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

WENDY B. DOLIN Individually and as Independent Executor of the Estate of STEWART DOLIN, deceased,	}	No. 12 CV 6403
Plaintiff,		
vs.	}	Chicago, Illinois
SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, a Pennsylvania Corporation,		
Defendant.)	9:20 o'clock a.m.

VOLUME 17 A
TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE WILLIAM T. HART

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

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9 [REDACTED] [REDACTED]

10 09:18:41 [REDACTED] [REDACTED]
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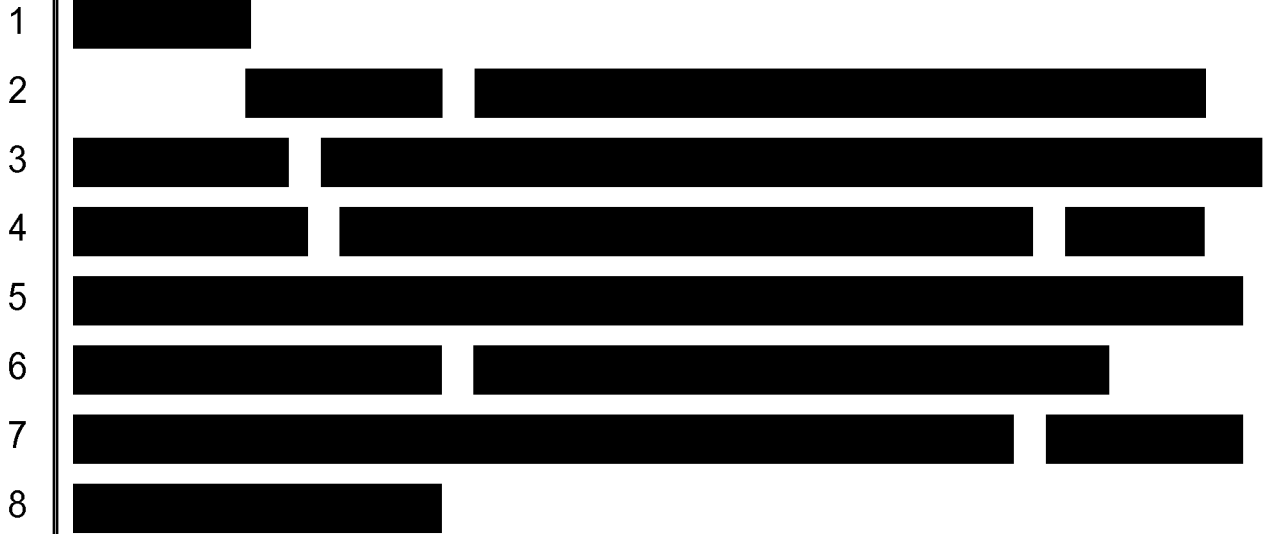
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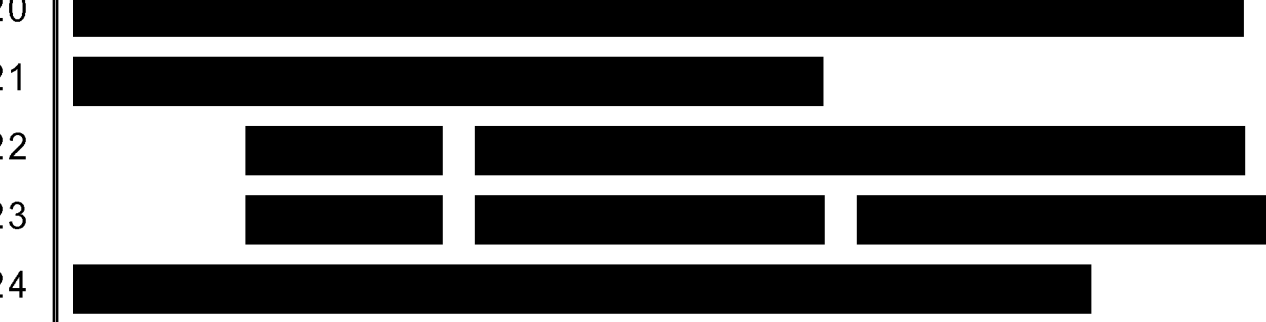
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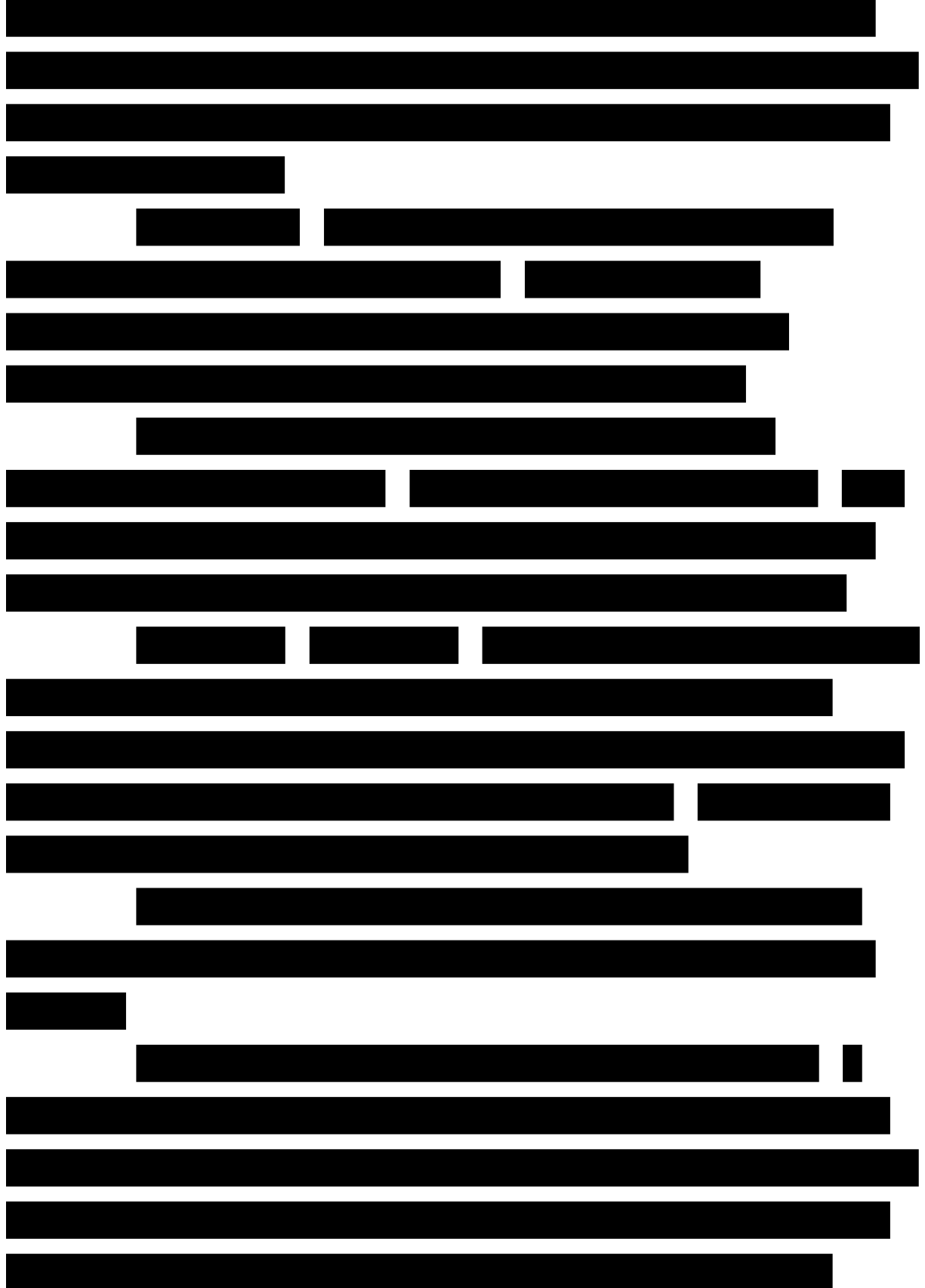


