 Mr. Witty from GSK to ask whether he could be interested too.

11 Q. Mr. Witty from GSK is not an owner of DMBG, correct?

12 A. No, but I told him about what we were doing. I explained  
13 that it's about collecting adverse events on drugs, generally.

10:16:13

14 It's the kind of thing that would put -- I told Mr.  
15 Baum when I approached him, look, if you want to invest in  
16 this, this would be awfully helpful, but it's likely to put you  
17 out of business because what we're on the business of doing is  
18 preventing adverse events which, of course, means less business  
19 for him.

10:16:28

20 Q. We'll get to that in a minute.

21 Is there not a shareholder summary that lists the  
22 owners of Database Medicines Global?

23 A. I would imagine that there probably is.

24 Q. You saw it at your deposition, correct?

10:16:42

25 A. Yes, I did, yes.

1 MR. WISNER: Your Honor, at this time I'm going to  
2 object. This is beyond the limitations instructed by the  
3 Court.

4 THE COURT: There's nothing pending right now.

10:17:06

5 MR. WISNER: Oh, sorry. I'll wait for the question.

6 (Brief pause).

7 BY MR. BAYMAN:

8 Q. Would you turn in your -- this is the exhibit notebook,  
9 Doctor.

10:17:27

10 A. Yes.

11 Oops. You want me to turn to what?

12 Q. Tab 6.

13 (Brief pause).

14 BY THE WITNESS:

10:17:50

15 A. Yes.

16 BY MR. BAYMAN:

17 Q. And Tab 6 contains -- that's the shareholder summary that  
18 we talked about a minute ago that you were shown at your  
19 deposition, correct?

10:18:01

20 A. Yes; correct.

21 MR. BAYMAN: Your Honor, may I publish that? I just  
22 want to show the jury the listing.

23 THE COURT: The list?

24 MR. BAYMAN: Yes, sir.

10:18:10

25 THE COURT: Why?

1 MR. BAYMAN: To show Mr. Baum and Mr. Vickery as  
2 owners.

3 THE COURT: I don't see any reason to do that. Let's  
4 go on with it.

10:18:20

5 BY MR. BAYMAN:

6 Q. In Tab 6, Mr. Baum's name is spelled incorrectly. It's  
7 spelled Michelle Baum, correct?

10:18:32

8 A. It appears to be. I've no idea how that happened. I  
9 assume it was because in the legal office which filed these  
10 things, it was the person on the phone listening to one of the  
11 people that works for me, Dr. Linure, and couldn't understand  
12 the accent and got the name wrong that's why --

13 THE COURT: Go on, Mr. Bayman.

14 BY MR. BAYMAN:

10:18:48

15 Q. So when we paid you for your time and we paid DMBG, you  
16 were serving as an expert witness for the plaintiff and also a  
17 business partner, Mr. Baum, correct?

10:19:12

18 A. And the money you paid was into trying to prevent people  
19 having adverse effects on drugs and giving people like members  
20 of the jury --

21 THE COURT: Doctor, please, let's get on, because we a  
22 lot to cover here today.

23 BY MR. BAYMAN:

10:19:22

24 Q. DMBG runs a web site called, and correct me if I'm  
25 pronouncing this incorrectly, rxisk.org?

1 A. That's correct. It's spelled for the jury, rxisk.org,  
2 that's correct.

3 MR. WISNER: And, Your Honor, I think we've gone well  
4 past the limits you've set.

10:19:35 5 THE COURT: Sustained. The objection is sustained.  
6 We're not going to get into all these details.

7 MR. BAYMAN: Your Honor, this is about suicide. This  
8 is not a blog. This is about drugs that cause suicide. This  
9 is a different matter than we discussed.

10:19:45 10 THE COURT: Well, we're not going into the  
11 organization of this firm that you have referred to.

12 MR. BAYMAN: No, I'm not going into the organization,  
13 Your Honor. I'm going --

14 THE COURT: Put another question, because we're not  
10:19:54 15 going into that issue.

16 BY MR. BAYMAN:

17 Q. Rxisk.org contains information about side effects on  
18 specific medications, including SSRIs like Paroxetine?

19 A. It does. It has the FDA and the database there, along with  
10:20:10 20 health database, and the reports from member of the public,  
21 like members of the jury who might report in problems that  
22 they're having.

23 Q. And Database Medicines, Ltd., runs that website, correct?

24 A. It does. It's trying to provide a free service to people.

10:20:23 25 Q. And what it is is a website where you claim there are drug



1 side effects so that claimants can bring lawsuits that to  
2 Mr. Baum and Mr. Vickery can file, correct?

10:20:40

3 A. Wholly incorrect. As I've indicated to you, when I  
4 approached Mr. Baum when -- I mean, this would operate whether  
5 Mr. Baum had put in the small amount of funds that he put in or  
6 not, but I told him this is likely to put you out of business  
7 if it works properly. It's knowing to do with supporting  
8 lawsuits.

10:20:52

9 Q. It's also a website where you claim the drug side effects  
10 so that patients can bring lawsuits and you can be an expert  
11 witness, correct?

10:21:09

12 A. Absolutely not. This is all trying to minimize the problem  
13 so that there won't be lawsuits. It's not giving patients who  
14 are on a drug, any drug at all, an ear drug, a gut drug, a  
15 heart drug, a tool drug that they can look at has their drug  
16 caused the problem that they think it may be causing and it  
17 gives them a score. And armed with a report, they can take to  
18 their physician and say, hey, look doc, this website says that  
19 there may be a link between the drug I'm taking and the problem  
20 I seem to be having.

10:21:26

10:21:40

21 Because a lot of people are very nervous about raising  
22 these things, as I indicated, in front of doctors who are just  
23 them doing the speaking, but if they got some support. The  
24 idea is a bit like a Groupon coupon, you know, the kind of  
25 coupons Groupon used to have. If you bring Groupon along, you

1 get things at a much reduced rate. It was the same kind of  
2 thing, it was trying to arm people.

3 Q. Let's -- let's talk about that. The home page for  
4 rxisk.org, turn to Tab 7.

10:22:06

5 The home page says "Could It Be My Meds," correct?

6 A. Well, I'm looking at an "us" page. I'm not saying the  
7 phrase "Could It Be My Meds," although it may well be there.

8 Q. I think I need to show it on the screen?

10:22:26

9 THE COURT: No, we're not going into this, Mr. Bayman.  
10 We're not going to study his blog or these other activities.

11 MR. BAYMAN: Your Honor --

12 THE COURT: This is a different issue entirely. I'm  
13 trying to guide you on that subject and I'm having difficulties  
14 with it.

10:22:39

15 MR. BAYMAN: With respect to, Your Honor, this is  
16 about drugs that suicide. This is not his blog. This or his  
17 website that where he alleges --

18 THE COURT: If you want to ask him about suicide and  
19 drugs, that's okay, but we're not going to go into the blogs  
20 and other things.

10:22:54

21 MR. BAYMAN: This is not a blog, this is his website  
22 where he --

23 THE COURT: His website, yeah.

24 MR. BAYMAN: It's his website where he lists which  
25 drug he says causes suicide.

10:22:59

1 THE COURT: Put a specific question to him, sir.

2 BY MR. BAYMAN:

3 Q. Okay. On this site, the people can look up a medicine and  
4 it will tell them side effects that have been reported,  
5 correct?

10:23:10

6 A. People can go into FDA and find these things. This is a  
7 user friendly way to go into FDA.

8 Q. And there's a way to search drugs A to Z on that website,  
9 correct?

10:23:22

10 A. There is, yes.

11 Q. And you can go to the page on the website and type in a  
12 drug, it will pull up the drug, and it will tell you the side  
13 effects that you believe were associated with that drug,  
14 correct?

10:23:37

15 A. No, it will give you --

16 MR. WISNER: Objection, Your Honor.

17 BY THE WITNESS:

18 A. -- FDA's data, the things that companies and doctors and  
19 increasingly members of the public have reported to FDA. It  
20 wouldn't necessarily give you anything that I think at all.

10:23:48

21 MR. WISNER: Well, Your Honor, I object to this whole  
22 line of testimony again. You've instructed Mr. Bayman that  
23 we're not talking about websites and yet he continues to ask  
24 questions.

10:24:01

25 THE COURT: Sustained.

1 BY MR. BAYMAN:

2 Q. Well, let's talk about some of the medicines. One of the  
3 medicines that's on there is Benadryl, correct?

4 A. Yes -- no, hang on.

10:24:24

5 Yes, it is, that's correct. Benadryl should be in  
6 there, anyway.

7 Q. And I'll represent that if we looked on there, that there  
8 would be 2676 side effects listed for Benadryl, correct?

9 A. There may be.

10:24:39

10 MR. WISNER: Your Honor, objection. I believe we're  
11 here to talk about SSRIs. If we start opening doors about  
12 other drugs and things that might be on his website, the  
13 redirect will literally take a month.

10:24:53

14 MR. BAYMAN: Your Honor, he went into psychotropic  
15 medications, he made comparisons to LSD, he talked about other  
16 medicines that were not in this class of drugs. I objected, he  
17 was allowed to testify about it. I should be entitled to get  
18 into this and his views on Benadryl and it causing suicide.

19 THE COURT: Objection sustained.

10:25:10

20 BY MR. BAYMAN:

21 Q. Dr. Healy, you told the jury last week there's a wide body  
22 of data here and if anybody is trying to work on what's  
23 actually going on, they need to take all of it into account,  
24 correct?

10:25:34

25 A. I believe I said words to that effect, yes.

1 Q. Did you leave anything out from the data and information  
2 you presented to the jury last week?

10:25:52

3 A. I may have well done so. When I indicated a wide body of  
4 data and began to numerate certain parts of the data, I'm -- I  
5 would think that there may well be bits of the data that I  
6 didn't touch on.

7 Q. That wasn't intentional, though, was it, to leave anything  
8 out?

10:26:05

9 A. I don't think so. You may persuade the jury it was. I'm  
10 interested to hear what you think I left out.

11 Q. And Mr. Wisner didn't leave anything out of his questioning  
12 of you, did he?

13 A. I don't know. I --

10:26:14

14 MR. WISNER: Objection to speculation as to my state  
15 of mind.

16 THE COURT: Objection sustain.

17 BY THE WITNESS:

18 A. You have to appreciate, when I'm not here I'm quite  
19 anxious. I'm not necessarily ticking all the boxes.

10:26:24

20 BY MR. BAYMAN:

21 Q. You told the jury on direct examination that the  
22 suicidality data that GSK submitted to the FDA hid the suicide  
23 risks of Paroxetine because, according to you, GSK didn't  
24 properly report suicides and suicide attempts during the run-in  
25 phase of the clinical trials, do you recall that testimony?

10:26:43

1 A. I do, roughly. Could I ask you to repeat the question?

2 Q. Basically, that you told the jury last week that GSK -- the  
3 data that GSK submitted to the FDA hid the suicide risks of  
4 Paroxetine because according to you the GSK didn't properly  
5 report suicides and suicide attempts that occurred during the  
6 run-in phase of clinical trials?

10:27:02

7 A. I said that all of the companies had done this to an  
8 extent. I said that in GSK there was an issue about the run-in  
9 phase, yes, and that they didn't properly report the suicides  
10 and the suicidal acts that had happened during that phase.

10:27:20

11 They moved them around to a place that I thought they hadn't  
12 ought to have been and that most other people thought they  
13 ought not have been.

14 Q. And that was one of the ways that GSK hid data when you  
15 were talking about the different ways GSK hid data?

10:27:35

16 A. Yes, that was a way in which the data was hidden, the risks  
17 were hidden.

18 Q. Pardon me?

19 A. The risks were hidden. There's no such thing as data.

10:27:50

20 There was data there, but it was the wrong place, and moving it  
21 where -- putting it where GSK had put it hid risks.

22 Q. The submissions you told the jury about with respect to the  
23 run-ins were in 1989 and 1991, correct?

24 A. That's where it opened up, yes.

10:28:10

25 Q. That's 15 -- 1991 is 15 years before GSK and FDA separately

1 analyzed the Paroxetine clinical trial data in 2006 to evaluate  
2 the risk of suicidality in adult patients?

3 A. In 1991 the FDA was evaluating GSK's data and Pfizer's data  
4 and Lilly's data and they offered to become companies a  
5 class-wide warning for suicide on SSRIs then in 1991.

10:28:37

6 Q. No, my question was, 2006, a lot simpler, 2006 was 15  
7 years --

8 A. I think it was very simple. In 1991 and that the FDA did  
9 it too and offered a class-wide warning that didn't happen  
10 then, it happened 15 years later, and a lot of people probably  
11 died who didn't need to die.

10:28:59

12 Q. During those 15 years that GSK applied for and received  
13 approval from the FDA for numerous indications for Paxil in  
14 adult patients, correct?

10:29:14

15 A. They did, that's correct.

16 Q. And some of those new indications included general anxiety  
17 disorder, correct?

18 A. Correct.

19 Q. And obsessive compulsive disorder, correct?

10:29:28

20 A. Correct.

21 Q. And GSK had to submit clinical trial data evidence showing  
22 efficacy in treating those conditions and results, correct, as  
23 part of their submission?

24 A. Yes.

10:29:40

25 Q. And they had to submit safety data as part of those

1 submissions?

2 A. Yes.

3 Q. And, in fact, many more trials -- clinical trials were  
4 conducted by GSK after Paxil was first approved in 1992,  
5 correct?

10:29:54

6 A. That's correct.

7 Q. It was a much more robust data set in 2006 as compared to  
8 1991, correct?

9 A. Not necessarily correct. It was a robust data set in 1991,  
10 and, of course, one of GSK's submissions for the data led to  
11 the black box warning.

10:30:07

12 Q. My question was, in terms of the number of trials and the  
13 number of patients, there were far more many trials and  
14 patients as of 2006 than there were in 1991, correct?

10:30:28

15 A. That doesn't necessarily make the data anymore robust. The  
16 data was very robust in 1991 and FDA thought they could offer  
17 the companies a class-wide warning then.

18 Q. Let's talk about that. Turn, if you would, to Tab 11A in  
19 your notebook.

10:30:58

20 (Brief pause).

21 BY MR. BAYMAN:

22 Q. That's Plaintiff's Exhibit 82 which is GSK's May 10, 1991  
23 submission.

24 A. It's -- well, I've got JX1 at the bottom, is that what you  
25 want me to look at, is it? Joint Exhibit 1?

10:31:17



1 Q. No, it's Plaintiff's Exhibit 82.

2 A. I might be looking at the wrong notebook.

3 MR. WISNER: Dr. Healy, under 11 there's an A after  
4 that. It's after the A.

10:31:29

5 BY THE WITNESS:

6 A. All right. Fine. Okay. Sorry.

7 BY MR. BAYMAN:

8 Q. That's -- that's a document you talked to with Mr. Wisner.

10:31:47

9 A. I believe this came up on either Wednesday or Thursday,  
10 yes.

11 Q. Sure. Turn to page 1.

12 A. By page 1 you mean the covering letter?

13 Q. The number at the top of the page. If you look at the PAR  
14 number in the corner, it ends with 8168.

10:32:06

15 A. Yes.

16 Q. And that's -- that's a table that you and Mr. Wisner showed  
17 the jury last week, correct?

18 A. Hang on. Well, I've got -- yes, it is. I believe it is,  
19 yes.

10:32:18

20 MR. BAYMAN: Your Honor, may I put that up on the  
21 screen?

22 THE COURT: Yes.

23 (Exhibit published to the jury.)

