

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

3	WENDY B. DOLIN Individually and as	}	No. 12 CV 6403
4	Independent Executor of the Estate of		
4	STEWART DOLIN, deceased,	}	Chicago, Illinois
5	Plaintiff,		
6	vs.	}	March 27, 2017
7	SMITHKLINE BEECHAM CORPORATION		
8	D/B/A GLAXOSMITHKLINE, a Pennsylvania	}	9:15 o'clock a.m.
8	Corporation,		
9	Defendant.		

VOLUME 8 A
TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE WILLIAM T. HART

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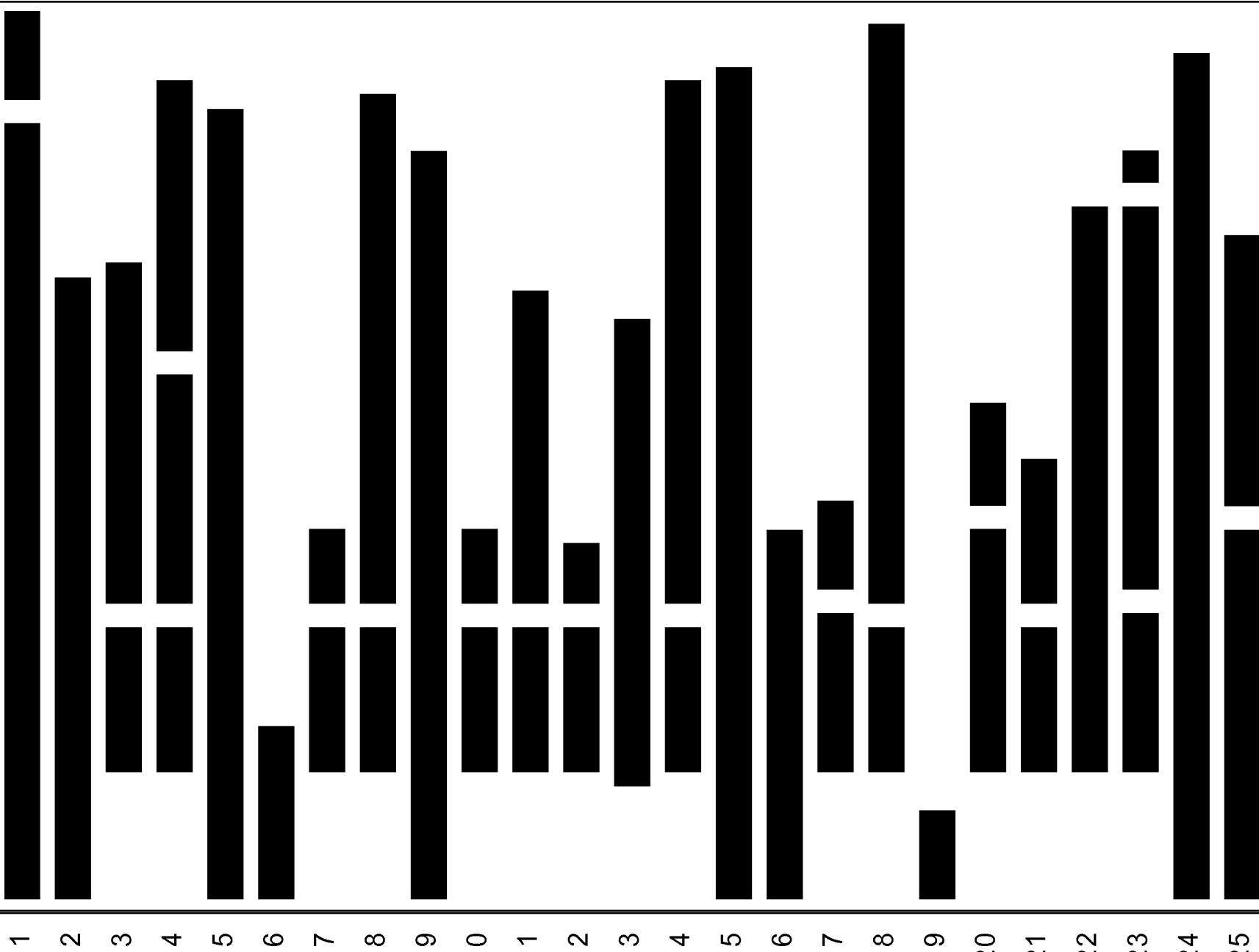
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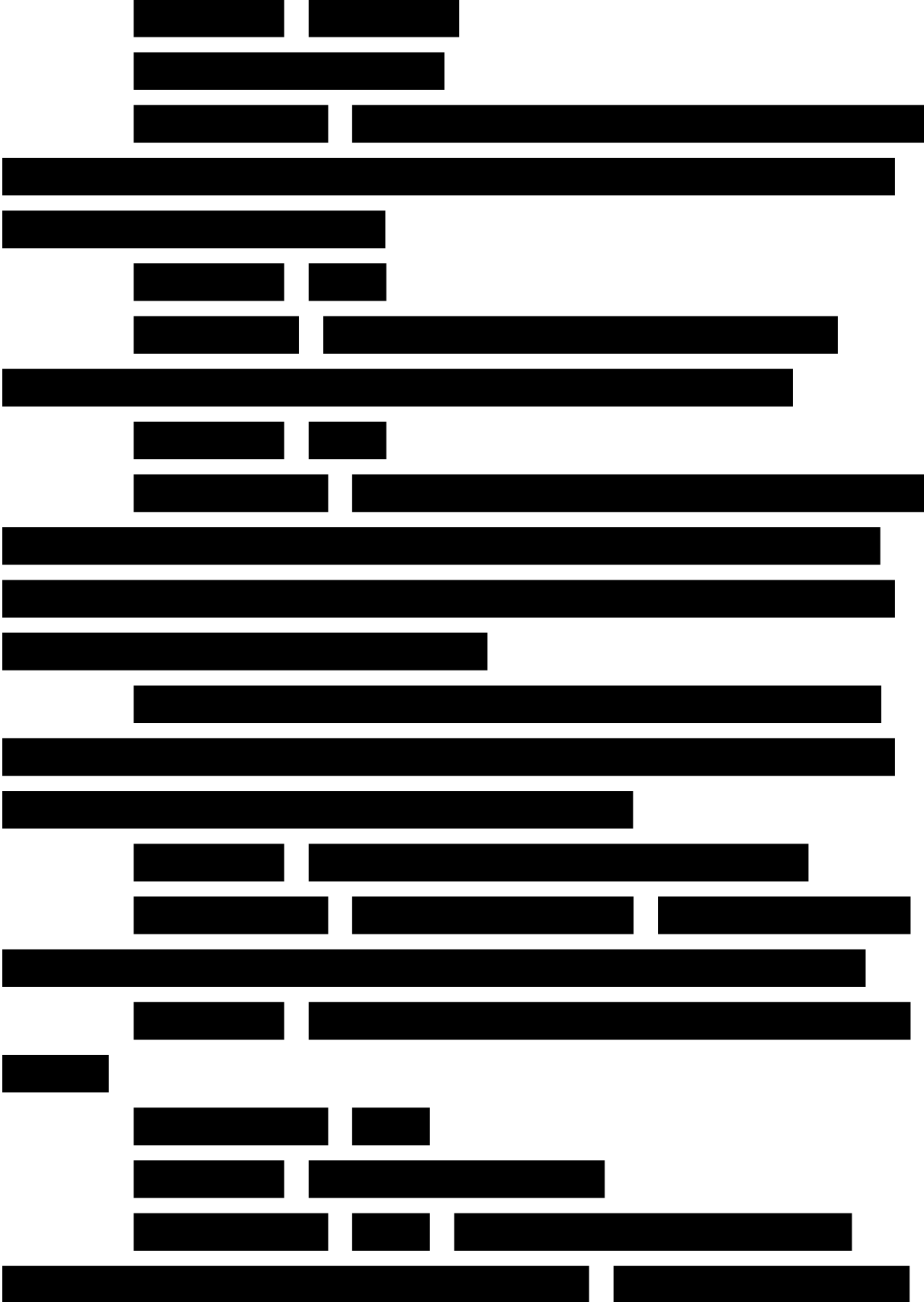
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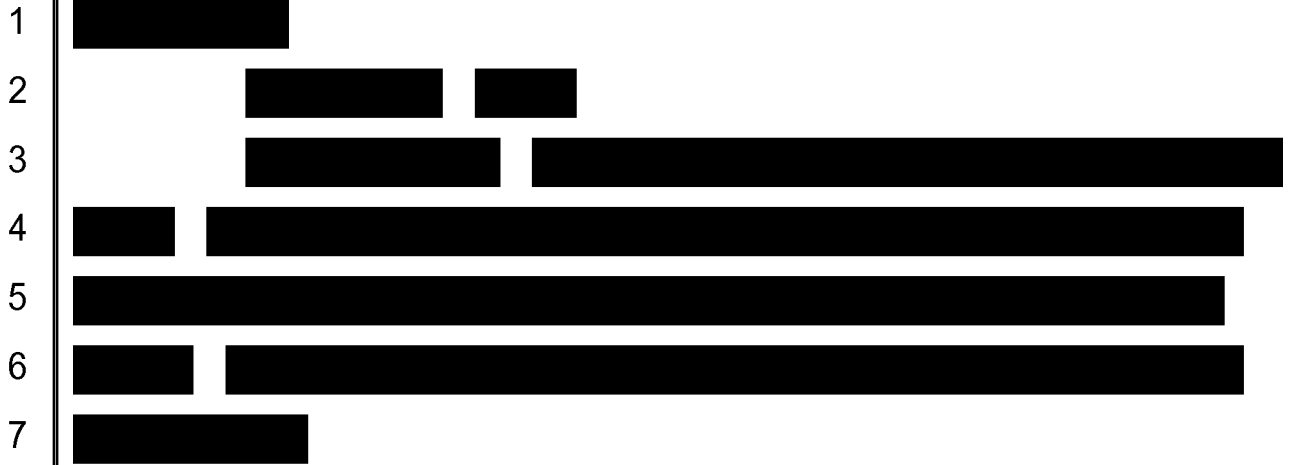
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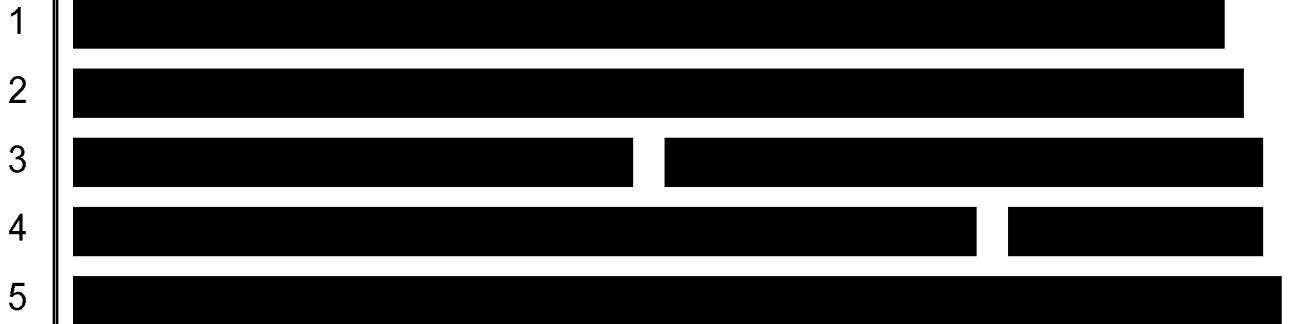
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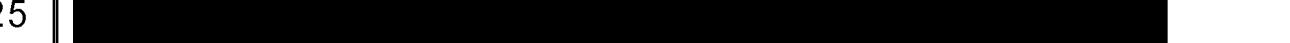
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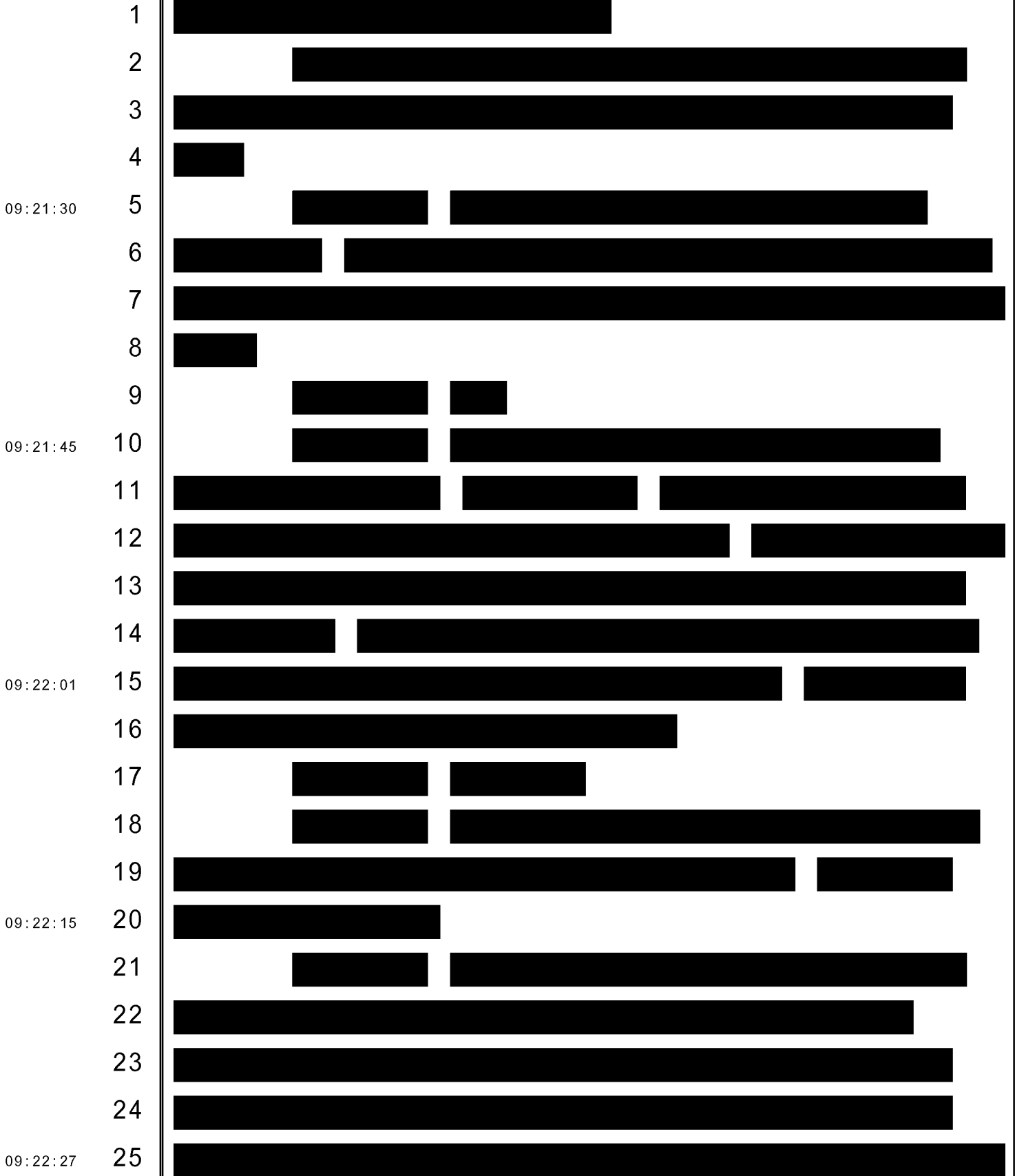


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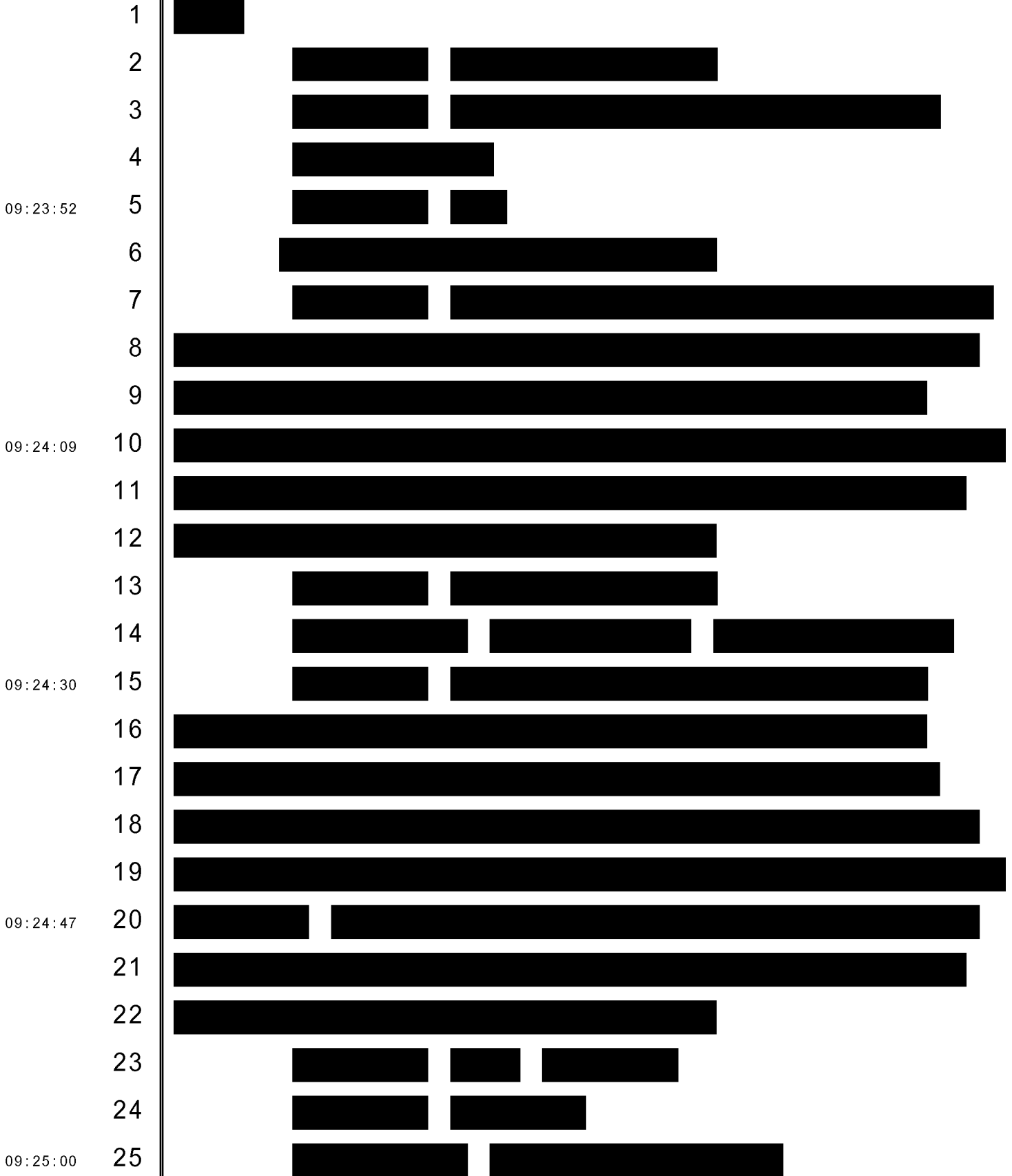


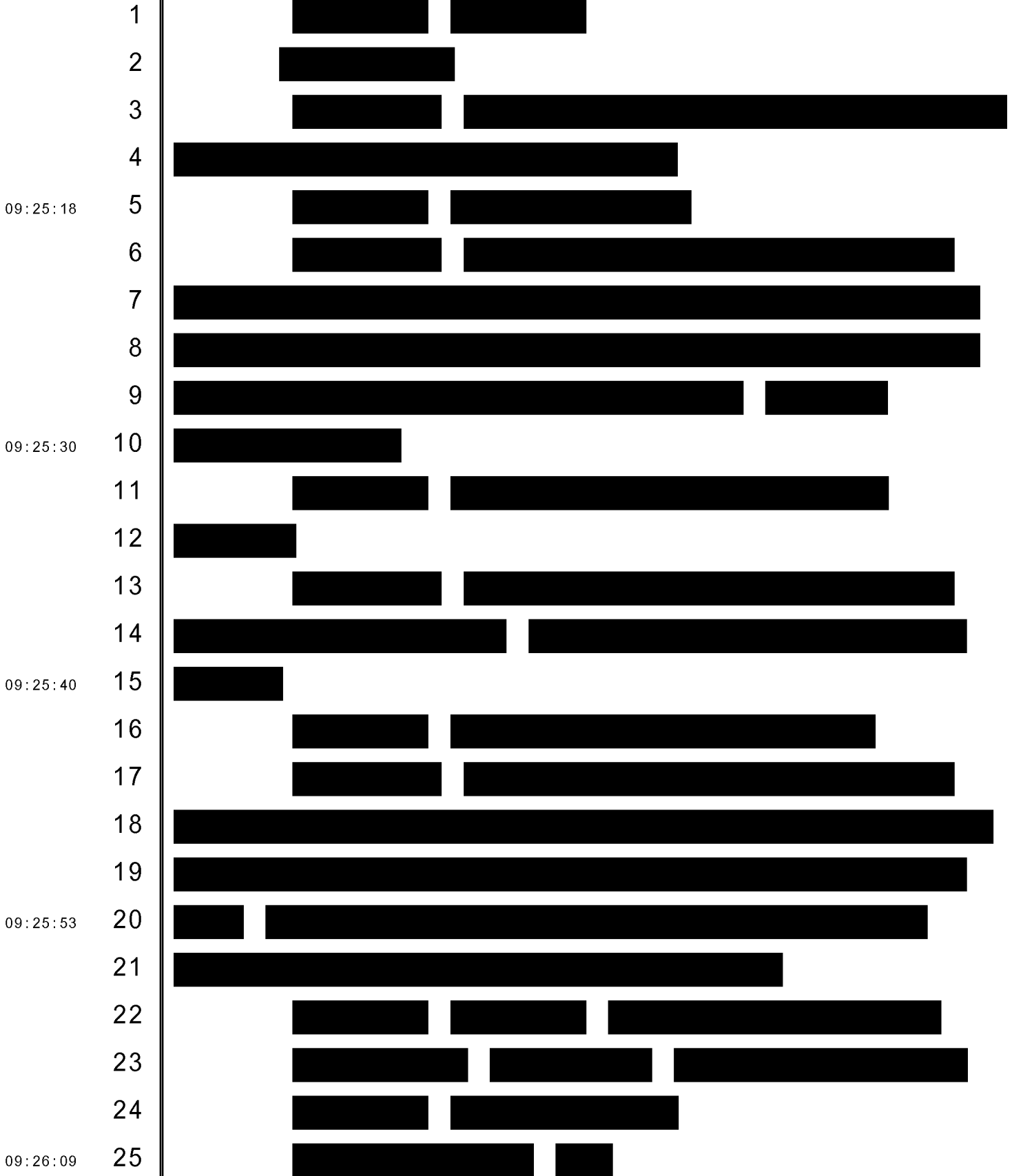


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16 (The following proceedings were had in the
17 presence of the jury in open court:)

18 THE COURT: All right. Thank you very much, ladies
19 and gentlemen. Please be seated.

09:27:53 20 We will resume. And we will have redirect examination
21 with respect to Dr. Ross.