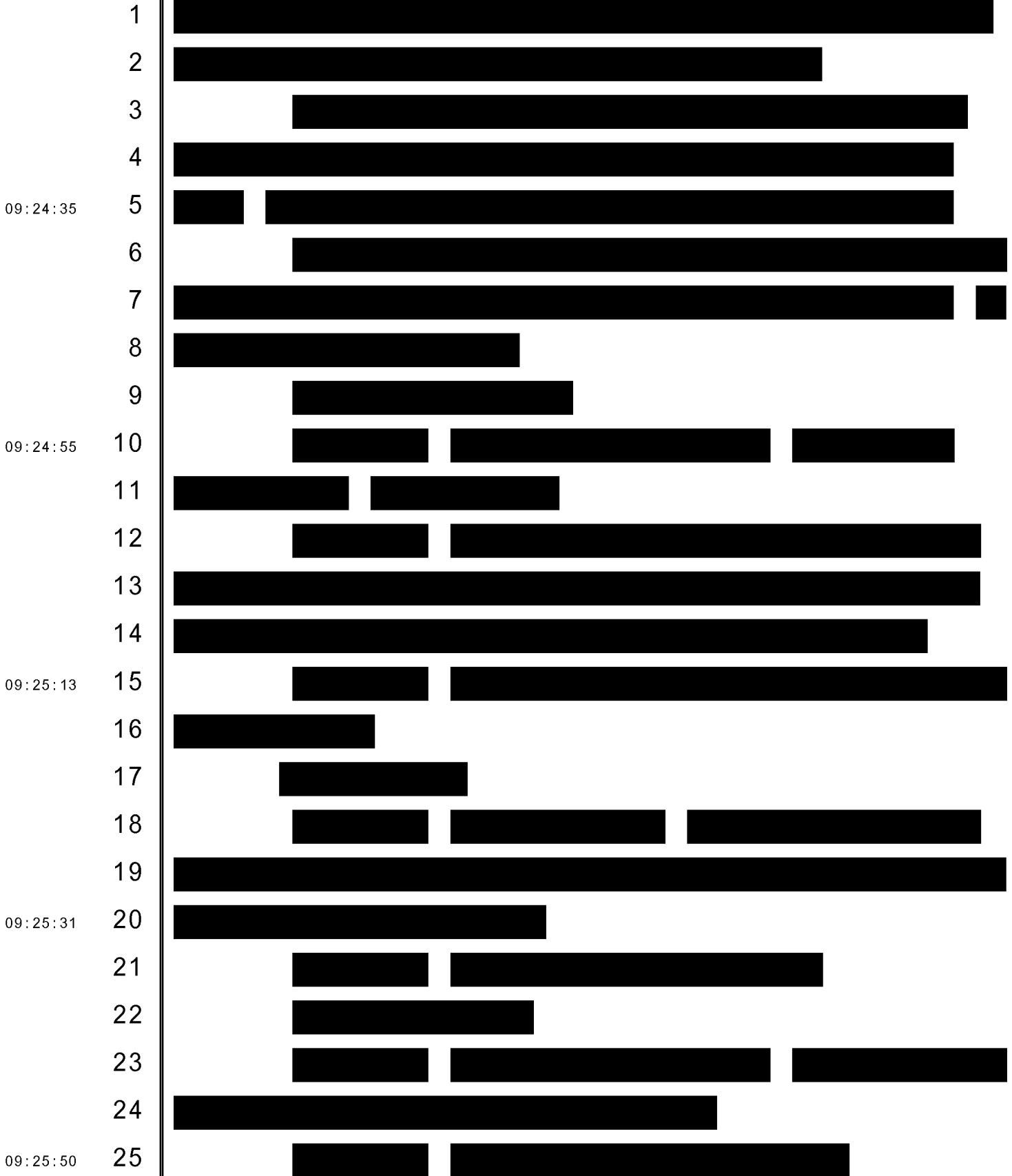
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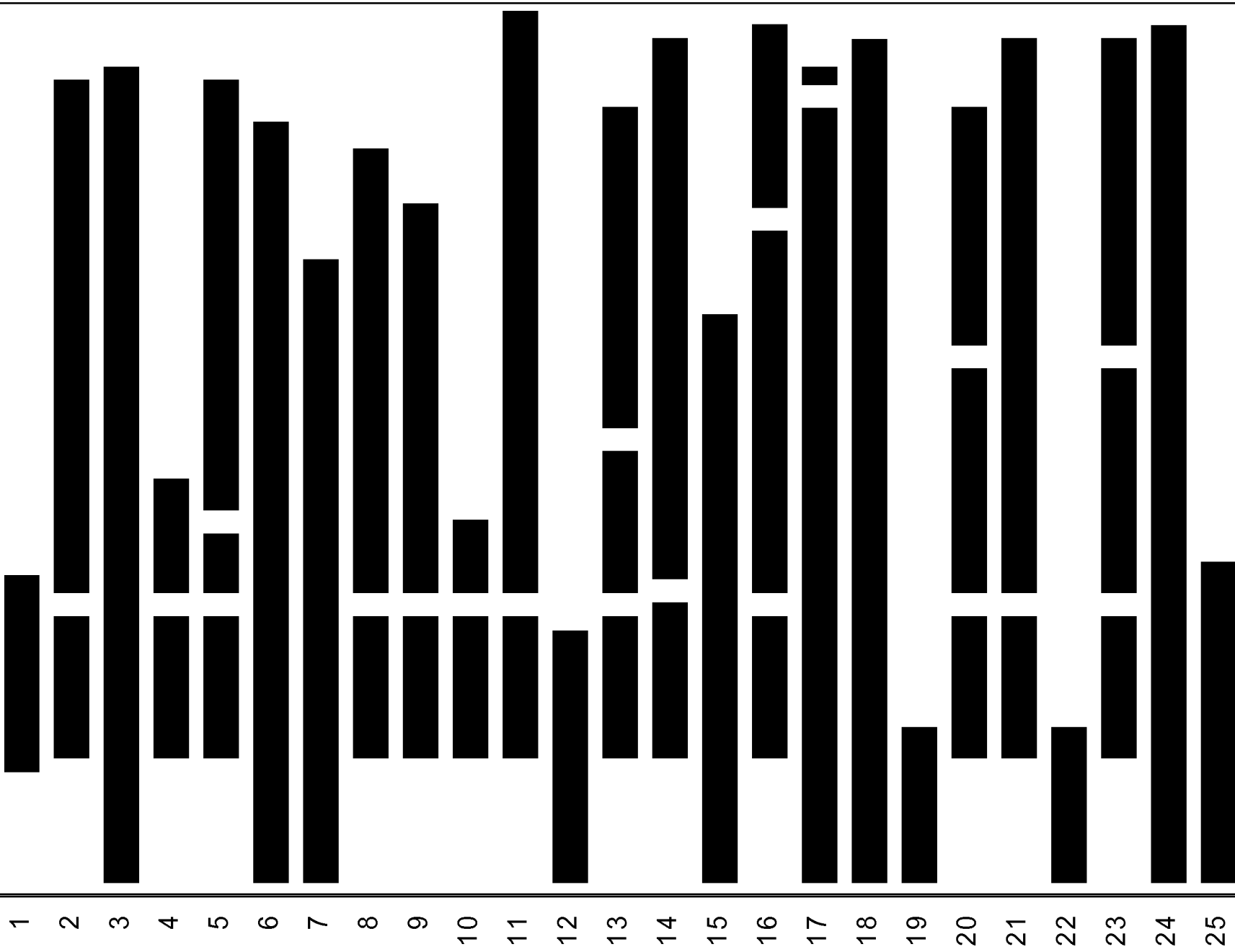