24 BY MR. BAYMAN:

10:32:23

25 Q. Okay. That table shows the number of patients in this 1991

1 analysis, correct?

2 A. It appears to do so, yes.

3 Q. And that's -- there were 2963 -- 2963 patients on Paxil or  
4 Paroxetine, correct?

10:32:44

5 A. Correct.

6 Q. And there were 554 patients taking placebo?

7 A. Correct.

8 Q. Now, these numbers, at least the Paroxetine numbers,  
9 include all kinds of clinical trials, correct?

10:32:57

10 A. Yes. Correct.

11 Q. Placebo-controlled trials?

12 A. Yes. Correct.

13 Q. Active control trials?

14 A. I believe so.

10:33:05

15 Q. Active control is when the medicine is compared against  
16 another medicine, is that right?

17 A. Correct. Yes.

18 Q. And uncontrolled trials?

19 A. Correct.

10:33:12

20 Q. What does "uncontrolled" mean?

21 A. Well, it may mean open label, that both the doctor and the  
22 patients know that the patient is being given a drug, a new  
23 drug, and that they would be monitored for efficacy and safety  
24 purposes.

10:33:28

25 Q. All right. I want to take the 2963 and the 554 and put

1 them in a chart.

2 MR. WISNER: Again, Your Honor --

3 MR. BAYMAN: Your Honor, there's no mystery. I'm just  
4 putting numbers on. Just drawing on an easel.

10:33:58 5 THE COURT: Okay. Proceed.

6 BY MR. BAYMAN:

7 Q. And you know that in 2002 GSK did analyses of suicidality  
8 that included just the controlled phases from the  
9 placebo-controlled clinical trials that were in the 1991  
10 submission, correct?

10:34:12

11 A. Correct.

12 Q. Turn, if you would, to 11B in that same notebook.

13 A. I'm here. Which phase did you want me to go to?

10:34:35

14 Q. I just want you to look at the first page. Do you  
15 recognize this a document that is an analysis of clinical  
16 trial, suicide related attempts that GSK submitted to the FDA  
17 on May 2, 2002, correct?

18 A. Yes.

19 Q. And you've seen that before. You've read it, correct?

10:34:48

20 A. I have, yes.

21 MR. BAYMAN: Your Honor, permission to publish this to  
22 the jury.

23 THE COURT: We're on -- what is the exhibit number?

10:35:00

24 MR. BAYMAN: Defense Exhibit 38, Your Honor. It's 11B  
25 in your notebook.

1 THE COURT: All right.

2 BY THE WITNESS:

3 A. I think this may be the binder that His Honor doesn't have.

4 He has my report, but --

10:35:10 5 THE COURT: Did you say 38?

6 MR. BAYMAN: Defendant's Exhibit 38, Your Honor.

7 THE COURT: Yeah.

8 MR. BAYMAN: Go ahead.

9 (Exhibit published to the jury.)

10:35:18 10 BY MR. BAYMAN:

11 Q. This is the cover letter, right?

12 A. Yes.

13 Q. You're familiar with it?

14 A. Yes.

10:35:24 15 Q. Turn, if you would, to the page with the PAR number in the  
16 corner ending in 822.

17 A. Yes.

18 Q. That's a chart that shows the number of patients in that  
19 analysis.

10:35:37 20 MR. BAYMAN: Could we blow that up, please, Roger.

21 (Brief pause).

22 BY THE WITNESS:

23 A. Yes.

24 BY MR. BAYMAN:

10:35:46 25 Q. Okay. And here, and again as we just established, this is

1 just from the controlled phases of the placebo-controlled  
2 trials, correct?

3 A. Yes. Correct.

4 Q. The number of patients on Paroxetine is 921, correct?

10:36:03

5 A. Correct.

6 Q. And there's 554 for placebo, which is the same number, and  
7 that makes sense because those are placebo-controlled trials,  
8 correct?

9 A. Correct. Yes.

10:36:15

10 Q. Okay.

11 MR. BAYMAN: Roger, if you would go back and put those  
12 on the next line.

13 (Brief pause)

14 BY MR. BAYMAN:

10:36:23

15 Q. We can see by just comparing the 2963 and the 921 that the  
16 majority of the patients in the 1991 report were not -- were  
17 not in placebo-controlled trials, correct?

18 A. Correct.

19 Q. Now, you've -- you talked at some length with Mr. Wisner  
20 about the analyses that GSK and the FDA did in 2006.

10:36:43

21 A. Correct.

22 Q. And to -- I want you to turn to Tab 11C which is  
23 Defendant's Exhibit 103.

24 A. Yes.

10:37:04

25 Q. And have you take a look at Tab 1.01.

1 A. And that's on page?

2 Q. Page 93, PAR/904. /PAR904904.

3 BY THE WITNESS:

4 A. This may take me a minute to get there. I think I may need  
5 your help.

10:37:38

6 BY MR. BAYMAN:

7 Q. Sure.

8 A. My PAR numbers don't seem to be matching up exactly. Maybe  
9 I'm in the wrong place.

10:37:49

10 MR. BAYMAN: May I approach?

11 THE COURT: Exhibit 103, isn't it?

12 MR. BAYMAN: Yes, Your Honor.

13 BY THE WITNESS:

14 A. Yes, I've got 103.

10:37:57

15 MR. BAYMAN: But the PAR number is 904. I'd be happy  
16 to help Dr. Healy.

17 BY THE WITNESS:

18 A. Please do. I'd welcome help as the jury has seen when I  
19 get up here and dealing with documents.

10:38:10

20 (Brief pause).

21 BY MR. BAYMAN:

22 Q. Do you see that?

23 A. Yes, I do. And the page is 08. So these don't follow  
24 sequentially, it seems.

10:38:36

25 Q. Well, I'm only interested in the table.

1 A. Oh, of course. Of course, yes.

2 Q. Do you see that table there?

3 A. I do.

4 Q. And the table shows --

10:38:43

5 MR. BAYMAN: Let's put that up. If you could blow it  
6 up, please.

7 (Brief pause)

8 BY MR. BAYMAN:

10:38:56

9 Q. So this is as of 2006. And the table shows that there were  
10 8958 patients on Paxil in placebo-controlled trials and 5953 on  
11 placebo, correct?

12 A. Yes.

13 MR. BAYMAN: So let's go back to our chart, Roger, and  
14 put those numbers --

10:39:11

15 BY THE WITNESS:

16 A. Well, it is a little misleading -- okay, you're putting in  
17 all of the trials, not just the MDD trials.

18 BY MR. BAYMAN:

10:39:22

19 Q. Yes, that's right, all the trials. Because the FDA  
20 considered all the trials, right, not just the MDD trials.

21 A. Okay. Fine. That's fine.

22 Q. All right. And then the FDA, in 2006, also did its  
23 analysis, which you talked to Mr. Wisner about last week,  
24 correct?

10:39:33

25 A. Yes, that's right.

1 Q. Okay. And if you turn, then, if you would, to 11D. And  
2 it's the FDA report on page 18. And I would call your  
3 attention to table 7.

4 THE COURT: What exhibit are you referring to?

10:39:49

5 MR. BAYMAN: I'm sorry, Your Honor. Joint Exhibit 13.  
6 It's in evidence.

7 THE COURT: Please refer to the exhibit.

8 MR. BAYMAN: Yes, sir.

9 THE COURT: Page?

10:39:59

10 MR. BAYMAN: Page 18, table 7, Your Honor.

11 BY MR. BAYMAN:

12 Q. I ask you to look then, the FDA analysis reports 8728  
13 patients on Paxil and 7005 on placebo, correct?

14 A. Correct. Yes.

10:40:33

15 Q. And the FDA had data about Paxil that it got from other  
16 manufacturers, right, that may have done trials involving  
17 Paxil?

18 A. It's extraordinary hard to look at exactly what was going  
19 on because, of course, there were a lot of GSK data that FDA  
20 don't have. So just trying to work out what's going on can be  
21 difficult.

10:40:48

22 MR. BAYMAN: Your Honor, move to strike that comment.

23 THE COURT: It may stand.

24 BY MR. BAYMAN:

10:40:56

25 Q. Do you have any reason to dispute these figures that the



1 FDA published?

10:41:10

2 A. Oh, I don't have any reason to dispute the figures, but I  
3 don't know what the basis of them is. I tried at various  
4 different points to find out the basis for FDA's figures, but  
5 they haven't made their data publicly available. They just say  
6 these are the figures. It can awfully hard for me, or the  
7 jury, or anyone else to work out how they come up with this  
8 particular number.

10:41:27

9 Q. You do know that manufacturers at trials where they  
10 compared their drugs to a competitor's drug, for example?

11 A. That's correct.

12 Q. And these GSK and FDA analysis that we've seen with these  
13 numbers included only the controlled phases of  
14 placebo-controlled trials, correct?

10:41:43

15 A. They included the phase up to the last date the person had  
16 the drug, yes.

17 Q. All right. And so the GSK and the FDA analysis contained  
18 about 10 times more patients on Paxil than were in the  
19 placebo-controlled studies in the 1991 submission?

10:42:00

20 A. That's correct, but that means that the data is less  
21 robust, not more robust.

22 Q. Less robust?

23 A. Yes. If you have the drug that works in a trial, you only  
24 need one patient. In a trial you only need one patient in a  
25 trial of Paxil for premature ejaculation, the effects of Paxil

10:42:20

1 on sexual functioning are so clear, you'll need 12 patients.

2 People often fear if the study has thousands of  
3 patients it's more robust, but, in fact, it means the effects  
4 you're trying to look at are so weak that we need more and more  
5 patients. So the analysis is much more robust and much able to  
6 meet the target if it was a clear effect with only 12 patients.

10:42:38

7 Q. So you're saying having more patients and more data is less  
8 helpful than having fewer patients and less data?

9 A. It's counterintuitive. It comes to a thing that's quite  
10 rare, like completed suicides, that it's extraordinary  
11 important to have a very large database because you don't see  
12 them otherwise.

10:42:56

13 But, for instance, in a case of Paxil, if we gave it  
14 to every single man in the court here, everyone within  
15 30 minutes would have genital numbing. The effect is very  
16 clear, so clear that we know we only need 12 patients in a  
17 placebo-controlled trial to get a statistically significance  
18 effect.

10:43:09

19 Q. Well, stay with me.

20 A. I will.

10:43:28

21 Q. And in addition to what we just had discussed, in terms of  
22 that there were ten times more patients on Paxil than there  
23 were -- as of 2006 than there were in the 1991 submission,  
24 there were 3 times as many patients on Paxil than there were in  
25 all of the studies in the 1991 submission, correct?

10:43:50

1 A. Yes, but I don't think that helps FDA, or anyone, because  
2 FDA hedged around with the companies, GSK included, having made  
3 various maneuvers and asking for FDA to include particular  
4 trials and FDA saying, no, we don't want those included.

10:44:11

5 Q. And they weren't included, correct?

6 A. Oh, they weren't included, that's correct, but FDA was  
7 faced with all the companies trying to put the best face  
8 forward, as it were, and we end up with a hodgepodge where it's  
9 been very hard to get a clear signal of anything, but that's  
10 not because the signal isn't there, it's because we've got a  
11 hodgepodge.

10:44:30

12 Q. And let's look at placebo. For placebo there were about 10  
13 times more patients on placebo?

14 A. Yes, but as I've indicated, we only need 6 patients on  
15 placebo to get a statistically significant effect if the result  
16 is clear cut.

10:44:46

17 If GSK had said that the emotional numbing was the key  
18 effect, the clear indication they were going for, rather than  
19 trying to get an indication for a major depressive disorder,  
20 they could have had a much more clear cut efficacy result and  
21 there be much less arguments than the kind we have now as to  
22 whether Paxil works at all or not, and they would've done so on  
23 much fewer patients.

10:45:01

24 Q. All right. Appreciate that, Doctor. All I'm trying to say  
25 is, the 2006 analyses by FDA and GSK were much bigger data sets

10:45:22

1 than the 1991 submission, you will agree with that, correct?

2 A. I agree it's a bigger data set, but in this case, it's  
3 worth noting for the Court, that means that FDA were limited.  
4 It was -- they were faced -- they were operating from a weaker  
5 position than people might like to think, and certainly a much  
6 bigger position than Dr. Juurlink was operating from when he  
7 had a bigger data set.

10:45:41

8 Q. So you would disagree with me that all things being equal,  
9 the bigger the data set, the more reliable the analysis?

10:46:00

10 A. In terms of control trials, yes. There is a point, which  
11 is, that, in some instances, there is a trade-off. We can get  
12 a more precise estimate of what the effect is if we have more  
13 patients, but if you got a very clear effect, then you need  
14 very, very few patients.

10:46:15

15 Q. And you will agree with me that when large data sets are  
16 handled, there are corrections that often need to be made  
17 because the findings could be thrown up by chance?

18 A. Not in this case. When some large data sets need to be  
19 handled, there are corrections that need to be made, sort of  
20 for controlling random effects, for instance, but this data  
21 set, FDA's data set, is so non-random, there is nothing random  
22 about FDA's data set, it's contrived. There's all sorts of  
23 studies that have to keep out, there's all sorts of selection  
24 biases in here. So the correcting for multiple effects is  
25 really neither here nor there.

10:46:32

10:46:52

1 Q. Now, whether including run-in events in the data tables in  
2 '91 was the right thing or wrong thing to do, the FDA was fully  
3 aware that suicide and suicide attempts during the run-in  
4 period for counted as placebo events, correct?

10:47:14

5 MR. WISNER: Objection. Speculation as to state of  
6 mind of FDA.

7 THE COURT: Well, he may answer, if he knows.

8 BY THE WITNESS:

10:47:23

9 A. Well, in terms -- I can answer the question like this, in  
10 terms of SSRI trials, FDA were aware, as of the time of  
11 application, that this was breaching FDA regulations.

12 BY MR. BAYMAN:

13 Q. FDA was aware that run-in events were being counted,  
14 correct?

10:47:37

15 A. And breaching regulations. Some people within FDA were  
16 aware. See, the issue here is when we talk about FDA, we're  
17 talking about tens of thousands of people perhaps, you know.  
18 It's not as though everyone in FDA knows all the same things  
19 and they all agree. Just as within GSK, there's some wonderful  
20 people within GSK, there's other people doing things that I  
21 might not think was so wonderful.

10:48:00

22 Q. The reviewer, Dr. Brecher, was aware that run-in events  
23 were being counted, correct?

24 A. I'm not exactly sure what Dr. Brecher was aware of in 1991.

10:48:09

25 I am aware that some years later, under oath, he said that this

1 was very unfortunate.