22 The plaintiff may proceed.

23 REDIRECT EXAMINATION (resumed)

24 BY MR. WISNER:

09:28:07 25 Q. Good morning, Dr. Ross. How are you?

1 A. Good morning.

2 Q. I hope you had a good weekend.

3 A. I did.

4 Q. We're going to get you out of here pretty quickly, all
5 right?

09:28:18

6 A. All right.

7 Q. So let's go back to where we stopped on redirect. And I
8 want to talk specifically about the 2006 Paxil label, okay?

9 A. Okay.

09:28:28

10 MR. WISNER: Permission to publish Joint Exhibit 5,
11 Your Honor.

12 THE COURT: You may proceed.

13 (Exhibit published to the jury.)

14 BY MR. WISNER:

09:28:34

15 Q. Doctor, this is a copy of 2006 label, right?

16 A. Yes.

17 Q. And this is the label that GSK referenced several times
18 during your cross-examination, do you recall that?

19 A. Yes.

09:28:45

20 Q. And do you recall there being a lengthy discussion about
21 various letters sent to the FDA and e-mails about including
22 some language from this label in the 2007 onward label, do you
23 recall that?

24 A. Yes.

09:29:01

25 Q. And do you recall that this specific language that we were

1 talking about, they wanted to put inside the class label, do
2 you recall?

3 A. Yes.

4 Q. Okay. And I asked you some questions yesterday -- on
5 Thursday about -- about this label. And just to be clear, do
6 you have an opinion about whether or not this label, this 2006
7 label is false and misleading?

8 A. I do have an opinion on that.

9 Q. What is your opinion, Doctor?

10 A. It is false and misleading, definitely.

11 Q. Okay. So let's go to the clinical worsening section.

12 We talked briefly during your direct about this, but I
13 just want to clarify. You mentioned the word "disease
14 management," do you recall that?

15 A. I do.

16 Q. What is disease management and how is that any way
17 different than a drug warning?

18 A. So it's advise recommendations on taking care of a disease
19 regardless in how you're treating a patient, whether for
20 depression if you're using psychotherapy, if you're using drug
21 therapy, if you're doing other things.

22 It's -- if I can give an analogy. It's a little bit
23 like when you go to the Department of Motor Vehicles you get
24 the booklet that says heres the rules of the road, come to a
25 complete stop when you see a stop sign, when there's a red

1 light. And that's fine, but it doesn't tell you the car that
2 you happen to be driving could blow up if it gets rear-ended.

3 Q. So then the disease management language is how to drive the
4 car; and the car could blow, that's the Paxil-specific drug
5 induced?

09:30:46

6 A. That's exactly right.

7 Q. So this is the paragraph that was sort of at issues during
8 cross, do you recall that, Doctor?

9 A. I do.

09:30:54

10 Q. And we briefly touched on this but I wanted to just
11 highlight it again. It says right here:

12 "... in the older age groups, age 25 through 64
13 years, and greater than have 65 years, no such
14 increase was observed."

09:31:06

15 Do you see that?

16 A. I do.

17 Q. And that's referring to an increased risk in suicidal
18 behavior, right?

19 A. Yes, that's correct.

09:31:12

20 Q. Is that a true statement?

21 A. No, it is not.

22 Q. Now we keep talking about suicidality and suicidal
23 behavior. Is there a difference between suicidality and
24 suicidal behavior?

09:31:23

25 A. There's a big difference.

1 Q. What's the difference?

2 A. So suicidality includes -- so behavior as people killing
3 themselves, trying to kill themselves, or making a plan to kill
4 themselves, like, you know, purchasing a gun, for example.

09:31:46

5 Suicidality includes another concept, which is
6 thinking about killing oneself.

7 And the importance of distinguishing between those two
8 is what we call suicidal ideation. The importance of that is,
9 suicidal ideation is very common in people who are depressed.

09:32:08

10 Fortunately, most people who have suicidal ideation don't go on
11 to suicidal behavior. They don't make plans, they don't try to
12 kill themselves, and they don't kill themselves.

13 If you look at suicidal ideation, it's not wrong to
14 look at it, but it's important to understand it. It's going to
15 drown out any effects that a drug might have on suicidal
16 behavior, the more severe kinds of suicide related adverse
17 events.

09:32:33

18 If I can go back to my car analogy for a minute. It's
19 a little bit like saying, well, we're going to consider not
20 only look at the cars that are driving that blow up and get
21 rear-ended, but also the cars that are parked. And when we at
22 those cars that are parked, there doesn't seem to be any
23 problem in terms of that that particular kind of car blowing
24 up.

09:32:53

09:33:09

25 So going back to this, you've got suicidal ideation

1 where there is a low risk of going forward to very serious
2 things and that drowns out any effects. So we're really
3 interested here in the more serious things.

09:33:28

4 Q. So when GSK focuses on suicidality, Doctor, is that an
5 appropriate way of discussing the suicide risk?

6 A. By itself, no. It's not wrong to look at it. You
7 certainly should, but the focus should be on the more serious
8 aspects of suicidal behavior.

09:33:47

9 Q. And when we talk about suicidal behavior, people planning,
10 taking actual actions, actually doing suicidal acts, is that
11 risk greater in depressed people who take Paxil versus
12 depressed people who don't?

13 MR. BAYMAN: Objection, Your Honor. No foundation.
14 It's beyond the scope of his expertise.

09:34:02

15 THE COURT: Overruled.

16 BY THE WITNESS:

17 A. Yes.

18 BY MR. WISNER:

09:34:11

19 Q. Now, it says in this label, that we were discussing in 2006
20 -- and again, the content here was also sent directly to
21 doctors, is that right, Doctor?

22 A. In that letter that GSK sent out, yes.

23 Q. Okay. And in that letter it also says here, "all events
24 were suicide attempts," do you see that, Doctor?

09:34:31

25 A. Yes.

1 Q. Is it true that in all the major depressive clinical trials
2 there were no suicides?

3 A. No, that is not true.

09:34:44

4 Q. So this statement right here, I believe you testified
5 earlier, is, in your opinion, false?

6 A. Yes.

7 Q. Okay. Now, Doctor, at this point, in the older age groups,
8 age 25 to 64, right, you said that was disputed in a
9 publication, is that right?

09:35:03

10 A. GSK had a publication, which I talked about, that was based
11 on their 2006 analysis. It was submitted for publication in
12 2008 and published in 2011 showing there was a very significant
13 increase in risk for individuals age 25 to 64.

09:35:26

14 MR. WISNER: Your Honor, permission to publish
15 Plaintiff's Exhibit 285, page 8 of it.

16 THE COURT: You may proceed.

17 MR. BAYMAN: Your Honor, this is just a rehash in what
18 he has covered on Thursday.

09:35:36

19 THE COURT: Are we covering again the same ground that
20 was covered?

21 MR. BAYMAN: Same article.

22 MR. WISNER: No, I have something new to add that
23 directly responds to their cross-examination.

09:35:43

24 THE COURT: All right. You may proceed.
25 (Exhibit published to the jury.)

1 BY MR. WISNER:

2 Q. All right, Doctor, so we're looking here at page 8 of
3 Plaintiff's Exhibit 285. And this is where that chart that had
4 the definitive suicidal behavior is on, Doctor, is that right?

09:35:58

5 MR. WISNER: I'll blow it up properly.

6 BY THE WITNESS:

7 A. I think it may actually be on a previous page.

8 BY MR. WISNER:

9 Q. Oh, you're right. Let me pull up the actual page.

09:36:10

10 (Brief pause).

11 BY MR. WISNER:

12 Q. So this is Plaintiff's Exhibit 285 and it's on page 7, do
13 you see that, Doctor?

14 A. Yes.

09:36:18

15 Q. And this is the part where it talks about suicidal behavior
16 and the bottom part it discusses patients 25 through 65, is
17 that right?

18 A. Yes.

19 Q. And, specifically, we have this risk right here

09:36:33

20 (indicating). We talked about this on direct. It's 8 events
21 in the Paxil group and zero events in the placebo group, do you
22 see that?

23 A. Yes.

24 Q. And it says "infinity," right?

09:36:45

25 A. Yes.

1 Q. Now, is there an actual way of calculating --

2 MR. BAYMAN: Your Honor, this has been covered on
3 direct already.

4 THE COURT: It was, sir, but it won't hurt to cover a
5 bit more.

6 MR. WISNER: I just want to ask this next question.

7 THE COURT: All right.

8 BY MR. WISNER:

9 Q. Is it accurate to say that the risk is infinity or is there
10 a way to actually calculate an odds ratio that gives you a real
11 number?

12 MR. BAYMAN: Objection. This was not a disclosed
13 opinion, beyond the scope of his expertise, Your Honor.

14 THE COURT: Overruled.

15 BY THE WITNESS:

16 A. So just to clarify. These numbers specifically deal with
17 patients taking Paxil or placebo who were age 25 to 64. This
18 is not all patients, these are people older, 25 or older.

19 Before I get to your question, if I could, as you
20 said, there's 8 events in that group. And as I said last week,
21 even though the company said in their label that 8 of the 11
22 suicide -- episodes of definitive suicidal behavior were in
23 people 18 to 30, here it says 8 events of suicidal behavior in
24 people 25 to 64. And that's the point I was making that it
25 depends -- you know, if you cut the data up, one way you can

1 make it look younger or older and therefore there's no age
2 description.

3 But anyway, I'm sorry, Mr. Wisner, to get to your
4 question, there is actually a way of doing this, what's called
5 the continuity correction.

09:38:22

6 Q. And what does that entail, briefly?

7 A. It's a mathematical technique where if you were to just
8 divide the Paroxetine percentage, a fraction proportion, which
9 is .29 and but the placebo .00, you'd be dividing by zero; you
10 can't do that.

09:38:41

11 So what you do you is you add 0.5 to each of these
12 numbers. So instead of "8" you have 8.5. Instead of "2713,"
13 you have 2713.5. Instead of "0," you have 0.35. And then
14 1567, 1567.5.

09:39:00

15 Q. And the continuity analysis, is that standard statistical
16 process when you have zero?

17 A. Yes.

18 Q. And when you do that analysis, what's the odds ratio here?

19 A. The odds ration is 9.7. So almost a ten-fold increase in
20 risk for people aged 25 to 64.

09:39:17

21 Q. And that ten-fold increase for patients 25 through 64, is
22 that statement anywhere found in the 2006, 2007 or any Paxil
23 label?

24 A. No.

09:39:33

25 Q. Do you think -- and this data was submitted to the journal

1 in what year?

2 A. 2008.

3 Q. And that was before Stewart Dolin's death?

4 A. That is correct.

09:39:44

5 Q. When was it published?

6 A. 2011.

7 Q. That's after Stewart Dolin's death?

8 A. Yes.

9 Q. All right. Let's move on then to defense exhibit 25.

09:39:59

10 Now, this is a document that --

11 MR. WISNER: Permission to publish Your Honor?

12 (Exhibit published to the jury)

13 THE COURT: Yes.

14 BY MR. WISNER:

09:40:03

15 Q. This is a document that the defendants showed you on
16 cross-examination, is that right, Doctor?

17 A. Yes.

18 Q. And this is a suicide and death report submitted by GSK to
19 the FDA in December of 1999, is that right?

09:40:14

20 A. Yes.

21 Q. Okay. Now, this death report, if we go into it, it has a
22 listing of all the suicides. And the first table highlights
23 suicides that occurred in the central database, do you see
24 that?

09:40:29

25 A. Yes.

1 Q. And it says here that there were 6 suicides, do you see
2 that?

3 A. Yes.

09:40:38

4 Q. Now, when it says "central database," there's also a
5 locally funded study as well, right?

6 A. Correct.

7 MR. BAYMAN: Your Honor, objection. This was covered
8 on Thursday. We're going back over the same ground.

09:40:48

9 MR. WISNER: This is foundation to the new stuff, Your
10 Honor. We'll get there very quickly.

11 THE COURT: All right. Proceed.

12 BY MR. WISNER:

13 Q. So the locally funded studies, those are performed by
14 companies affiliated with GSK, is that right?

09:40:58

15 A. Correct.

16 Q. And in that table, there were a total of 5 completed
17 suicides, do you see that?

18 A. Yes.

09:41:15

19 Q. So in total, what is the number of -- these are completed
20 suicides in people taking Paxil in the clinical trial database
21 as of 1999?

22 A. Yes.

23 Q. What's the total number?

24 A. Total number would be 11.

09:41:25

25 Q. Okay. Now, let's focus here on table 1 for a second.

1 This is the completed suicides in GSK's clinical
2 trials, is that right?

3 A. Yes.

09:41:39

4 Q. Now, what clinical trials, types of clinical trials are
5 included in that number?

6 A. So I believe these are both active-controlled and
7 placebo-controlled trials. So some patients got Paroxetine and
8 in the active-controlled trials they got another
9 antidepressant. In the placebo-controlled, those are different
10 kind of trial, some patients got a placebo.

09:42:01

11 Q. All of these patients were in double-blind trials, is that
12 right?

13 A. Correct.

09:42:13

14 Q. All of these patients were in controlled clinical trials,
15 is that right?

16 A. Randomized-controlled trials, yes.

17 Q. And all of these patients were in GSK's own database, is
18 that right?

19 A. Yes.

09:42:20

20 MR. BAYMAN: Objection; leading.

21 THE COURT: Proceed.

22 BY THE WITNESS:

23 A. I'm sorry, Your Honor. Yes.

24 BY MR. WISNER:

09:42:25

25 Q. Now we again have a problem of a number versus zero, do you

1 see that?

2 A. I do.

3 Q. Did you calculate using the continuity analysis, the odds
4 ratio here?

09:42:35 5 A. I did.

6 Q. What was it?

7 MR. BAYMAN: Objection; outside the scope of his
8 report, the scope of his expertise.

9 THE COURT: Overruled.

09:42:41 10 BY THE WITNESS:

11 A. The odds ratio was 3.5.

12 BY MR. WISNER:

13 Q. Now, to be clear, when we say 3.5, we're talking about a
14 350 percent increase in completed suicides in depressed

09:42:57 15 patients taking Paxil versus either another drug or placebo --

16 MR. BAYMAN: Objection.

17 BY MR. WISNER:

18 Q. -- is that right?

19 THE COURT: You are leading, you know.

09:43:07 20 MR. WISNER: Fair enough.

21 THE COURT: Let the witness tell the facts.

22 MR. WISNER: Sure.

23 THE COURT: Just ask him about it.

24 MR. WISNER: Yes, Your Honor.

09:43:11 25 BY THE WITNESS:

1 A. So if --

2 BY MR. WISNER:

3 Q. Hold on. Let me ask the question.

4 A. I'm sorry, sir.

09:43:15

5 Q. What does that 3.5 increase risk or odds ratio indicate?

6 A. So if you take all these controlled trials which are done
7 with similar populations, using the same data collection
8 methods, and you combine the patients who got Paxil, on the one
9 hand, and those who got a control, whether it was placebo or an
10 active comparator, and that's completely valid thing to do from
11 clinical trials and the regulatory standpoint, the chances that
12 somebody is going to commit suicide are 350 percent if they're
13 taking Paxil compared to one of these other, either placebo or
14 active control.

09:43:42

09:44:07

15 Q. And we've talked about ideation, we talked about behavior.
16 Here, what are we talking about?

17 A. We're talking about people killing themselves.

18 Q. People who actually die?

19 A. Yes.

09:44:17

20 Q. And of these 6 and of the 5 that we looked at a second ago
21 with in the locally funded trials, of those 11 people who died
22 taking Paxil, were any one of those people included in GSK's
23 2006 analysis?

24 A. No.

09:44:36

25 Q. Were any of those people included in the FDA's 2006

1 analysis?

2 A. No.

3 Q. Now, we spend some time looking at the label for Paxil, do
4 you recall that, Doctor?

09:45:00 5 A. Yes.

6 Q. And it seemed like it was a fairly lengthy document, do you
7 remember that?

8 A. Yes.

9 Q. Has there been any change in the way labels are presented
10 or formatted by federal regulation?

09:45:11

11 MR. BAYMAN: Objection, Your Honor. This is beyond
12 the time period that's at issue in this case. It doesn't tie
13 to the drug in this case.

14 THE COURT: At this point I have to sustain that
15 objection.

09:45:23

16 BY MR. WISNER:

17 Q. When did that format labeling change?

18 A. 2006.

19 Q. So this is before the class labeling in 2007?

09:45:30

20 A. Correct.

21 Q. Okay. And that new format --

22 MR. BAYMAN: Your Honor, objection. This new format
23 does not apply to this drug, so it's a misleading.

24 MR. WISNER: Can I ask the question?

09:45:40

25 THE COURT: Yes. You're in the timeframe now.

1 BY MR. WISNER:

2 Q. In 2007 could GSK have implemented the new format?

3 A. To clarify, the new format was introduced after a lot of
4 work, it's called a physician labeling rule. And it makes drug
5 labels much clearer.

09:46:00

6 Anybody who has looked at one of these old-stype
7 labels, and Paxil is an example of this, I need a new pair of
8 glasses just like every time I've looked at a certain number of
9 these.

09:46:11

10 So it starts out with highlights, what the drug is
11 used for, what the dose is, and what the serious side effects
12 are, that do you get warned about. You can go right to it, and
13 so it is much clearer. And that's based not just on what the
14 FDA thinks, there was an enormous amount of work.

09:46:31

15 MR. BAYMAN: Objection, Your Honor. I move to strike.
16 This is no where disclosed in his expert report or in any of
17 his opinions in the case. This is a brand new opinion.

18 MR. WISNER: So far he hasn't said. He is just giving
19 facts.

09:46:41

20 THE COURT: Well, let's go to sidebar on this.

21 (Proceedings heard at sidebar on the record.)

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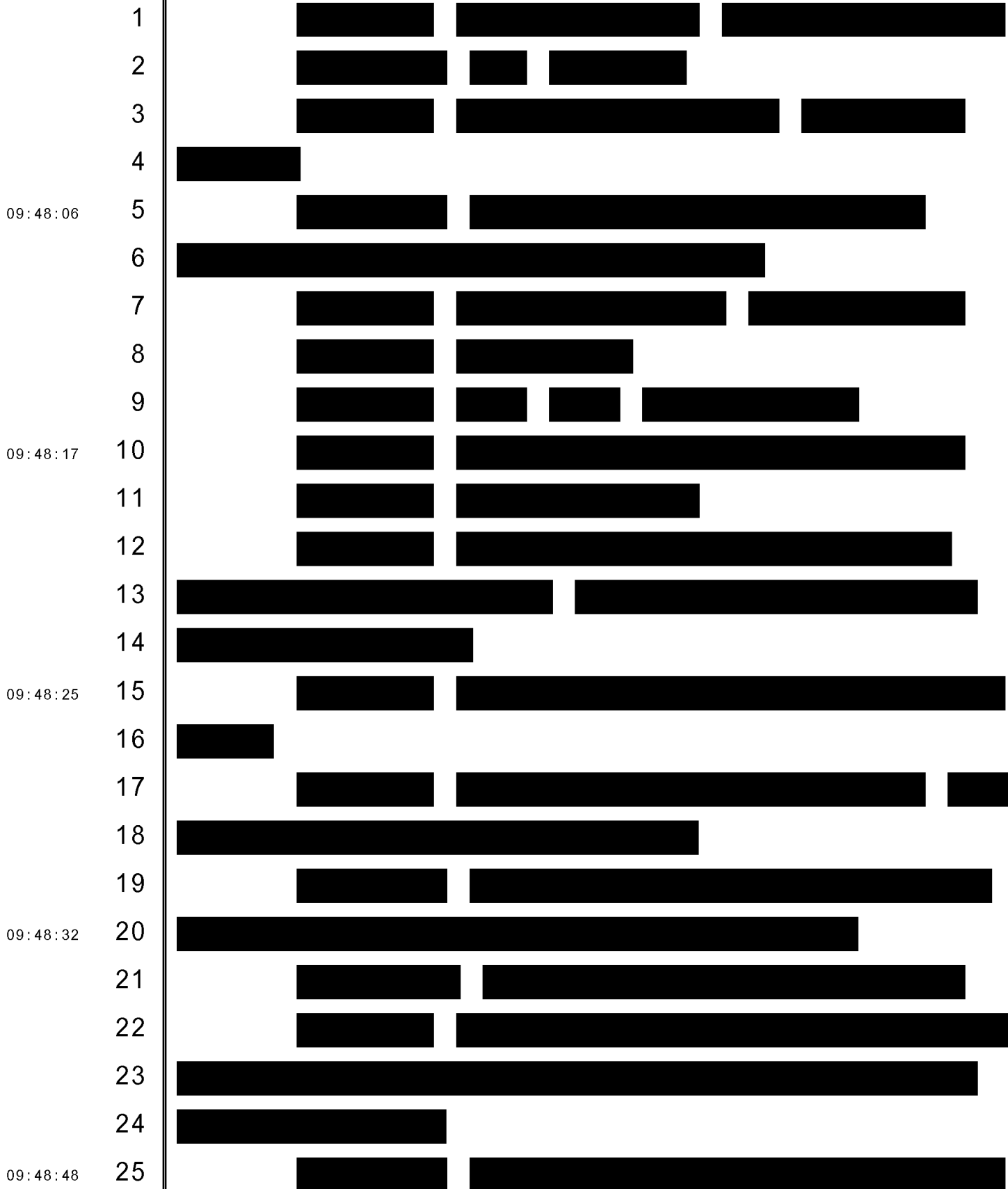
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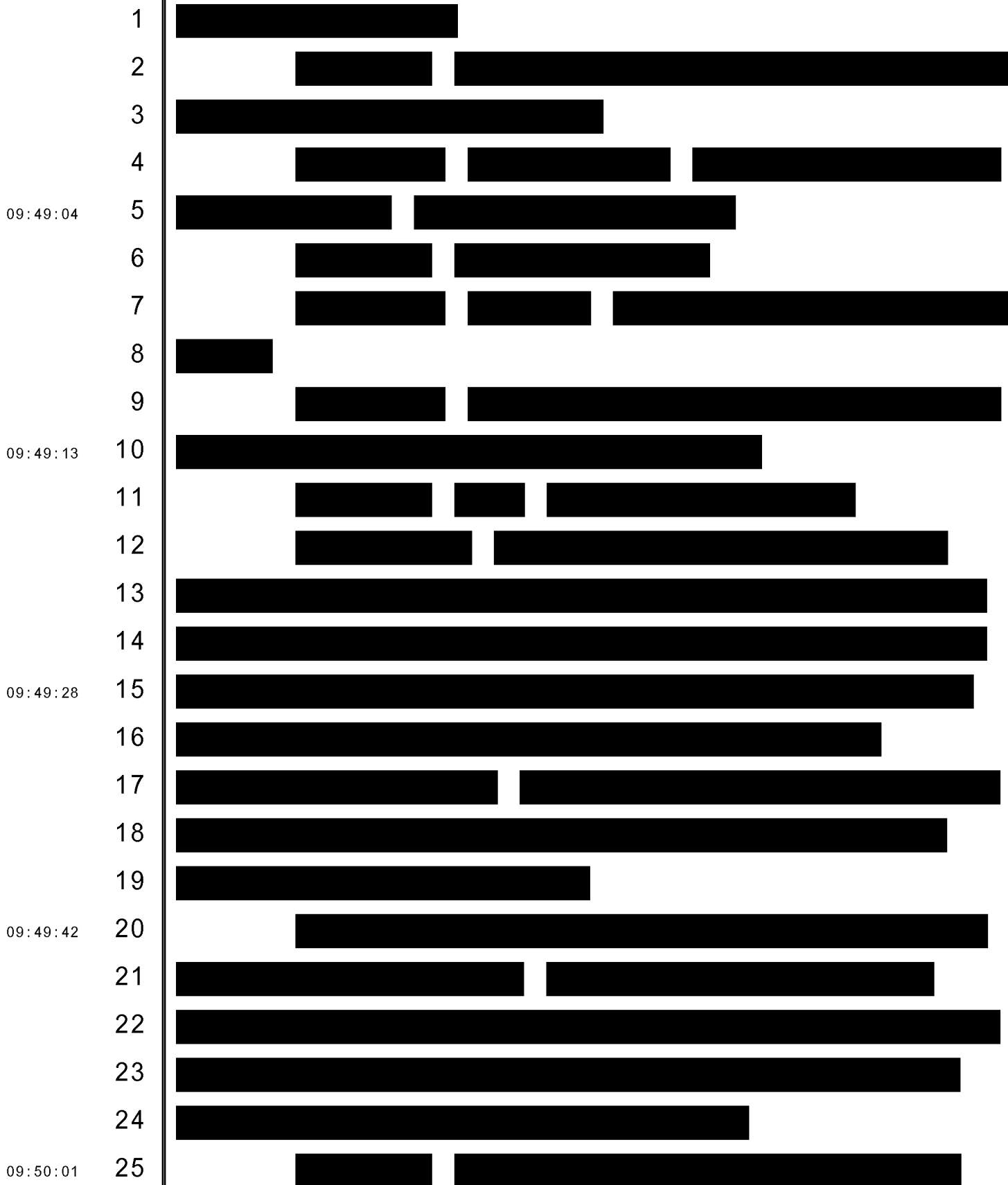
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2 [REDACTED] [REDACTED] [REDACTED]