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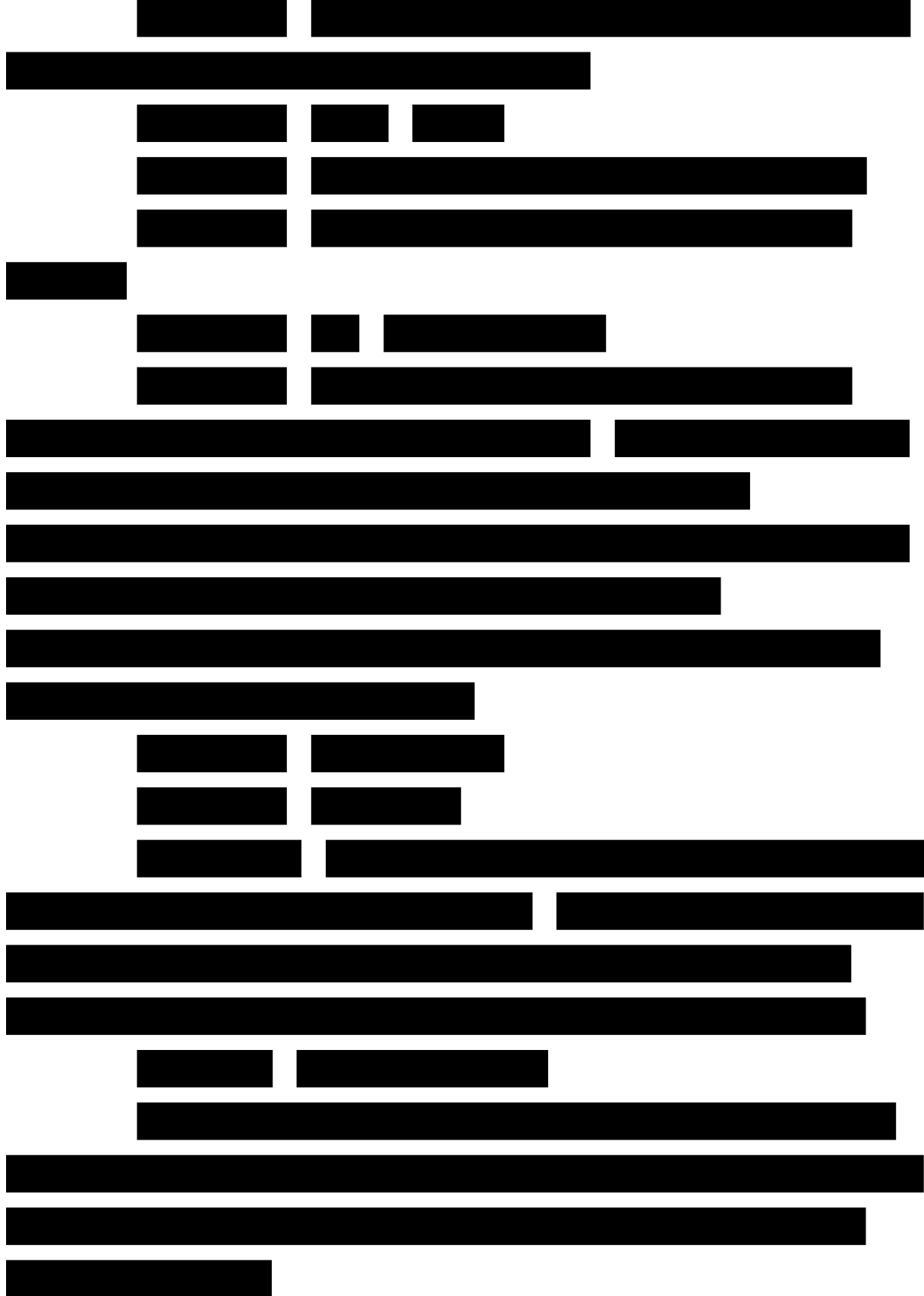
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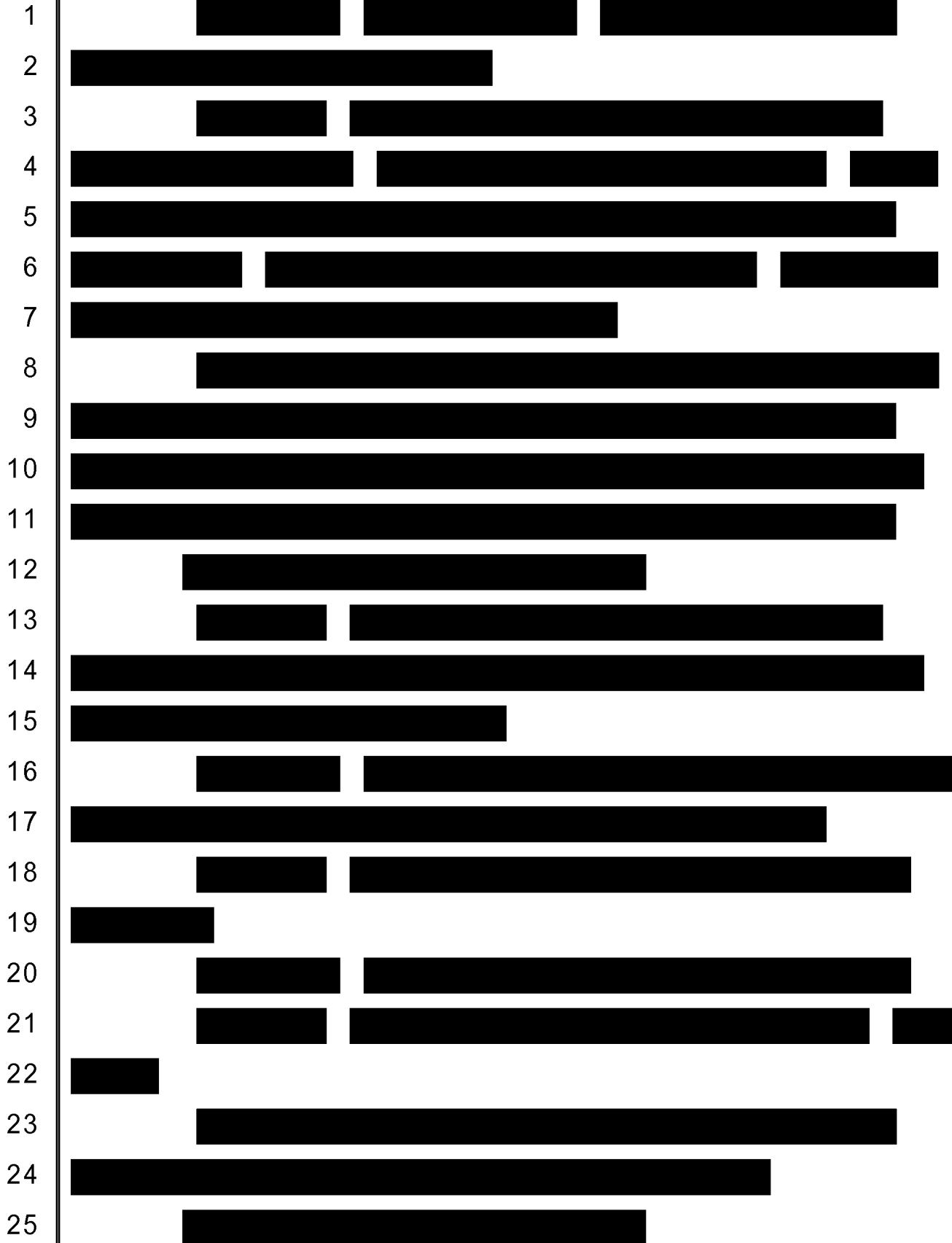
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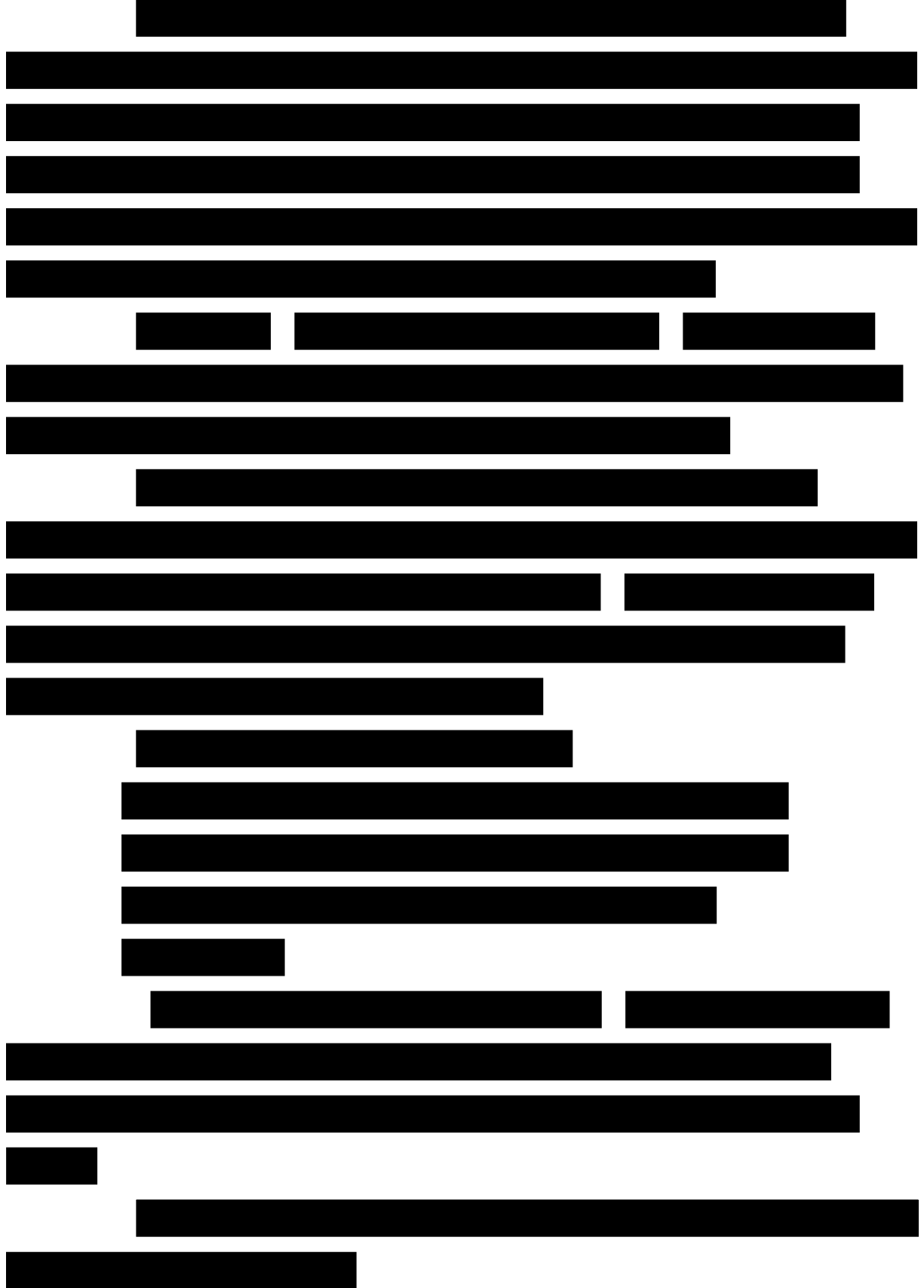