2 Q. Let's look back at Defendant's Exhibit 38, which is 11B  
3 again. That's the 2002 analysis of suicide attempts.

4 This is the chart that I showed you.

10:48:43

5 A. Yes.

6 Q. In this submission to the FDA in 2002, GSK informs the FDA  
7 that:

10:48:52

8 "... 5 patients with attempted suicide had been  
9 excluded from the figures above for the placebo  
10 group because they occurred during the placebo  
11 run-in phase."

12 Did I read that correctly?

13 A. Just give me one moment. Just one second.

14 Q. Sure.

10:48:58

15 A. This is the --

16 Q. 2002.

17 A. Yes. This is 10, 12 years later.

18 Q. But since 2003, the FDA has never, to your knowledge, asked  
19 GSK to include language about run-in events in the Paxil label,  
20 has it?

10:49:16

21 A. I'm not quite absolutely sure what you're asking me here.  
22 I don't know that FDA has ever required any company to include  
23 that kind of language at the label of their pills.

24 Q. FDA you've never -- since 2003, you've not seen any

10:49:35

25 correspondence where FDA has mentioned run-in events to GSK,

1 correct?

2 A. No. Well, we're clear that GSK, as of this point in time,  
3 realized there was a problem and have analyzed the data in a  
4 different way here. So given the way that they analyzed it  
10:49:51 5 here, there won't be any run-ins in this data set, that's  
6 correct.

7 Q. And there have been additional adult indications for Paxil  
8 approved by the FDA since 2003, correct?

9 A. There have been -- well, actually I'm not actually for sure  
10:50:06 10 about that. You have to tell me.

11 Q. I'll come back to that, Doctor.

12 Turn, if you would, back to Tab 12 which is  
13 Defendant's Exhibit 8.

14 (Brief pause).

10:50:35 15 BY MR. BAYMAN:

16 Q. You see that, Doctor?

17 A. Yes, I do.

18 Q. That's a letter from GSK to the FDA, May 10, '91, along  
19 with the enclosed report, "suicidal ideation and behavior and  
10:50:54 20 analysis of the Paroxetine worldwide clinical database"?

21 A. Yes, it would appear to be.

22 Q. And you reviewed that report in your -- in preparing your  
23 opinions in this case?

24 A. Yes, I believe I actually reviewed this or one very, very  
10:51:15 25 similar to it. What's actually throwing me slightly is the

1 tradename here, which is the Australian tradename and I can't  
2 actually remember being there before, but --

3 Q. But you went over the report in your direct examination,  
4 correct?

10:51:30 5 A. Yes, we did go over material very like this, definitely,  
6 yes.

7 Q. And, in fact -- you, in fact, testified that that report  
8 was sent to the FDA in 1991, correct?

9 A. Well, I testified that it appeared to be a document and it  
10:51:50 10 appeared to be one that was going to FDA. I didn't actually  
11 testify that it was sent. I assumed it was sent, but --

12 Q. Okay. Look at the first paragraph of the cover letter.

13 You got that?

14 A. Yes, I have.

10:52:09 15 MR. BAYMAN: Your Honor, permission to publish the  
16 letter.

17 THE COURT: Yes.

18 MR. BAYMAN: Thank you.

19 (Exhibit published to the jury.)

10:52:16 20 BY MR. BAYMAN:

21 Q. It says:

22 "... we are submitting our response to Dr. Martin  
23 Brecher ..."

24 That's who we talked about a minute ago, correct?

10:52:23 25 A. Yes. Correct.



1 Q. (Reading:)

2 "... request that we provide an analyses of the  
3 Paroxetine clinical trial database for the  
4 occurrence of suicide, suicide attempts and  
5 suicide ideation."

10:52:34

6 Do you see that?

7 A. I do, yes.

8 Q. And you have read Dr. Brecher's report?

9 A. Yes, I do.

10:52:49

10 Q. The safety review, correct?

11 A. Yes, I have.

12 Q. And you know from reading that that the clinical trial data  
13 discussed in GSK's 1991 report included data from the  
14 randomized controlled clinical trials?

10:53:00

15 A. Yes.

16 Q. And it included data from uncontrolled trials?

17 A. Correct.

18 Q. Included data from open labels?

19 A. Correct.

10:53:06

20 Q. Extension-phase studies, correct?

21 A. Yes.

22 Q. Okay. And it also included data from what we called active  
23 control studies, correct?

24 A. Correct.

10:53:15

25 Q. So that the Paxil NDA data set, New Drug Application, the

1 data set when SmithKline Beecham then applied for approval and  
2 that's the subject of this report, included not only controlled  
3 data but also uncontrolled data?

4 A. Correct.

10:53:34

5 Q. And FDA didn't consider uncontrolled data in its 2006  
6 analysis, correct?

7 A. Correct.

8 Q. Turn, if you would, to -- it's page 1 of the report but  
9 it's page 7 of the exhibit. It ends PAR 227617.

10:53:53

10 A. Yes.

11 Q. And there's a section entitled "1.0 suicides," do you see  
12 that?

13 A. Yes, I do.

14 Q. It says:

10:54:08

15 "Data were available for 4668 patients who  
16 randomized to Paroxetine and equals 2963,  
17 placebo equals 554 and other active treatment  
18 regimens ..."

10:54:24

19 THE COURT: Now, Mr. Bayman, you're not going to  
20 cooperate with the court reporter if you read like that.

21 MR. BAYMAN: I'll slow down, Your Honor. Sorry.

22 THE COURT: We want to make a record here.

23 MR. BAYMAN: Sure. I understand.

24 THE COURT: I think it's time for a recess.

10:54:35

25 MR. BAYMAN: Okay. Good place for it. Thank you.

1 THE COURT: All right. Ladies and gentlemen, you may  
2 step out and we will take 10 to 15 minutes, I hope. Closer to  
3 10, but maybe 15.

4 (The following proceedings were had out of the  
5 presence of the jury in open court:)

10:55:12

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10:55:29

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

11:09:23

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

11:09:37

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

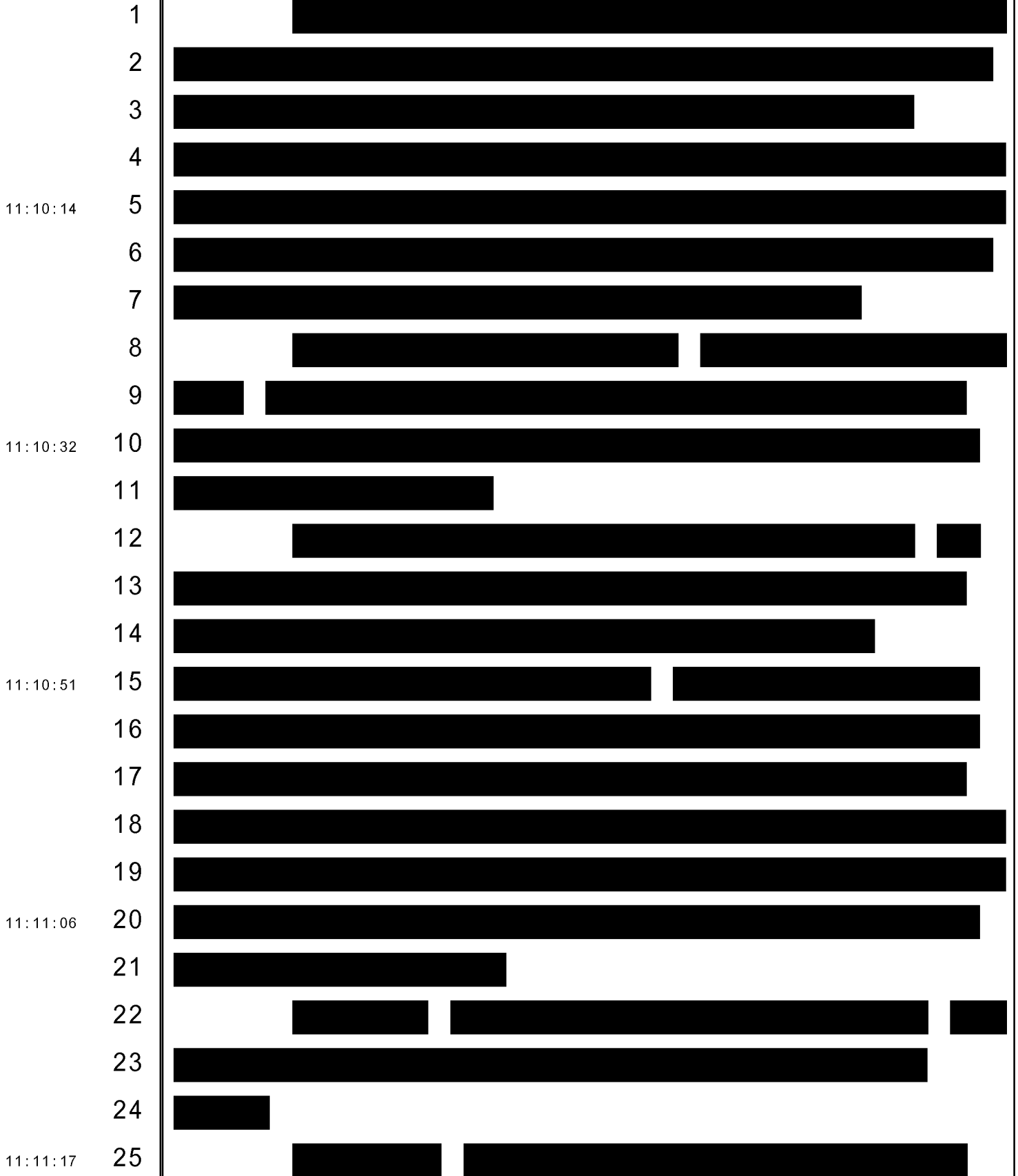
24 [REDACTED]

11:09:46

25 [REDACTED]