3 (Proceedings resumed within the hearing of the
4 jury.)

09:50:32

5 BY MR. WISNER:

6 Q. Dr. Ross, did GSK have the opportunity to change the Paxil
7 label to the new format?

8 A. Yes.

9 Q. Did they ever propose doing so?

09:50:42

10 A. Not that I'm aware of.

11 Q. All right, Doctor, you were cross-examined for nearly an
12 entire day. You were asked a lot of questions by GSK's
13 counsel, do you recall that?

14 A. Yes.

09:51:04

15 Q. Have your opinions in any way changed because of that
16 cross-examination?

17 A. No.

18 Q. Did you --

09:51:15

19 MR. WISNER: And if I may, Your Honor, permission to
20 publish the summary of opinions that was previously published
21 at the beginning of his direct.

22 MR. BAYMAN: I think that's cumulative and we object.

23 THE COURT: No, the objection is sustained.

24 MR. WISNER: Okay.

09:51:32

25 BY MR. WISNER:

1 Q. Doctor, do you still believe that there's an increase
2 associated risk of adult suicidal behavior for patients taking
3 Paxil versus those not?

4 A. I do.

09:51:48

5 Q. Do you still believe that GSK was not up front with the FDA
6 about that risk?

7 A. I believe that very strongly.

8 Q. Do you believe that GSK had the ultimate responsibility to
9 change that label once they knew of that risk?

09:52:04

10 A. Yes.

11 Q. Do you believe that GSK exercised or fulfilled that
12 responsibility during the entire 30-year period when this drug
13 was being marketed by GSK?

14 A. No.

09:52:14

15 Q. Now, when it comes to the issue of suicide risk, do you
16 believe that risk emerged as early as 1992, is that right?

17 A. Actually, I would say that the data showing an increased
18 risk was available to GSK in 1989 when they submitted to the
19 NDA.

09:52:36

20 Q. And under federal regulations, is the defendant, or GSK,
21 allowed to tell physicians things that are not in the label?

22 MR. BAYMAN: Your Honor, this is entirely cumulative.
23 This is just --

24 THE COURT: Yes. Sustained.

09:52:48

25 MR. BAYMAN: Thank you.

1 BY MR. WISNER:

2 Q. Assuming that the suicide risk -- you testified the suicide
3 risk was not in the label starting in 1992 and did not make its
4 way into the label to the present, is that right?

09:52:59

5 A. That is correct.

6 Q. In your opinion, could the marketing efforts by GSK
7 directly to physicians have discussed that suicide risk because
8 it was not in the label?

9 A. No.

09:53:14

10 MR. WISNER: Pass the witness, Your Honor.

11 MR. BAYMAN: Briefly, Your Honor.

12 THE COURT: Very brief.

13 MR. BAYMAN: Yes.

14 FURTHER RECROSS EXAMINATION

09:53:22

15 BY MR. BAYMAN:

16 Q. Dr. Ross, you gave a few minutes ago some opinions about
17 suicidality and suicidal behavior, correct?

18 A. Yes.

19 Q. You're not an expert in suicidality, correct?

09:53:41

20 A. I don't claim to be.

21 Q. And you don't have a degree in statistics, correct?

22 A. Besides the training and experience that I have at FDA for
23 10 years, no.

24 Q. No degree, correct?

09:53:59

25 A. That is correct.

1 Q. No degree in biostatistics, correct?

2 A. No.

3 Q. And you talked about suicidal ideation and the difference
4 with suicidal behavior. Isn't it correct that the FDA was
5 looking not just at suicidal ideation, but rather, suicidal
6 ideation and behavior, correct, in its analysis?

09:54:15

7 A. Among other things, yes.

8 Q. GSK was also looking at suicidal ideation and behavior in
9 its analysis, correct?

09:54:30

10 A. That's correct.

11 Q. Not just ideation, correct?

12 A. Yes.

13 Q. You mentioned on Thursday in the redirect that akathisia
14 might be what's called newly acquired information that would
15 warrant a label change, correct?

09:54:49

16 MR. WISNER: Objection; misstates his testimony.

17 BY THE WITNESS:

18 A. I don't recall.

19 BY MR. BAYMAN:

09:54:54

20 Q. You don't recall talking about akathisia?

21 A. I remember we talked about it, I don't remember the
22 specific thing that you're saying.

23 Q. Well, you mentioned akathisia in your report as a potential
24 mechanism by which antidepressants can induce suicide along
25 with others, correct?

09:55:08

1 A. I believe so.

2 Q. But you don't outline anywhere in your report where there's
3 any scientific confirmation that any of these possible
4 mechanisms has been confirmed, correct?

09:55:20

5 A. No.

6 Q. And that's why you used in your report the term
7 "potential," because it's simply that these are biologically
8 plausible mechanisms, correct?

09:55:36

9 A. With the understanding that adding information of this sort
10 to the label does not require that a causal relationship be
11 proved, no.

12 Q. My question was, these -- these are possible mechanisms
13 that have been discussed in the literature, but none of them
14 have been scientifically confirmed, correct?

09:55:50

15 A. That's correct.

16 Q. You mentioned on Thursday that you said FDA regulations are
17 a floor, you remember that?

18 MR. WISNER: Objection; misstates his testimony.

19 BY THE WITNESS:

09:56:04

20 A. I don't recall the exact wording. It's been 3 days. So I
21 do remember we discussed the issue of a floor, but I don't
22 remember exactly what my testimony was.

23 BY MR. BAYMAN:

09:56:18

24 Q. Doctor, there's nothing in your report where you say FDA
25 regulations are minimum standards, correct?

1 MR. WISNER: Objection; misstates his testimony. The
2 floor related to the class labeling. He's misstating what he
3 said.

4 THE COURT: Well, you may inquire, sir.

09:56:28

5 MR. BAYMAN: Thank you.

6 BY THE WITNESS:

7 A. In terms of -- I don't use those explicit words, that's
8 correct.

9 BY MR. BAYMAN:

09:56:39

10 Q. Are you aware of any situation, since 2005, involving an
11 SSRI, an antidepressant, or a psychiatric medication where the
12 FDA has determined that reasonable evidence of an association
13 exists between suicidality, suicide attempt, suicidal ideation,
14 or behavior based on data that is other than randomized double
15 blind placebo-controlled trials?

09:57:06

16 A. Not that I'm aware of.

17 Q. And with respect to -- you recall talking about the chart
18 that you showed the jury with 47 Paroxetine events and 1
19 placebo event?

09:57:35

20 A. With the understanding that it was actually Mr. Wisner who
21 showed that exhibit, yes.

22 MR. WISNER: Your Honor, this was all on direct. He's
23 limited to redirect and that was never discussed in redirect.

24 THE COURT: That wasn't discussed on redirect, sir.

09:57:50

25 BY MR. BAYMAN:

1 Q. You did -- on redirect you mentioned the -- and Mr. Wisner
2 just showed you the label with respect to GSK's 2006 MDD
3 analysis, correct?

09:58:16

4 A. There are statements in there from -- that -- on --
5 actually, given the discrepancy between the results of that
6 analysis and the statements in the label, I'm not sure how to
7 answer that.

8 Q. Well, you remember discussing the 2006 GSK analysis,
9 correct, and the finding on MDD?

09:58:29

10 A. Yes.

11 Q. Other than that single finding in MDD patients in the 2006
12 analysis, you're not aware of any analysis of randomized
13 placebo-controlled data conducted by anyone that shows a
14 statistically significant increased risk of either suicidality,
15 suicidal ideation or behavior or suicidal behavior in adult
16 patients over 30 using Paroxetine, are you?

09:58:49

17 A. So -- I respectfully ask if you can ask that -- you're
18 using a bunch of overlapping terms here. I'm not trying to be
19 difficult, but I don't understand your question because there's
20 so many things that are overlapping: Suicidality, suicidal
21 behavior and ideation, and so on. Suicidality is a term that,
22 as I said in my deposition, that everyone is recommending that
23 we get away from.

09:59:15

24 Q. Are you aware -- other than the finding of the MDD patients
25 in GSK's 2006 analysis, you're not aware of any analysis of

09:59:33

1 randomized placebo-controlled data conducted by anyone that
2 shows a statistically significant increased risk of either
3 suicidal ideation or behavior or suicidal behavior in adult
4 patients over 30 using Paroxetine, correct?

09:59:54

5 A. With the understanding that that certainly would not be the
6 only data source one would look at and that GSK actually
7 published that analysis that was submitted in 2008, no.

10:00:21

8 Q. And you mentioned that analysis, that was written up in the
9 Carpenter report, you're aware that GSK's analysis was posted
10 on its website as far back as 2006, correct?

11 A. From a regulatory perspective, that's irrelevant.

12 Q. That's not my question.

13 A. I actually wasn't aware of that.

10:00:51

14 Q. And you were shown some data involving the article where
15 you did a continuity correction, is that right?

16 A. I'm sorry, when you say -- sorry, when you say "the
17 article."

18 Q. The Carpenter article.

19 A. Yes.

10:01:01

20 Q. And then you were also shown the data from what was called
21 the death reports where you did a continuity correction to get
22 a 3.5 odds ratio?

23 A. Yes.

24 Q. That's compared to other drugs, correct?

10:01:15

25 A. So that's compared to other drugs and placebo taken

1 together. The Carpenter, however, I believe is against
2 placebo.

3 Q. I'm asking you about the death report.

10:01:37

4 A. I'm sorry, you mentioned both Carpenter and the death
5 report, so I was responding to both.

6 In the death report, you're correct, that was active
7 comparator and placebo.

8 Q. But you didn't include the number of suicides and active
9 comparators in those trials, did you?

10:01:51

10 A. No.

11 Q. You recall, just a minute ago, you were shown the language
12 from the GSK 2006 label that was -- the change made by changes
13 being affected, correct?

14 A. Yes.

10:02:13

15 MR. BAYMAN: Can you put that up, Roger, the 2006
16 label with the MDD finding.

17 (Brief pause).

18 (Exhibit published to the jury.)

19 BY MR. BAYMAN:

10:03:09

20 Q. While he pulls that up, do you recall being shown the
21 language that the majority of suicide attempts in the 2006
22 analysis in MDD patients, 8 out of 11, were in younger adults
23 age 18 through 30, and you were asked if that was an accurate
24 statement, correct?

10:03:24

25 A. Yes.

1 Q. And you said no, it was not, correct?

2 A. Correct.

3 (Brief pause).

4 BY MR. BAYMAN:

10:03:55

5 Q. That's the small type, but that's the data we were talking
6 about, correct?

7 A. Correct.

8 Q. Okay.

9 MR. BAYMAN: Can you pull up --

10:04:08

10 BY MR. BAYMAN:

11 Q. Can you go to Tab 1? Do you have your notebook there?
12 Your expert report?

13 A. I'm sorry, I don't have any binders up here.

14 (Binder tendered to the witness).

10:04:24

15 THE WITNESS: Thank you.

16 BY MR. BAYMAN:

17 Q. Look at figure 1, page 16 in your expert report.

18 (Brief pause).

19 BY THE WITNESS:

10:04:48

20 A. Do you have a page number, by any chance?

21 BY MR. BAYMAN:

22 Q. Page 16.

23 A. 16. Thank you. Okay.

24 Q. You did a figure where you distributed the age of

10:04:59

25 Paroxetine treated patients with suicide attempts, correct?

1 A. Well, I didn't -- I plotted them, I wouldn't say
2 distributed.

3 Q. Okay. It's called Figure 1, correct?

4 A. Yes.

10:05:12

5 Q. And if we can count --

6 MR. BAYMAN: Your Honor, may I show that table to the
7 jury?

8 THE COURT: Yes.

9 MR. BAYMAN: Thank you.

10:05:17

10 (Exhibit published to the jury.)

11 BY MR. BAYMAN:

12 Q. If we look up here, if we look at the total study
13 population that was patients age 18 to 30, there are, in fact,
14 8 age 30 and below, correct?

10:05:33

15 A. That's a correct statement.

16 Q. And 8 is the majority of 11, correct?

17 A. It is not the majority, sir. It is a majority. As I just
18 pointed out, you could also just as easily say there were 8 out
19 of 11, 25 to 64.

10:05:50

20 And, you know, to say if -- a few minutes ago you
21 asked me -- you told me that this had been posted on GSK's
22 website. If I said 8 out of 11, the majority were in the
23 younger patients, that actually would be false and misleading.

24 Q. Dr. Ross, it was accurate for GSK to say that the vast

10:06:13

25 majority of adverse events in the study population for suicide

1 attempt occurred at 30 years or younger, correct?

2 A. No, sir. The -- with -- if you say "the majority," you're
3 talking about something that is askew population. That would
4 be true if everything were clustered towards younger patients,
5 but that's not what we see here.

10:06:36

6 The median is 29, half the patients are above that
7 age, half are below. You cannot say accurately that it is the
8 majority. That's a question of slicing the data to give you a
9 result that you want.

10:06:53

10 Q. Do you have your deposition up there?

11 A. Ah, I'm not sure I do.

12 MR. WISNER: Your Honor, I believe this is prefaced by
13 a short recross. This is well beyond the scope at this point
14 of the redirect and this has taken forever.

10:07:11

15 MR. BAYMAN: This is my last series of inquiry, Your
16 Honor.

17 THE COURT: All right. Proceed.
18 (Binder tendered to the witness).

19 THE WITNESS: Thank you.

10:07:21

20 BY MR. BAYMAN:

21 Q. Turn to page 375, Line 5.

22 (Brief pause).

23 BY THE WITNESS:

24 A. Yes.

10:07:45

25 BY MR. BAYMAN:

1 Q. You were asked:

2 "Question: And it was accurate for GSK to say
3 that the vast majority of the adverse events in
4 the study population for suicide attempt
5 occurred at 30 years or younger."

10:07:54

6 And your answer was "yes," correct?

7 A. That's correct.

8 Q. Now, I noticed your chart here ends at age 52, correct?

9 A. Yes.

10:08:05

10 Q. Okay. You know that there were patients in the MDD studies
11 included in that analysis that went up to age 91, correct?

12 A. Yes.

13 Q. You didn't list those on your chart, though, beyond age 52,
14 did you?

10:08:17

15 A. This is a graph of suicide attempts, not of all the
16 patients. You could extend, certainly extend that out, but it
17 would not change the median, which, by the way, is almost
18 identical to the mean. This is like a belt-shaped curve. So
19 you, you could extend it out to a million and it wouldn't
20 change the distribution of ages of people who tried to kill
21 themselves.

10:08:37

22 MR. WISNER: I object to this document, Your Honor.

23 THE COURT: Well, I don't know what the document is,
24 sir.

10:09:00

25 MR. BAYMAN: May I approach, Your Honor?

1 (Document tendered to the Court.)

2 MR. BAYMAN: Your Honor, the second page. He just
3 said you could extend it out and it wouldn't make any
4 difference. I just want to show this graph.

10:09:17

5 THE COURT: Is this your document or his document?

6 MR. BAYMAN: The first one is his, the second one is
7 ours where we extended it out.

8 THE COURT: No, sir, you are beyond the scope now,
9 anyway. The objection is sustained.

10:09:27

10 MR. BAYMAN: Okay.

11 BY MR. BAYMAN:

12 Q. Is it your testimony that if we extended this graph out all
13 the way to age 91 it would not show an clustering of suicide
14 attempts below age 30?

10:09:40

15 A. You could try and use a visual trick to make it look like
16 that, but the median would remain unchanged.

17 Q. And as a result of the analysis that we talked about, the
18 2006 analysis that -- have you done any statistical analysis to
19 determine the likelihood that this distribution of suicide
20 attempts is due to chance and not due to the influence of
21 increased risk in younger patients?

10:10:01

22 A. Actually, that is such an interesting question, because
23 there was so much data based on Defense Exhibit 25 on patients,
24 older patients, who committed suicide that was not reported to
25 the FDA and not included in these analyses that artificially

10:10:25

1 lowered the apparent age.

2 So if you looks at those suicides that were not
3 included in these analyses, the average age of those patients
4 was 47. By excluding those patients, you shift the apparent
5 risk towards younger patients.

10:10:44

6 Q. My question was, have you done a statistical analysis?

7 A. Of whether this is due to chance?

8 Q. And not due to the influence of increased risk in younger
9 patients.

10:10:57

10 A. Actually, I didn't have to. Dr. Carpenter and his group
11 published a paper, as I said, addressing that.

12 So they looked at that issue. They calculated the P
13 value about whether this was due to chance alone, and they
14 found that they got a significant -- it was statistically
15 significant result, in other words, not due to chance. So I
16 didn't have to do that, GSK did it for me.

10:11:24

17 Q. We'll hear from the GSK who co-authored that paper in the
18 trial.

19 You would agree with me that -- strike that.

10:11:34

20 Is it your testimony that FDA would approve a label
21 that has language in one place that contradicts class labeling
22 in a different place?

23 A. That contradicts it? No, I have not said that, sir.

24 Q. You would agree that a label cannot be internally

10:11:47

25 inconsistent, correct?

1 A. Internally inconsistent? Ideally it shouldn't be.

2 Q. Now, you testified just a minute ago that that labeling
3 supplement that GSK requested by CB in 2006 was false and
4 misleading, correct?

10:12:07

5 A. Yes.

6 Q. But you will agree with me that the FDA informed GSK, in
7 April 2006, that it had not no objection to GSK's plan to
8 proceed with implementing that language and to send out a Dear
9 Healthcare Provider letter regarding the new language,

10:12:27

10 correct?

11 A. Ah, I actually don't know what response FDA provided to GSK
12 prior to their approval letter in May 1st, 2007, to the
13 submission. I don't know if there were any proceeding
14 communications from FDA, one way or the other.

10:12:46

15 Q. So you don't know that FDA said it didn't have any
16 objection for GSK to proceed with the CB label change and to
17 sent out a Dear Healthcare Provider letter?

18 A. The way the CB supplements work is that if the FDA does not
19 -- the FDA doesn't have to say anything. If the company has
20 not heard back from the FDA within 30 days, they're free to
21 proceed, but the FDA doesn't have to say anything, one way or
22 the other.

10:13:07

23 Q. You haven't reviewed that correspondence about what the FDA
24 did as a regulatory expert in this case?

10:13:22

25 MR. WISNER: Objection; misstates the roll of the FDA

1 completely. Move to strike.

2 THE COURT: What --

3 MR. WISNER: He just called the FDA a regulatory
4 expert.

10:13:32 5 THE COURT: I think we're beyond the scope.

6 MR. BAYMAN: I called him a regulatory expert.

7 THE COURT: We're beyond the scope of redirect.

8 Recross is very limited.

9 MR. BAYMAN: Well, he said it was false and
10:13:40 10 misleading, Your Honor, and I was just trying to see if he knew
11 what the FDA said about whether it was false or misleading and
12 he says he wasn't reviewed it.

13 MR. WISNER: So then why are you asking the question
14 over and over.

10:13:50 15 MR. BAYMAN: I just want to see is that right.

16 BY MR. BAYMAN:

17 Q. You have not reviewed that correspondence about what the
18 FDA said about GSK's proposed CB in 2006, is that correct?