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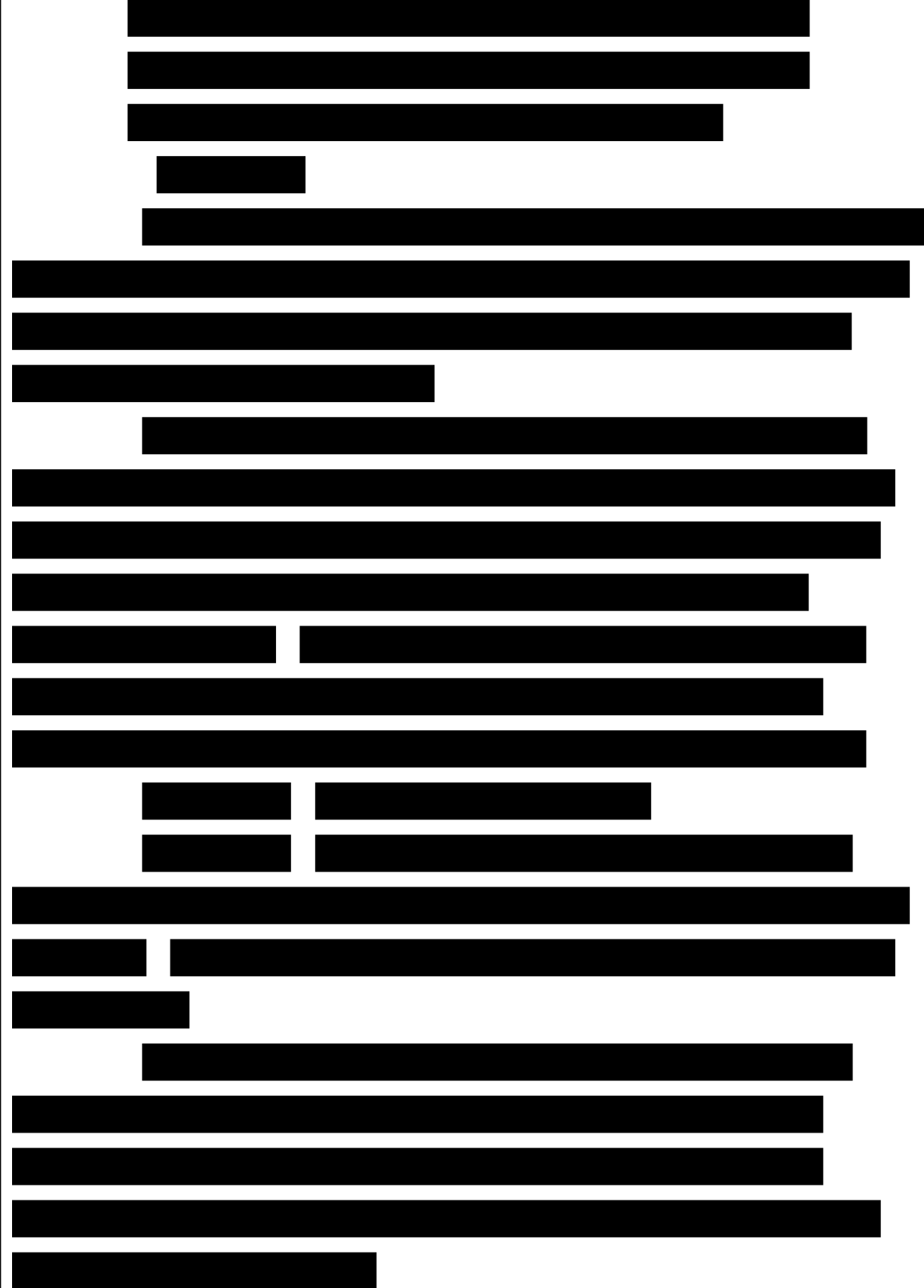




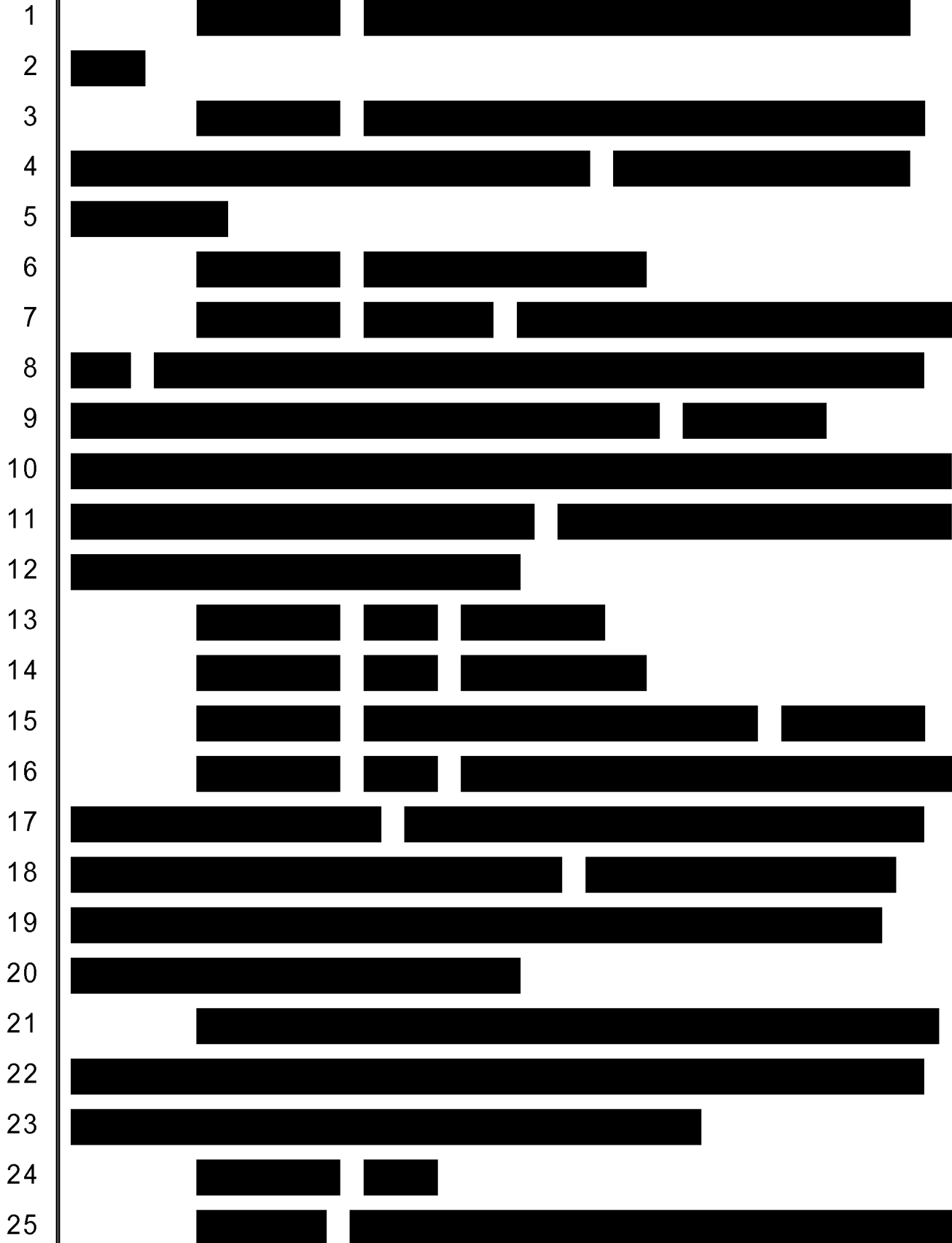
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09:40:07

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(The following proceedings were had in the

6

presence of the jury in open court:)

7

THE COURT: Can't you use your overhead for this

8

purpose?

9

MR. WISNER: No, Your Honor. We're putting together a

09:40:18

10

board. I don't think this blocks anybody. He can see the

11

witness just fine, and the jury, and myself.

12

THE WITNESS: When I sit down, I probably can't see my

13

counsel.

14

MR. WISNER: Let's check it out.

09:40:30

15

(Brief pause).

16

THE COURT: All right. Thank you very much, ladies

17

and gentlemen. Please be seated. We'll proceed.

18

JOHN KRAUS, DEFENDANT'S WITNESS, PREVIOUSLY SWORN

19

CROSS EXAMINATION (resumed)

09:40:44

20

BY MR. WISNER:

21

Q. Good morning, Doctor. How are you.

22

A. Good morning.

23

Q. I apologize. I've only become less well over the evening.

24

So, I apologize if I've been coughing again.

09:41:06

25

During your direct examination you specifically

1 addressed the 11 suicide attempts that occurred in the
2 placebo-controlled NDA trials, correct?

3 A. Yes, I did.

09:41:23

4 Q. And you went into them with considerable detail, looking at
5 the length of time that they were on the drug, whether or not
6 they experienced, in your opinion, akathisia, as well as a
7 whole host of other demographic and specific information about
8 those, right?

09:41:37

9 A. Right. Just to clarify, it wasn't the opinion about
10 akathisia. It was based on the data from each of the subjects.

11 Q. I see. Was there a diagnosis in each one of those that
12 there was no akathisia?

09:41:52

13 A. There was no adverse event listed of akathisia. And as we
14 talked about in the rating scales, agitation showed no evidence
15 of the increase in most of the subjects.