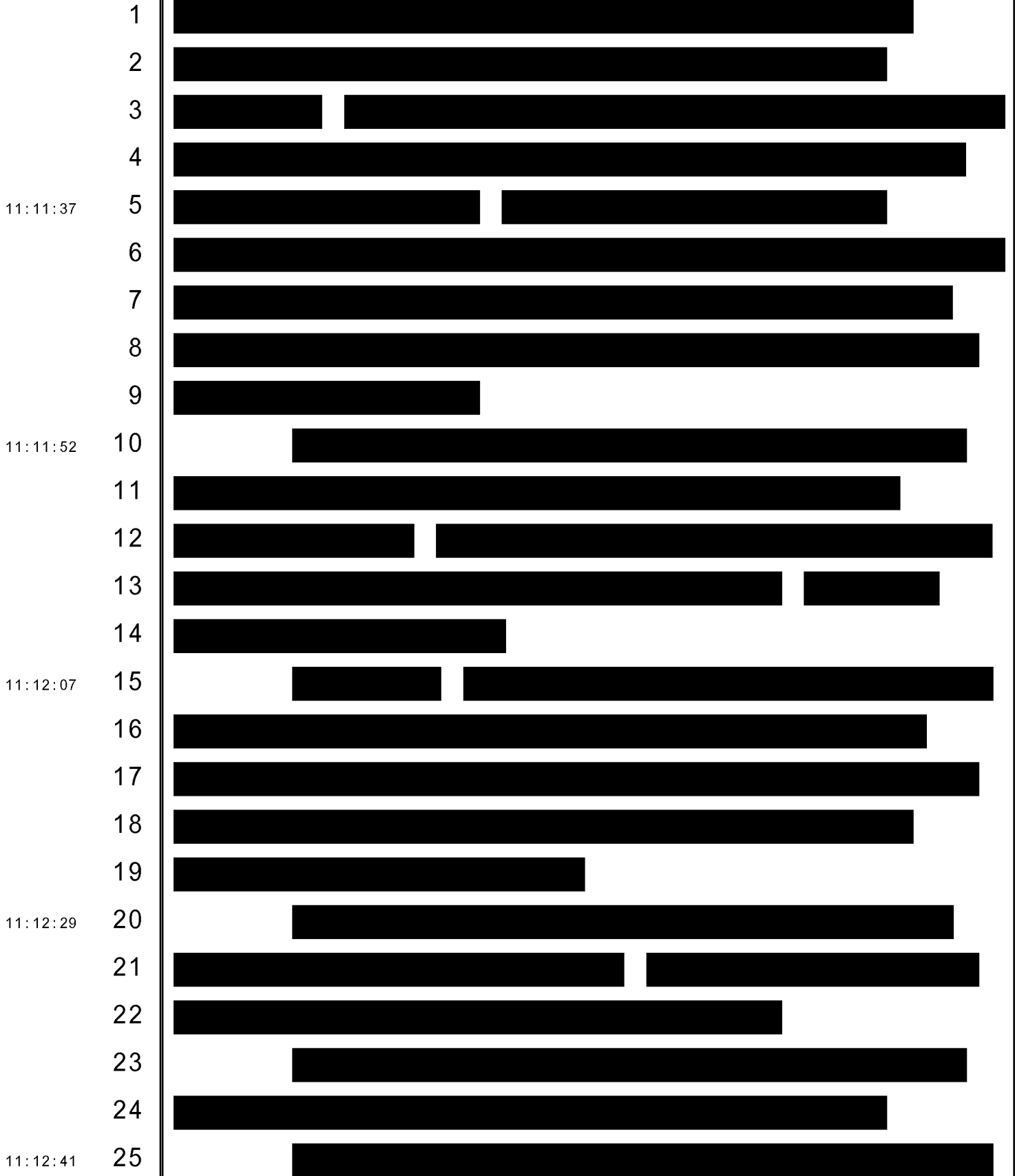
Healy - cross by Bayman

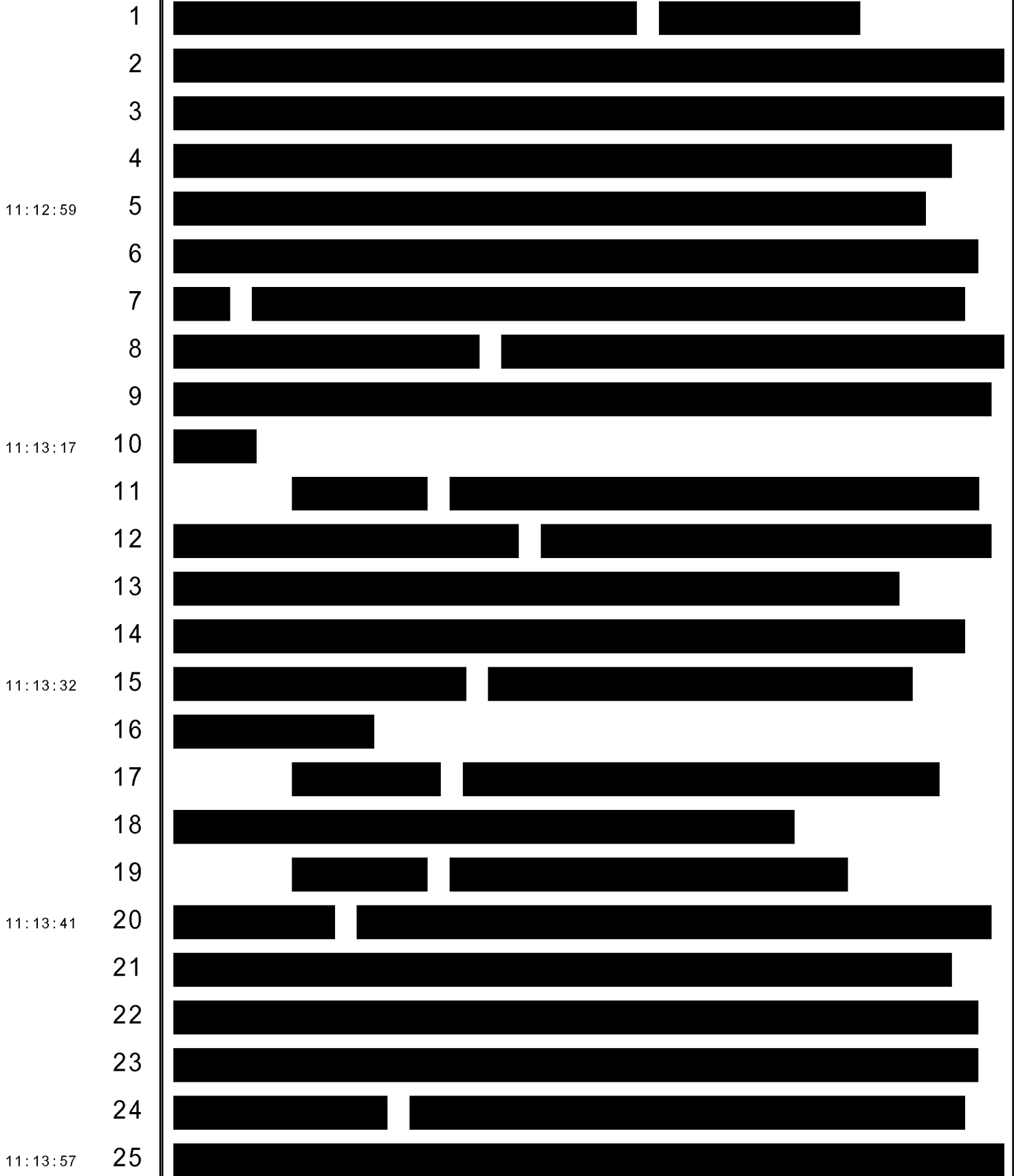
687



Healy - cross by Bayman

688





1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]

11:14:06

11:14:18

(The following proceedings were had in the presence of the jury in open court:)

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

11:15:27

You may proceed, sir.

MR. BAYMAN: Thank you, Your Honor.

BY MR. BAYMAN:

Q. Dr. Healy, when we took a break we were looking at the 1991 suicide report that you have -- do you still have that open?

11:15:49

A. Yes, I do.

Q. Tab 13, Plaintiff's Exhibit 78.

A. Yes.

Q. And we had --

11:16:01

MR. BAYMAN: Could you put that up again, Roger.

1 (Exhibit published to the jury.)

2 BY MR. BAYMAN:

3 Q. We're looking at this passage in the report. It goes on to  
4 state:

11:16:15 5 "10 suicides were committed by patients who had  
6 participated in the worldwide Paroxetine  
7 clinical trials. 5 suicides were committed by  
8 patients who were randomized to Paroxetine, 2  
9 were committed by patients randomized to  
11:16:33 10 placebo, and 3 were committed by patients  
11 randomized to other active control regimen."

12 Did I read that correctly?

13 A. Yes.

14 Q. And then looking down on that same page, if you look down  
11:16:46 15 to the fourth paragraph, do you see that?

16 A. Yes.

17 Q. GSK provides --

18 A. Well, it's actually the third paragraph, not the fourth,  
19 isn't it?

11:17:01 20 Q. My mistake.

21 A. Yeah.

22 Q. You've got the paragraph there, right?

23 A. Yes. Yes, I have.

24 Q. GSK provides FDA with additional data about the two  
11:17:10 25 suicides committed by patients on placebo, correct?



1 A. Yes.

2 Q. And GSK wrote:

3 "... of the two suicides committed by patients  
4 randomized .."

11:17:19

5 and "randomized" is in quotes, correct?

6 A. Yes.

7 Q. (Reading:)

8 "... to placebo, the method by which they took  
9 their lives was unknown. Although these

11:17:28

10 patients were participating in an active control  
11 study, the acts of suicide were committed during  
12 participation in the placebo run-in phase."

13 Do you see that, Dr. Healy?

14 A. I do, yes.

11:17:41

15 Q. So GSK told the FDA right here in this document that two  
16 placebo suicides in the Paxil clinical trials occurred during  
17 the run-in phase, correct?

18 A. They appear to have said that, yes.

19 Q. All right. And you also know that there are appendices to  
20 that report that also disclosed to the FDA when each of the  
21 suicides and suicide attempts occurred for the patients taking  
22 Paxil, correct?

11:17:57

23 A. Correct.

24 Q. Would you turn to appendix 1, which is the number at the  
25 lower, it's 227632.

11:18:11

1 THE COURT: 32?

2 MR. BAYMAN: Yes, sir. Same exhibit, Your Honor,  
3 that's the page number.

4 BY MR. BAYMAN:

11:18:34

5 Q. Are you with me?

6 A. Yes.

7 Q. Okay. And there are negative numbers in this chart of  
8 suicides in appendix 1 for two patients in the placebo column,  
9 correct?

11:18:49

10 A. Correct.

11 Q. And that reflects pre-baseline or run-in suicides, correct?

12 A. Yes; in trials that didn't have a placebo arm at all.

13 Q. Okay. If you would, Doctor, turn now to Defendant's  
14 Exhibit 6316 which is Tab 14 in your notebook.

11:19:12

15 A. Yes.

16 Q. You got that?

17 A. Yes, I do.

18 Q. You recognize that is the safety review for Paxil that was  
19 done by Dr. Martin Brecher of the FDA?

11:19:31

20 A. I do, yes.

21 Q. You are familiar with that document?

22 A. I am, yes.

23 MR. BAYMAN: Your Honor, I don't think this one has  
24 been admitted yet. I move for the admission of Defendant's  
25 Exhibit 6316, the FDA safety review.

11:19:51

1 MR. WISNER: Your Honor, we object to the admission of  
2 this document into evidence; although, we don't object  
3 presenting portions of it for the purposes of  
4 cross-examination.

11:20:01

5 THE COURT: All right. You may proceed.

6 MR. BAYMAN: Okay. Thank you.

7 BY MR. BAYMAN:

8 Q. If you would, let's turn to page 23 of the FDA's report  
9 which is page 28 of the exhibit. It's PAR 808105.

11:20:16

10 A. Give me a moment.

11 Q. Sure. Take your time.

12 (Brief pause).

13 BY THE WITNESS:

14 A. Yes.

11:20:24

15 BY MR. BAYMAN:

16 Q. If you look at the first full paragraph, last sentence, the  
17 FDA's report says:

18 "... 2 of the 5 placebo suicides occurred during  
19 the run-in."

11:20:39

20 Correct?

21 A. Correct.

22 Q. And then if you look down at the very bottom of that page,  
23 Dr. Brecher, from the FDA, identifies both of the two suicides,  
24 a 49-year old man and a 43-year old man who committed suicide  
25 during the placebo run-ins, correct?

11:20:53

1 A. Yes. This is a very hard page to interpret in ways,  
2 because you see the line just below that you haven't  
3 highlighted, there's some missing detail about the patient, as  
4 there is further up.

11:21:08

5 I mean, this is one of the difficult pages for a  
6 juror, for instance, if they were looking at this document and  
7 trying to figure out what is going on, and for me when I looked  
8 at it first. This is a difficult page, but yes, you're right,  
9 it does appear to identify to placebo suicides.

11:21:24

10 Q. So the jury is clear, this is the FDA's document, correct?

11 A. This is Martin Brecher's document. It's probably a mistake  
12 to say it's FDA's document. Dr. Brecher shortly afterwards  
13 applied for a job at GSK.

14 Q. Well, at the time he was working at the FDA, correct?

11:21:38

15 A. He was, yes.

16 Q. And just to be clear, the patients -- these patients that  
17 he identified, they were taking placebo, not Paxil when they  
18 committed suicide, right?

11:21:52

19 A. Well, they weren't taking placebo in the sense that most  
20 people would understand that. They were in a placebo run-in  
21 phase and they were given an inert pill, but they weren't  
22 taking placebo in the sense of being in the randomized arm of a  
23 trial.

24 Q. But they weren't taking Paxil?

11:22:05

25 A. They weren't taking Paxil. They may have been withdrawing

1 from other drugs.

2 Q. You would agree with me, though, that based on what you've  
3 seen, that there's no doubt that Dr. Brecher knew these 2  
4 suicides occurred during the placebo run-in period, correct?

11:22:24

5 A. Well, it's very difficult to know what Dr. Brecher  
6 understood. I know he's been deposed since, and even there,  
7 it's not clear that he makes clear what he understood then. So  
8 if you're asking me to interpret what he understood just then,  
9 I'm not the right person to doing it.

11:22:41

10 Q. Fair enough. He says that, thought, in the document,  
11 correct? We can agree with that?

12 A. Well, it's here in the document. I'm not sure he would  
13 have written all of this, but yes, it's here in the document.

14 Q. He signed it, correct?

11:22:52

15 A. He signed it, yes.

16 Q. And if you look, if you will on page 25 of that same  
17 document, which is PAR 808107, in the middle of the page.

18 A. Yes.

19 Q. He says:

11:23:12

20 "... although the instruments available may not  
21 be ideal to capture the elusive clinical events  
22 reported by Teicher in 6 patients..."

23 and we'll get to that later because you've talked  
24 about the Teicher article, correct.

11:23:26

25 A. Yes.

1 Q. (Reading:)

2 "... there is no signal in this large database  
3 that Paroxetine exposes a subset of depressed  
4 patients to additional risk of suicide, suicide  
5 attempts, and suicidal ideation."

11:23:37

6 Did I read that correctly?

7 A. Yes, you did.

8 Q. And turn, if you would, to the same report, page 21 to 22.

9 THE COURT: What number are you referring to now, sir?

11:24:04

10 Report page number?

11 MR. BAYMAN: Yes, sir. Yes, sir, the report.

12 THE COURT: Page 22?

13 MR. BAYMAN: Yeah, I'm going to ask him about 21.

14 THE COURT: Yes. Okay.

11:24:13

15 MR. BAYMAN: Thank you, Your Honor.

16 BY MR. BAYMAN:

17 Q. Are you with me?

18 A. I hope so.

19 Q. Okay. Dr. Brecher also reviewed the listings of people who  
20 dropped out of the trials and that's what he discusses on  
21 page 21 and 22 of the report, correct?

11:24:25

22 A. Well, I'm looking at the page that says "Deaths Medical  
23 Causes." 21, 22 down at the bottom, it seems 21 heading is  
24 "Deaths Medical Causes."

11:24:47

25 Q. Sorry. Look at page 20 and 21. Excuse me.

1 A. Okay.

2 Q. And if you look, it's PAR 808102.

3 A. Yes.

4 Q. It's -- I think the section is "significant adverse  
5 clinical events possibly attributable to Paroxetine"?

11:25:05

6 A. Yes.

7 Q. Okay. Dr. Brecher reviewed the case reports for those  
8 patients, did he not?

9 A. I don't know.

11:25:16

10 Q. Well, it says here the case reports were -- or the sources  
11 for the descriptions and serious adverse clinical events  
12 possibly attributable to Paroxetine, correct?

13 A. Yes.

14 Q. And at the end of the paragraph he writes:

11:25:34

15 "... there was no single occurrence of a serious  
16 unusual clinical event which was reasonably  
17 attributable to Paroxetine."

18 Did I read that correctly?

19 A. You did. And that would be extraordinary if it were the  
20 case, but that's what you read.

11:25:47

21 Q. Thank you.

22 Okay. Now, we talked a little before the break the  
23 analysis that GSK did in 2002 that excluded the run-ins that  
24 were not part of the control portion of the trial?

11:26:18

25 A. Yes.

1 Q. Okay. And GSK also included Paxil or Paroxetine events  
2 that were not part of the controlled phase of those clinical  
3 trials, correct?

4 A. Sorry, you're losing me slightly.

11:26:31

5 Q. Sure. In 2002 --

6 A. Yes.

7 Q. -- Defendant's Exhibit 38, which is Tab 11B in your  
8 notebook.

9 A. Yeah.

11:26:41

10 Q. We talked about that a little bit when we were doing the  
11 numbers, do you remember?

12 A. Yes.

13 Q. Okay. GSK also excluded Paxil or Paroxetine events that  
14 were not part of the controlled phase of the clinical trials,  
15 correct?

11:26:56

16 A. I hope so, yes, but I'm not absolutely certain about that,  
17 but I hope so.

18 Q. Well, let's look at, if you would, the third page of  
19 Defendant's Exhibit 38, which is PAR 10318.

11:27:20

20 A. Sorry, PAR 18 --

21 Q. 1817. The cover letter.

22 A. 1817. Yes. Okay.

23 Q. And the letter says what's being submitted, correct?

24 A. Yes.

11:27:47

25 Q. And I'm not going to read the entire thing for benefit of



1 the court reporter and it's on the screen, but it does say,  
2 does it not, that these are additional analyses from a review  
3 of the data regarding suicide attempts originally submitted May  
4 10, 1991, correct?

11:28:14

5 A. Yes.

6 Q. And it also says:

7 "... it is an analysis of attempts in  
8 placebo-controlled studies, patients randomized  
9 to Paxil versus those randomized to placebo."

11:28:32

10 Correct?

11 A. Yes.

12 Q. And please turn, if you would --

13 A. Well, just to be clear, I mean they're not giving all the  
14 suicides and all the suicide attempts that happened in their  
15 MDD trials, for instance, here.

11:28:44

16 Q. They're dealing with the ones just from the controlled  
17 portions of the clinical trials, correct?

18 A. I mean, they aren't actually including all of them.

19 Q. Well, Doctor, let's look at -- turn over to page which PAR  
20 ends in 822. The chart we looked at earlier.

11:29:06

21 A. Yes.

22 Q. That chart indicates that in placebo controlled trials  
23 there were only 5 attempts on Paroxetine versus one on placebo,  
24 correct?

11:29:28

25 A. Correct; except on much of the all placebo-controlled

1 trials included here, and I'm not sure that all the events from  
2 the trials that are included here are included in the table.

3 Q. That's 5 Paroxetine events out of 921 patients?

4 A. Correct.

11:29:45

5 Q. And one placebo event out of 554?

6 A. Yes.

7 Q. That's what it says, right?

8 A. That's what it says.

9 Q. It lists a P value of 0.42?

11:29:55

10 A. Well, it does, and for me that's irrelevant. 5 remains  
11 significantly greater than 1.

12 Q. Okay. And the difference between Paroxetine and placebo,  
13 that .42, that's not statistical significant, correct?