19 A. I haven't seen any documents related to that.

10:14:03 20 Q. And as of 2006, the FDA did not issue a final determination
21 on whether it would accept GSK's CB supplemental or not,
22 correct?

23 A. To the best of my knowledge, no.

24 Q. And they did not ultimately approve that CB because they
10:14:24 25 suggested their own language, correct?

1 A. For class labeling, yes.

2 Q. And you agree that by approving the final labeling in 2007,
3 FDA determined the statements in Paxil's label are neither
4 false nor misleading, correct?

10:14:40

5 A. Based on the information that they had--excuse me--yes.

6 MR. BAYMAN: I've no further questions, Your Honor.

7 THE COURT: All right.

8 MR. WISNER: I don't know if this witness should be
9 excused or not.

10:15:02

10 THE COURT: I think he should be excused.

11 MR. BAYMAN: One further question, Your Honor.

12 BY MR. BAYMAN:

13 Q. And the FDA approved the format of that labeling in 2007
14 also, correct?

10:15:11

15 A. I'm sorry, what do you mean by "the format."

16 Q. Well, you talked about an old format and a new format. FDA
17 approved the formatting of that label in 2007, correct?

18 A. GSK is not subject to the new format. They can use it if
19 they like, if they choose to make their warnings clear.

10:15:31

20 Q. But my question is, FDA approved the label in the format in
21 which it was submitted, correct?

22 A. Yes.

23 Q. And that same language in the labeling, you talked about
24 30 years, those same warnings in the labeling are there today,
25 correct, with respect to suicidality?

10:15:45

1 A. I'm actually not aware of specific warnings about Paxil in
2 the label with regard to anything about suicide, with the
3 exception of, as we've discussed last week, the inclusion of
4 emotional lability, which is the code used for suicide
5 attempts, that's in the adverse reaction section, but other
6 than that, I'm not aware of any Paxil-specific warnings.

10:16:08

7 Q. No, my question was, the labeling that was approved in 2007
8 and the language with respect to the suicide warnings, that is
9 still the same language that is in the labeling today based on
10 your review of the January 2017 label last week, correct?

10:16:25

11 A. GSK has not updated the label to include what it knows
12 about Paxil-induced suicide, you're correct.

13 Q. And nor has FDA changed the label, correct?

14 MR. WISNER: Your Honor, Objection; asked and
15 answered.

10:16:43

16 THE COURT: Yes. I think it was covered.

17 Thank you very much.

18 You are excused. Thank you very much, Doctor.

19 THE WITNESS: Thank you so much, Your Honor.

20 THE COURT: You may leave.

10:16:47

21 THE WITNESS: Thank you.

22 (Witness excused.)

23 THE COURT: Call your next witness, please.

24 MR. RAPOPORT: That would be Martin Sachman, Your
25 Honor, who is here and will be in the room momentarily.

10:16:56

1 (Brief pause)

2 MR. RAPOPORT: We have a book with a courtesy copy of
3 his deposition transcripts and the exhibits that are planned to
4 be used for the witness.

10:17:10 5 (Brief pause).

6 (Binder tendered to the Court.)

7 THE COURT: Doctor, step up here, please.

8 (Brief pause).

9 THE COURT: Right around there, Doctor (indicating).

10:17:32 10 MR. RAPOPORT: I should --

11 THE COURT: Place raise your right hand, sir.

12 (Witness duly sworn.)

13 THE COURT: You may take the wand.

14 You may proceed, sir.

10:17:51 15 MR. RAPAPORT: Thank you, Your Honor. I was just
16 looking for the portable mike.

17 (Brief pause)

18 MARTIN SACHMAN, PLAINTIFF'S WITNESS, SWORN

19 DIRECT EXAMINATION

10:17:52 20 BY MR. RAPOPORT:

21 Q. Good morning.

22 A. Good morning.

23 Q. Please tell the folks your name.

24 A. Martin Sachman.

10:18:31 25 Q. And how long have you been living in Chicago?

1 A. All of my life.

2 Q. What do you do for a living?

3 A. I'm a physician and internist.

4 Q. We'll get to that in a little while, but I want to talk,
5 ask questions about your personal life a little bit first.

10:18:42

6 Going back to before July 15 of 2010, who was your
7 closest friend?

8 A. Stu Dolin.

9 Q. You're the first witness in the case that has had a chance
10 to discuss Mr. Dolin.

10:18:59

11 Let's start by tell the folks a little bit about what
12 he was like.

13 A. Stu was a very reserved, quiet, intelligent, loving man. I
14 never heard him raise his voice over our 25-year relationship.

10:19:19

15 We were like brothers. We spent weekends together, travel
16 together. He was my closest friend. A loving person and a
17 loving family man.

18 Q. Are you married?

19 A. Yes, I am.

10:19:31

20 Q. What is your wife's name?

21 A. Cheryl.

22 Q. How long you and Cheryl been married?

23 A. 35 years.

24 Q. Did you have children together?

10:19:38

25 A. Yes.

1 Q. How many of those?

2 A. 2.

3 Q. And what are their names and ages?

4 A. Jason is 33 and Gena 30.

10:19:45

5 Q. Was Stu married?

6 A. Yes.

7 Q. Who was he married to?

8 A. Wendy.

9 Q. And, roughly, for how long?

10:19:53

10 A. Oh, longer than we have. Closer to 40 maybe years, I
11 think.

12 Q. Now, you mentioned that it was roughly a 25-year
13 relationship at the time that Mr. Dolin's life ended?

14 A. Yes.

10:20:06

15 Q. How did it begin, in general?

16 A. It began -- we met each other on a trip we were both on.
17 His parents had been patients of mine. And I was talking about
18 being away for a little bit, and we got to talking, and it
19 turned out we'd be on the same trip. So we sought each other
20 out.

10:20:24

21 Q. And over what -- were you couple friends? Friends
22 together, the four of you?

23 A. Yes.

24 Q. Did you also spend time with Mr. Dolin individually as
25 guys?

10:20:34

1 A. Absolutely.

2 Q. And what would you say your frequency of contact, we won't
3 take the entire span, but let's say for the 5 years before he
4 passed away, with what frequency would you see him?

10:20:47

5 A. I would say we saw them as couples at least once a month,
6 maybe more, sometimes a little less, but frequently.

7 Q. Okay. The folks haven't had a chance to really see a good
8 photograph of Mr. Dolin. And I know we have one of those
9 prepared. We're having a couple of technical difficulties. So

10:21:09

10 I'm going to ask my team --

11 MR. WISNER: We can that.

12 MR. RAPOPORT: Oh, you can.

13 MR. WISNER: Yes.

14 MR. RAPAPORT: Great. Because we can just use the
15 Elmo, too.

10:21:15

16 (Brief pause)

17 BY MR. RAPAPORT:

18 Q. Okay. We have some images and other things that we can use
19 soon.

10:21:27

20 All right. We have up what is Plaintiff's Exhibit
21 Number 1. Who are we looking at here?

22 A. Stu Dolin.

23 Q. And, roughly, how old would you say he was in that picture?

24 A. Mid 50's, maybe. Mid 50's.

10:21:43

25 Q. Is that pretty much what he looked like around the time of

1 his death?

2 A. Yes, it is.

3 Q. Is that a fair and accurate image of Mr. Dolin?

4 A. Absolutely.

10:21:53

5 Q. Okay. Now, what was his -- let me back up. What are some
6 examples of the kinds of things you and he and your families
7 would do together?

8 A. You know, other than just sometimes just hanging at each
9 other's houses --

10:22:10

10 THE COURT: Doctor, you're going to have to stay
11 closer to that microphone. Keep your voice up. We want to
12 hear everything you say.

13 BY THE WITNESS:

10:22:21

14 A. Other than dinners together the four of us, sometimes our
15 entire families would be together. Sometimes he and I would
16 just go to a sports game, hang, watch sports, go to sports
17 events, things like that.

18 BY MR. RAPAPORT:

19 Q. Tell the folks a little bit about Stu and Wendy's children.

10:22:35

20 A. Her children, they have two. A son Zack and daughter Bari.
21 Zack is a computer designer. And Bari lives in New York in
22 real estate.

23 Q. Great. And they're friends with your own kids?

24 A. Yes.

10:22:59

25 Q. Now, what do you do for a living?

1 A. I'm a physician.

2 Q. How long have you been a physician?

3 A. Practicing about 38 years.

4 Q. We put together a quick summary of your qualifications.

10:23:17

5 MR. RAPAPORT: And, Your Honor, with your permission

6 I'll read that to the jury.

7 THE COURT: Read that to the jury, right.

8 MR. WISNER: (Reading:)

9 Dr. Sachman's qualifications: Dr. Martin

10:23:27

10 Sachman is a physician who is licensed to

11 practice medicine in Illinois. He earned his

12 undergraduate degree in Liberal Arts and

13 Sciences from the University of Illinois in

14 1970, after which he attended Chicago Medical

10:23:43

15 School where he graduated in 1975. After

16 earning his medical doctorate degree, Dr.

17 Sachman completed an internship and residency in

18 internal medicine at Michael Reese Hospital. He

19 has been Board Certified by the American Board

10:24:01

20 of Internal Medicine since 1978. Dr. Sachman's

21 office is in Northbrook, Illinois, and he has

22 privileges at the four North Shore University

23 Health System Hospitals."

24

10:24:14

25 BY MR. RAPAPORT:

1 Q. Now, just a few questions. First of all, I know hospital
2 systems change names. What four hospitals are those?

3 A. These are Highland Park Hospital, Evanston Hospital,
4 Glenbrook and Skokie.

10:24:30

5 Q. What is it to be an internal medicine doctor such as
6 yourself?

7 A. Well, I'm a general internist, so I take care of all the
8 medical problems of an adult. I don't take care of children.
9 My practice begins at about age 16 or so. We take care of all

10:24:47

10 kinds of general medical problems, from heart disease to
11 endocrinology to GI problems.

12 Q. Was Mr. Dolin one of your patients?

13 A. Yes, he was.

14 Q. Was Mrs. Dolin one of your patients?

10:25:00

15 A. Yes, she is.

16 Q. Do you have other friends or family members that are
17 patients?

18 A. Yes.

19 Q. Is that unusual in the practice of internal medicine when
20 you live in the same community as your practice?

10:25:07

21 A. Not at all.

22 Q. Do you know any internal medicine doctors who have those
23 kind of circumstances that don't have some friends and family
24 as patients?

10:25:19

25 A. Sure. We all take care of friends and family.

1 Q. And are there any ethical rules within your profession that
2 prohibits that kind of thing?

3 A. None.

4 Q. Now, we have admitted into evidence already Joint
5 Exhibits 11 and 12.

10:25:36

6 Joint Exhibit 11 would be your medical records for
7 Mr. Dolin and Joint Exhibit 12 would be pharmacy records
8 concerning certain prescriptions, okay?

9 A. Yes.

10:25:51

10 Q. So before getting -- and those are Joint Exhibits 11 and
11 12. Have you prepared some summaries of those in order to take
12 what might be more volumes information and distill it down to
13 the bottom line?

14 A. Yes. Yes, I have.

10:26:10

15 Q. And we've marked as those as Plaintiff's Exhibit 68 and 69
16 for purposes of our trial, is that correct?

17 A. Yes.

18 Q. Is Exhibit 68 a fair and accurate summary of your office
19 visits with Mr. Dolin?

10:26:23

20 A. Yes, they are.

21 Q. And is Exhibit 69 a fair and accurate summary of the
22 prescriptions for SSRI medications?

23 A. Yes, it is.

24 Q. Okay. Great.

10:26:38

25 MR. RAPOPORT: At this time, Your Honor, we would like

1 to move these into -- 68 and 69 into evidence as summaries of
2 voluminous material.

3 THE COURT: They may be received.

4 MR. RAPOPORT: Thank you, Your Honor.

10:26:48

5 (Plaintiff's Exhibits 68 and 69 were received in
6 evidence.)

7 MR. RAPOPORT: Thank you, Your Honor. And I see we're
8 going to use the Elmo to display these.

9 Maybe I'll just take some assistance.

10:26:58

10 (Brief pause)

11 BY MR. RAPAPORT:

12 Q. All right. We're going to place up the first one, 68. I
13 know you have a small copy in front of you.

10:27:30

14 All right. Here we have a summary of your medical
15 records for Mr. Dolin, Joint Exhibit 11. Would you roughly
16 walk us through that.

17 A. This is just a summary of office encounters with Stewart
18 over the course of those 6 years or so.

10:27:49

19 Most of the time he was just in for a physical exam.
20 He was basically a healthy person. A couple of those visits
21 were because he was ill with minor illness, and the last entry
22 is just a note I made of a conversation.

23 Q. Okay. And that note on July 8th of '10 related to the
24 Paxil that brings us here today, correct?

10:28:09

25 A. Yes. Yes.

1 Q. Now, let's go ahead and put 69 up for a moment.

2 (Exhibit published to the jury.)

3 BY MR. RAPAPORT:

10:28:24

4 Q. And 69 is a summary of Joint Exhibit 12 being prescription
5 records from Parkway or is it Parkview drugs?

6 A. Parkway.

7 Q. Parkway Drugs. So what are we looking at here?

10:28:47

8 A. This is a summary of prescriptions that I wrote for Stewart
9 between '05 and 2010, first was for Paxil and then there's a
10 series of entries for Zoloft, and the last was for Paxil.

11 Q. And we'll talk in some more detail about this, but just to
12 zero in.

13 MR. RAPAPORT: And I'm going to have Mr. Wisner put
14 his finger on June 27 of '10.

10:28:59

15 (Brief pause).

16 BY MR. RAPAPORT:

17 Q. Great. Gets a little green arrow on it.

18 So that is the prescription --

19 A. Yes.

10:29:10

20 Q. -- that we were talking about today?

21 A. Yes, it is.

22 Q. Now, what I'd like to do is take Joint Exhibit 12, and I'm
23 simply going to rely on the excellent team here, Joint
24 Exhibit 12.

10:29:23

25 I'm not sure who is going to do that one, but what I'd

1 like to show is that Paxil record from the pharmacy for
2 June 27. We'll have it up in a moment.

3 (Brief pause).

4 (Exhibit published to the jury.)

10:29:40

5 BY MR. RAPAPORT:

6 Q. Okay. There we go.

7 Now, I'm going to blow up so we can all see it.

8 This is a record from the pharmacy rather than from
9 your medical office, would that be correct?

10:30:19

10 A. That's correct.

11 Q. And when you make a prescription, there are various ways
12 that this would be -- that this can be communicated to a
13 pharmacy, is that correct?

14 A. That's correct.

10:30:30

15 Q. That you were showing me this morning before court, you
16 actually have a device in your pocket that has something to do
17 with the whole process of getting certain prescriptions, right?

18 A. Correct.

19 Q. Would you show folks what that is.

10:30:45

20 A. This is a little FAB that we use to electronically
21 prescribe prescriptions. I can e-mail a prescription to a
22 pharmacy and I hit this little button (indicating) and a random
23 number comes up, and then I hit a four-coded number, which is
24 my identification, and we can prescribe controlled substances

10:31:06

25 with this FAB from a distance.

1 Q. Okay. So it's security like some of us see with banks.

2 A. Right.

3 Q. If you have the right to prescribe meds, this is kind of a
4 security system?

10:31:16 5 A. Exactly.

6 Q. Okay. Now, in your office records, do you have any
7 indication of making a written prescription for the Paxil that
8 brings us here today?

9 A. You know, I don't know if it was written or called in.

10:31:31 10 Q. Okay. You really don't remember?

11 A. I remember the prescription being authorized, though.

12 Q. Are you aware of any better record of what was ordered by
13 you on June 27th of '10 other than the one that we have up
14 here?

10:31:45 15 A. No.

16 Q. And would you put that all that jargon into plain English
17 for people and tell us what story that document tells?

18 A. Well, this highlighted entry is for prescription that I
19 wrote for Stewart Dolin for Paxil, 10 milligrams. It was for
20 30 tablets and the direction was to take one tablet daily.

10:32:01

21 Q. All right. Now, did you care whether it was filled with a
22 generic or the name brand?

23 A. I did not and he did not.

24 Q. Is there any difference, that you know of?

10:32:25

25 A. Functionally, no.

1 Q. Now, when was it that he was supposed to begin taking this
2 drug that was filled on June 27th?

10:32:43

3 A. Right. He wasn't going to take this drug until we again
4 spoke. I had started him actually on a different SSRI about
5 ten or so days before, that was Zoloft. And he had taken
6 Zoloft before and had done well on that.

10:33:03

7 This time he didn't feel well. He was nonspecifically
8 just not right, he felt off. And we didn't know what it was,
9 but we thought it might be the Zoloft. So at that time we
10 stopped the Zoloft, I wrote the prescription for Paxil, and
11 instructed him not to take it until we spoke. And then after
12 several days he began to feel better.

10:33:19

13 Q. All right. And so we'll talk about all that in a little
14 more detail, but right now what I've done here is put this
15 other thing with some emphasis from the same drug pharmacy
16 record.

17 What are we looking at there? We can see the date of
18 June 18 of '10.

10:33:36

19 A. This is a different prescription for Zoloft that I
20 referenced a second ago.

21 Q. All right. Now, I want to take a sidestep away from care
22 and treatment of Stewart Dolin and talk with you about your own
23 knowledge and history with use of antidepressant medications.
24 So that's the next topic.

10:33:57

25 A. Okay.

1 Q. So let's take that all the way back to your initial
2 exposure to antidepressant medications. Would that have been
3 medical school, internship?

4 A. Probably early practice, maybe residency.

10:34:15

5 Q. Okay. Now, back in those days, was it common or uncommon
6 for internal medicine doctors to be giving antidepressant
7 medications?

8 A. In the beginning of my career it was much less common.

9 Q. Who was doing that kind of prescribing?

10:34:34

10 A. Mostly psychiatrists. We referred people much sooner to
11 psychiatrists in those days, even with people who had more
12 minor -- sorry, minor episodes of depression. The drugs
13 weren't as user friendly, so to speak. We weren't as
14 comfortable with them. And the drugs out there actually had a
15 lot of other side effects different than SSRIs that made them
16 more difficult to use.

10:34:58

17 Q. Now, going back to the early years of your practice with --
18 were you seen very much either depression or anxiety in your
19 practice?

10:35:16

20 A. Some, I think -- I think in the later years more, after
21 several years of practice and in the years, more recent years
22 there's more, more anxiety, a little more depression. People
23 seem more stressed, there's more chronic stress in the world,
24 it seems. People talk about it more freely. So the simple
25 answer is, we see a lot more of it, for sure.

10:35:39

1 Q. And were you seeing -- withdraw it.

2 Can you please explain to folks a little bit, first
3 with anxiety, how that ranges, you know, from a little to a
4 lot? How do you think about that in medicine?

10:35:57

5 A. Well, you know, you sort of talk to the patient, you judge
6 how the patient appears to you in what they tell you.

7 Anxiety can be just someone saying that they can't
8 sleep to, you know, to a range where they can't function at
9 work, where they can't think straight, where they're physically
10 moving around, can't sit still, psychomotor anxiety,
11 nervousness inside and obvious motion and nervousness on the
12 outside.

10:36:18

13 Q. And is there any simple language that can be used to
14 describe -- you know, it's really a continuum --

10:36:36

15 A. Correct.

16 Q. You have things that aren't much on one end to things that
17 are a big deal. And I'm intentionally using just loose lay
18 language because I want to find out from you what would be more
19 technical terms for that kind of a continuum when you talk
20 about anxiety.

10:36:53

21 A. Well, a simple way to term it is simple just nervous, that
22 word works still in lay terms and in medical terms. And, you
23 know, chronic stress and anxiety can lead to depression.

24 There's this term akathisia, which is a psychomotor kind of
25 anxiety, which I referenced, where people are quietly anxious,

10:37:10

1 they're emotionally upset, they can't think straight, and they
2 can't be still, they're moving around, sweaty, can't sit still,
3 can't be still, can't think straight.

10:37:31

4 Q. All right. And let's talk about the range of similar sort
5 of a thing, a continuum of depression. You have a lot of
6 different things under that label, don't you?

7 A. Yes.

8 Q. Go ahead and just describe the kind of swing from not much
9 to a lot there.

10:37:43

10 A. We see patients every day in the office who are depressed
11 about something, some simple thing, we call that a active
12 depression where something happens in their life, a situation
13 or situations that depress them. And these people are not
14 seriously depressed, they're reacting to a situation. And
15 they're usually easily treated with a medication.

10:38:04

16 People who are more clinically depressed, who have a
17 major depressive disorder, act differently. They can't -- they
18 tell you different things. They can't sleep, they can't eat.
19 They're physically ill within a variety of symptoms. And these
20 are people who -- who shouldn't be treated, I don't believe, by
21 an internist, who should be referred to a psychiatrist. The
22 people who have simple reactive depressions are those who
23 internists can say we treat.

10:38:22

24 Q. Now, coming back to this sort of change in both your habits
25 and really your profession of internal medicine in particular

10:38:42

1 where it moved toward more of that being done by internal
2 medicine or is it fair to say family practice doctors?

3 A. Yes.

4 Q. So, roughly, when did that become more common in your life?

10:39:01

5 A. Well, it truly -- with the advent of the SSRIs coming on
6 the market.

7 Q. And you folks here know more than the average person now
8 about SSRIs. Let's get it, though, from how it came to you in
9 your real life.

10:39:19

10 So when these drugs -- and we all know the timeframe
11 of the early '90s, maybe 1990 or a little bit before for Prozac
12 and then others. So when you're out in your medical practice,
13 and back in those days, you know, how many patients would you
14 be seeing a day on a workday?

10:39:37

15 A. Back in those days, 20-ish, give or take a couple.

16 Q. And you've always had patients that are hospitalized as
17 well?

18 A. Yes.

19 Q. So your day would, you know, involve some hospital visits
20 sometimes?

10:39:52

21 A. Correct.

22 Q. Otherwise, seeing a bunch of patients.

23 So and other than seeing patients, would you have the
24 opportunity to see drug representatives that were coming over
25 and telling you about their new drugs?

10:40:05

1 A. Yes.

2 Q. Is that a common kind of occurrence in the medical practice
3 like yours?

4 A. Very common.

10:40:12 5 Q. And you've been in a few different practice situations, did
6 that occur in every one of them?

7 A. Yes.

8 Q. With respect to Paxil in particular, was GSK sending over
9 sales representatives over the years to talk with you about
10 Paxil regularly?