16 Q. So, to be clear, Doctor, whether or not they had akathisia,
17 that's your opinion as a medical doctor, right?

09:42:10

18 A. It's based on the data from the cases. So, it's an
19 informed from the data. So I wouldn't call it an opinion. I'd
20 call it an interpretation of data.

21 Q. Now, you looked at 11 suicide attempts in the NDA
22 placebo-controlled clinical trials. It's fair to say, though,
23 that they were significantly larger number of suicide attempts
24 in all of the Paxil clinical trials, correct?

09:42:25

25 A. There were a larger number in the clinical trials, but

1 there's a good reason why we --

2 THE COURT: Doctor, Doctor, just answer the question.
3 Your lawyer will get a chance.

4 BY THE WITNESS:

09:42:35

5 A. Yes, there were more.

6 BY MR. WISNER:

7 Q. Okay. In fact, in the original NDA back in 1989, there
8 were 40, correct?

9 A. That's correct.

09:42:41

10 Q. And those 40 individuals who attempted suicide, did you do
11 a similar analysis to see if they were experiencing akathisia,
12 how long they've been on the dose, or the same exercise that
13 you went into detail during your direct?

14 A. No, and there's a reason for that, because it was not
15 scientifically valid. They were not in the placebo-controlled
16 portion of the trials.

09:43:01

17 Q. I understand it's your opinion to this jury that it is not
18 scientifically valid to look at people who attempted to commit
19 suicide while taking Paxil in GSK's clinical trials when it's
20 not placebo-controlled, I understand that opinion, Doctor, but
21 my the question to you is very simple, did you do that same
22 sort of rigorous analysis, digging down into the details for
23 those 40 attempts?

09:43:17

24 A. No, I did not --

09:43:27

25 Q. Okay.

1 A. -- because it would not have informed our analysis.

2 Q. Do you have a binder in front of you?

3 A. I have your binder, yes.

4 Q. Yeah. Can you please turn to Plaintiff's Exhibit 324.

09:43:43

5 (Brief pause).

6 BY THE WITNESS:

7 A. Okay.

8 BY MR. WISNER:

9 Q. Do you recognize this document, Doctor?

09:43:53

10 A. Yeah; I suspect this was shown to me in the deposition.

11 Q. As you can tell, it says "Kraus Exhibit 10" at the bottom
12 right corner, right?

13 A. Yes.

14 Q. And this is a document that reflects the very suicide
15 attempts in the original NDA application, correct?

09:44:07

16 A. Yes, I believe that's correct.

17 Q. You went through this with my colleague during your
18 deposition and verified that the information was generally
19 correct, correct?

09:44:21

20 A. Yes, I believe that's correct.

21 MR. WISNER: At this time, Your Honor, I move
22 Plaintiff's Exhibit 324 into evidence.

23 MR. BAYMAN: Objection, Your Honor. This isn't a
24 company document. It's something created by counsel and I
25 would object to it.

09:44:31

1 THE COURT: Let me see it, please.

2 MR. WISNER: This is a document that was shown during
3 Mr. Gibbons cross-examination as well. It's not been
4 authenticated and he's admitted that's it's true and accurate.
5 So, regardless of whether or not it's a company document, it's
6 admissible testimony.

09:44:44

7 MR. BAYMAN: Just because it's shown to him doesn't
8 mean that a foundation has been laid.

9 (Brief pause).

09:45:11

10 MR. BAYMAN: I don't have objection to him using it as
11 a demonstrative, but I object to it being moved into evidence
12 with no foundation being laid.

13 MR. WISNER: He just testified that it was accurate.

14 THE COURT: It may be received.

09:45:21

15 (Plaintiff's Exhibit No. 324 was received in
16 evidence.)

17 MR. WISNER: Permission to publish, Your Honor?

18 THE COURT: You may publish.

19 (Exhibit published to the jury.)

09:45:26

20 BY MR. WISNER:

21 Q. All right. Doctor, this is the exhibit, I showed it to
22 Dr. Gibbons, as well, and if you look at the top we have
23 "suicide attempts," do you see that?

24 A. Yes, I do.

09:45:34

25 Q. And then we have the patient ID number in the left column,

1 right?

2 A. Yes.

3 Q. And then in the next column we have the age, right?

4 A. Yes.

09:45:42

5 Q. And then the next column it says "how long the suicide
6 attempt occurred after the initiation of Paxil," correct?

7 A. It doesn't say that exactly.

8 Q. That's what --

09:45:58

9 A. It says "day number SA occurred start date," so I assume
10 that's what that is, yes.

11 Q. And then the next column is the number of days after the
12 last dose of Paxil was increased, correct?

13 A. Yes.

09:46:12

14 Q. And then in the last column, it's the last day of taking
15 Paxil before the incident occurred, correct, if it applies?

16 A. And -- I guess that's correct, yes.

17 Q. All right. Now, going through the attempted suicides, in
18 the original NDA, isn't it true that 70 percent of the attempts
19 were over the age of 30?

09:46:36

20 A. I'd have to go through the numbers to assess that, but it
21 wouldn't surprise me if that were the case, because as we've
22 discussed over the last couple of days, the mean age was 46 and
23 in our studies across-the-board you would expect suicidal
24 ideation and behavior, as a part of the disease, the age would
25 merit the population.

09:46:59

1 Q. I'm sorry, Doctor --

2 A. So it's not a surprise.

3 Q. -- you told this jury that the risk occurs in younger
4 populations. Wouldn't we expect to see them in younger
5 populations?

09:47:07

6 A. What I said to the jury is, when you look at the
7 placebo-controlled portion of the trials when you're trying to
8 understand whether this is a drug effect or not a drug affect,
9 and looking contemporaneously, when we look at that data, which
10 is where those 11 subjects came from, which is why we need to
11 look at those closely, because they were part of the
12 informative analysis, we saw clearly that the risk in terms of
13 drug versus placebo is in younger adults.

09:47:20

14 What I have said to you also is, the age of patients
15 in the Paxil trials, placebo-controlled, open-label extension,
16 was older age group.

09:47:38

17 And so as suicidal behavior, ideation is part of the
18 disease, as if you follow patients over time these events can
19 occur, it doesn't surprise me that the age of these things
20 occurring as part of the disease would be older.

09:47:58

21 Q. So, that's a "yes," 70 percent were over the age of 30?

22 A. I -- I have to do the calculation here, but I'll take your
23 estimate. I don't know if you're good at math or not, but it
24 looks about right.

09:48:16

25 Q. Okay. Well, 82 percent were in fact over the age of 24.

1 You testified to that fact during your deposition, didn't you?

2 A. Right. And as we talked about yesterday, in our clinical
3 trials database, in the placebo-controlled portion, 80 percent
4 of patients were in that age group in the trials as well, 30
5 and over.

09:48:39

6 Q. You keep going back to the placebo-controlled portion.

7 A. Right.

8 Q. There was 11 suicide attempts on that Paxil in that group,
9 right?

09:48:46

10 A. Right. And I keep going back to it because --

11 THE COURT: Please, please, just questions, answers.

12 BY THE WITNESS:

13 A. I'm trying to give you full answers --

14 THE COURT: No, no, Doctor, please.

09:48:55

15 And, counsel, stick with your questions.

16 MR. WISNER: I'm asking a yes or no.

17 THE COURT: Ask the question and then get an answer
18 and then we'll move on.

19 BY MR. WISNER:

09:49:01

20 Q. All right. Yes or no, there were 11 suicide attempts in
21 the placebo-controlled trials?

22 A. The major depressive disorder placebo-controlled trials,
23 yes.

24 Q. And in the original NDA all involved major depressive
25 disorder, correct?

09:49:16

1 A. Yes; that was the indication.

2 Q. And they had 40 suicide attempts back in 1989, correct?

3 A. Yes.

4 Q. And just to be clear, 80 percent of them were over the age
5 of 24? Yes?

09:49:27

6 A. Again, approximately that may be right. I'd have to make
7 the calculation.

8 Q. 70 percent were over the age of 30, correct?

9 A. Again, I'm taking your word on that. I'm looking at the
10 distribution here. I haven't calculated it myself.

09:49:41

11 Q. Now, Doctor, do you know standing here today--and this is
12 data from back in 1989--do you know standing here today the
13 total number of suicide attempts in every single Paxil clinical
14 trial ever conducted where patients were on Paxil?

09:50:02

15 A. I -- I personally don't know that, but we've collected the
16 adverse events and they're in our central database.

17 Q. So you don't know the full number, is that right?

18 A. I personally can't tell you that today.

19 Q. Okay. Now, back in 1999, there was an investigator

09:50:18

20 brochure that said there was over 91 suicide attempts, do you
21 recall that?

22 A. I don't recall that, no.

23 Q. You don't recall seeing that in deposition?

24 A. I don't. I just said that.

09:50:28

25 Q. Okay. Is it true though, Doctor, that it would be fair to

1 say that there were well over 100 suicide attempts of patients
2 on Paxil in the entire clinical trial database?