11:30:16

14 A. Well, as I've indicated here, I think, that's a  
15 misapplication of P values.

16 Q. We know your views on statistical significance.

17 A. Well, I'm not sure you do or you wouldn't have asked the  
18 question that you've asked but ...

19 Q. Just wanted to make sure I knew your position.

11:30:30

20 And, of course, then there's the box that points out,  
21 that we looked at earlier, about the 5 run-in attempts not  
22 being included, correct?

23 A. Correct. And I should add that it isn't just my view.  
24 It's Kevin Otsman and others.

11:30:42

25 Q. All right. I'm finished with that one, Dr. Healy.

1

2

MR. BAYMAN: May I approach?

3

(Document tendered.)

4

11:31:18

5

MR. WISNER: Your Honor, I object to this exhibit as argument.

6

7

THE COURT: I said no to this exhibit. I sustained the objection to it earlier.

8

9

11:31:25

10

MR. BAYMAN: This was in displayed to the jury during the opening statement, Your Honor, and there was no objection to it.

11

12

13

14

11:31:38

15

THE COURT: Well, I allowed in opening statement illustrative exhibits for purposes of argument, but this exhibit is not evidence, it's simply argument. So on the same basis that I previously sustained your objection, it's their exhibit which is similar in form and I sustained the objection.

16

17

MR. BAYMAN: Okay. I won't show it to the jury. I just want to ask him one question, Your Honor.

18

19

11:31:51

20

21

22

MR. RAPOPORT: Your Honor, forgive me, I need to put on the record that there was an agreement before the opening statements for either party to object to the demonstrative, that was not an agreement that anything was admissible and since Mr. Bayman --

23

24

11:32:01

25

THE COURT: Well, I've already ruled.

MR. RAPOPORT: No, it's not for a ruling, just for the record.

1 THE COURT: I'm much more liberal about this sort of  
2 thing in opening and closing, but not during the trial. It's  
3 not evidence.

4 MR. BAYMAN: I ask you just --

11:32:12

5 THE COURT: Just put the question, sir.

6 (Document tendered to the witness).

7 BY MR. BAYMAN:

11:32:25

8 Q. I asked you before the break, wasn't it true that there  
9 were Paxil indications, Paxil has some indications after 2002  
10 and you said you didn't know.

11 A. I didn't quite say I didn't know, I said I didn't have the  
12 answer at the time.

13 Q. Okay.

11:32:37

14 A. And I know that as of that point in time it was being  
15 turned down for indications.

16 Q. But it is true that Paxil was approved for SAD in 2003 and  
17 PMDD in 2004, correct?

18 A. Well, I think it was --

19 Q. By the FDA?

11:32:48

20 A. It didn't get approved for children. It may got approved  
21 for adults, it didn't get approved for children --

22 Q. I didn't ask about children, I asked about indications --

23 A. Well, you said SAD, and I now that for SAD in children it  
24 didn't get approved.

11:32:59

25 Q. Okay. It was approved for SAD, correct?

1 A. It was, yes.

2 Q. And PMDD?

3 A. It appears to have been, yes.

4 THE COURT: You're too sophisticated for me, anyway.

11:33:10

5 The jury knows what PMDD means, but I sure don't.

6 BY MR. BAYMAN:

7 Q. What's PMDD, Doctor?

8 A. It's what used to be called PDR PMS.

9 THE COURT: Which is?

11:33:22

10 THE WITNESS: Premenstrual dysphoric disorder, is what  
11 it stands for here.

12 BY MR. BAYMAN:

13 Q. And SAD is social anxiety disorder, correct?

14 A. Yes. Correct.

11:33:32

15 Q. I want to turn you now to a different topic. You remember  
16 you told the jury about relatedness or causality assessments  
17 made by clinical investigators?

18 A. Yes.

11:33:48

19 Q. And you told the jury when a clinical investigator says a  
20 patient's adverse experience is probably or possibly related to  
21 the drug, that's important information?

22 A. Yes. It is important information, yes.

23 Q. Okay. Turn, if you would, to Tab 30, which is Exhibit  
24 Defendant's 601.

11:34:21

25 THE COURT: I have Defendant's Exhibit 1197.

1 MR. BAYMAN: It's right beyond that, Your Honor.  
2 There's a tab A right after it.

3 THE COURT: Oh, yes. Okay. That's 601. Thank you.

11:34:35

4 MR. WISNER: Your Honor, I'm going to object to this  
5 document. It was specifically excluded in pretrial because it  
6 relates to European regulatory submissions.

11:34:49

7 MR. BAYMAN: Your Honor, this part is not the  
8 submission, it's a data analysis, done of the data. And  
9 Dr. Healy has talked about a lot of things that, frankly,  
10 happened in Europe, including his hospital. This is just a  
11 data analysis. This is not a submission.

12 THE COURT: Data analysis of whom?

13 MR. BAYMAN: The data analysis that the company did,  
14 Your Honor, of its data.

11:35:04

15 MR. WISNER: Your Honor, this is -- this is the  
16 European submission. This is Article 31. We didn't go into it  
17 on direct because you excluded it. I don't think it's  
18 appropriate to on to it on cross.

19 THE COURT: It is. Objection sustained.

11:35:27

20 BY MR. BAYMAN:

21 Q. You agree with me that -- I think you said, in fact, in  
22 your direct that because in a situation where the investigators  
23 are blinded, they make relatedness or causality assessments  
24 that something is probably related or possibly related,  
25 correct?

11:35:51

11:36:11

1 A. Well, it doesn't always happen when they're blinded. In  
2 Paxil trials, in the case of placebo suicidal event where the  
3 blind was broken, the investigator made the relatedness  
4 assessment after the blind was broken and said the placebo had  
5 caused the suicidal event.

6 Q. And there were also assessments made before the blind was  
7 broken when an investigator said placebo caused the suicide,  
8 correct?

11:36:22

9 A. Well, certainly in the trial that I'm thinking of where I  
10 have access to the raw data and know exactly what happened,  
11 then it was after the blind was broken, but there may well be  
12 trials, as you say, when that happened too.

11:36:38

13 Q. I don't want to talk to you about that trial, I just to  
14 ask, in your experience, you know that clinical investigators  
15 make relatedness assessments before the blind is broken and  
16 sometimes they say placebo caused the suicide, correct?

17 A. Correct -- well, hang on. And there isn't anything which  
18 says that which gives them the saying that placebo causes the  
19 suicide.

11:36:53

20 Q. I'm sorry. Was definitely related or probably related,  
21 correct?

22 A. There will be to some events certainly, yes.

23 THE COURT: What do we mean the blind is broken?

24 THE WITNESS: Well, in a double blind trial, Your

11:37:07

25 Honor, the doctor and the patient, neither of them know which

11:37:28

1 drug the person is on. And strictly speaking, when an adverse  
2 event happens, the relatedness coding should happen before the  
3 blind is broken, before the doctor, for instance, knows. And  
4 the ideal situation would be both the patient and the doctor  
5 making the relatedness kind of assessment because the patient  
6 may have a hunch about what they were on.

7 BY MR. BAYMAN:

11:37:42

8 Q. And sometimes before the blind is broken, investigators  
9 attribute an adverse event like suicidality to placebo,  
10 correct?

11:38:02

11 A. Well, it's a complicated one. As I've indicated to you,  
12 all sorts of things can happen. I mean, having done trials  
13 with SmithKline Beecham, what you've got is a monitor from the  
14 company standing beside you asking you to make a relatedness a  
15 segment often, and that's an interesting situation.

11:38:22

16 Q. The monitor doesn't know, though, one way or the other --  
17 A. Well, it's the kind of situation that leads to the doctor  
18 knowing the patient was on a placebo and then they can make a  
19 relatedness assessment that placebo had caused the suicidal  
20 act.

21 Q. Okay. I think we understand what you're saying and what  
22 you said on direct.

11:38:35

23 Now, you testified last week, in response to Mr.  
24 Wisner's question, that GSK's used sort of the preferred term  
25 "emotional lability" was a coding maneuver by which you claim



1 GSK hid suicidality in clinical trials, correct?

2 A. Well, yes, this term was used, and it did fool a lot of  
3 people, including the FDA, it would appear.

4 Q. Okay. Let's talk about that. I'd like you to look at  
5 Plaintiff's Exhibit 75 which is Tab 19 in your notebook.

11:38:55

6 You got that?

7 A. Yes.

8 Q. That is the Integrated Safety Summary for Paroxetine that  
9 you discuss with Mr. Wisner last week, correct?

11:39:23

10 A. Yes, I think so.

11 Q. And the document is dated, is it not, November 10, 1989?

12 A. Correct.

13 Q. And that's the document that GSK submits to the FDA as part  
14 of the formal New Drug Application when it's seeking to get a  
15 new drug approved?

11:39:44

16 A. Correct.

17 MR. BAYMAN: Your Honor, may I publish it?

18 THE COURT: You may go to whatever part you want to.

19 MR. BAYMAN: Yes. Exactly.

11:39:53

20 THE COURT: As distinguished from the entire document.

21 MR. BAYMAN: Yes. Yes, sir.

22 BY MR. BAYMAN:

23 Q. Turn to page 301 of the document, Dr. Healy. You see the  
24 numbers in the lower right-hand corner.

11:40:14

25 Are you with me?

1 A. Yes.

2 Q. Okay. There's -- that's the start of a section called  
3 Summaries of Suicide Attempts in U.S. Clinical Trials, correct?

4 A. Correct.

11:40:28 5 Q. Turn to page 2008A and look at the second listing, if you  
6 would.

7 MR. BAYMAN: We'll put that up.

8 THE COURT: 2?

9 BY MR. BAYMAN:

11:40:48 10 Q. 208A is down in the center.

11 It's sideways, Doctor.

12 A. Yes.

13 Q. So look in the right-hand column. Do you see 208A?

14 A. Yes.

11:41:01 15 Q. This is a report of a suicide attempt and below "adverse  
16 experiences the heading at the top says "suicide attempt,"  
17 correct?

18 A. Yes.

19 Q. If we could blow that up.

11:41:15 20 And we're going to have to go to the top, there's a  
21 column that -- there's some columns on the top.

22 It gives the patient number, it gives the adverse  
23 experience, and then it says "PT," that's preferred term,  
24 correct?

11:41:35 25 A. Correct.

1 Q. And so this indicates that the suicide attempt was coded  
2 and it was intentional overdose. It was coded to the preferred  
3 term of emotional lability, correct?

4 A. Correct.

11:41:51

5 Q. Okay. Let's look at the next page, 208B.

6 Look at the suicide attempt on that page. And again,  
7 we see the same thing. This document submitted to the FDA  
8 disclosed the suicide attempt was coded to the preferred term  
9 of emotional lability, correct?

11:42:24

10 A. Correct.

11 Q. And then look in your -- I want to show you another  
12 document that you used with Mr. Wisner, Tab 37.

13 MR. BAYMAN: Your Honor, that's Plaintiff's  
14 Exhibit 263.

11:42:50

15 (Brief pause).

16 BY THE WITNESS:

17 A. I don't recall this being used with Mr. Wisner, so I'm not  
18 sure if we're on the same number.

19 BY MR. BAYMAN:

11:43:01

20 Q. Well, he showed portions of the document.

21 A. Did he?

22 Q. Yeah.

23 (Brief pause).

24 MR. WISNER: For the record, that's Exhibit 263A.

11:43:10

25 MR. BAYMAN: Thank you.

1 BY THE WITNESS:

2 A. He did. Yes, he did.

3 BY MR. BAYMAN:

4 Q. He did, right?

11:43:15

5 A. Well, he may well have done, yes. Yes, okay.

6 Q. And I'm not going to -- believe me, I'm not going to take  
7 the jury's time wading through it, I just want to -- he showed  
8 you some portions of it, I want to show you some other parts of  
9 it.

11:43:30

10 A. Okay.

11 Q. Look, if you would, to page ending with PAR number 347126.

12 MR. BAYMAN: Your Honor, may I publish to the jury  
13 that page?

14 THE COURT: Yes.

11:43:42

15 MR. BAYMAN: The table. Thank you.

16 (Exhibit published to the jury.)

17 BY MR. BAYMAN:

18 Q. There's a table on -- are you there yet? I'm sorry.

19 A. Yes.

11:43:55

20 Q. There's a table entitled:

21 "... adverse events reported during GSK  
22 sponsored Paroxetine clinical trials in the  
23 aggregated clinical trial data as of 16 January,  
24 2006."

11:44:10

25 Do you see that?

1 A. Yes. Yes.

2 Q. And that has -- if we could blow that up, please.

3 (Brief pause).

4 BY THE WITNESS:

11:44:27

5 A. Am I --

6 BY MR. BAYMAN:

7 Q. Go down to the fifth entry, if you would.

8 A. Okay.

9 MR. BAYMAN: Let's highlight that.

11:44:38

10 (Brief pause).

11 BY MR. BAYMAN:

12 Q. Again, in the column for the a preferred term/verbatim  
13 term, which up at the -- the columns are up at the top, it  
14 lists the preferred term of emotional lability and a verbatim  
15 term of suicide attempt, correct?

11:44:56

16 A. That's correct.

17 Q. So it has both the preferred term and the verbatim term the  
18 report used, correct?

19 A. Yes, correct. This is an interesting document in which two  
20 Paxil suicide attempts seem to have gone missing, but apart  
21 from that ....

11:45:10

22 Q. I'm sure you are going to talk to your counsel about that.

23 Let's look at the next page, 347149.

24 I'm not going to belabor this. You see that there are  
25 multiple entries on this page where the preferred term is

11:45:41

1 emotional lability and the verbatim term is suicide attempt or  
2 overdose, correct?

3 A. Yes. And what translates over on to this spreadsheets the  
4 FDA would look at is emotional lability rather than suicide  
5 attempt.

11:45:58

6 Q. But this document was provided -- was submitted to the FDA,  
7 correct?

8 A. It may well have been, yes.

9 Q. And so we've seen, just in the last two documents, at least  
10 9 examples in which GSK identified to the FDA suicides coded to  
11 the term emotional lability, correct?

11:46:08

12 A. It is the case that if you get into documents like this and  
13 the jury, for instance -- as I keep saying, people like the  
14 jury could find out what was going on, the rest of the outside  
15 world couldn't. What exactly happened inside the FDA I'm not  
16 here to comment on.

11:46:27

17 Q. And I know I'm not asking you what FDA did with it. This  
18 was submitted to the FDA in this form, correct?

19 A. Yes.

11:46:43

20 MR. BAYMAN: You can take that down.

21 BY MR. BAYMAN:

22 Q. You talked on direct with Mr. Wisner about the phenomenon  
23 of SSRIs and other medications to cause violent suicide, do you  
24 remember that?

11:46:57

25 A. Yes, they can cause alcoholism as well, and that can lead

1 to violent suicide, but independent to alcoholism they can  
2 cause violent suicide.