11 A. Yes.

12 Q. Now, we have marked as exhibit -- Plaintiff's Exhibit 272,
13 just a few pages of some of that sort of activity. And you
14 have a copy of it in front of you as well, is that correct?

10:40:45 15 A. Yes.

16 THE COURT REPORTER: Counsel, could you move the
17 microphone closer to you.

18 MR. RAPAPORT: Sure.

19 (Brief pause).

20 MR. RAPAPORT: Let me get to a place where you can
21 hear me better.

22 MR. DAVIS: Your Honor, I don't believe there's a
23 foundation that's been laid for use of this.

24 THE COURT: THE COURT: I don't know what is ahead of
10:41:17 25 us. I need a few more questions to understand.

1 MR. WISNER: Yeah, which I was doing.

2 MR. DAVIS: It wasn't on the screen.

3 MR. RAPAPORT: Yeah, I wasn't putting up anything on
4 the screen.

10:41:25 5 BY MR. RAPAPORT:

6 Q. So with respect to Exhibit 272, you've had a chance to look
7 at that agreed?

8 A. Agreed.

9 Q. And you can see, by looking at it, that it's documentation
10 of various visits from drug representatives from GSK over a
11 period of time that's described in the exhibit, correct?

10:41:38

12 A. Yes.

13 Q. And the period, the first date on there --

14 MR. DAVIS: Excuse me, Mr. Rapoport.

10:41:56

15 Your Honor, I don't believe a foundation has been laid
16 with this witness to show that this witness has knowledge of
17 it, can speak to it, or has any background information about
18 this particular document.

19 MR. RAPAPORT: I can do better.

10:42:07

20 THE COURT: Well, I haven't seen the document.

21 Do you have it?

22 MR. RAPAPORT: Yeah, it's in your book, Your Honor.
23 It's 272.

24 THE COURT: Okay.

10:42:17

25 (Brief pause).

1 MR. RAPOPORT: While you're looking, I'll keep asking
2 questions.

3 BY Mr. Rapoport:

10:42:31

4 Q. So, Doctor, you know from your own personal knowledge about
5 drug reps coming in and the sort of things that happened in the
6 those discussions, correct?

7 A. Yes.

8 Q. You don't keep records necessarily in your own side of this
9 of how often they come in, right?

10:42:46

10 A. Correct.

11 Q. But you know sometimes in the early years they buy lunch,
12 right?

13 A. Yes.

10:42:58

14 Q. And some of that kind of thing is a little less nowadays,
15 agreed?

16 A. Correct.

17 Q. But there are drug reps that are coming into your office
18 fairly constantly, are they not?

19 A. Yes.

10:43:05

20 Q. And you would understand that these drug reps are reporting
21 back to the mother ship things like how often they saw you,
22 right?

23 A. Correct.

24 Q. Like how many free samples they gave you, right?

10:43:16

25 A. Right.

1 Q. And in looking at this record, you didn't prepare this
2 record, agreed?

3 A. Agreed.

10:43:25

4 Q. This is a record that I've represented to you was produced
5 by GSK in this lawsuit, right?

6 A. Yes.

7 Q. Do you have any reason to think that GSK would be
8 inaccurately reporting how often they sent a sale rep in to see
9 you?

10:43:38

10 A. No.

11 MR. RAPOPORT: Your Honor, at this time I move to
12 admit Exhibit 272 into evidence.

10:43:49

13 MR. BAYMAN: I still don't believe they've laid the
14 foundation for this witness to talk about anything on that
15 particular document, Your Honor.

16 THE COURT: These are the notes of the salesman as and
17 distinguished from the doctor's own notes, aren't they?

10:43:59

18 Mr. Rapoport: They are, but they also record when the
19 person was there and how many samples were left, which is what
20 I'm about --

21 MR. DAVIS: I don't believe they need that particular
22 document to ask those particular questions and they still
23 haven't laid the foundation that this witness can speak to
24 what's on this particular document.

10:44:08

25 THE COURT: Well, ask the witness questions and use

1 this to refresh his recollection if you want to, but he didn't
2 prepare it, it's not his record, sir.

3 MR. RAPOPORT: Yeah, totally agreed.

4 BY Mr. Rapoport:

10:44:20

5 Q. Let's just go through it.

6 So you have it in front of you, correct?

7 A. Yes.

8 Q. All right. So the total period of time covered by this is
9 from October 5th of '05 -- oh, excuse me. I started in the
10 wrong place.

10:44:31

11 MR. DAVIS: Mr. Rapoport, excuse me.

12 Your Honor, to refresh recollection, I believe the
13 witness gets the document, then the witness -- the document is
14 taken away after a witness's recollection is refreshed, and
15 then the witness testifies.

10:44:49

16 MR. RAPOPORT: Your Honor, I'll move on. I'll move.
17 I don't blame him for not wanting to know how many samples they
18 give.

19 MR. DAVIS: Your Honor, Mr. Rapoport is free to ask
20 that question of the witness and the witness can testify from
21 his own personal knowledge.

10:44:59

22 THE COURT: Proceed.

23 MR. DAVIS: Thank you.

24 MR. RAPOPORT: Thank you.

10:45:09

25 BY Mr. Rapoport:

1 Q. All right. So with regard to this particular document,
2 have you had a chance to see the timeframe that it covers?

3 A. Yes, I have.

4 Q. The first date on there is January 8th of 2004, is that
5 correct?

10:45:23

6 A. Yes.

7 MR. DAVIS: Your Honor, I don't mean to belabor this,
8 but there's still no foundation laid of this witness needs this
9 document to refresh his recollection or has personal knowledge
10 of the contents.

10:45:38

11 THE COURT: Proceed.

12 MR. DAVIS: Thank you, Your Honor.

13 MR. RAPOPORT: Thank you.

14 BY Mr. Rapoport:

10:45:43

15 Q. The last date covered by this particular exhibit is
16 August 30th of 2006, correct?

17 A. Yes, it is.

18 Q. And if we just eyeball the first page of it, there are a
19 dozen different visits documented on that page, correct?

10:46:07

20 A. Yes.

21 Q. And if we go down, the thing is 5 pages long, correct?

22 A. Yes.

23 Q. And page 2 and 3 and 4 all have about a dozen entries on
24 it, don't they?

10:46:25

25 A. Yes.

1 Q. And the fifth page has only 3 entries, agreed?

2 A. Agreed.

3 Q. Now, various of these entries document that you were left
4 samples of Paxil, correct?

10:46:39

5 A. Yes.

6 Q. So, for example, the first documented thing here says that
7 you were left 8 packages, 7 pills each --

8 MR. DAVIS: Objection. Leading, Your Honor.

9 THE COURT: All right. The objection is sustained.

10:46:54

10 Mr. Rapoport: Okay.

11 THE COURT: I understand that this is taken from Mr.
12 Obenland's notes, otherwise to do this.

13 Mr. Rapoport: Okay.

10:47:05

14 THE COURT: To ask the witness whether he agrees with
15 it or not is really not important. It's what's shown in the
16 record and not whether he agrees or disagrees. So the
17 objection is sustained. Proceed, please.

18 BY Mr. Rapoport:

10:47:19

19 Q. The point and, you know, maybe get at that, is over the
20 period from 1992 through the time that Mr. Dolin died, you were
21 regularly receiving free samples of Paxil from GSK, correct?

22 A. Yes.

23 Q. They typically came -- what kind of packages were these?

10:47:43

24 A. Yes, I remember they were in boxes, small boxes with
25 tablets in them.

1 Q. Typically a one-week supply?

2 A. Often.

3 Q. And what were you being encouraged to do with these?

10:47:55

4 A. Well, you're encouraged to start a patient on the drug and
5 start them off with samples.

6 Q. Now, you first had an opportunity to see a label for Paxil
7 use right when the drug came out, would that be correct?

8 A. Yes.

10:48:18

9 Q. And we have marked the Paxil label from 1992 as Plaintiff's
10 Exhibit 48. And it's already in evidence in our case.

11 So would you -- did you have occasion to read that
12 recently?

13 A. Yes; recently.

10:48:39

14 Q. Now, sir, did that label have any warning in it that
15 informed you, as a treating doctor, that there was a risk of
16 drug-induced suicide that had been discovered in the clinical
17 trials of Paxil?

18 A. No.

10:48:54

19 Q. Now, I want to just call your attention to the label that
20 was in effect when -- on June 27th of '10 when you wrote the
21 prescription for Stewart Dolin.

22 You've had a chance to look that label over, have you
23 not?

24 A. Oh, yes.

10:49:05

25 Q. Was there any warning in that label that told you that

1 people over 24 were at risk of a drug-induced suicide from
2 Paxil?

3 A. Absolutely not.

4 Q. Would you -- if you knew that, would you have ever
5 prescribed Paxil for Mr. Dolin?

6 A. Absolutely no.

7 Q. Why not?

8 A. Because I wouldn't have wanted to risk that ultimate side
9 effect with that drug. There were other choices I could've
10 used.

11 Q. All right. Now, let's go ahead, and I'm going to put up
12 again the board that shows various prescriptions of SSRI's that
13 you gave to Mr. Dolin and the next thing I'd like to do is walk
14 through that with you.

15 And while that is being set up, I want to ask
16 something different. Let's hypothetically assume that I was a
17 patient in your office, but that it's 2010, and that you've
18 talked to me and you formed an impression that I had some mild
19 to moderate anxiety, you did not believe that I was depressed,
20 and you had decided that you were going to recommend Paxil.

21 Got the scenario?

22 A. Yeah.

23 Q. If you would, please recreate in the courtroom, as if we're
24 all sitting there in your office watching this interaction
25 between you and I, tell me what it is, based on your usually

1 customs and practices, that you would've explained to me about
2 that drug.

3 A. Well --

4 Q. Based on what you knew then, not what you know now.

10:50:47

5 A. Yes. You know, we'd have discussion on what the issues
6 were. I would assess the level of anxiety that you may have.
7 And explain to you that drugs like Paxil are very good for
8 anxiety. I would explain to you how the drug worked and what
9 to expect in the initial days of treatment.

10:51:07

10 I would say to you that you could feel a little more
11 anxious. You could even feel a little depressed even if you
12 weren't depressed to start with. You could have some physical
13 symptoms, headache, nausea, diarrhea. And I would instruct you
14 to call me if there's any symptom at all that's different.

10:51:26

15 Q. All right. And coming back briefly to the 1992 label, was
16 there anything in that label that told you that people were,
17 anybody of any -- people were at an increased risk of suicidal
18 behavior--in other words, before I asked you about suicide but
19 now I'm including suicidal behavior, attempts--was there
20 anything in there that warned you that people were at an
21 increased risk of suicide attempts in the '92 label?

10:51:49

22 A. No.

23 Q. Because of the drug.

24 A. No.

10:51:59

25 Q. And similar question for the 2010 label. Was there

1 anything in the 2010 label that told you, as a doctor, that
2 people above 24 in that label were at an increased risk of
3 suicide attempts?

4 A. Not at all.

10:52:12

5 Q. All right. Now, have you told us everything that in a
6 normal discussion with a patient you would've -- and the
7 setting we described, clinically, that you would've told them
8 about the whole discussion of recommending Paxil?

10:52:36

9 A. I think so. And in a patient who I would access as mildly
10 anxious, I think that was a fair summary of what I would talk
11 to them about.

12 Q. All right. And at the other end of the spectrum, if you
13 had somebody in your office that you thought was horribly
14 depressed and at risk in a big way, how did you deal with that?

10:52:54

15 A. Well, what I would do and what I have done, as I would make
16 an immediate referral to a psychiatrist, call him on the phone,
17 get the person an appointment. Refer a patient to an emergency
18 room if I felt the situation was really imminent. You react to
19 the situation and do what you need to do to protect the patient
20 based on your best assessment.

10:53:14

21 Q. All right. Now let's go ahead and display I think it's
22 Exhibit 69. And let's walk through these prescriptions of
23 SSRIs for Stu Dolin in the order that they are on the board.

10:53:41

24 So going back to October 3rd of 2005, the prescription
25 record, same kind that we've looked at, but this is simplified,

1 would show that you prescribed 10 milligrams of Paxil, and that
2 this was refilled by Mr. Dolin until the last refill, 10/29/06,
3 correct?

4 A. Yes. Sorry, yes.

10:54:00

5 Q. So about a year, a little bit more than a year, almost
6 13 months.

7 Please tell the jury everything you can remember about
8 what triggered that prescription.

10:54:16

9 A. Right. So I was hoping you'd ask me that. Stewart was an
10 extremely successful attorney. He was a mentor in his firm.
11 He worked on cases and at times he had a lot of stress related
12 to his work. He was -- he was over the top sometimes in terms
13 of how busy he was.

10:54:42

14 And he had recurrent situational anxiety. And it just
15 turned out that these drugs used in short increments always
16 helped him. Got him through the anxiety period and he went
17 back to functioning just fine without any medication.

10:55:00

18 Q. Okay. So that jumped ahead and kind of covered a whole lot
19 of it, and that's okay, but let's break it up a little bit
20 more.

21 So this one on October 3rd of '05, do you have a
22 definitive memory of that yourself or is that a vague thing in
23 your past?

10:55:15

24 A. No, I don't have a definitive memory of that particular
25 prescription or date, but I have a definitive memory of all the

1 things that went on with my best friend.

2 Q. Yes. And so let's start with what diagnosis you would have
3 had, if anything, that led to the prescription of Paxil back in
4 October of '05.

10:55:32

5 A. It would be a recurrent scenario kind of, where he would be
6 anxious because of pressures at work. It was always pressure
7 at work, too many things going on at once, and he would become
8 increasingly anxious about those kinds of things.

9 Q. And how did that work out the first time with Paxil?

10:55:55

10 A. He did very well.

11 Q. Fair enough.

12 Now, what then -- I see we have a gap of not quite a
13 year, but there's a prescription of Zoloft for the first time
14 in June of '07 for 50 milligrams a day. Tell us about that.

10:56:11

15 A. It was -- it was most likely a similar situation. Time
16 management, stresses at work. I can't exactly tell you, in all
17 honesty, why we used Zoloft that date rather than Paxil, but,
18 again, he had a good response to it.

19 Q. All right. And with respect to the documentation in your
20 medical records, tell us a little bit about what's in there and
21 what's not in there with respect to the anxiety situation that
22 you were treating.

10:56:35

23 A. Well, I think you're referring to documentation in my
24 record.

10:56:54

25 Q. Yeah.

10:57:14

1 A. My record may be lacking in document in Stewart's case more
2 so than documenting an average patient, because I had a lot of
3 personal contact with him that may not be entered into the
4 record. We talked about these situations socially on a weekend
5 often and the results of those conversations often didn't make
6 it back to the chart.

10:57:29

7 Q. Okay. So is there any better record than the pharmacy
8 record for indicating what prescriptions you did write for
9 SSRIs?

10 A. No, this is very accurate. As my recollection is, I don't
11 think they used any other pharmacy. That was their
12 neighborhood pharmacy.

10:57:47

13 Q. Now, do you -- they're called antidepressants, is that a
14 fair label for what these things are?

10:58:14

15 A. You know, it's a -- it's fair to a point. I and a lot of
16 us, others like me, use these for anxiety even more than
17 depression. And they work well for that also. I never thought
18 Stewart was depressed in any of these instances, from '05 up
19 through 2010. It was always anxiety and he responded as
20 situation in which an anxious person would.

10:58:31

21 Q. Now, in looking in retrospect, obviously in real time you
22 were doing these things one day at a time, but looking at it in
23 retrospect, it appears to be an on and off thing with these
24 meds, right?

25 A. Correct.

1 Q. What's that about? Tell us about that.

2 A. I think it's more of the same, Mr. Rapoport. Periods where
3 he would be a little bit more overwhelmed with work, his
4 responsibilities, and these were very effective for him in
5 helping him.

10:58:49

6 Q. And when he would get off, what would be either your
7 considerations or his in moments in time that are shown in the
8 right-hand column where he got off?

9 A. He would -- he would tell me that things were quieting
10 down, he felt much better. And we would just wean him off
11 slowly and make sure he had no withdrawal from stopping the
12 drug and making sure he had no rebound anxiety. And he was
13 able to come off each time for a period.

10:59:04

14 Q. Okay. And was it either your preference or his that if
15 things are going fine, that he be off the meds instead of on
16 them?

10:59:24

17 A. It was mostly his call.

18 Q. All right.

19 A. Can I -- there was a caveat. I want to say that there was
20 maybe a time or two when I kind of overruled him a little bit.
21 If things are better for a week, you don't make a rash
22 adjustment to stop a medication. You make sure they stay okay
23 for a little bit. Patients are always anxious to get off
24 medication. Sometimes you just have to slow things down and
25 make sure they're ready.

10:59:36

10:59:55

1 Q. So if I understand that correctly then, when we look at the
2 right-hand column where the medications were stopped at various
3 points, these would be moments in time where you and he were in
4 agreement that he should get off the med?

11:00:13

5 A. For sure.

6 Q. But the other dates reflect dates where you believe he
7 should be on the med, and, in some instances, he might've
8 wanted to come off it sooner?

11:00:28

9 A. Yeah, but he was -- he was pretty agreeable to -- to my
10 advice.

11 Q. Okay. So let's talk some, then, about your record, your
12 note on July 8th of 2010, which is found in Exhibit 11, I
13 believe.

14 (Brief pause).

11:01:05

15 BY Mr. Rapoport:

16 Q. Is that the correct entry, then, July 11th of '10?

17 A. Yes.

18 Q. Now, the first thing that I would like for you to do is
19 just read what that says, but convert any abbreviations into
20 full English so that we can understand what's written here.

11:01:27

21 A. Okay. So the date is 7/8/10. "Tel" indicates a telephone
22 entry, telephone conversation:

23 "... patient with increased work-related anxiety
24 did well on Paxil in the past."

11:01:48

25 It says:

1 "Paxil 10 milligrams daily. Call if problems.

2 Call in 10 to 14 days regardless."

11:02:11

3 Q. Okay. Now, on July 27th, we've already seen that a
4 prescription was given by you or on your authority to Parkway
5 Drugs for the very same thing that is documented here, correct?

6 A. Yes.

11:02:29

7 Q. And walk us through. You may have touched upon this before
8 but a little slower, walk us through what led up to the
9 prescription on June 27th and why this entry is in here for
10 July 8th.

11:02:49

11 A. What I said before, and maybe I jumped the gun, was that I
12 had originally prescribed Zoloft at this particular period for
13 him. He wasn't feeling well, very nonspecifically. More
14 physical than emotional, but couldn't put his finger on. So we
15 just stopped the Zoloft thinking maybe it was a reaction to the
16 Zoloft.

17 At the same time I gave him a prescription for Paxil,
18 10 milligrams, and told him not to start it and that we would
19 decide together when to start the Paxil.

11:03:02

20 He was off the Zoloft. And on this particular date,
21 we talked. Having been off the Zoloft for 10, 12, 14 days, I
22 thought it was safe to start the Paxil, and that's what this
23 reflects.

11:03:22

24 Q. Okay. And so is it your -- well, in reflecting back on
25 July 8th, do you believe that you spoke to Mr. Dolin that day?

1 A. Yes.

2 Q. And do you have a specific memory of what you said and what
3 he said or are you deriving this from your usual procedures in
4 what you believe most likely happened?

11:03:43 5 A. No, I think -- I think I remember talking to him.

6 Q. Okay.

7 A. He -- you know, he was feeling okay physically and I told
8 him to start the Paxil. And I reminded him of my usual
9 instructions to patients, that if he begins to feel worse in
10 any way, physically or emotionally, he should call me right
11 away. If not, I said, call me in 10 to 14 days.

11:04:02

12 Q. Okay?

13 A. Now, it's possible I would've talked to him before 10 to
14 14 days, but at least for professionally to document, at least
15 in that period.

11:04:17

16 Q. Okay. So in a sense, he already had the pills because he
17 filled the prescription on June 27th and this is the thumbs up
18 to okay and start.

19 A. To go ahead and start that prescription.

11:04:28

20 Q. Now, the records that are in evidence already, but the jury
21 hasn't had a chance to see them, contain an entry by
22 Dr. Sahlstrom that is dated, I believe, July 12th that
23 indicates that he started taking the Paxil the Saturday
24 before --

11:04:50

25 MR. DAVIS: Excuse me, Mr. Rapoport.

1 MR. RAPOPORT: I withdraw the question.

2 MR. DAVIS: Your Honor, I believe there's no
3 foundation for that question.

4 MR. RAPOPORT: It's a withdrawn question.

11:04:57

5 MR. DAVIS: Thank you.

6 BY Mr. Rapoport:

7 Q. If Mr. Dolin started taking the pills on July 10th instead
8 of July 8th, would that have been any problem you with?

9 A. Two days later?

11:05:10

10 Q. Right.

11 A. Of course not.

12 Q. And why not?

13 A. Well, the -- the -- the point in -- in not allowing him to
14 start the Paxil right on top of the Zoloft, we always want a
15 washout period and not use two SSRIs at the same time. So any
16 time he would start after an adequate washout period would be
17 safe.

11:05:25

18 Q. All right. Let's move forward in time then, from July 8th
19 of 2010, to the next time that you remember seeing or talking
20 with Mr. Dolin.

11:05:44

21 A. That was probably two days before his death.

22 Q. All right. So his death was on July 15th, a Thursday.

23 A. Yes.

24 Q. And what were the circumstances that brought you together
25 that Tuesday night?

11:05:58

1 A. We had gone to a mutual friend's father's memorial service.
2 He, Wendy and I were there, my wife was out of town at a
3 meeting. So we spent some time there and then we went to
4 dinner.

11:06:15 5 Q. All right. And please describe, to the best of your
6 ability, what you remember about Mr. Dolin from that night.

7 A. Ah, there was really nothing special about that night in
8 terms of his -- he was just Stu. His demeanor was as usual,
9 our conversation was as usual. He was calm. I was -- I had
11:06:36 10 some issues, some administrative issues in my office and I was
11 trying to pick his brain for some advice.

12 Q. Okay. Different topic: I want to zero in for a few
13 minutes on each member of Mr. Dolin's immediate family --

14 THE COURT: This was July 12th that you saw him?

11:06:55 15 THE WITNESS: 13th, sir.

16 THE COURT: 13th. Okay. That was the last time you
17 saw him?

18 THE WITNESS: Yes.

19 BY Mr. Rapoport:

11:07:02 20 Q. I want to zero in on some different issues and focus
21 initially on Wendy.