3 A. Again, I can't say that. As I said before, I don't know
4 the total number.

09:50:44

5 Q. Okay. But you do know that there was 11 in the
6 placebo-controlled NDA trials, right?

7 A. Yes. Obviously I know that because that was part of the
8 analysis we did in 2006.

09:50:58

9 Q. Isn't it true that the reason why you don't know the number
10 of suicide attempts is because, in your view, it would be too
11 burdensome to collect all that information?

12 A. No, that's -- that's a very inaccurate characterization.

13 And I ask the judge if I can go further why that is,
14 but --

09:51:11

15 THE COURT: No. Your counsel, sir, your counsel is
16 going to ask you some questions.

17 THE WITNESS: Okay.

18 BY MR. WISNER:

09:51:22

19 Q. Please turn to Plaintiff's Exhibit 324 -- no, I'm sorry.
20 Please turn to Plaintiff's Exhibit 343, Doctor.

21 A. 343?

22 Q. Uh-huh.

23 A. Okay.

24 Q. Are you there, Doctor?

09:51:44

25 A. Yes.

1 Q. That's a declaration by John Davies, correct?

2 A. Yes, that's correct.

3 Q. And you've testified that the information contained in that
4 declaration is true and accurate, haven't you?

09:51:57

5 A. Or John Davies did.

6 Q. I didn't ask about John Davies. I asked about you. You've
7 confirmed the accuracy of that declaration, haven't you?

8 A. Oh, I see what you're asking.

9 Yes, this is John Davies' declaration.

09:52:08

10 Q. No, that's not my question.

11 The information contained in that declaration is
12 accurate in your personal opinion, correct?

13 A. Correct.

09:52:16

14 MR. WISNER: At this time I move it into evidence,
15 Your Honor.

16 MR. BAYMAN: Your Honor, I object to that. This is
17 promulgated in response to a discovery request relating to the
18 efforts that would be undertaken to search the database, and it
19 is --

09:52:27

20 THE COURT: I haven't read it. Do you need it right
21 now?

22 MR. WISNER: Yes, Your Honor. He just said that --

23 THE COURT: No, no. Do you need it to go on?

24 MR. WISNER: Yes, Your Honor.

09:52:36

25 THE COURT: Now?

1 MR. WISNER: Yes, Your Honor.

2 THE COURT: Well, then, I'll have to take a minute and
3 read it.

4 THE WITNESS: I'll do the same.

09:52:44

5 MR. BAYMAN: And then also, Your Honor, it's from
6 another case. It's not from this case.

7 THE COURT: Are you interested in of it or not just
8 part of it?

09:52:53

9 MR. WISNER: No, I'll show you the paragraphs, Your
10 Honor, so you can see what I'm focusing on.

11 If you turn to paragraph numbers 6 and 8.

12 THE COURT: 6 and 8, okay.

13 MR. WISNER: Yes.

14 (Brief pause).

09:53:56

15 THE COURT: You can read those paragraphs into the
16 record.

17 MR. WISNER: That's what I would like to do, Your
18 Honor.

19 THE WITNESS: Which paragraph, sir?

09:54:05

20 THE COURT: 6 and 8.

21 THE WITNESS: Can I read 9 into the record?

22 THE COURT: I'm sure eventually you will, but not
23 during the cross-examination.

09:54:14

24 MR. BAYMAN: I just want to note my objection on the
25 record.

1 THE COURT: Yes, your objection is noted.

2 BY MR. WISNER:

3 Q. All right. Doctor, paragraph 6 reads:

4 "... if GSK were required -- "

09:54:20

5 Actually, before I read this I just want to set up
6 one important contextual thing.

7 Back in 2009, we asked GSK to identify all the suicide
8 attempts, do you recall that?

09:54:34

9 A. I -- I assume this is what's related to this deposition,
10 yes.

11 Q. And GSK put forward a witness with a person most
12 knowledgeable in that area, and you showed up at the
13 deposition, didn't you?

09:54:47

14 A. I've been to many depositions. So, if it was me, I was
15 there.

16 Q. So you were asked to testify about the total number of
17 attempted suicides in all GSK clinical trials, do you recall
18 that?

19 A. I now recall that, yes.

09:54:55

20 Q. That was back in 2009, right?

21 A. Right. 8 years ago.

22 Q. Okay. Great. I'm going to read these paragraphs into the
23 record:

09:55:05

24 "... if GSK were required to identify suicide
25 attempts in any clinical trial conducted by or

1 funded by any GSK related entity, GSK would need
2 to manually collect and review materials from
3 the entities who conducted the trials. A
4 complete collection would be virtually
09:55:19 5 impossible because there is no comprehensive
6 list of all such studies, making it impossible
7 to determine if GSK has all of the noncentral
8 database materials. Also, given that paroxetine
9 has been marketed by GSK since 1983, and based
09:55:34 10 on my experience, it would be necessary for GSK
11 to have searches done throughout the world, this
12 would require a manual search of records located
13 in a host of countries throughout the world
14 since those documented would be located in local
09:55:48 15 operating or business units worldwide. Given
16 that paroxetine has been marketed since 1993,
17 and based on my experience, this likely would
18 require searchers of archived documents not
19 readily assessable, such a search would be
09:56:03 20 time-consuming, expensive, and burdensome."

21 Did I read that correctly, Doctor?

22 A. You read that correctly.

23 Q. All right. Paragraph 8:

24
09:56:11 25 "...in addition to the problems outlined in

1 paragraph 6 above, identifying "suicide
2 attempts" in all clinical trials is also far
3 more difficult than identifying completed
4 suicides for a number of additional reasons:
5 First, it would be highly unlikely that such a
6 review would identify all suicide attempts in
7 any clinical trial conducted by or funded by any
8 GSK related entity because it would be
9 impossible to determine if GSK has all of the
10 noncentral database materials.

11 Furthermore, in order to identify a bona fide
12 suicide attempt, it would be first necessary to
13 identify any adverse event that could possibly
14 have been a suicide attempt in a clinical trial,
15 this would require a manual review of a variety
16 of information sources, including clinical trial
17 reports, adverse event data and regulatory
18 submissions from around the world, using broad
19 search criteria designed to capture possible
20 suicide attempts. One such event was
21 identified, all documentation surrounding such
22 events would have to be located and collected
23 from the entity that maintains such files, which
24 would include numerous GSK's companies around the
25 world. That documentation would have to be

1 reviewed by clinicians who would be required to
2 make judgments about whether an event should be
3 considered a bona fide suicide attempt to not
4 only attempt to identify responsible clinical
09:57:29 5 trials, but also to search for and locate
6 information unnecessary to identify suicide
7 attempts reported in those studies would be
8 time-consuming, expensive, and burdensome."

9 Did I read that correctly?

09:57:43 10 A. Yes. Yes, you did.

11 Q. All right. Doctor, to be clear, when I asked you earlier
12 if you knew the number of suicide attempts in all of GSK's
13 clinical trials, the answer is not that it's somewhere, but
14 it's, in fact, impossible to locate, correct?

09:57:56 15 A. Yes.

16 Q. And, in fact, it's impossible to locate because it would be
17 time-consuming, expensive, and burdensome, right?

18 A. That is part of the reason. The other part is in
19 paragraph 9 --

09:58:14 20 THE COURT: We'll get to paragraph 9, Doctor.

21 THE WITNESS: Okay.

22 BY MR. WISNER:

23 Q. Doctor, how much money did GSK make off Paxil?

24 MR. BAYMAN: Your Honor, objection. You ruled this
09:58:23 25 out pretrial.

1 THE COURT: Yes. Sustained as to how much money they
2 made on Paxil.

3 BY MR. WISNER:

09:58:31

4 Q. Let me put it this way, fair to say, Doctor, that the cost
5 of going and identifying suicide attempts is a fraction of what
6 GSK's --

7 MR. BAYMAN: Same objection, Your Honor.

8 MR. WISNER: -- made from the drug.

9 MR. BAYMAN: And move to strike that.

09:58:43

10 THE COURT: Overruled.

11 BY MR. WISNER:

12 Q. Is it fair to say, Doctor --

09:58:55

13 THE COURT: No, wait. You know, I don't allow that.
14 We read back the questions because then we get two questions
15 and we have to decide which is the correct answer to the
16 correct question. I'm trying to teach you both that during the
17 course of this trial. We read back, we do not restate unless
18 you withdraw the question.

09:59:08

19 MR. WISNER: I withdraw the question and would like to
20 restate.

21 THE COURT: Okay. Now the question is withdrawn. Now
22 you may ask another question.

23 BY MR. WISNER:

09:59:16

24 Q. Would it be fair to say, Doctor, that the cost associated
25 with identifying suicide attempts, that is a fraction of the

1 cost associated with a fraction of the amount of money GSK made
2 off the drug?

3 MR. BAYMAN: Same objection, Your Honor.

4 THE COURT: Overruled.

09:59:25

5 BY THE WITNESS:

6 A. I don't know the answer to that. That's likely true, but
7 it would be an exercise that would not help us understand the
8 answer as to whether or not paroxetine would be associated with
9 suicidality, because there's not the appropriate control,

09:59:43

10 that's why we've looked and FDA has looked at the
11 placebo-controlled studies.