3 Q. Do you consider yourself knowledgeable about the frequency  
4 of violent suicide as compared to nonviolent suicide?

11:47:14

5 A. Offhand, as I sit here, I haven't come today prepared to  
6 answer what the ratio between the two is.

7 Q. Would you agree with me that in the United States  
8 approximately 80 percent of all suicides by men ages 55 to 64  
9 were violent?

11:47:33

10 A. I would -- no, I wouldn't be happy to agree with you on the  
11 issue. I'm an expert, and I know I'm the kind of person who  
12 can go to the right kind of place to find the answer to just  
13 that question. Sitting here in the witness stand, I don't have  
14 it with me.

11:47:51

15 Q. Would you agree that the vast majority of suicides by men  
16 ages 55 to 64 are by violent means?

17 A. I don't know that I would agree with that. A term like  
18 "vast majority" is one that's open to a wide degree of  
19 interpretation.

11:48:08

20 Q. Where would one go to find the information that you said  
21 you would go look it up? Where would you go to do that?

22 A. Well, of course, these days you can go to Google and you  
23 can go to Google Academic as well and locate the articles on  
24 this issue. I mean, these things change. Over the years, the  
25 ratio between violent and nonviolent changes. It's not a fixed

11:48:25

1 thing. The rate in which men used to hang themselves 50 years  
2 ago might be quite different to the rate in which they hang  
3 themselves now.

11:48:41

4 So you want to look at -- I mean, if people are  
5 interested in what's happened this year or last, or perhaps  
6 what happened back when Mr. Dolin killed himself, you can get  
7 the data for that, but it's a variable thing.

8 Q. Hanging is a violent suicide event, correct?

9 A. It's fairly violent, yes.

11:48:55

10 Q. And another source, another organization that collects and  
11 reports that data is the Center of Disease Control in the  
12 United States, would you agree with that?

13 A. They certainly probably do collect data like that, yes.

14 Q. Now, I promised you that we'd get to this Teicher.

11:49:14

15 A. Uh-huh.

16 Q. You told the jury that when the Teicher article regarding  
17 that was fluoxetine or Prozac, correct?

18 A. Yes.

11:49:31

19 Q. When that came out, a lot of people, including companies,  
20 said well, those are just antidotes, correct?

21 A. A lot of response was that they would suggest antidotes,  
22 yes.

23 Q. And they're from what we call case reports, correct?

11:49:48

24 A. That may have been the kind of thing they said. Case  
25 reports at the time had much greater premium and proper case



1 reports in prestigious journals were highly regarded in 1990  
2 when that article came out.

3 Q. You would agree with me, wouldn't you, the case reports are  
4 an unreliable form of information?

11:50:05

5 A. No, I wouldn't necessarily agree with you on that at all.  
6 They include details of challenge, de-challenge and  
7 re-challenge they can be a very reliable form of information.

11:50:25

8 As I indicated under direct, FDA and the company  
9 involved have seen fit to say our drug causes a serious brain  
10 disease on the basis of three case reports. So, you know, it's  
11 knowing unreliable for information. The company that goes  
12 through the trouble of taking their drug off the market in case  
13 of case reports, they obviously think it's a very reliable form  
14 of information.

11:50:41

15 Q. So you're saying it depends on the context?

11:50:58

16 A. It depends on the quality of the reports. If you're  
17 talking about the nameless, faceless reports that appear in the  
18 media and things like that, if we're talking about reports  
19 stripped down, yes, but if we're talking about a report that a  
20 doctor makes when the patient perhaps has contributed to it  
21 also, and when you've got a number of reports made by a number  
22 of doctors with a number of patients contributing and they're  
23 saying we can't see any way to explain this other than the drug  
24 caused it, I think the legal system would come to a full stop

11:51:13

25 if that weren't fairly reliable.

1 Q. All right. Doctor, let's get back to what I was asking you  
2 about, which was case reports and specifically the Teicher  
3 article.

4 The Teicher article reported on some case reports,  
5 correct?  
11:51:25

6 A. The Teicher article reported on a series of 6 cases where 3  
7 different investigators faced with 6 different patients, among  
8 them, as I said, one of the most senior investigator in the  
9 United States at the time had concluded that the only way to  
10 explain what we were seeing here, and both patients and the  
11 doctors concluded, is that the drug has played a part.

12 Q. Okay. Let's, if you will, Mr. Wisner and Dr. Healy, Tab 36  
13 in your notebook. That's Defendant's Exhibit 7001.

14 This is article you wrote, correct?

15 A. It is, yes.  
11:52:25

16 Q. And it was published in 1994, correct?

17 A. Right.

18 Q. And in a publication called CNS Drugs?

19 A. Correct.

20 Q. And you're the only author, right?  
11:52:35

21 A. I am.

22 Q. And it's an article about fluoxetine or Prozac and suicide,  
23 correct?

24 A. Correct.

25 Q. Now, in 1994 you had not yet become involved in any  
11:52:42

1 litigation involving SSRIs and suicide, correct?

2 A. No, that's not correct.

3 Q. Okay. I thought -- I thought I heard last week that you  
4 first became involved in 1997.

11:53:02

5 A. 1997 was the first time I gave a view that Prozac had  
6 caused a person to become suicidal. The first time I came to  
7 Chicago was two years later after a man had taken Prozac and  
8 jumped off a building.

11:53:20

9 But in 1994 I offered a view in several cases that the  
10 drug had not caused a problem that people thought it had  
11 caused, and Lilly had consulted with me at that stage that the  
12 issue is linked to the drug on the basis of an article that  
13 I've written which was published in 1991, I believe.

11:53:38

14 Q. Fair enough. You had not yet expressed an opinion in the  
15 case that an SSRI caused a suicide in 1994?

16 A. Correct. I've done the opposite.

17 Q. Okay.

18 MR. BAYMAN: May I publish the article, Your Honor?

19 THE COURT: Yes?

11:53:53

20 MR. BAYMAN: Thank you.

21 (Exhibit published to the jury.)

22 BY MR. BAYMAN:

23 Q. This is the article we mentioned a minute ago, the  
24 fluoxetine and suicide controversy?

11:54:07

25 A. Yes.

1 Q. If you would, could you turn to page 227, which is really  
2 the fifth page of the article.

3 A. Okay.

4 Q. There's a section that starts databases versus case  
5 reports?

11:54:19

6 A. Correct.

7 Q. You wrote:

8 "... in reply to the case reports of fluoxetine  
9 induced suicidality. Beasley and colleagues  
10 scrutinized the Eli Lilly database for evidence  
11 of increased suicidality in patients receiving  
12 fluoxetine. No such evidence was found. These  
13 data from several thousand patients and the  
14 evidence that fluoxetine reduces suicidal  
15 ideation must, on any scientific scale, outweigh  
16 the dubious evidence of a handful of cases."

11:54:29

11:54:46

17 That's what you wrote, correct?

18 A. Well, you haven't read it correctly. If you read the whole  
19 article, I'm happy for you to give the entire article to the  
20 jury. They'll be under no illusions that I am being happily  
21 ironic here. The response from Lilly is "our control trials  
22 show no problem" when there was an infinitely increased risk of  
23 suicidal acts on Prozac compared to a placebo in their  
24 controlled trials at that time.

11:55:03

11:55:16

25 Q. So you were being ironic in a scientific journal?

1 A. Yes. Before in legal cases, it was the kind of thing you  
2 couldn't be. Irony doesn't work in to everyone in court.  
3 Lawyers don't like it.

4 (Laughter in the courtroom)

11:55:30 5 BY MR. BAYMAN:

6 Q. And, you, of course, can't --

7 A. I'm happy to give the entire article to the jury to read  
8 and so they can make up their own mind about what I've said.

11:55:48 9 Q. So you comment in the article about the Teicher case  
10 reports, correct?

11 A. I may have. I can't quite remember. You'll have to take  
12 me back to it.

13 Q. Well, how about just the first sentence?

14 A. Yes, that says that --

11:56:09 15 Q. If we could go back to the first page.

16 (Brief pause).

17 BY MR. BAYMAN:

18 Q. You're commenting in this article, in part, about the  
19 Teicher case reports we've talked about, correct?

11:56:25 20 A. Yes. And I go on to say the article reviews this and other  
21 evidence in an attempt to answer the question can Prozac lead  
22 to the emergence of suicidal ideation.

23 Q. Fair enough.

11:56:41 24 A. With a view to concluding that with the appropriate  
25 warnings, this is a problem that can be handled.

1 Q. With appropriate warnings this is a problem that can be  
2 handled?

3 A. That's what I say in 1994, that if, you know, the right  
4 warnings, if people are alerted to the fact that this drug  
5 doesn't suit everyone, both the doctor and the patient are  
6 going to get a much better conditions. This is, I think, the  
7 message I've been giving consistently and I'm sure the jury is  
8 tired of hearing it at this stage.

9 Q. Okay. If you would look, if you would, back on a page 227,  
10 I had you read the fifth page of the article, the section  
11 database versus case reports.

12 A. Yes.

13 Q. And if you go down further, go to the next -- the column --  
14 the second column on that page --

15 A. You don't want to have the second paragraph where it says,  
16 "with the right rating scales, the evidence would be much  
17 better"?

18 Q. No, I want the paragraph beginning "case reports."

19 A. Yes.

20 Q. You wrote:

21 "... case reports are clearly an unreliable form  
22 of information."

23 A. Yes. And I go on to say that several criteria have been  
24 proposed. And when criteria like that are built into reports  
25 like the Teicher report -- the American Journal of Psychiatry

1 wouldn't publish antidotes. They would want a report from a  
2 doctor to have the kind of criteria that we've outlined earlier  
3 about challenge, de-challenge and dose responsiveness and use  
4 of antidote to be built into the reports to make them  
5 scientifically reliable.

11:58:41

6 Q. Were you being ironic here when you said case reports are  
7 clearly --

8 A. Well, that one phrase yes, I was, but I go on to explain  
9 that I can't unpack it. That a simple report by a doctor I've  
10 seen a problem would carry some water, a report from a patient,  
11 in my book, will often carry a lot more water, but if you build  
12 criteria like challenge, de-challenge and re-challenge in there  
13 with dose titration, you know, if a low dose is out there but  
14 it emerges on a high dose --

11:58:54

15 THE COURT REPORTER: Doctor ...

11:59:06

16 THE COURT: Not so fast, doctor.

17 THE WITNESS: Sorry. If on a low dose the problem is  
18 not there, but if it emerges from the dose that is put up, and  
19 if an antidote can make a difference, these are the kinds of  
20 things that make case reports the most reliable kind of  
21 information we have.

11:59:27

22 In terms of GSK and Paxil, it was exactly those  
23 criteria that led them to conclude even in their  
24 healthy-volunteer studies that Paxil causes genital numbing and  
25 sexual dysfunction, for instance.

11:59:48

1 BY MR. BAYMAN:

2 Q. So it's your testimony that this article is not critical of  
3 the Teicher case reports?

4 A. This article is not critical of the Teicher case reports.

12:00:01

5 Q. Turn, if you would, to Tab 38, which is Defendant's  
6 Exhibit 1242, 1242.

7 Is this an article you've reviewed before?

8 A. It's an article I believe I've seen before, yes.

9 Q. Okay.

12:00:37

10 MR. BAYMAN: Your Honor, permission to publish that as  
11 a learned treatise under Federal Rule of Evidence 803-18.

12 THE COURT: Well, I think you haven't covered all the  
13 steps yet. He said he's seen it before.

14 MR. BAYMAN: I'm sorry. Pardon me.

12:00:53

15 BY MR. BAYMAN:

16 Q. This is an article in a journal called the European  
17 Archives of Psychiatry in Clinical neuroscience?

18 A. Yes, which is one that I haven't seen a hardcopy of it.  
19 It's also a supplement to the article, it's not as a journal.

12:01:09

20 It's not a journal, proper. It's likely not been  
21 peer-reviewed. Peer-reviewed articles are half -- articles  
22 that appear in a journal supplement are usually not  
23 peer-reviewed.

12:01:23

24 Q. You don't know one way or the other whether this is  
25 peer-reviewed?



1 A. I think it's -- I think it's high likelihood it was not  
2 peer-reviewed.

3 Q. Are you -- this is a consensus statement by the World  
4 Psychiatric Association, correct?

12:01:35 5 A. Well, no --

6 THE COURT: Wait. Wait.

7 BY THE WITNESS:

8 A. -- it's not a consensus --

9 THE COURT: Wait. Wait. You don't get into it. He  
12:01:37 10 hasn't accepted it yet as authoritative. You have to approve  
11 that first before.

12 MR. BAYMAN: That's what I was trying to do.

13 THE COURT: All right.

14 MR. BAYMAN: I'm not going to get into the article.

12:01:44 15 THE COURT: All right.

16 BY MR. BAYMAN:

17 Q. This is a consensus statement from the World Psychiatric  
18 Association?

19 A. No, it's not.

12:01:56 20 Q. It's not?

21 A. No.

22 Q. So you're familiar with it but you're not willing to say  
23 that this is authoritative, is that right?

24 A. I definitely don't think it is authoritative.

12:02:04 25 Q. Okay. That's fine. We'll move on then.

1           You mentioned just before we got into this about  
2 healthy volunteers.

3 A. Correct.

4 Q. And healthy volunteers studies. I want to ask you about  
5 that.

12:02:18

6           You talked some, in fact more than some, you talked at  
7 some length about the Paxil healthy volunteer studies that GSK  
8 performed?

9 A. Yes.

12:02:27

10 Q. And you mentioned there was a suicide by a patient in one  
11 of those studies, correct?

12 A. That's my understanding.

13 Q. Okay. And that was from the study 8678, is that right?

14 A. I'm not absolutely sure about the number.

12:02:47

15 Q. Volunteer number 23?

16 A. It may well be.

17 Q. Okay. You will admit, Dr. Healy, that not a single health  
18 volunteer in your reviews of the paraxanthine healthy volunteer  
19 data committed suicide or made a suicide attempt while on

12:03:11

20 Paroxetine or Paxil, correct?

21 A. Ah, I -- that is probably, correct.

22 Q. Okay. Turn, if you would, to your deposition notebook. I  
23 want you to turn to tab H.

24           (Brief pause).

12:03:48

25 BY MR. BAYMAN:

1 Q. Have you got it?

2 A. Yes, I do.

3 Q. At page 187, Line 1 through 10 --

4 A. If you would give me just a moment to get there.

12:04:03

5 Q. Sure. Take your time.

6 (Brief pause).

7 BY THE WITNESS:

8 A. Yes.

9 BY MR. BAYMAN:

12:04:16

10 Q. You were asked by Dr. Healy:

11 "... you will admit that not a single healthy

12 volunteer in your reviews of the Paroxetine

13 healthy volunteer data committed suicide or made

14 suicide attempt while on Paroxetine, correct?"

12:04:28

15 A. Correct.

16 Q. Your response was:

17 "I know of none."