22 Please tell the folks what kind of husband Stewart was
23 to Wendy.

24 A. He -- you know he -- by nature, Stu was just a very loving
11:07:19 25 guy. He was very, very supportive of Wendy and his kids. They

1 always seem to show they had a wonderful marriage. They seemed
2 happy together. And we -- we never saw any issues. He was
3 publicly very supportive. They were supportive of each other,
4 actually.

11:07:41

5 Q. What was the impact of the loss Mr. Dolin had on his wife?

6 A. Well, she's certainly a lost soul. Heart broken, alone, as
7 one would expect the --

8 THE COURT: All right. We're going to take a break
9 at this time, ladies and gentlemen.

11:08:02

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

12

[REDACTED]

13

[REDACTED]

14

[REDACTED]

11:08:47

15

[REDACTED]

16

[REDACTED]

17

[REDACTED]

18

[REDACTED]

19

[REDACTED]

11:26:43

20

[REDACTED]

21

[REDACTED]

22

[REDACTED]

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[REDACTED]

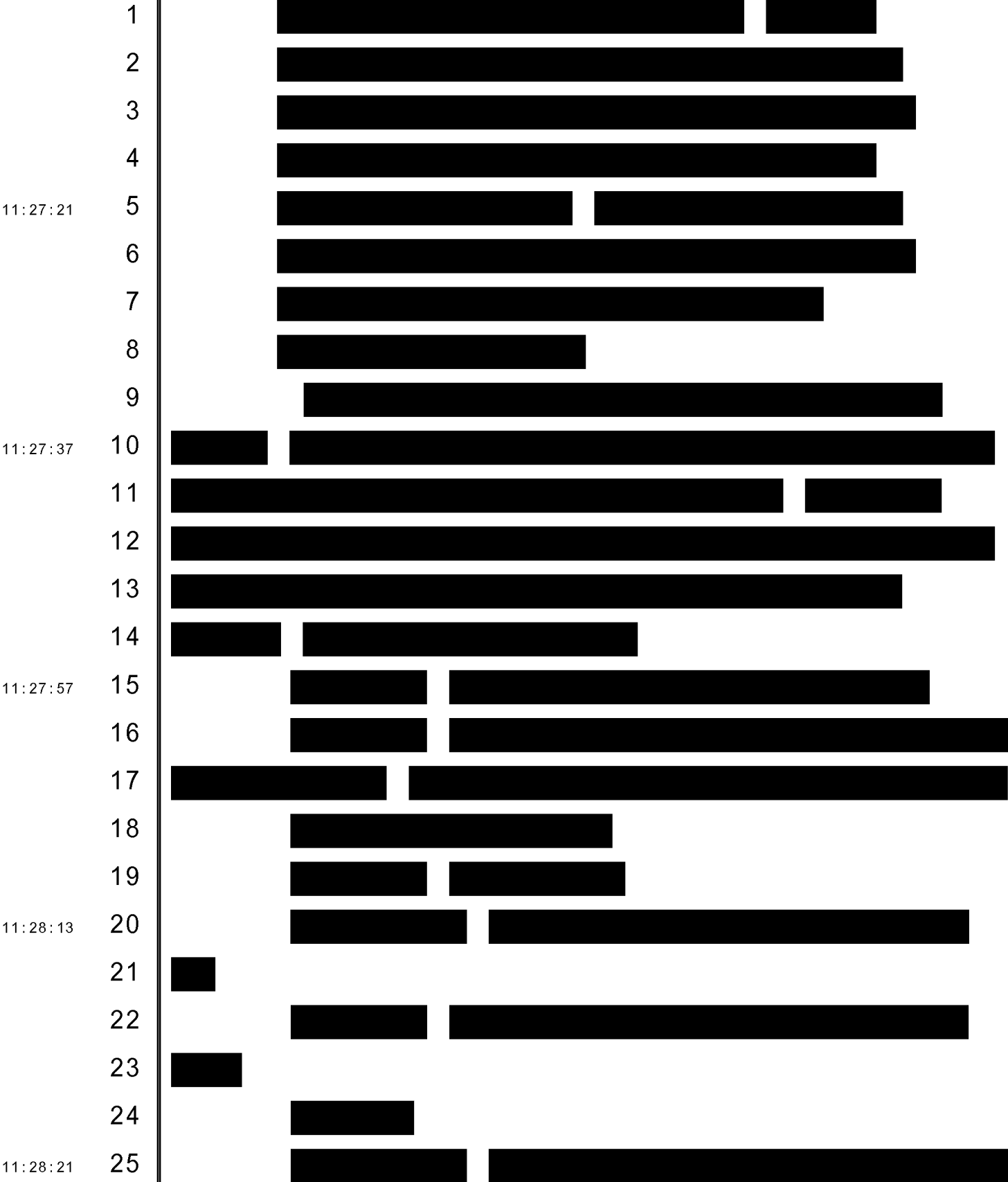
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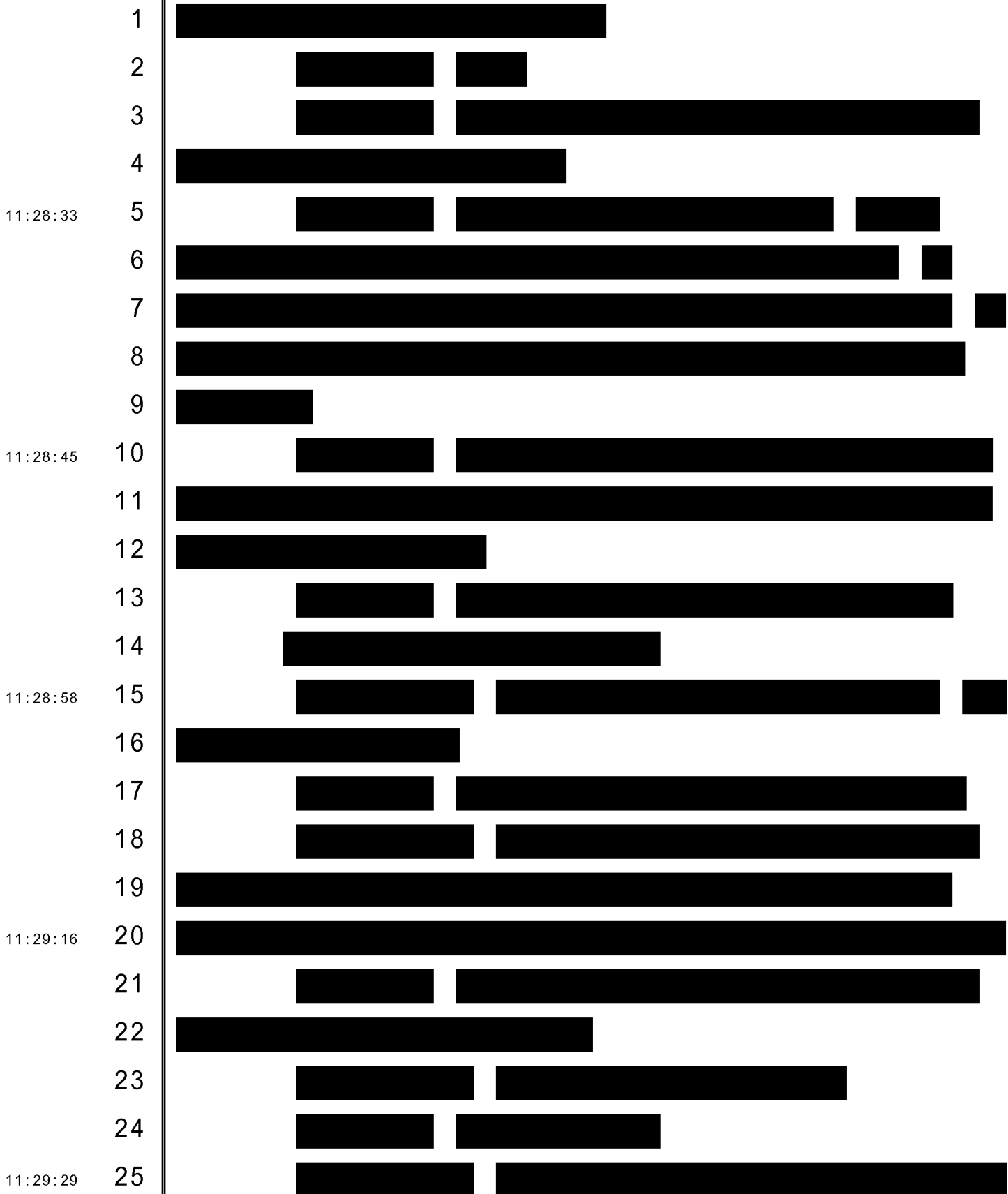
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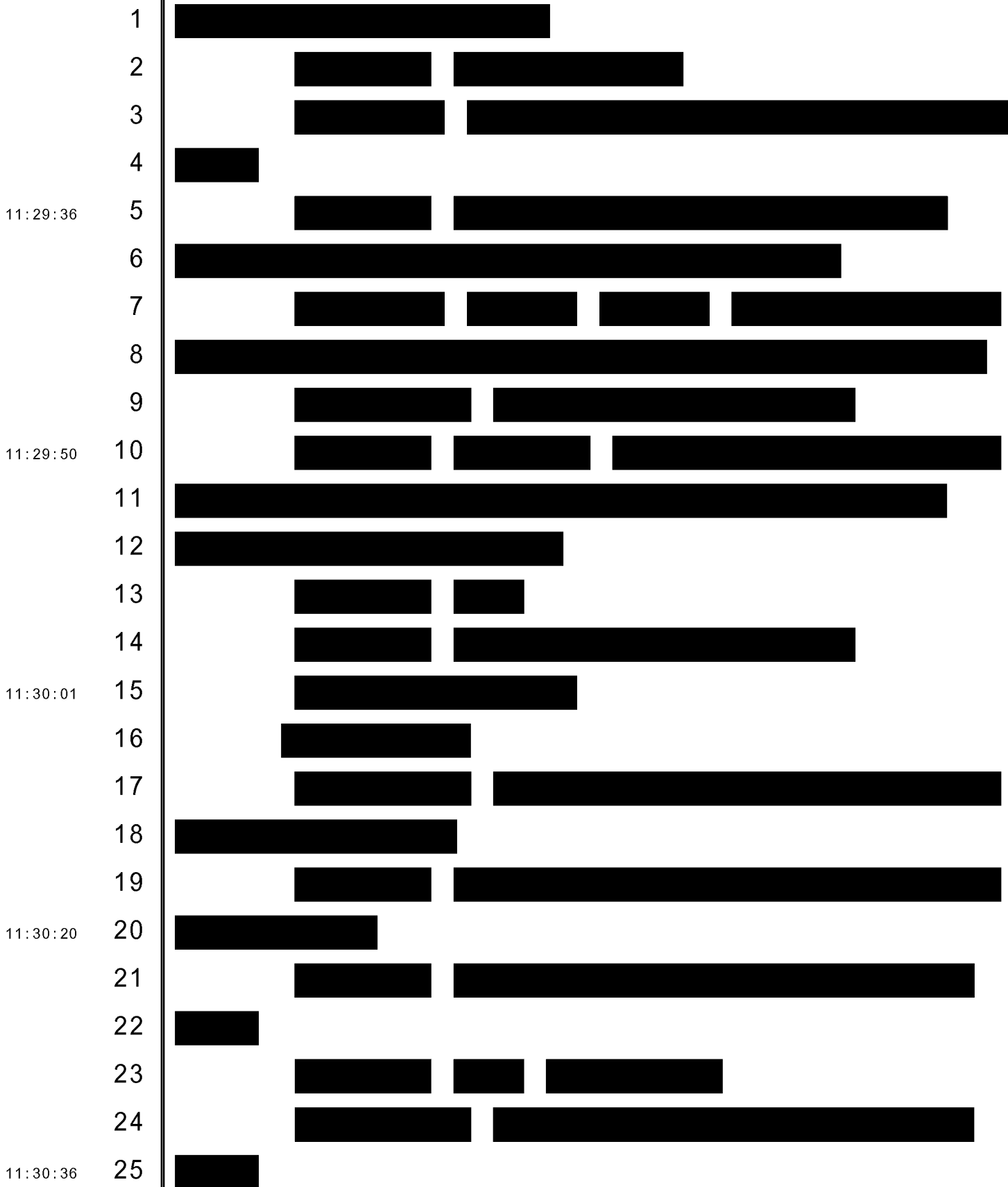
11:27:04

25

[REDACTED]







1 supporter. They're sort of making their way without him.

2 Wendy is doing a great job, as best she can, on her own.

3 Q. What is it that your group of friends do, if anything, to
4 try to help this family?

11:33:34

5 A. Well, I am fortunate to be involved with a great group of
6 people, as is Wendy. She has a large group of friends and
7 family. And we're very well supportive of her because we love
8 her. She is a very generous, giving person. And we all sort
9 of make sure she's as best she can be.

11:33:55

10 Q. Let me ask you a few questions about what you know, if
11 anything, about the talk therapy that Stewart was getting over
12 the years.

13 A. I do not know much about it.

14 Q. Tell us everything you did know about it.

11:34:08

15 A. I knew at various times he was talking to him. I honestly
16 don't recall knowing their names. I don't recall being told
17 any of the content of the visits, to be hones.

18 Q. Okay. And you were generally aware that he was seeing some
19 people for --

11:34:21

20 A. Yes, in a very remote way.

21 Q. Okay. Now, please tell us a little bit about the privacy
22 aspect of patients who are either getting talk therapy or who
23 are on antidepressant medications.

11:34:45

24 A. Well, unless there are specific permission to talk to the
25 therapist, the therapist talk to the internist and vice versa,

1 not much communication happens, in general, between the
2 psychotherapist and the internist.

3 Q. Did you feel well in touch with Mr. Dolin during the time
4 that you were both his friend and his doctor?

11:35:04 5 A. I did. I thought I knew him very well.

6 Q. Are you comfortable with your own judgments throughout?

7 A. Yes.

8 Q. What was your reaction when you heard what happened to him?

9 A. Absolute shock.

11:35:16 10 Q. Why? Tell us about it.

11 A. Because this situation -- this particular time was no
12 different than any of the others, in my mind. He was going
13 through one of his stress periods because of his work
14 responsibilities. He seemed to be getting through it like he
15 did the other times. At no time did I ever judge him to be
16 depressed in any way. He was anxious. Something I become --
17 I'd become to be used to with Stu and I knew it would pass
18 again.

11:35:34 15 did the other times. At no time did I ever judge him to be
16 depressed in any way. He was anxious. Something I become --
17 I'd become to be used to with Stu and I knew it would pass
18 again.
19 Q. Doctor, please tell the jury what the importance is of
11:35:53 20 honesty by pharmaceutical companies in their labels that
21 communicate to people like you.

22 A. Well, you know, physicians, myself and millions of other
23 physicians, every day try to protect people, try to help people
24 and protect them. We rely on truth and honesty from
11:36:14 25 pharmaceutical companies and to falsify information or hold

1 back information is totally criminal. It affects the lives of
2 our patients.

3 MR. BAYMAN: Your Honor, I move to strike the last
4 comment about some kind of criminality.

11:36:28 5 THE COURT: That may go out.

6 MR. DAVIS: Ask the jury to disregard.

7 THE COURT: That may go out.

8 MR. DAVIS: Thank you.

9 THE COURT: Proceed.

11:36:32 10 BY Mr. Rapoport:

11 Q. If you were not done, please proceed, otherwise --

12 A. No, I just think that we depend on honesty in reporting
13 research and data. How can we treat people effectively and
14 safely if we can't depend on that.

11:36:47 15 Q. Doctor, just a couple of last questions here. That's a
16 nice tie you're wearing, tell us about it.

17 A. It was Stewart's (crying).

18 Q. Why are you wearing that?

19 A. As a memory.

11:36:59 20 Q. I'm sorry?

21 A. Just to remember him today (crying). Sorry.

22 Q. Do you have anything else of his on you?

23 A. Belt.

11:37:16 24 Q. You were his best friend. Are you putting spin on your
25 testimony here to try to help him or just telling the truth?

1 A. Just the truth. There's nothing to -- it's very simple
2 truth (crying).

3 MR. RAPOPORT: Thank you very much. I don't have any
4 other questions. Thank you.

11:37:54

5 MR. DAVIS: MR. DAVIS: Your Honor, may I approach?

6 THE COURT: Yes. To my law clerk.

7 (Exhibits tendered to the Court.)

8 MR. DAVIS: Handing a notebook of exhibits, as well as
9 some slides that may be used with Dr. Sachman.

11:38:09

10 (Brief pause).

11 MR. DAVIS: May I approach the witness, Your Honor?

12 THE COURT: Yes, sir.

13 MR. DAVIS: Thank you.

14 (Binder tendered to the witness).

11:37:27

15 CROSS EXAMINATION

16 BY MR. DAVIS:

17 Q. Dr. Sachman, do you need water or anything else before we
18 start?

19 A. No. Thank you.

11:38:26

20 Q. Here are a notebook that I'm going to ask you some
21 questions about.

22 (Binder tendered to the witness).

23 BY MR. DAVIS:

24 Q. Good afternoon -- good morning.

11:38:34

25 A. Hi.

1 Q. My name is Todd Davis. You and I met at your deposition
2 some time ago, do you remember that?

3 A. Yes.

4 Q. Nice to see you again, Dr. Sachman.

11:38:42

5 A. You too.

6 Q. Let's talk a little bit about the time period that you
7 prescribed Paroxetine for Stewart Dolin.

8 The first record of any prescription that you wrote
9 for Mr. Dolin for either Paxil or Paroxetine is October 3,
10 2005, right?

11:38:58

11 A. Yes.

12 Q. Okay. And if you need help in referring to the --

13 (Brief pause).

14 MR. DAVIS: I think you took my notebook.

11:39:29

15 MR. WISNER: Oh, is this yours (indicating)?

16 MR. DAVIS: Yeah, I think you took my notebook.

17 MR. WISNER: I'm sorry.

18 MR. DAVIS: Sorry about that. I looked and it had
19 disappeared.

11:39:36

20 MR. WISNER: Sorry.

21 BY MR. DAVIS:

22 Q. If you need help referring to the pharmacy records, they're
23 behind Tab 1, okay?

24 A. I got them.

11:39:43

25 Q. Your medical records that have been marked as a Joint

1 Exhibit are behind Tab 2. I'm going to try to walk you through
2 some of these records. And I'll refer you to the tab and I'll
3 refer you to the Joint Exhibit number, all right.

11:40:04

4 Okay. So the first time that you wrote Paxil or
5 Paroxetine prescription for Mr. Dolin was October 3, 2005,
6 right?

7 A. Yes.

8 Q. And that prescription was for 10 milligrams per day, right?

9 A. Yes.

11:40:16

10 Q. All the prescriptions that you wrote for Mr. Dolin for
11 Paroxetine were for 10 milligrams per day, right?

12 A. That could be. I don't know.

13 Q. I'm sorry?

14 A. I -- I imagine so. I don't know, though, that offhand.

11:40:29

15 Q. Why don't you look --

16 A. This prescription was for 10 milligrams.

17 Q. Why don't you look behind Tab 1, which is Joint Exhibit 12.
18 If you go to the very --

19 MR. DAVIS: Could we pull that up.

11:40:46

20 (Exhibit published to the jury.)

21 BY MR. DAVIS:

22 Q. It's Joint Exhibit 12. And if you go to page -- JX12-014.

23 A. Got it.

24 Q. Second to the last page.

11:41:13

25 Do you see on the left-hand side there, in this Joint

1 Exhibit -- you see on the left-hand side there's a whole
2 listing of Paroxetine prescriptions that Mr. Dolin filled? Do
3 you see that?

4 A. Yes.

11:41:27

5 Q. And all of those are 10 milligrams, right?

6 A. Yes, they are.

7 Q. And if turn to the very first page of Exhibit 12, which is
8 the prescription that you wrote on June -- that you wrote on
9 June 27th, 2010, that was also for 10 milligrams, right?

11:41:45

10 A. Yes.

11 Q. Okay. And you're not aware of another prescription for Mr.
12 Dolin for Paxil or Paroxetine that was higher than 10
13 milligrams, are you?

14 A. No.

11:41:54

15 Q. All right. Thank you.

16 You prescribed Paroxetine in October of 2005 to Mr.
17 Dolin because his primary symptom was anxiety, and Paxil had a
18 specific indication for general anxiety disorder, right?

19 A. Yes.

11:42:10

20 Q. And you thought it would be a good medication for him,
21 given what he was suffering from?

22 A. Correct.

23 Q. And you told the jury that Paxil was very good for anxiety,
24 right?

11:42:22

25 A. Yes.

1 Q. And when initiated Paroxetine treatment for Mr. Dolin in
2 October of 2005, you believed that the pressures he was having
3 at work were becoming, as you put it, more than he could handle
4 without help, correct?

11:42:38

5 A. Correct.

6 Q. And despite his success that you told the jury about,
7 despite his success as a lawyer, he still took antianxiety
8 medication, right?

9 A. Correct.

11:42:58

10 Q. Now, if you look at the Elmo, please. If I could turn your
11 attention back to Plaintiff's Exhibit PTX069.

12 Do you see this particular document that you were
13 shown by Mr. Rapoport?

14 A. Yes.

11:43:14

15 Q. Now, this lists prescriptions that Mr. Dolin filled for
16 either generic Paroxetine or generic sertraline?

17 A. Yes.

18 Q. This is not the prescription Mr. Dolin filled, is it?
19 There's more?

11:43:34

20 A. Would there be prescriptions in order to fill that period
21 of time.

22 Q. Sure. For example, what's not listed on here is all the
23 refills that Mr. Dolin had for both Paroxetine and sertraline,
24 right?

11:43:46

25 A. Right. It's obvious. Right.

1 Q. Let me talk a little bit about those refills, if we can.

2 Well, let me back up. After you prescribed Paroxetine
3 for Mr. Dolin on October 3, 2005, you saw him 12 days later in
4 the office, right?

11:44:06

5 A. I have to look.

6 BY MR. BAYMAN:

7 Q. I think if you turn to PTX 068.

8 A. Yes.

9 Q. Right here (indicating)?

11:44:24

10 A. That's correct.

11 Q. He had an annual physical, right?

12 A. Right.

13 Q. And that took place on October 16th?

14 A. Correct.

11:44:28

15 Q. And it's actually 2003, not 2004, right -- excuse me.

16 2004. I'm sorry, let me back up.

17 A. 2004 is correct.

18 Q. I'm sorry. October 15, 2005, is the 12 days after you

19 prescribed Paroxetine to Mr. Dolin, right?