12 Q. So you don't know the average age of the suicide attempts
13 in all Paxil clinical trials, do you?

14 A. I do not. But again --

09:59:54

15 Q. You don't know --

16 A. -- the informative information is from the
17 placebo-controlled studies in this question of whether
18 paroxetine versus placebo --

19 THE COURT: Doctor --

10:00:04

20 THE WITNESS: -- can result in --

21 THE COURT: Doctor, Doctor you are going to get a
22 chance to testify to all of that. I don't mean to be impolite,
23 but we can't follow the cross examination unless we get the
24 answers and then you get the opportunity. Your able counsel
25 will ask you all these things, including paragraph 9. And I

10:00:16

1 promise you that if he doesn't, I'll ask you.

2 (Laughter n the courtroom).

3 THE COURT: Let's follow the progression here.

4 THE WITNESS: I apologize, sir.

10:00:27

5 THE COURT: All right.

6 BY MR. WISNER:

7 Q. So that's a "no," you do not know the average age of
8 suicide attempts --

9 A. No, I.

10:00:33

10 Q. Hold on. Let me finish my question please.

11 -- while people were taking Paxil in all of GSK's
12 clinical trials, correct?

13 A. I can't answer that today, that's correct.

10:00:47

14 Q. You don't know how many of those individuals who attempted
15 suicide were experiencing akathisia prior to the suicide
16 attempt, correct?

17 A. Sitting here today I can't answer that, that's correct.

18 Q. You don't know how long they've been on Paxil before they
19 attempted their suicides, correct?

10:01:00

20 A. Again, sitting here today I can't answer that question.

21 Q. Simple fact is, Doctor, those people were never considered
22 in the 2006 analysis that you conducted or the FDA's 2006
23 analysis, correct?

24 A. That's correct, and for very good reasons.

10:01:15

25 Q. One of the things that I thought about yesterday, Doctor,

1 last night while I was trying to sleep was, how much money
2 would it have cost GSK to take that meeting to change the label
3 in 2006?

10:01:40

4 A. Is that a question or are you telling me what you think it
5 meant?

6 Q. I asked you how much it would cost, Doctor?

7 A. No, I'm serious. You didn't ask that. It wouldn't cost
8 much money. It's a meeting. Usually a teleconference.

10:01:53

9 Q. Okay. So to be clear, to be clear, Doctor, it wouldn't
10 have cost GSK much money to take that meeting in 2006, right?

11 A. That's correct, but for the reasons I said earlier, we
12 didn't take the meeting. It had nothing to do with the
13 monetary consideration.

10:02:07

14 Q. Yeah. And to be sure, before you made the decision not to
15 take the meeting I just want to be clear, did you consult your
16 lawyers before that?

17 MR. BAYMAN: Objection, Your Honor.

18 THE COURT: Sustained.

19 MR. BAYMAN: Thank you.

10:02:14

20 BY MR. WISNER:

21 Q. All right. Doctor, while you don't know the number of
22 suicide attempts, you have been able to identify the number of
23 people who actually killed themselves while taking Paxil,
24 correct?

10:02:32

25 A. Yes, I have reviewed those cases in the past.

1 Q. And you have actually gone through and looked at all the
2 different people who took their lives while taking Paxil in
3 GSK's clinical trials, correct?

4 A. Yes. I did that in the past, that's correct.

10:02:45

5 Q. All right. All but one of those individuals was not
6 counted in your 2006 analysis, correct?

7 A. That's correct. There was one individual that was in the
8 placebo-controlled phase, all others were in uncontrolled
9 phases.

10:03:04

10 Q. That's not true. I mean, we know 559 and 593, those were
11 placebo-controlled trials and they were not counted in your
12 2006 analysis, correct?

13 A. Correct. And I explained to the jury why that was.

10:03:22

14 Q. Because they were locally funded and you didn't have access
15 to the data, right?

16 A. I believe they were investigator-initiated studies and we
17 didn't own the data.

18 Q. And you didn't go out and ask the investigators for the
19 data, did you?

10:03:28

20 A. No. Again, they weren't in the scope of the analysis as
21 I've described.

22 Q. Would that have cost a lot of money to do that, Doctor?

23 A. Probably not, no.

10:03:41

24 Q. Okay. Well, since you didn't count them in your 2006
25 analysis, I'd like to count them today.

1 If we could go to the board.

2 Turn to Exhibit -- Plaintiff's Exhibit 330 in your
3 binders, Doctor.

4 A. 330?

10:03:54

5 Q. That's correct.

6 MR. BAYMAN: Judge, I've never seen this. I don't
7 know what this is.

8 THE COURT: I haven't either.

9 BY THE WITNESS:

10:04:01

10 A. There is several -- there are several 330's, sir.

11 BY MR. WISNER:

12 Q. Yeah. The one that says Plaintiff's Exhibit 330.

13 A. Just without any 1, 2 or 3, that sort of thing?

14 Q. That's right.

10:04:14

15 A. Okay.

16 Q. Are you there, Doctor?

17 A. Yes, I've got it. I don't know if I have seen this
18 document before.

19 Q. You actually created that document in your deposition,
20 didn't you, to identify all people who committed suicide?

10:04:34

21 A. I don't know if I created this or not. I know in that
22 deposition I reviewed all the suicide that considered in the
23 studies.

24 Q. And during the deposition you gave us this document, didn't
25 you?

10:04:42

1 A. Again, I can't recall. It was some years ago.

2 Q. Okay. Well, in any event, I'm going to go through all the
3 suicides. And as we go through, we're going to try to identify
4 the information.

10:04:57

5 And if you go to Plaintiff's Exhibit 330 -1, 330-2,
6 330-3, those are going to be the individuals as we go through
7 them one at a time, all right?

8 A. Right. I understand what you're doing.

10:05:16

9 Q. Okay. Let's start off with 330-1. If you could turn to
10 it, Doctor.

11 And as we go through this, Doctor, I'm going to create
12 an age plot for the age of these individuals who committed
13 suicide, Okay?

10:05:34

14 A. Will I be able to comment during this or am I just
15 listening to you?

16 Q. Unfortunately, you're going to answer yes or no to my
17 questions.

18 So isn't it true, the first person had the ID number
19 of 6.4703?

10:05:42

20 A. Yes.

21 Q. It was a female, correct?

22 A. Yes.

23 Q. Age 56 years old?

24 A. Yes.

10:05:46

25 Q. And if you turn the page, you'll see that the suicide

1 occurred on April 3rd, 1983.

2 Do you see that?

3 A. Yes.

4 Q. All right. I'm going to mark "53" here on this chart.

10:06:11

5 Turn to the next one, Doctor. It's a male, age 50
6 years old.

7 Do you see that, Doctor?

8 A. Yes, I see it.

9 Q. Okay. And if you look at it, it says after 3 months of
10 long-term therapy the patient died by hanging.

10:06:28

11 Do you see that?

12 MR. BAYMAN: Your Honor, I object to this as
13 argumentative. He wants to do this with Dr. Gibbons is one
14 thing, but this is -- and also under 403 grounds.

10:06:42

15 MR. WISNER: Your Honor, may I respond? They put up a
16 diagram of silhouettes yesterday for those 11 suicide attempts.
17 We're doing the same thing for people who actually committed
18 suicide. I didn't object to it. I let it go through. It's
19 only fair that I get to do the same thing with people who
20 actually killed themselves in these trials.

10:06:57

21 THE COURT: All right. You may proceed.

22 BY MR. WISNER:

23 Q. So this is 50-year old individual who committed suicide by
24 hanging, correct?

10:07:08

25 A. That's correct.

1 Q. If you turn the page --

2 MR. BAYMAN: I have an objection to this entire line,
3 Your Honor.

4 THE COURT: Yes, you have a standing objection.

10:07:15

5 MR. BAYMAN: Thank you.

6 BY MR. WISNER:

7 Q. The incident number is B0138931A, do you see that, Doctor?

8 A. Hold on, what? What are you asking me?

10:07:31

9 Q. The incident number is B0138931A, top left corner on the
10 second page.

11 A. Okay.

12 Q. And this person committed suicide on July 28, 1984, is that
13 right?

14 (Brief pause).

10:07:47

15 THE COURT: I don't think we got an answer.

16 BY THE WITNESS:

17 A. I can't find it.

18 BY MR. WISNER:

19 Q. It's in the second page.

10:07:52

20 A. Oh, I see it at the bottom. July 28th, yes.

21 Q. Okay. The next individual, female, 42; correct?

22 A. Yes.

23 Q. Died of overdosing on doxepin, do you see that?

24 A. Yes.

10:08:20

25 Q. And if you look below that, she experienced hyperkinesia,

1 do you see that?