18 Correct?

12:04:40

19 A. Well, hang on a second. That's not my response. My

20 response is "that is correct" and then you go -- then I

21 respond, "none are recorded." "So you know of none?" And I

22 know of none, that's on the question on Paxil. And -- on

23 Paxil, "on" being the key word.

24 Q. Okay. Well, let's see if we can cut through this. No

12:05:01

25 healthy volunteer was reported to have committed suicide while

1 taking Paroxetine, correct?

2 A. No healthy volunteer -- in these brief often one-day  
3 trials, no healthy volunteer committed suicide on the day they  
4 took one Paxil pill. Later in slightly longer trials, they had  
5 a range of disturbances that may have included suicidal  
6 ideation neither you nor I know, but there doesn't appear to  
7 have been a recorded suicidal act on Paxil.

12:05:19

8 Q. And there is no healthy volunteers reported to have  
9 attempted suicide in healthy volunteer trials while taking  
10 Paroxetine or Paxil?

12:05:38

11 A. Well, first of all, the healthy volunteer trials that I  
12 haven't had a chance to look at, okay. I've seen a selective  
13 set that were said to have been done before the trial comes on  
14 the market. So I can't be absolutely sure. From the trials  
15 that I have seen, there's no recorded suicidal act on Paxil.

12:05:54

16 Q. Fair enough. Fair enough. You can only comment on what  
17 you've seen and I should've said that.

18 In a healthy volunteer trial data that you've seen, no  
19 healthy volunteer committed suicide within 30 days of stopping  
20 Paxil or Paroxetine, correct?

12:06:12

21 A. Well, as I understand it from the Tobin trial, it was  
22 longer than 30 days.

23 Q. In fact, it was 90 days after stopping?

24 A. I don't know whether it was 90 days or not. I think -- my  
25 understanding was, it was less, but ....

12:06:29

1 Q. Well, I want to go, let's look at -- let's look at again  
2 tab H.

3 A. Tab H from which book?

4 Q. I'm sorry. From the depositions.

12:07:02

5 A. Yeah.

6 Q. Look at -- I'll have you turn to page 195.

7 A. Yes.

8 Q. You were asked at Line 21:

12:07:34

9 "... okay. And, in fact, didn't volunteer 23  
10 commit suicide 3 months after completion of the  
11 study?"

12 And your answer was, "yes," correct?

12:07:44

13 A. That appears to be the answer there. I'm not sure what  
14 basis for it was because I'm not sure that I knew it was  
15 3 months, but the basis for what's just above it was had a  
16 healthy volunteer who was actively suicidal 2 months after an  
17 SSRI. So this was not inconceivable.

18 Q. Well, my question was as to the Paxil healthy volunteers,  
19 I'm not talking about --

12:08:01

20 A. That's correct.

21 Q. Do you understand that?

22 A. Yes, I do. Yes.

23 Q. All right. And then, in fact -- do you have your Dolin  
24 report up there?

12:08:10

25 A. I can find it.

1 (Brief pause).

2 BY MR. BAYMAN:

3 Q. It's actually Tab 1.

4 A. Yes.

12:08:47

5 Q. And I want to turn to appendix 1, page 90.

6 A. Ah, okay, I'm getting this slowly.

7 THE COURT: You want to give the doctor the exhibit  
8 number?

12:09:26

9 MR. BAYMAN: Your Honor, I'm sorry. The exhibit is  
10 Plaintiff's Exhibit 252. It's his expert report.

11 THE COURT: I understand that, but if you don't refer  
12 to the exhibit number, the record isn't going to show what  
13 we're talking about.

14 MR. BAYMAN: Yes. Yes, sir. Sorry.

12:09:36

15 THE COURT: Page 90?

16 MR. BAYMAN: Yes.

17 BY THE WITNESS:

18 A. Yes.

19 BY MR. BAYMAN:

12:09:42

20 Q. You talked about, you said, and I wasn't testing your  
21 memory, you didn't recall whether that was study 6/78. Now  
22 looking at your report, have you had a chance to refresh your  
23 recollection?

12:10:04

24 A. I'm not sure I have had a chance to reflect -- to -- ah, to  
25 refresh my recollection. The original report talks about these

1 where trials were taking place at a gastrointestinal unit  
2 because of SmithKline Beecham was interested in GIT drugs. It  
3 was not healthy volunteer trials that were being undertaken by  
4 a person like me who might've even inquired for more about  
5 people becoming suicidal.

12:10:31

6 Q. Okay. But appendix 1, page 51, the title of it is  
7 SmithKline Beecham's Healthy Volunteer Studies With Paroxetine?

8 A. Yes.

9 Q. Prepared by David Healy, right?

12:10:41

10 A. Yes.

11 Q. And then on page 90 there is a discussion of the healthy  
12 volunteer suicide we've been talking about, correct?

13 A. Well, you'll have to point me to exactly the spot you want  
14 me to look at.

12:10:51

15 Q. At the very bottom of page 90.

16 A. Yes.

17 Q. It says:

18 ".... volunteer 23, suicide 3 months afterwards."

19 Doesn't it?

12:10:59

20 A. It does, yes.

21 Q. Thank you.

22 Now, the authors of the study report, and you've  
23 reviewed the study report for study 86/78, correct?

24 A. I certainly have. This was under rushed circumstances for  
25 the Tobin trial when I had access to SmithKline Beecham's

12:11:17

1 archives of healthy volunteer studies.

2 My recollection of this particular event is primarily  
3 shaped by Charles --

12:11:34

4 MR. BAYMAN: Your Honor, we're talking about other  
5 trials now.

6 THE COURT: Let's not refer to other cases, Doctor.

7 THE WITNESS: Okay.

8 THE COURT: We've got enough work here.

9 BY MR. BAYMAN:

12:11:42

10 Q. The authors of the study report for study 86/78 determine  
11 wrote that suicide was not considered to be related to the  
12 Paroxetine treatment, correct?

12:11:58

13 A. They may well have done that. I have to see the names of  
14 the authors, I have to see the article, but they may very well  
15 have to done that, yes.

16 Q. And --

17 A. As I explained, they were largely doctor people rather than  
18 mental healthy being who were doing these trials.

12:12:13

19 Q. Look at, if you would, Tab 21 which is Defendant's  
20 Exhibit 355.

21 Do you see that? That's the study report, is it not?

22 A. Final report, yes.

23 Q. Uh-huh. Study for 86/78, correct?

12:12:41

24 A. Well, hang on a second. I'm on Tab 21. Final report of --  
25 I can't see the study number here offhand, but I assume you're



1 right.

2 Q. Look at the lower right.

3 A. Yes. Yes, you're right. Yup.

4 MR. BAYMAN: Your Honor, may I publish this to the  
5 jury?

12:12:52

6 THE COURT: 355?

7 MR. BAYMAN: Yes, sir.

8 (Exhibit published to the jury.)

9 MR. BAYMAN: Blow that up, will you, and then go down  
10 to the lower right.

12:13:01

11 BY MR. BAYMAN:

12 Q. Just showing the jury, doctor, where you and I were  
13 looking.

14 A. Yeah.

12:13:06

15 Q. And then turn, if you turn, to page 10, and there's a  
16 column there, a summary column. And there's -- you see one on  
17 death in the middle?

18 A. Give me one moment.

19 Q. Sure. Take your time.

12:13:24

20 A. Give me one moment. Actually there's a lot of missing  
21 pages here, for start. But go on, yes.

22 Q. I just want to take you to this relevant one.

23 A. Okay.

24 Q. (Reading:)

12:13:38

25 "... the study authors a report that no deaths

12:13:51

1 reported during the study. However, volunteer  
2 23 committed suicide 3 months after the  
3 completion of the study. This was not  
4 considered to be related to the Paroxetine  
5 treatment."

6 Did I read that correctly?

7 A. You did. And I know the author of the report and he had no  
8 mental health experience that I know of.

12:14:04

9 Q. So is it your view that this suicide 90 days after the  
10 person was taking Paroxetine was related to Paroxetine?

12:14:25

11 A. Well, I think in the light of other healthy volunteer  
12 material we have where you might, in this early healthy  
13 volunteer trial I thought possibly no link, in the light of  
14 what we now know about withdrawal that can be linked to Paxil  
15 and in the light of other healthy volunteer studies that have  
16 been published, people might --

17 MR. BAYMAN: Your Honor, you've removed withdrawal  
18 from this case. We talked about it this morning. That was the  
19 subject of the motion in limine.

12:14:36

20 MR. WISNER: Your Honor --

21 MR. BAYMAN: Withdrawal and discontinuation of  
22 litigation.

12:14:49

23 MR. WISNER: He's asking how after discontinuing it 3  
24 months it could be related to suicide. He opened the door to  
25 withdrawal and he's explaining his answer.

1 THE COURT: You may answer.

2 BY THE WITNESS:

12:14:57

3 A. Yes. I think in the light of what we know now and in the  
4 light of GSK's clinical trial data on the facts that happened  
5 after treatment ends, someone like Dr. Ratlich would be much  
6 less sure about his judgment, judgment call.

7 BY MR. BAYMAN:

8 Q. So you believe then that that suicide 90 days later was  
9 caused by taking --

12:15:10

10 A. No, I'm not saying that. I hope the jury don't pick that  
11 up. What I'm saying is there are grounds to be concerned about  
12 the effects of these drugs and I don't think just because you  
13 come up to the magic figure of 90 days, and it probably wasn't  
14 90 days, then that that gives you a clear pass, and I just  
15 don't see it there in light of everything else we know.

12:15:31

16 Q. Well, the study report says it was 90 days, right?

17 A. This is 1985, before the drug was on the market. Dr.  
18 Ratlich is still thinking it might be a GIP drug. SmithKline  
19 Beecham aren't sure they're going to bring it on the market as  
20 an antidepressant at this stage. This is in the very early  
21 days.

12:15:48

22 Q. So that impacts his ability to count how many days it was  
23 after --

12:15:56

24 A. No, no, but it in terms of the judgment he's making about  
25 whether it's likely to be a link or not, that certainly impacts

1 his ability to be able to make a judgment call that, you know,  
2 that there is a thing here that might need to be explained  
3 further.

12:16:11

4 Q. You've -- you've published about healthy volunteer studies,  
5 have you not?

6 A. Yes.

7 Q. Okay. I want to turn you now to Defendant's Exhibit 7002,  
8 Tab 37B.

9 THE COURT: Exhibit number?

12:16:33

10 MR. BAYMAN: 7002, Your Honor.

11 BY MR. BAYMAN:

12 Q. Got that?

13 A. Yes, I have.

12:16:56

14 Q. That's an article entitled Emergence of Any depressant  
15 introduced Suicidality written by you, correct?

16 A. Correct.

17 Q. And you published that in 2000, correct?

18 A. Correct.

19 Q. And that was published in Primary Care Psychiatry, correct?

12:17:11

20 A. Correct.

21 MR. BAYMAN: Your Honor, may I have permission to  
22 publish to the jury?

23 THE COURT: Yes.

24 MR. BAYMAN: Thank you.

12:17:15

25 (Exhibit published to the jury.)

1 BY MR. BAYMAN:

2 Q. And this article discussed the healthy volunteer study that  
3 you were involved in that studied two medications, Sertraline  
4 and Zoloft and non-SSRI called reboxetine?

12:17:32

5 A. Yes, this is one of two articles. There's also a book  
6 chapter on this particular study. So it's not the only source  
7 of information.

8 Q. Thank you for that clarification.

9 The study had 20 patients in it, correct?

12:17:43

10 A. It didn't have 20 patients. It had 20 doctors and nurses;  
11 members of the jury, you know, healthy volunteers.

12 Q. Okay. So let me clarify that. By that, when you say  
13 doctors and nurses, those weren't doctors and nurses tending to  
14 the patients, those were doctors and nurses who were actually  
15 in the healthy volunteer study?

12:18:02

16 A. These were doctors and nurses, mental health staff who were  
17 interested in what these drugs do and volunteered to be part of  
18 the study.

19 Q. So the doctors and nurses were taking the medications.

12:18:17

20 A. They were given one of the two drugs, whether -- given each  
21 of the two drugs.

22 Q. Okay. I want to turn you to page 24, there's a section  
23 called Methods.

24 A. Yes.

12:18:30

25 Q. It says:

1 "... 20 healthy volunteers, aged between 28 and  
2 52, with a mean age of 37.8 years, were  
3 recruited to a study comparing reboxetine with  
4 Sertraline on a range of personality,  
5 self-report and quality of in life measures.  
6 The study was aimed at establishing the effects  
7 of antidepressants."

12:18:55

8 Did I read that correctly?

9 A. Yes.

12:19:06

10 Q. Okay. And in the article, at page 24, still on page 24,  
11 you represented that all volunteers were free of medical  
12 conditions, none were on concurrent drug treatment?

13 A. Yes.

12:19:27

14 Q. And none had a history of previous psychiatric illness,  
15 correct?

16 A. Correct.

12:19:44

17 Q. All right. And then under the Method section, that first  
18 paragraph, third to the last sentence, that's where you  
19 indicate that in the article, correct, that they were what we  
20 just put up? That's where it is in the article, under Methods,  
21 correct?

22 A. Yes.

12:19:57

23 Q. You had a rigid rule not to allow anyone in the study to be  
24 taking medication except for oral contraceptives because you  
25 didn't want any of the subjects to be taking any pills of any

1 kind for any physical or psychological condition because you  
2 didn't want another -- you didn't want the confounding factor  
3 of another medicine to affect the results, true?

4 A. True.

12:20:14

5 Q. But one of the subjects in the study was taking a four mask  
6 which is not an oral contraceptive?

7 A. Can you point me to what?

12:20:34

8 Q. I'm asking you if you recall that. You testified that one  
9 of the studies subjects in the study was taking Efformast which  
10 was not an oral contraceptive, true?

11 A. Sorry, can you point me to the spot?

12 Q. I'm just asking you if you recall that.

12:20:36

13 You've testified that one of the studies -- one of the  
14 subjects in the study was taking Efformast which is not an oral  
15 contraceptive?

16 A. I'm not sure I testified to that. I definitely have all  
17 the records from the healthy volunteer studies and maybe I have  
18 testified to it, but you'll have to even spell the name of the  
19 drug for me because this was 20 years ago so I can't  
20 necessarily agree with you straight off.

12:20:47

21 Q. Okay. Let's start with the spelling.

22 A. Yeah.

23 Q. E-f-f-o-r-m-a-s-t.

12:21:05

24 A. Okay. Do you happen to know which of the healthy  
25 volunteers was actually taking this?

1 Q. I'll get that when we break.

2 So sitting here today you don't recall that one of the  
3 subjects was taking a Efforemast which is not an oral  
4 contraceptive, is that right?

12:21:26

5 A. I haven't come here today fully brief on the details of a  
6 trial that happened 20 years ago, so I can't answer to every  
7 single thing, no, but I may agree with you. You may be able to  
8 provide me with testimony much closer into the event than we  
9 are now.