11:44:46

20 A. Right.

21 Q. That one right there (indicating).

22 And at that visit, after Mr. Dolin is on the
23 medication for 12 days, he reports to you that he's feeling
24 fine?

11:44:57

25 A. He was feeling better.

1 Q. Yes?

2 A. Yes.

3 Q. Okay. And he did not report to you that after starting
4 Paroxetine, that he had any problems or side effects from the
5 medication at that visit, did he?

11:45:18

6 A. He did not.

7 Q. Yeah. And if we look at -- if you go back to Joint
8 Exhibit 12, which is the pharmacy records, and you turn back to
9 the page we looked at earlier, JX12-014, which is the listing
10 of all the Paroxetine prescriptions, right?

11:45:36

11 MR. DAVIS: If you can pull that up, Mr. Holtzen.

12 BY THE WITNESS:

13 A. Yes.

14 BY MR. DAVIS:

15 Q. We count here that he had -- he refilled the medication 30
16 pills each time, right? On each --

11:45:44

17 A. Yes.

18 Q. And he refilled it 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
19 additional times, correct?

11:46:03

20 A. (Nodding.)

21 Q. Yes?

22 A. Correct. Sorry.

23 Q. And so for the total number of pills, Paroxetine pills that
24 Mr. Dolin would've taken per these prescriptions, would've been
25 150 pills, right?

11:46:11

1 A. Taken for 12 months.

2 Q. Yes?

3 A. Yes.

11:46:23

4 Q. And at no time during that 150 pill-taking by Mr. Dolin,
5 did he report to you that he had any problems or side effects
6 from Paroxetine?

7 A. Right.

8 Q. I'm sorry?

9 A. Yes, he did not.

11:46:30

10 Q. Thank you.

11 If we can go back to Joint Exhibit 12 --

12 MR. RAPOPORT: Your Honor, I hate to object, but the
13 year still has 365 days and I don't think it's 150.

14 THE COURT: Proceed.

11:46:45

15 BY MR. DAVIS:

16 Q. I'm sorry. My math may be a little bit off. If we have
17 30 -- we have 30 tablets times 13 prescriptions, that's
18 actually 390 days, right?

19 A. Yes, it is.

11:46:58

20 Q. So he takes Paroxetine for over a year and he doesn't
21 report any problems or side effects, right?

22 A. Right.

23 Q. Okay.

11:47:13

24 MR. DAVIS: Thank you, Mr. Rapoport, for fixing my
25 math.

1 BY MR. DAVIS:

2 Q. And we go to this prescription history, look at the one
3 where he fills a prescription on April 1, 2006.

4 MR. DAVIS: Can you put that up, Mr. Holtzen.

11:47:30

5 BY MR. DAVIS:

6 Q. Do you see that where he fills the prescription?

7 Do you see that?

8 A. Which day are you talking about?

11:47:44

9 Q. If you look 7 down from the top, you see there's a
10 prescription that he fills of Paroxetine, 10 milligrams, on
11 April 1, 2006, right?

12 A. Right.

13 Q. Yes?

14 A. Yes.

11:47:51

15 Q. Okay. And then the next refill of pills is on May 6, 2006,
16 right?

17 A. Yes.

18 Q. And so if Mr. Dolin took Paroxetine as prescribed, he
19 would've been off the medication for about 4 days, right,
20 between the refills?

11:48:06

21 A. It -- if he actually ran out of pills. I mean -- yes, it
22 looks that way.

23 Q. Yes. And let's take a look at the August 27, 2006, refill
24 of 30 pills that's also there.

11:48:21

25 Do you see that?

1 A. Yes.

2 Q. Okay. And his 30 pills of 10 milligrams per day would have
3 run out on September 26th, 2006, if he took it as prescribed,
4 one pill a day?

11:48:35 5 A. Would you say the date again, please?

6 Q. His pills of 10 milligrams per day would have run out on
7 September 26, 2006, if he took the one pill per day as
8 prescribed?

9 A. Yes.

11:48:47 10 Q. So Mr. Dolin's next refill for his Paroxetine was
11 October 29, 2006, right?

12 A. Yes.

13 Q. And so he would've been without Paroxetine for about
14 33 days if he had taken it as prescribed, right?

11:49:04 15 A. Possibly.

16 Q. Yeah. That is kind of what this shows, right?

17 A. Yeah.

18 Q. Okay. And at no time during any of these times that we've
19 just went over where he may not have taken a dosage or he
20 missed doses, did he report any problems or side effects with
21 Paroxetine, right?

11:49:20

22 A. Correct.

23 Q. And when you prescribe the medication to Mr. Dolin, you
24 prescribe Paroxetine and you allow -- you probably prescribe

11:49:36

25 Paroxetine and you allow the generic to be dispensed, correct?

1 A. Yes.

2 Q. And you can't remember if you wrote Paroxetine or Paxil on
3 the prescription, right?

4 A. My head would've been to write the brand.

11:49:50

5 Q. Okay. Can you look back at the very end of your deposition
6 that's in the notebook. Can you look at page 24, Line 12
7 through 16.

11:50:19

8 MR. RAPOPORT: Your Honor, forgive me. I object on
9 relevance grounds since whether it's generic or a label doesn't
10 make any difference.

11 MR. DAVIS: I believe this was brought up on direct,
12 Your Honor, about what he prescribed.

13 THE COURT: Right. You may proceed.

14 MR. DAVIS: Thank you.

11:50:25

15 BY THE WITNESS:

16 A. What page is it?

17 BY MR. DAVIS:

18 Q. Yes, it's page 24 Lines 12 through 16.

19 A. In this book that you handed me?

11:50:34

20 Q. Yes, sir. It's at the very end of your deposition. Very
21 last tab.

22 A. Oh, I see. Okay.

23 (Brief pause).

24 BY THE WITNESS:

11:50:44

25 A. Okay.

1 BY MR. DAVIS:

2 Q. Can you look at page 24, lines 12 through 16.

3 (Brief pause).

4 BY MR. DAVIS:

11:51:02

5 Q. Are you there?

6 MR. RAPOPORT: I object, Your Honor. Improper
7 impeachment.

8 THE COURT: Well, I guess I'll have to look at it.
9 Let me see it, please.

11:51:14

10 (Binder tendered to the Court.)

11 THE COURT: You may read the whole page if you want
12 to.

13 MR. DAVIS: All right.

14 THE COURT: The objection will be sustained.

11:51:50

15 MR. DAVIS: May I read it, Your Honor?

16 THE COURT: You read the whole page. Read it all.

17 MR. DAVIS: Sure.

18 Beginning at what line, Your Honor?

19 THE COURT: Start at the top.

11:51:57

20 MR. DAVIS: Sure.

21 BY MR. DAVIS:

22 Q. (Reading:)

23 "Question: Is that what you remember
24 prescribing?

11:52:00

25 "Answer: That's about when -- yeah, I mean

1 it's close enough. My recollection tells me it
2 was a little bit later, but that's close
3 enough."

11:52:09

4 "Question: Okay. And did you, when you
5 prescribed the drug to Stewart, did you describe
6 Paxil or did you prescribe Paroxetine?"

7 "Answer: Probably Paroxetine. I mean, I
8 allowed the generic to be dispensed."

11:52:21

9 "Question: Fair enough. But when you wrote
10 the prescription, I don't know how -- how do you
11 do the prescription writing, generally?"

12 "Answer: I can't remember if I wrote
13 Paroxetine or Paxil."

14 "Question: Okay. If you look down here --"

11:52:34

15 MR. DAVIS: Is that enough, Your Honor, or do you want
16 me to continue? Because the rest is about sertraline.

17 THE COURT: That's enough.

18 MR. DAVIS: Okay.

19 BY MR. DAVIS:

11:52:41

20 Q. Did I read that testimony from you that was taken under
21 oath?

22 A. Yes.

23 Q. Thank you.

11:52:51

24 And other than the prescriptions for Paroxetine filled
25 at Parkway Drugs pharmacy, which is now Walgreens, you're not

1 aware of Stewart Dolin filling any other prescriptions for
2 Paxil or Paroxetine, are you?

3 A. No.

11:53:05

4 Q. And you're not aware of Mr. Dolin ever receiving Paroxetine
5 or Paxil in any other way other than through a filled
6 prescription at the pharmacy, right?

7 A. Yes.

11:53:17

8 Q. Okay. You mentioned in direct that you had a close
9 relationship with Mr. Dolin, both as a patient and as a friend,
10 right?

11 A. Correct.

12 Q. And Mr. Dolin would call you about medical issues that he
13 might be having, right?

14 A. Right.

11:53:27

15 Q. And, in fact, there were times that he will call and
16 complain of things that were just simple things on a weekend or
17 at night around 10:00 o'clock and you would take care of it,
18 right?

19 A. Yes.

11:53:38

20 Q. And by taking care of it, you would either give him a
21 prescription or you would give him some medical advise, right?

22 A. Correct.

23 Q. And during the visits that you had with Stewart Dolin that
24 you've reflected in your medical records, after starting him on
25 Paroxetine you routinely asked him how he was doing on that

11:53:54

1 medication, true?

2 A. Yes.

3 Q. That was part of your stated practice to ask that question,
4 right?

11:54:05

5 A. Yeah, I would ask him how he was doing, regardless.

6 Q. Stewart Dolin and you had the kind of relationship where he
7 would share any side effects or ill feelings that he had while
8 on the medication and that included Paxil, Paroxetine,
9 sertraline or Zoloft, right?

11:54:22

10 A. I would imagine.

11 Q. And when Stewart Dolin came in for periodic assessments by
12 you, from 2005 to the last time you saw or spoke with him, he
13 never voiced any problems or concerns about being on Paxil or
14 Paroxetine, did he?

11:54:41

15 A. No.

16 Q. No, he did not?

17 A. No, he did not.

18 Q. Isn't it a fact the reason why Mr. Dolin went back on
19 Paroxetine in 2010 is because he had done well on it
20 previously, right?

11:54:56

21 A. Correct.

22 Q. And, in fact, Mr. Dolin always reported to you that
23 Paroxetine was working effectively for him?

24 A. Yes.

11:55:05

25 Q. And, in fact, you believe that Paroxetine was effectively

1 treating Mr. Dolin's anxiety?

2 A. Yes, I did.

3 Q. If you could turn back to Tab 1 to the sertraline records.

4 If you go to page JX12-011.

11:55:33

5 MR. DAVIS: And Mr. Holtzen, can we pull that up,

6 please.

7 BY MR. DAVIS:

8 Q. Let me know when you're there, Dr. Sachman.

9 A. JX?

11:55:49

10 Q. Yeah, JX12-011.

11 (Brief pause).

12 BY MR. DAVIS:

13 Q. Are you in Tab 1?

14 A. I thought I was. I'm not.

11:56:22

15 (Brief pause).

16 BY THE WITNESS:

17 A. There we go.

18 BY MR. DAVIS:

19 Q. Okay.

11:56:32

20 A. --- 0?

21 Q. 011. JX 12-011.

22 It's about 5 pages from the back.

23 Are you there?

24 A. Yes.

11:56:43

25 Q. Do you see that on January 22, 2007, you prescribed

1 sertraline to Mr. Dolin, right?

2 A. Yes.

3 Q. And that's what he started taking the medication, right?

4 A. Yes.

11:56:54

5 Q. And if you look there, you see that there are 5
6 prescriptions for sertraline of 30 tablets of sertraline 50
7 milligrams, correct?

8 A. Correct.

11:57:12

9 Q. And if we added that up, that would be 150 tablets taken
10 over 150 days, right?

11 A. Yes.

12 Q. Okay. And Mr. Dolin didn't report any side effects or
13 problems with Zoloft or sertraline as of 2007 for any of these
14 150 tablets that he took during this time period?

11:57:29

15 A. Correct.

16 Q. And if you look -- if you look on JX 12010, which is a page
17 before, you see that there's another prescription for
18 sertraline, do you see that?

19 A. Yes.

11:57:49

20 Q. And, in fact, if you count them up, there's 8 prescriptions
21 of filling 60 tablets of sertraline at 50 milligrams between
22 October 16, 2007, and September 1, 2008?

23 A. Right.

11:58:10

24 Q. And so if we looked at and counted up that number of pills,
25 we'd have 480 tablets, correct?

1 A. Something like that.

2 Q. Okay. Close enough?

3 A. Yes.

4 Q. And the next visit, office visit that you had with

11:58:21

5 Mr. Dolin was on December 15, 2007, right?

6 A. Yeah.

7 Q. Okay. And at that office visit, Mr. Dolin reported that he
8 was doing fine and that's what you wrote down in your medical
9 chart, correct?

11:58:35

10 A. Yes.

11 Q. And Mr. Dolin never reported to you that he had any
12 suicidal thoughts at that December 15, 2007, office visit, did
13 he?

14 A. No.

11:58:46

15 Q. And if he had -- if he had suggested that or said that, you
16 would've wrote that down on your chart, right?

17 A. Yes.

18 Q. And your notes reflect --

19 MR. DAVIS: If we could call that up, Mr. Holtzen,
20 Joint Exhibit 11, at 11-002, which is Dr. Sachman's medical
21 records.

11:58:59

22 BY MR. DAVIS:

23 Q. You have a notation in here in your medical records that
24 says "Zoloft 50, BID." And BID just means twice a day,
25 correct?

11:59:14

1 A. Correct.

2 Q. So here, when he comes in at this time, Mr. Dolin has been
3 taking two tablets of 50 milligrams of generic sertraline two
4 times a day -- or excuse me --

11:59:26

5 A. Two tablets.

6 Q. Or excuse me. Two tablets --

7 A. A day.

8 Q. A day. Yes, thank you.

9 And it was your belief at the time that generic
10 sertraline was benefitting Mr. Dolin?

11:59:36

11 A. Yes.

12 Q. And effectively treating his anxiety?

13 A. Correct.

14 Q. If we go to the next page of the pharmacy records, behind
15 Tab 1, JX 12-007.

11:59:49

16 And this is another filling of generic sertraline of
17 50 milligrams, 60 tablets, and he's supposed to take 2 tablets
18 a day, right?

19 A. Yes. Yes.

12:00:25

20 Q. Okay. And if you look down the next sertraline,
21 prescription that was filled -- if you look at November 29.
22 Right there (indicating).

23 Here we've got 6 times that Mr. Dolin fills
24 prescriptions for generic sertraline, and at 60 pills each
25 time, and he's supposed to take two pills a day, correct?

12:00:49

1 A. Yes.

2 Q. Okay. And throughout the time that he was taking
3 sertraline, all the way through the end of 2009, he didn't
4 report any problems or side effects from the medication,
5 correct?

12:01:11

6 A. Correct.

7 Q. And so if we add up the number of pills that Mr. Dolin took
8 for generic sertraline over time, we come up to about 900
9 pills, right?

12:01:20

10 A. Maybe.

11 Q. I'm sorry?

12 A. A lot of pills.

13 Q. Yes. And those pills lasted well over a year if he took
14 them as prescribed, correct?

12:01:29

15 A. Yes.

16 Q. Okay. And if you look at -- if we can go to page 6 of JX
17 12, which is behind Tab 1.

18 (Brief pause).

19 BY MR. DAVIS:

12:01:51

20 Q. Are you there?

21 MR. DAVIS: If we can pull that up Mr. Holtzen.

22 BY MR. DAVIS:

23 Q. We got a listing of prescriptions here for Mr. Dolin. He
24 has a fill on December 26th, 2008, correct?

12:02:03

25 A. Yes.

1 Q. And then that -- that filling was for 60 sertraline tablets
2 and he was to take two tablets each day, correct?

3 A. Yes.

12:02:18

4 Q. And the next prescription of sertraline that he filled was
5 on May 2, 2009, do you see that?

6 A. Yes.

7 Q. And so if he took the sertraline as prescribed, he would
8 have run out in January of 2009 --

9 A. We may have stopped treatment in between those two dates.

12:02:30

10 Q. Do you know which -- if that was the case?

11 A. Unless it's in the record, I couldn't recall it.

12 Q. Okay. So for whatever the reason, there's a break in when
13 he's taking sertraline that's between January of 2009 until the
14 refill of sertraline in May of 2009, correct?

12:02:47

15 A. Correct.

16 Q. And so he takes -- he's on a dose of two 0 milligram
17 tablets of sertraline per day and he drops to zero, correct?

18 A. Doesn't necessarily drop to zero all at once.

19 Q. He tapers off --

12:03:03

20 A. If he went off, he tapered off.

21 Q. Okay. And so at no time when that dosage was decreasing
22 over that time did Mr. Dolin come back and report to you that
23 he had any problems or side effects from sertraline and
24 tapering off and lowering the dose?

12:03:18

25 A. Correct.

1 Q. Okay. And throughout the time period he took sertraline,
2 you believe it was effectively treating his anxiety?

3 A. Yes.

12:03:37

4 Q. Okay. Doctor, I want to turn our attention now to some
5 information about your practice that you have.

6 You operate what's called a concierge or boutique
7 medical practice?

8 A. Correct.

12:03:52

9 Q. That name of that practice is called Martin N. Sachman &
10 Associates, right?

11 A. Yes.

12 Q. And you've operated that concierge or boutique practice
13 from September of 2005, correct?

14 A. Correct.

12:04:00

15 Q. And there's a yearly fee of \$1,800 to be a member of this
16 concierge or boutique practice?

17 A. Correct.

18 Q. Stewart Dolin became a patient of that concierge or
19 boutique medical practice when you started it in 2005?

12:04:19

20 A. Correct.

21 Q. And the concierge medical practice that you started in 2005
22 was quite different from the medical practice that you had
23 before in terms of the patient volume, correct?

24 A. Yes.

12:04:29

25 Q. And the other things that happened that were different was,

1 it was a much smaller practice because you had about 5 times as
2 many patients before than what you had when you cut it down to
3 the boutique practice, correct?

4 A. Yes.

12:04:41

5 Q. Patients in the boutique practice could be seen for an
6 appointment the same day they asked for one, right?

7 A. Yes.

12:04:55

8 Q. And you are available to a patient in your boutique medical
9 practice, such as Stewart Dolin, 24 hours a day, 7 days a week,
10 right?

11 A. Correct.

12 Q. And a patient, such as Stewart Dolin, could call you up at
13 any time that he or she wanted to?

14 A. Yes.

12:05:00

15 Q. And call-backs to patients in this boutique practice are
16 made the same day and you don't wait a day or two to give a
17 call back to the patient?

18 A. That's correct.

19 Q. And you described it as a very hands-on practice?

12:05:14

20 A. Yes.

21 Q. And your current patient population includes adults over
22 the age of 24 and even adults as high as the age of 90?

23 A. Even higher.

24 Q. Or higher, yes.

12:05:26

25 A. (Laughing).

1 Q. And you mentioned something in your direct testimony with
2 Mr. Rapoport about the drugs that -- the medications that
3 preceded the SSRIs, do you remember that discussion?

4 A. Yes.

12:05:39

5 Q. And I think the medications you're talking about was a
6 class of drugs called tricyclic antidepressants or TCA's,
7 right?

8 A. Yes.

12:05:52

9 Q. And those medications were more difficult because they had
10 side effects that had to be managed, correct?

11 A. Correct.

12 Q. And, for example, the side effects of the TCA's made it
13 more difficult for a patient to stay on the medication and get
14 the benefits of the medication?

12:06:06

15 A. That is true.

16 Q. And when you are weighing a decision to prescribe an
17 antidepressant, an antidepressant to a particular patient, you
18 weigh the risks of the side effects against the potential for
19 effectiveness of the medication, right?

12:06:22

20 A. Yes.

21 Q. And you believe that there are some side effects for
22 antidepressants, generally, that are potentially very serious,
23 right?

24 A. Correct.

12:06:28

25 Q. And before you prescribe an antidepressant to a particular

1 patient, you have to be convinced that the probability of
2 effectiveness outweighs the risk of a serious side effect,
3 right?

4 A. Right.

12:06:42

5 Q. And, in fact, you have to be convinced, as well as you can
6 be convinced by your own interpretation of availability data,
7 right?

8 A. Correct.

12:06:54

9 Q. And before prescribing an antidepressant to a patient for
10 the first time, you receive that patient's informed consent for
11 the medication, right?

12 A. Yes.

12:07:14

13 Q. And by that you mean you do that in an informal way in
14 which you describe the drug, it's major side effects, and what
15 to expect in terms of benefits, right?

16 A. Yes.

12:07:26

17 Q. And with regard to antidepressants, when you're speaking to
18 a patient about potentially prescribing that medication, you go
19 over the potential side effects associated with that
20 medication, correct?

21 A. Yes.

22 Q. All right. Dr. Sachman, I'm going to read you a statement
23 and I'm going to ask you some questions about it, okay.

24 First, here's the statement:

12:07:34

25 "The following symptoms, anxiety, agitation,

12:07:52 1 panic attacks, insomnia, irritability,
2 akathisia, psychomotor restlessness, hypomania
3 and mania have been reported in adult and
4 pediatric patients being treated with
5 antidepressants for major depressive disorder,
6 as well as for other indications, both
7 psychiatric and nonpsychiatric. Although a
8 causal link between the emergence of such
9 symptoms in either the worsening of depression
10 and/or the emergence of suicidal impulses has
11 not been established, there is concern that such
12 symptoms may represent precursor to emerging
13 suicidality."

14 Got all of that?

12:08:23 15 A. Got it.

16 Q. Okay. To you, this is just a statement of the most common
17 side effects seen with these drugs, SSRIs, true?

18 A. Yes.

12:08:49 19 Q. And if you turn to Joint Exhibit 6, that's behind Tab 3,
20 and if you turn to page JX 6005, third full paragraph, you see
21 that this statement was in the Paroxetine and Paxil labeling in
22 2005 before you first prescribed it to Mr. Dolin, right?

23 A. Yes. Yes.

12:09:27 24 MR. DAVIS: Can we pull up the graph, Mr. Holtzen.
25 (Exhibit published to the jury.)

1 BY MR. DAVIS:

2 Q. So this is the statement that we were just talking about
3 that's in the February 2005 labeling, correct? For Paxil,
4 right?

12:09:36

5 A. Yes.

6 Q. Okay. And then if you turn now to Tab 4, which is Joint
7 Exhibit 1, the June 2010 Paxil labeling, and if you turn to
8 page 12, fourth full paragraph.

9 (Brief pause).

12:09:48

10 BY MR. DAVIS:

11 Q. Are you there?

12 A. Fourth paragraph, did you say?

13 Q. Yes. It's page 12, fourth full paragraph.

14 A. Yes.

12:10:11

15 Q. Do you see that that exact statement that we put up on the
16 screen and that we read earlier is in the June 2010 Paxil
17 labeling?

18 A. Yes.

12:10:25

19 Q. Okay. And if we pull up both of them and have the
20 statement side by side, you see that these are identical,
21 correct?

22 A. Yes.

23 Q. Okay.

12:10:41

24 And you recognize that as part of your
25 responsibilities as a physician, that you have to keep up with

1 the labeling as it exists for certain medications, and that's
2 for all medications, correct?

3 A. Correct.

12:10:54

4 Q. And one of the ways you do that is by going to the
5 Physicians Desk Reference and looking at the labeling for
6 prescription medication that's located there, right?

7 A. Right.

12:11:07

8 Q. And you also pay attention to pronouncements by the Food
9 and Drug Administration about changes to labeling for
10 medication?

11 A. Yes.

12 Q. You've done that throughout the course of your career as a
13 physician, haven't you?

14 A. Yes.

12:11:13

15 Q. You pay attention and read their healthcare provider
16 letters that are sent to you that discuss changes in the
17 labeling for prescription medications, right?

18 A. Yes.

12:11:28

19 Q. And, in fact, you have a practice in your office that if a
20 Dear Healthcare Provider letter comes in to you, it's put on
21 your desk rather than in the basket, right?

22 A. Yes.

23 Q. And that's the practice that you've asked your office staff
24 to do since you've been prescribing medications, right?

12:11:42

25 A. Correct.

1 Q. And when you review Dear Healthcare Provider letters you
2 incorporate the information in those Dear Healthcare Provider
3 letters into your prescribing additions, true?

4 A. Yes.

12:11:52

5 Q. I'm sorry?

6 A. Yes. Sorry.

7 Q. And you don't ignore Dear Healthcare Provider letters
8 because there might be something important in them?

9 A. Yes.

12:12:00

10 Q. And with respect to the information that's in the
11 prescription medications labeling, you just don't pay attention
12 to what's in the black box for that prescription medication,
13 but you instead read the entire labeling?

14 A. Right.

12:12:15

15 Q. I'm sorry?

16 A. Yes.

17 Q. And you -- if you're not comfortable and familiar with the
18 entire labeling of a prescription medication, you don't
19 prescribe that medication, did you?

12:12:26

20 A. No. This label says nothing about suicidality in people
21 over 24.

22 MR. DAVIS: Your Honor, I move to strike. There's no
23 question pending before the witness.

24 THE COURT: Proceed. Yes.

12:12:41

25 MR. DAVIS: Thank you.

1 BY MR. DAVIS:

2 Q. You have followed the practice, if you're not comfortable
3 with an entire labeling or prescription medication, you don't
4 prescribe the medication. You've followed that practice your
5 entire career, have you not?

12:12:53

6 A. Right.

7 Q. Can you turn to May -- the May 2004 Dear Healthcare
8 Provider letter that's behind Tab 5, it's Joint Exhibit 7.

9 You let me know when you're there, Dr. Sachman.

12:13:19

10 (Brief pause).

11 BY THE WITNESS:

12 A. What page was it on?

13 BY MR. DAVIS:

14 Q. That's Tab 5. Behind Tab 5. It's Joint Exhibit 7.

12:13:29

15 A. Okay.

16 Q. The May 2004 Dear Healthcare Provider attached labeling.

17 A. Yes.

18 Q. Are you there?

19 A. Yes.

12:13:36

20 Q. You don't have any reason to disagree that GSK sent this
21 Dear Healthcare Provider letter and labeling to you, true?

22 A. True.

23 Q. And let's -- if we can go back -- we have a timeline here.

24 If you can set this up in terms of when you got this Dear

12:13:54

25 Healthcare Provider letter of May 2004.

1 You have a prescription of October 2005, which is the
2 first prescription of Paroxetine to Mr. Dolin and you received
3 a Dear Healthcare Provider letter before that, correct?

4 A. Correct.

12:14:06 5 Q. And this letter says that on March -- it says:

6 "... on March 22, 2004, the FDA issued a public
7 health advisory cautioning physicians, their
8 patients, and families about the need to closely
9 monitor all patients being treated with
10 antidepressants."

11 Correct?

12 A. Correct.

13 Q. And this document discusses how patients who were started
14 on an antidepressant, such as Paroxetine or Paxil, may
15 experience worsening of their depression and/or the emergence
16 of suicidal ideation and behavior such as suicidality, correct?

17 A. Yes.

18 Q. And the GSK letter, the May 2004 Dear Healthcare Provider
19 letter says, in the last sentence of the first paragraph:

12:14:56 20 "... these changes include a new warning
21 recommending close observation of adult and
22 pediatric patients treated with antidepressants
23 for worsening depression or the emergence of
24 suicidality, particularly at the beginning of
12:15:12 25 treatment or at the time of increases or

1 decreases."

2 True?

3 A. True.

12:15:23

4 Q. And this was not new information to you and you knew it at
5 the time that you received the letter, correct?

6 A. Yes.

7 Q. I'm sorry?

8 A. Yes.

12:15:31

9 Q. And on page of this May 2004 Dear Healthcare Provider
10 letter, it asks you to familiarize yourself with these
11 revisions to the Paxil labeling, correct?

12 A. Yes.

13 Q. And following your standard practice, you did that?

14 A. Yes.

12:15:39

15 Q. And on the third page of the May 2004 Dear Healthcare
16 Provider letter there is a section called "Warnings, Clinical
17 Worsening Suicide Risk," correct?

18 A. Yes.

19 Q. The second sentence of that section states, quote:

12:15:57

20 "Although there has been a long-standing concern
21 that antidepressants may have a role in inducing
22 worsening of depression and the emergence of
23 suicidality in certain patients, a causal role
24 for antidepressants and inducing such behaviors
25 has not been established. Nevertheless patients

12:16:14

1 treated with antidepressants should be observed
2 closely for clinical worsening and suicidality,
3 especially at the beginning of a course of drug
4 therapy, or at the time of dose changes, either
5 increases or decreases."

12:16:29

6 That's what it says, right?

7 A. Yup. Yes.

8 Q. And this language that we just read is not limited to
9 patients age 24 or less, is it?

12:16:43

10 A. No.

11 Q. No, it's not?

12 A. No, it's not.

13 Q. This May 2004 Dear Healthcare Provider letter sent to you
14 by GSK also goes on to state in that first paragraph, under
15 Warnings, that, quote:

12:16:54

16 "Consideration should be given to changing the
17 therapeutic regimen, including possibly
18 discontinuing the medication, in patients whose
19 depression is persistently worse or whose
20 emergent suicidality is severe, abrupt in onset,
21 or was not part of the patient's presenting
22 symptoms."

12:17:07

23 True?

24 A. That's what it says.

12:17:17

25 Q. You knew that information in May of 2004, correct?

1 A. Yes.

2 Q. And the next paragraph in this May Dear Healthcare Provider
3 letter sent by GSK to you states, quote:

4 "Because of the possibility of comorbidity
5 between major depressive disorder and other
6 psychiatric and nonpsychiatric disorders, the
7 same precautions should be observed when
8 treating patients with major depressive disorder
9 should be observed when treating patients with
10 other psychiatric and nonpsychiatric disorders."

11 Correct?

12 A. Yes.

13 Q. And you knew that in May 2004 because that was just common
14 knowledge, correct?

15 A. That's right.

16 Q. And you agree, that in May 2004, the information under the
17 Clinical Worsening and Suicide Risk section of the May 2004
18 Dear Healthcare Provider letter was known to the medical
19 community, true?

20 A. Yes.

21 Q. And, in fact, you believe most physicians, including
22 yourself, know that when you initiate the drug or change the
23 dose -- let me start that again.

24 In fact, you believe that most physicians, including
25 yourself, know when you initiate the drug or change the dose,

1 there is an increase risk of depression and anxiety and an
2 increase in anxiety, correct?

3 A. Yes.

12:18:44

4 Q. These warnings alert doctors and physicians to be on the
5 lookout for increasing suicidality in patients who are taking
6 an antidepressant, such as Paroxetine or Paxil, true?

7 A. Yes.

8 Q. The warnings change also advise the doctor, such as
9 yourself, to look out for certain symptoms, right?

12:19:00

10 A. Correct.

11 Q. Those symptoms included anxiety, agitation, panic attacks,
12 impulsivity, akathisia, or psychomotor restlessness, right?

13 A. Right.

14 Q. You know what akathisia is, don't you?

12:19:13

15 A. Yes.

16 Q. And you're familiar with it, you've been familiar with it
17 since your medical training, correct?

18 A. Yes.

19 Q. And you understand it to be the onset -- let me back up.

12:19:23

20 You described akathisia to the jury in your direct
21 examination, right?

22 A. Yes.

23 Q. And you understand it also to be the onset of increasing
24 very uncomfortable anxiety, right?

12:19:38

25 A. Correct.

12:19:55

1 Q. These warning changes also alerted physicians, and
2 healthcare providers such as yourself, to have discussions with
3 family and caregivers of patients who are being treated with
4 antidepressants for major depressive disorder or other
5 indications that they should be alerted about the need to
6 monitor patients for the emergence of agitation, irritability,
7 and the other symptoms described in the revised labeling, as
8 well as the emergence of suicidality and to report such
9 symptoms immediately to healthcare providers?

12:20:15

10 A. Correct.

11 Q. That was your practice in May of 2004 to do that, correct?

12 A. Yes.

13 Q. And under the Information For Patient Section, the May 2004
14 labeling states:

12:20:27

15 "Patients and their families should be
16 encouraged to be alert to the emergence of
17 anxiety, agitation, panic attacks, insomnia,
18 irritability, hostility, impulsivity, akathisia,
19 hypomania, mania, worsening of depression, and
20 suicidal ideation, especially early during
21 antidepressant treatment."

12:20:45

22 Correct?

23 A. Yes.

24 Q. And, in fact, it also went on to say:

12:20:54

25 "... symptoms should be reported to the

1 patient's physician, especially if they are
2 severe, abrupt in onset, or were not part of the
3 patient's presenting symptoms."

4 A. Correct.

12:21:04

5 Q. And for each part of the May 2004 revised labeling we have
6 discussed, it does not say that it only applies to patients
7 age 24 or less, does it?

8 A. It does not say that.

9 Q. I'm sorry?

12:21:18

10 A. It does not say that.

11 Q. You told Stewart Dolin to be on the lookout for the signs
12 and symptoms that are described in the May 2004 labeling in the
13 Dear Healthcare Provider letter, true?

14 A. Yes.

12:21:30

15 Q. You told him to be on the lookout for worsening of his
16 condition, true?

17 A. Uh-huh. Yes.

18 Q. You did that when you first started him on Paroxetine in
19 2005, yes?

12:21:40

20 A. Yes.

21 Q. And while you did not numerate or identify every single one
22 of the symptoms in the labeling to be on the lookout for, you
23 enumerated or identify several so he would get the idea,
24 correct?

12:21:54

25 A. Correct.

1 Q. And you were trying to convey to Mr. Dolin that after he
2 started Paroxetine or Paxil, that if his symptoms or his
3 conditions worsened, as outlined in the warnings from May 2004,
4 to let you know?

12:22:08

5 A. Correct.

6 Q. You did the same with your sertraline and Zoloft patients
7 as well, did you not?

8 A. Yes.

12:22:17

9 Q. And when you first initiated treatment of Paroxetine for
10 Mr. Dolin in 2005, you also had a discussion with him about how
11 his family and other caregivers needed to know that he was on
12 the medication and if he had any of these signs or symptoms so
13 that they could be alerted to them as well, correct?

14 A. Yes.

12:22:34

15 Q. Mrs. Wendy Dolin knew when he was on the medication when
16 you started him on Paroxetine in 2005, correct?

17 A. Yes.

12:22:53

18 Q. And you had discussions Mrs. Dolin where you said to her
19 that you told her that her husband was on Paxil or Paroxetine
20 or Zoloft or sertraline and you need to look out for these
21 signs and symptoms, correct?

22 A. Yes. These were done in an informal way, probably
23 socially, not in the office.

12:23:07

24 Q. And even though this was done in an informal or social way,
25 you did not make an effort to minimize or down-play the

1 significance of what's prescribed in the labeling, did you?

2 A. No.

3 Q. And you had the conversation with Mrs. Dolin at the
4 beginning -- I think you said at the beginning of Mr. Dolin's
5 treatment with Paroxetine in 2005, right?

12:23:23

6 A. Yes.

7 Q. And Mrs. Dolin absolutely did not voice any objection or
8 opposition to Mr. Dolin taking Paroxetine or Paxil, did she?

9 A. No.

12:23:38

10 Q. No, she did not?

11 A. No, she did not.

12 Q. And at the time when you started the medication,
13 Paroxetine, you were trying to convey to Mr. Dolin that there's
14 a possibility or the potential of an increased risk of the
15 signs and symptoms that are outlined in this warning sent to
16 you in May of 2004, true?

12:23:53

17 A. I told him in an informal way he could feel worse, being
18 more anxious or feeling depressed. I did not outline every
19 symptom you enumerated.

12:24:09

20 Q. Okay. Could you come back to my question. And I'll read
21 it again so you can have it fresh in your head.

22 At the time when you started the medication of
23 Paroxetine, you were trying to convey to Mr. Dolin that there's
24 a possibility or the potential of an increased risk of the
25 signs and symptoms that are outlined in the warnings sent to

12:24:25

1 you in May of 2004?

2 MR. RAPOPORT: Your Honor, I object to the form and
3 the implication that the doctor didn't answer the question that
4 counsel asked before.

12:24:36

5 MR. DAVIS: I don't believe he's answered the
6 question, Your Honor.

7 MR. RAPOPORT: He's made no motion to strike an answer
8 and he's behaving as if the doctor didn't answer is question.

9 MR. DAVIS: I don't believe he's answered.

12:24:45

10 THE COURT: Proceed. Go forward.
11 You may answer.

12 BY THE WITNESS:

12:24:57

13 A. The answer is that I spoke to him about the possibility of
14 him becoming more anxious and/or depressed in the initiation of
15 therapy with Paxil or Zoloft, whether it's Paxil or Zoloft.

16 BY MR. DAVIS:

17 Q. Would you be so kind as to turn to your deposition, which
18 is the last tab in your notebook. Could you turn to that,
19 please, and turn to page 189.

12:25:14

20 MR. RAPOPORT: Lines, please?

21 MR. DAVIS: Lines 5 through 12.

22 (Brief pause).

23 BY THE WITNESS:

24 A. What page did you say? I'm sorry.

12:25:25

25 BY MR. DAVIS:

1 Q. 189, Dr. Sachman.

2 (Brief pause).

3 BY MR. DAVIS:

4 Q. Lines 5.

12:25:42

5 A. Okay.

6 Q. Through 12.

7 Are you there?

8 A. I see it.

12:25:49

9 Q. Were you asked this question and did you give this answer
10 under oath:

11 "Question: And were you trying to convey at the
12 time that you had the discussion with Mr. Dolin
13 that -- that when you start this medication,
14 Paxil or Paroxetine, there's the possibility or
15 the potential of an increased risk of the signs
16 and symptoms that are outlined in this warning?"
17 And your answer was, "right."

12:26:02

18 A. Right.

19 Q. Did I read that correctly?

12:26:16

20 A. You did. And I would correct it somewhat to say that at
21 the time of the deposition I was a bit anxious, nervous about
22 the deposition, a bit worried about my own liability in this
23 case. And thinking back over it, I probably did not go through
24 every one of those detailed symptoms. I did it in a more
25 general way, as I've stated before.

12:26:36

1 Q. Doctor --

2 THE COURT: Proceed. Put another question.

3 MR. DAVIS: Yes.

4 THE COURT: Put another question.

12:26:46

5 MR. DAVIS: Yes.

6 BY MR. DAVIS:

7 Q. When you answered that question in your deposition, you
8 didn't say you were confused or didn't understand it, did you?

9 A. No.

12:26:52

10 Q. And, in fact, you swore to tell the truth at your
11 deposition?

12 A. Yes.

13 Q. And when you said you were worried about some liability on
14 your part, you were worried about some lawsuit being filed
15 against you?

12:27:07

16 A. Yeah, possibly.

17 Q. Okay.

18 A. A person died. I prescribed the drug.

19 Q. After you said this to Mr. Dolin, about how he had to be --
20 how you were trying to convey to him that there's a possibility
21 or the potential of increased risk of the signs and symptoms
22 that are outlined in the warning sent to you in May of 2004,
23 Mr. Dolin acknowledged to you that he understood that, correct?

12:27:26

24 A. Are you asking me the same question? I don't understand
25 the question now.

12:27:45

1 Q. This time I'm asking, after you conveyed the information to
2 him about what we just talked about --

3 A. He understood the information as I conveyed it.

12:27:56

4 Q. Yes. And if Mr. Dolin had not acknowledged to you the
5 information that you told him, you would not have continued him
6 on the medication, true?

7 A. Correct.

12:28:12

8 Q. And if you go to pages 10 -- if you look at the labeling
9 that's attached to the May 2004 Dear Healthcare Provider
10 letter, the same information that's in the Dear Healthcare
11 Provider letter about risk of suicidality or suicidal thoughts
12 or behavior is in the actual labeling, true?

13 A. Yes.

12:28:31

14 Q. Okay. And through this labeling, of May of 2004, GSK
15 disclosed to you that possible or potential side effects or
16 adverse reactions after starting Paroxetine or Paxil were the
17 symptoms that are outlined in the Dear Healthcare Provider
18 letter and the labeling, including the labeling section under
19 Clinical Worsening of Suicide Risk, true?

12:28:53

20 A. True.

21 Q. And the warnings that were included in the May of 2004 Dear
22 Healthcare Provider letter, along with the accompanying revised
23 labeling, included the risk of suicidal thoughts or behavior,
24 true?

12:29:13

25 A. True.

1 Q. I'm sorry?

2 A. True.

3 Q. And if we could turn to the next tab, which is Tab 3. It's
4 Joint Exhibit Number 6 -- I'm sorry, it's Joint Exhibit 6.

12:29:44

5 Do you see that Joint Exhibit 6 is a February 2005
6 Dear Healthcare Provider letter that GSK sent?

7 A. Right. Yes.

8 Q. And you received this Dear Healthcare Provider letter as
9 well around February 2005, right?

12:29:58

10 A. Right.

11 Q. And you received it also before you initiated treatment for
12 Stewart Dolin for Paxil or Paroxetine in October of 2005,
13 correct?

14 A. Yes.

12:30:09

15 Q. Okay.

16 THE COURT: All right. I'm going to recess at this
17 time until 1:30 this afternoon.

18 Ladies and gentlemen, you're excused until 1:30.

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

12:30:43

21 [REDACTED]

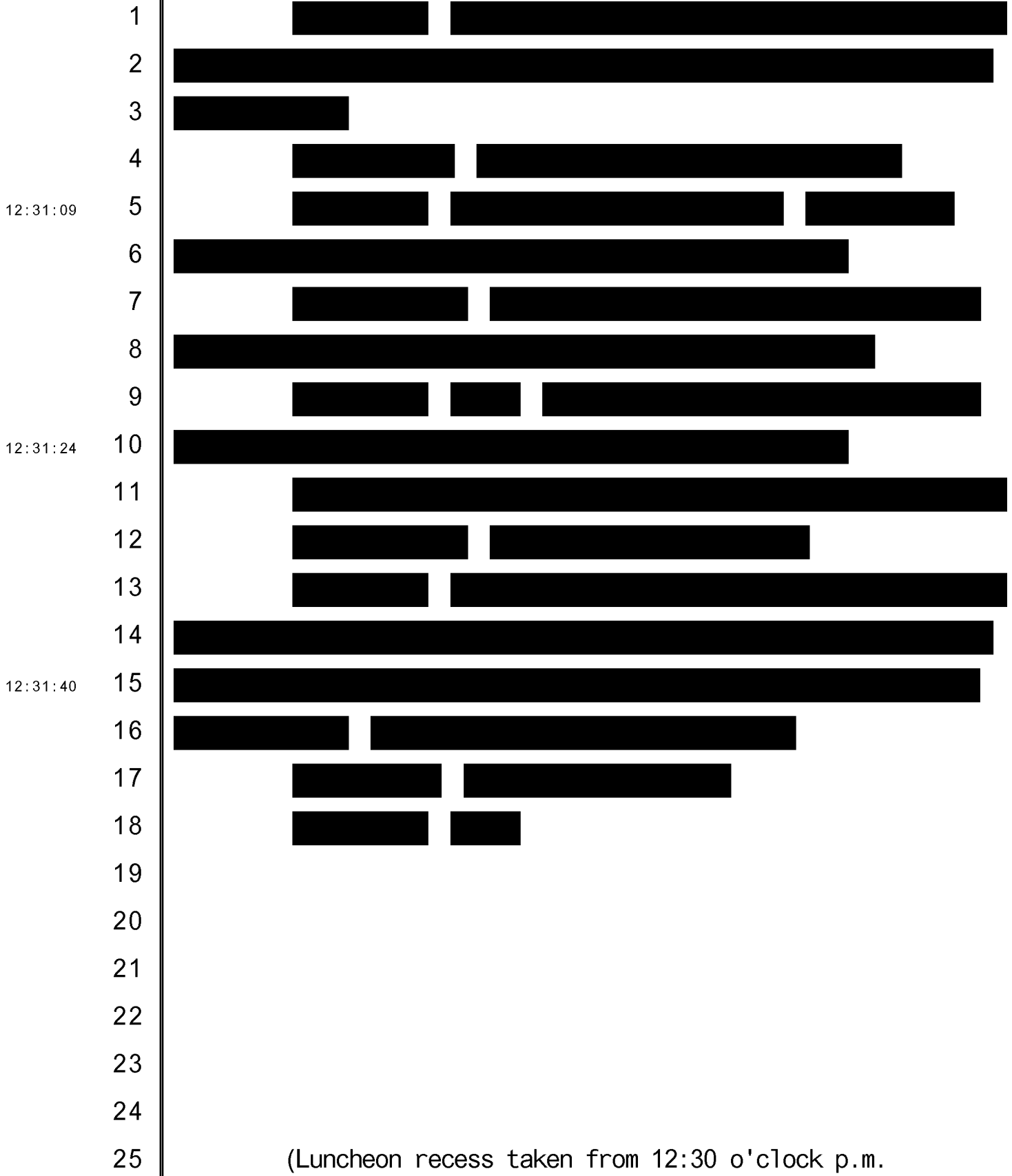
22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

12:30:58

25 [REDACTED]



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to 1:30 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 27, 2017