12:21:41

10 Q. Doctor, I understand that, that you can't remember  
11 everything you testified every place, but you did on direct  
12 examination talk to the jury about your healthy volunteer  
13 experience, including with Zoloft and sertraline, correct?

14 A. Yes, that's correct.

12:22:01

15 Q. Okay. Doctor, if you will, turn in your testimony  
16 notebook.

17 A. Okay.

18 Q. Tab 0 -- Tab 0, excuse me.

19 A. Tab?

12:22:30

20 Q. Tab 0, excuse me.

21 A. Okay.

22 Q. You got it?

23 A. Yes.

24 Q. Turn to page 311, if you would, Line 3.

12:22:56

25 A. Yes.



1 Q. Do you see that?

2 And you asked me, I said I would try to see if I could  
3 find it.

4 A. Hmm. Well done.

12:23:02

5 Q. The question is:

6 "... the truth is, Dr. Healy, that one of the  
7 subjects named --"

12:23:10

8 MR. WISNER: Your Honor, this is a refreshing  
9 recollection. I don't believe reading the testimony is  
10 appropriate.

11 THE COURT: That's right. You use it to refresh  
12 recollection. Just show it to the witness and ask him if it  
13 refreshes his recollection. At this time it does not come into  
14 evidence in this case.

12:23:20

15 BY MR. BAYMAN:

16 Q. Does that refresh your recollection.

17 THE COURT: You're on page?

18 MR. BAYMAN: 311, Line 3.

19 BY MR. BAYMAN:

12:23:26

20 Q. Does that refresh your recollection that there was a  
21 patient named Margaret Harris who was taking Efformast?

22 A. Yes, it does.

23 Q. And Efforemast is not an oral contraceptive, correct?

24 A. That's correct.

12:23:40

25 Q. Okay. And there was another patient taking a medication

1 called Arthrotec, A-r-t-h-r-o-t-e-c.

2 A. Yes. Correct.

3 Q. And that's not an oral contraceptive?

4 A. That's correct. Neither of these patients were the  
5 patients who became suicidal on the SSRI.

12:23:57

6 Q. And another --

7 A. They aren't patients of healthy volunteers, remember. And  
8 neither of them were healthy volunteers who became suicidal on  
9 an SSRI.

12:24:09

10 Q. Thank you for --

11 A. Maybe these pills were protective.

12 Q. Thank you for that correction.

13 Another healthy volunteers was taking Disprins, did I  
14 pronounce that correct?

12:24:16

15 A. Yes. That's an aspirin.

16 Q. That's what we call an inset and nonsteroid?

17 A. That's correct, yes.

18 Q. That's not an oral contraceptive?

19 A. No, it's not.

12:24:27

20 Q. And so you told your scientific colleagues in the article  
21 that none of the patients were on concurrent medications, you  
22 later had to admit that that was not, in fact, true, correct?

23 A. Well, let's be clear here. First of all, this is me  
24 volunteering the information, Pfizer didn't have it otherwise.

12:24:47

25 And secondly, the point is you're looking

1 over-the-counter medications principally, you're not talking  
2 about prescription medications. I think when I wrote the  
3 article, I would've been referring to people not being on  
4 prescription medications.

12:24:59

5 Q. Arthrotec is a prescription medication, is it not?

6 A. I don't know that -- I don't know that it is in U.K. or was  
7 then.

8 Q. I'm sorry, Efforemast.

12:25:07

9 A. Yes, that may -- I honestly don't know. This is the only  
10 person that I've ever met who was taking this. There may be  
11 lots of other people that take it.

12 Q. So it's not correct that none of the patients were on  
13 concurrent medications, correct?

12:25:26

14 A. We it may be correct that none of them were on concurrent  
15 medication. It may be the case that what you've got in the  
16 case of these health volunteers, that during the course of a  
17 6-week trial that they took medications at one point or  
18 another, that's correct.

12:25:44

19 Q. Your published article we saw earlier also represented that  
20 none of the subjects in the study had a history of psychiatric  
21 illness, true?

22 A. That's correct, yes.

23 Q. Okay. You since submitted that's not true, correct?

24 A. I don't know that I have? Have I?

12:25:53

25 Q. Okay?

1 A. I suspect you are going to try and persuade me that I have,  
2 but let's see. Let's see if we agree at the end, yes.

3 Q. Look at page 312. Same tab.

4 A. Yes. Okay. Same page even, almost.

12:26:13

5 Q. Almost.

6 A. Yes.

7 Q. It actually --

8 THE COURT: No, wait. He gets to read the page and  
9 then you put questions to him.

12:26:25

10 MR. BAYMAN: Sure.

11 (Brief pause).

12 THE COURT: Let us know when you have read the page.

13 (Brief pause).

14 BY THE WITNESS:

12:26:54

15 A. Yes.

16 BY MR. BAYMAN:

17 Q. If you would, I think one of the questions that carried  
18 over from the previous page, why don't you go look at the  
19 bottom of 311, Line 22, that's where the questioning starts.

12:27:06

20 A. Yes.

21 Q. I just want to make sure you had a chance to read that.

22 A. Yup. Yup. I have.

23 Q. So my question was, you've since admitted that that  
24 representation, none of the subjects in the study had a history  
25 of previous psychiatric illness was not true, correct?

12:27:26

12:27:44

1 A. Well, it is, it became clear to us afterwards when we  
2 investigated the healthy volunteers in greater detail that one  
3 of them had a prior history of being depressed. I don't know  
4 that they ever got treatment -- well, actually they did get  
5 treatment with an antidepressant and did well on an SSRI, and  
6 this was not one of the subjects that -- that became suicidal.

7 I mean, it just shows that you can't depend on doctors  
8 and nurses to tell the truth.

9 Q. Well --

12:27:59

10 A. But it also makes clear what I said here, I have an  
11 independent person do the examinations. I didn't examine the  
12 healthy volunteer who went into the study. I had a totally  
13 independent person do that.

14 Q. But you were asked and that was also false, wasn't it?

12:28:13

15 A. Well, as I say very clearly, it was not false. It's not  
16 false in the sense that I was being untrue. I mean at the  
17 point the statement was made, what you've got is we took -- we  
18 kept very detailed records. And after the published article,  
19 because these became -- I mean, this sort of particular trial  
20 became a very interesting trial, I went back and scrutinized  
21 the records in more detail and I am the one that found that  
22 detail which had been overlooked.

12:28:34

23 Q. And you were asked, that was not in your published article,  
24 was it?

12:28:48

25 A. And that's why I'm saying I wasn't informed, because I gave

1 the truth as I understood it at that time. And I made clear  
2 that in all publications since that I've laid out the position.

3 Q. And, in fact, the patient wrote on her past medical  
4 history, concurrent medical history form, that she suffered  
5 from depression, correct?

12:29:04

6 A. Yes. It appears she did, yes.

7 Q. And that -- and by indicating that that should've triggered  
8 an automatic exclusion from your study, but it didn't, correct?

9 A. It didn't, that's correct.

12:29:19

10 Q. And it should have, correct?

11 A. Yes, it should.

12 Q. Neither you nor anybody else obtained medical records or  
13 spoke to any of the doctors that treated any of these 20  
14 subjects, correct?

12:29:31

15 A. That's correct.

16 Q. Of the --

17 A. Actually, we did inform -- my recollection is, we did  
18 inform all of the doctors who were looking after all of the  
19 patients in this particular study, both before and after, and  
20 would've asked them to let us know if there were any relevant  
21 medical details.

12:29:48

22 Q. But you didn't obtain medical records or speak to any of  
23 the doctors who were treating the healthy volunteer subjects in  
24 the study, that's my question.

12:30:03

25 A. I'm not sure how it would be particularly relevant. The

1 issue here is trying to maintain blinding, and things like  
2 that. It was important that I didn't know what anyone was  
3 actually taking.

12:30:18

4 Q. Well, it's important because of the 20 subjects in the  
5 study, the documents from the study showed that 12 of the 20  
6 had nothing completed on their documents as to whether a mental  
7 state examination had been done on these subjects before the  
8 study started, correct?

9 A. I don't know that that is correct.

12:30:32

10 Q. All right. Let's turn, if you would, to the same  
11 transcript.

12 A. Uh-huh.

13 Q. Page 316, starts at Line 21, and then it goes to 317, line  
14 8. I'll give you a chance to read that.

12:30:49

15 (Brief pause)

16 BY THE WITNESS:

17 A. Yes.

18 BY MR. BAYMAN:

19 Q. You were asked:

12:31:08

20 "...and truth of the matter is, Dr. Healy, you  
21 have the documents right in front of you, of the  
22 20 subjects the box for yes, whether the mental  
23 state examination --"

12:31:17

24 MR. WISNER: Your Honor, I'm sorry. Is this a  
25 refresher or are we impeaching?

1 MR. BAYMAN: I'm impeaching.

2 BY THE WITNESS:

3 A. And I'm happy to take the question.

4 THE COURT: Proceed.

12:31:26

5 BY MR. BAYMAN:

6 Q. (Reading:)

7 "... of the 20 subjects, the box for yes,  
8 whether a mental state examination was done is  
9 checked for only 8 of the 20 subjects, true?"

12:31:38

10 And your answer was:

11 "Yes, but you see the treating, the physician  
12 looking after the healthy volunteer, there was  
13 no onus on them to do a mental state on those  
14 patients, on those volunteers, because they were  
15 all going to be screened later with detailed  
16 personality screening. So we could have a  
17 situation where all 20 boxes have been left  
18 unmarked and I don't think that would really  
19 change the position."

12:31:52

12:32:02

20 Did I read that correctly?

21 A. That's correct, you did. And let me explain to you and to  
22 the jury, what you're looking at is we were using a per forma  
23 set of questionnaires of pre-health screening. And this was  
24 done for patients who enter respiratory drug trials and cardiac  
25 drug trials, and all sorts of other trials. There's a lot of

12:32:22



1 other physical information at the start that was irrelevant to  
2 healthy volunteers.

12:32:35

3 So from that point of view, given in particular that  
4 it was very detail screen throughout this study, all of our  
5 healthy volunteers filled up multiple mental health questions,  
6 personality inventory and others. The fact that that  
7 particular box was left unchecked, as I say, if it had been  
8 left unchecked of all 20 subjects, it would've made no  
9 difference.

12:32:50

10 Q. Well, you mentioned earlier that what was important was the  
11 two subjects who you claim became suicidal after starting  
12 Zoloft. In fact, one of those subjects left the mental  
13 examination screening form blank and the other it was marked  
14 that it was not done, correct?

12:33:05

15 A. Correct.

16 THE COURT: All right. So we will break now until  
17 1:35.

18 MR. BAYMAN: Thank you, Your Honor.

19 THE COURT: It's now 12:35.

12:33:19

20 (The following proceedings were had out of the  
21 presence of the jury in open court:)

22 [REDACTED]

23 [REDACTED]

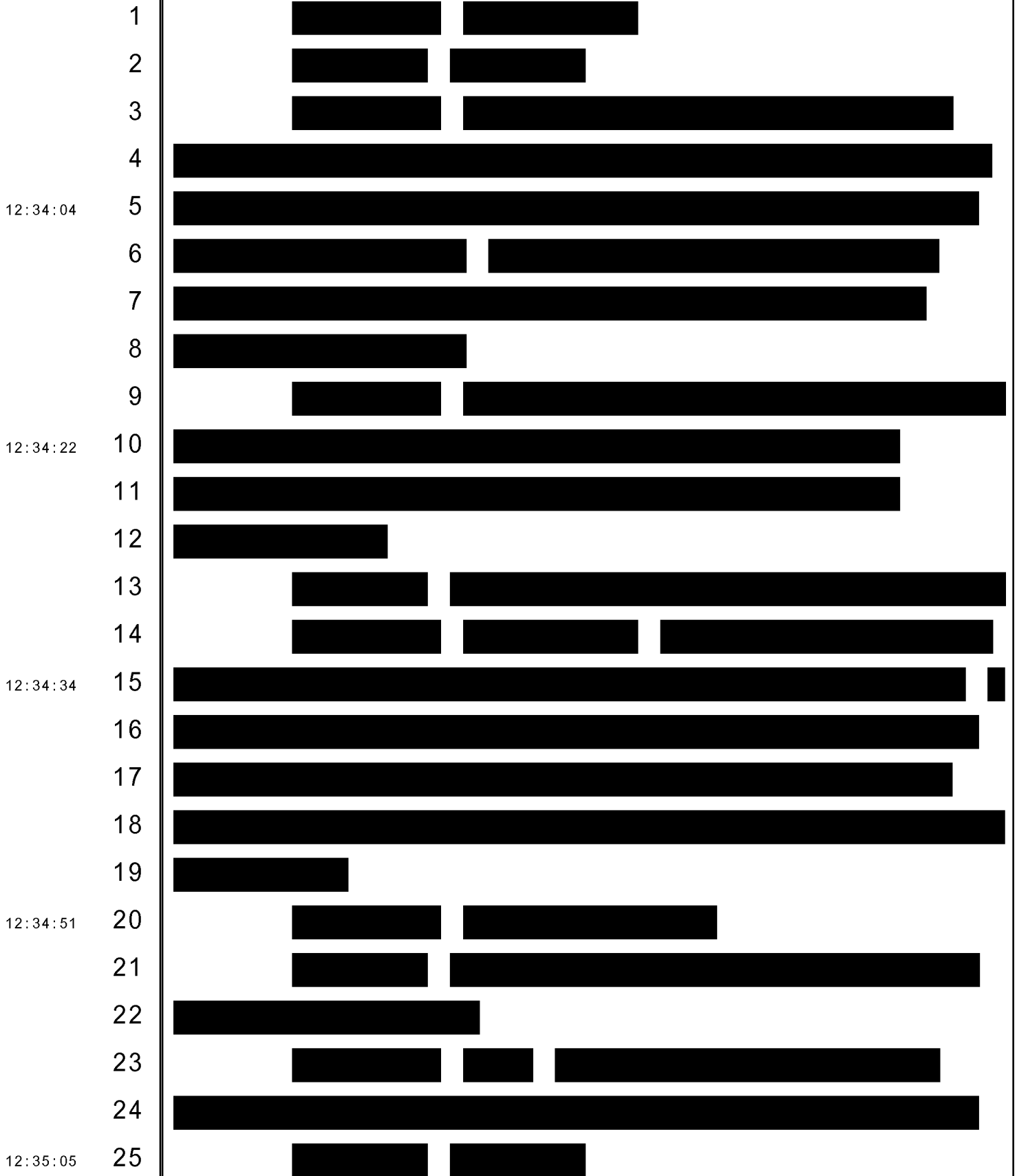
24 [REDACTED]

12:33:56

25 [REDACTED]

Healy - cross by Bayman

749



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

[REDACTED] [REDACTED]  
[REDACTED] [REDACTED]

(Luncheon recess taken from 12:35 o'clock p.m.  
to 1:35 o'clock p.m.)

\* \* \* \* \*

I CERTIFY THAT THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE  
RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER

/s/Blanca I. Lara

March 20, 2017