2 A. Yes, mild hyperkinesia.

3 Q. And that's physical restlessness, isn't it?

4 A. Increased moving, yeah.

10:08:31

5 Q. She was 42 years old?

6 A. That's what it says.

7 Q. If you turn the page. Her ID number was 7124012, do you
8 see that?

9 A. I do see that.

10:08:41

10 Q. And she committed suicide on May 17th, 1987, didn't she?

11 A. Yes, I see that now.

12 Q. All right. Let's go to the next one.

13 This has a patient incident number, case ID of
14 B0142501A, do you see that?

10:09:07

15 A. Ah, this top one (Indicating)?

16 Q. It's the one that has the box around it in the bottom.

17 A. Oh, the bottom one. B0142501A, is that what you said?

18 Q. That's right.

19 A. Yes, I see it.

10:09:23

20 Q. And it says she committed suicide on June 24th, 1987?

21 A. Yes.

22 Q. 18 years old, right?

23 A. I don't see the age.

24 Q. If turn the page, the second to the last page, there's a

10:09:54

25 circled ID number "paroxetine suicide," do you see that, and it

1 lists her age?

2 A. Okay. Wait a minute.

3 Q. You got that, Doctor?

4 A. It doesn't look like -- let's see.

10:10:18

5 (Brief pause).

6 BY MR. WISNER:

7 Q. The one just above it. See the "18-year old"?

8 A. Oh, okay. I thought you were asking me to look at the
9 circled one.

10:10:27

10 Q. Do you see that, Doctor?

11 A. Yes, I see it.

12 Q. Okay. Great. The next one was also a female, 58 years
13 old; do you see that?

14 A. The next one? Is it the different -- the next tab?

10:10:36

15 Q. Yeah. Keep moving through the tabs.

16 (Brief pause).

17 BY THE WITNESS:

18 A. Yes, I see that, 58.

19 BY MR. WISNER:

10:10:51

20 Q. Committed suicide by hanging, correct?

21 A. Yes.

22 Q. And this is patient ID number 083.003.1090?

23 A. Yeah, the ID number if you just read?

24 Q. Yes.

10:11:14

25 A. Okay.

1 Q. And she committed suicide on April 18th, 1989, didn't she?

2 A. Yes.

3 Q. All right. Let's go to the next one.

4 This is case number B0167368A, correct?

10:11:33

5 A. Yes, that's at the top of the page.

6 Q. And this person was on Paxil but then was hit by a train,
7 right?

8 A. Direct me to where you want me to look.

9 Q. Look at the narrative.

10:12:02

10 A. Yes, I see it.

11 Q. And it's unclear whether or not this was a suicide or not,
12 but the person got Paxil and was hit by a train, correct?

13 A. Right. Due to history of suicide attempts, suicide could
14 not be ruled out but that may have been accidental.

10:12:21

15 Q. Male, 24 years old?

16 A. And death unrelated study to medicine. Yes, male 24 years
17 old.

18 Q. All right. Let's go to the next, patient ID number B01 --
19 I'm sorry, case ID number of B0167499A, do you see that?

10:12:38

20 A. I do see that.

21 Q. Male, 34 years old?

22 A. Yes, I see that.

23 Q. He committed suicide on February 14, 1993, right?

24 A. Yes, that's correct.

10:13:03

25 Q. Okay. Next person, case ID number B0167791A, do you see

1 that?

2 A. Yes, I see that.

3 Q. Female, 48 years old?

4 A. Yes, I see that.

10:13:28

5 Q. Committed suicide on April 8, 1993?

6 A. Yes.

7 Q. Let's go to the next one.

8 Patient ID number 356.006.0092, do you see that?

9 A. Ah, I -- I don't see that. Where is it?

10:14:01

10 Q. Turn the page, second page, 356.006.0092.

11 A. Yes, now I see it.

12 Q. Okay. The patient was 46 years old, correct?

13 A. Ah, I see one above that says 43. I don't see an age --

14 Q. If you turn to the first page, you'll see her age which is

10:14:28

15 46 and female.

16 A. Okay, yeah. I see that there.

17 Q. Committed suicide by hanging, discovered by her son; do you
18 see that?

19 A. I do see that, yes.

10:14:48

20 Q. August 1st, 1993, right?

21 A. I mean, I'm sorry, it's true, but I just can't --

22 Q. It's on the first page, do you see the incident? Event
23 onset, "1 Aug 1993" next to her age and sex?

24 A. Yes, I see that now.

10:15:12

25 Q. All right. Turn the page.

1 This is case ID number B0173175A, correct?

2 A. Yes.

3 Q. This is a male, 54 years old, right?

4 A. Yes.

10:15:34

5 Q. If you go to the narrative, it reads "54-year old severely
6 depressed male patient was being treated with psychotherapy and
7 RO --"

8 A. Wait. Let me go to the narrative.

9 Q. Sure.

10:15:47

10 A. Okay. I see it.

11 Q. He was an officer and missed a chance for promotion, do you
12 see that?

13 A. I do.

14 Q. Committed suicide by jumping under a train, right?

10:15:56

15 A. Yes.

16 Q. That was November 28, 1993, right?

17 A. Yes.

18 Q. Let's go to the next one, Doctor.

19 Case number B0173490A, do you see that?

10:16:21

20 A. Yes.

21 Q. This was a 66-year old female?

22 A. Yes.

23 Q. Enrolled in a double blind study; do you see that?

24 A. Right.

10:16:37

25 Q. On the fourth day of the study she threw herself out of a

1 third floor window and died, right?

2 A. Yes.

3 Q. And that was January 22nd, 1994?

4 A. Yes.

10:16:49

5 Q. 67 years old, right?

6 A. No, it says 66.

7 Q. Oh.

8 A. Actually, it's two different things. Age at time of event

9 67, and then she may have been 66 when she enrolled and then

10:17:07

10 had a birthday.

11 Q. So looks like she died when she was 67, is that right?

12 A. That's what it says at the top.

13 Q. Okay. The next one, 325.017.04202, do you see that?

14 A. It's "XX" in the one I'm looking at, for some reason.

10:17:29

15 Q. Fair enough. Starts off with "324," though, right?

16 A. No, 325.

17 Q. Sorry. 325, I'm sorry. You got that, Doctor?

18 A. Yeah.

19 Q. 32-year old female; do you see that?

10:17:40

20 A. Yes.

21 Q. And the cause of death was identified as suffocation due to

22 vomiting; do you see that?

23 A. Yes.

24 Q. May 24, 1994, correct?

10:18:01

25 A. Yes.

1 Q. The next person, ID 412.152.00002, do you see that?

2 A. Yeah. It's on the second page.

3 Q. All right. 33-year old female, correct?

4 A. Yes.

10:18:33

5 Q. She dropped off a 4th floor balcony at 5:00 o'clock in the
6 morning, right?

7 A. Yes.

8 Q. November 20, 1994, right?

9 A. Yes.

10:19:08

10 Q. Let's go to the next person.

11 Case ID B0188426A; do you see that, Doctor?

12 A. Yes.

13 Q. Male, 65 years old?

14 A. Yes.

10:19:22

15 Q. Committed suicide by an unknown method on February 12,
16 1995?

17 A. Yes.

18 Q. Let's go to the next person.

19 ID number 502 --

10:19:44

20 A. Wait. Hold on.

21 Q. Sure.

22 A. I think I'm on the right tab.

23 Q. All right. ID number 502 -- we're at 330-15, Doctor.

24 A. Okay.

10:20:01

25 Q. ID number 502.037.05146; do you see that?

1 A. Yes.

2 Q. 23-year old male, correct?

3 A. Yes.

4 Q. Committed suicide on July 14th, 1997?

10:20:25

5 A. Yes.

6 Q. Let's go to the next one.

7 This is patient "559.," and we don't know the rest; do
8 you see that, Doctor?

9 A. Yes.

10:20:40

10 Q. This is actually a placebo-controlled trial for major
11 depressive disorder, isn't it?

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

13 Q. Study 559, we talked about that before, that was a
14 placebo-controlled trial, right, Doctor?

10:20:55

15 A. The investigator-initiated study.

16 Q. Placebo-controlled?

17 A. Yes.

18 Q. All right. 31-year old female committed suicide July 14,
19 1998, right?

10:21:07

20 A. 31-year old female, yes.

21 Q. Let's go to the next one.

22 Study 622; do you see that, Doctor?

23 A. (No response.)

24 Q. Do you see that, Doctor?

10:21:44

25 A. I can't see what study number that is, actually.

1 Q. Oh, Okay. Well, in any event, it's patient ID incident
2 number B0216713A, right?

3 A. Yes.

4 Q. All right. And this individual was 86 years old, right?

10:22:01

5 A. Yes.

6 Q. And on September 11, 1998, committed suicide by hanging,
7 correct?

8 A. Yes.

9 Q. All right. Turn the page.

10:22:25

10 PTX330-18, patient ID 1998030913-1; do you see that,
11 Doctor?

12 A. I think I'm on the wrong one. Which number are we on?

13 Q. 330-18.

14 A. I have PID looks like 51300100566.

10:22:48

15 Q. It says PTX 330-18 at the bottom of your first page.

16 A. Yes, it does. PTX 330-18 it says at the bottom of the
17 page.

18 Q. And what's that ID, number, sir?

19 A. PID, it looks like, 51300100566.

10:23:08

20 Q. Okay. But just before that there's an incident number, do
21 you see that 1998030913-1. Do you see that reference number?
22 Case reference number, right there, in the narrative?

23 (Indicating).

24 A. Yes. In the first sentence, yes.

10:23:28

25 Q. Okay. It says:

1 "... on December 14, 1998, the patient went to
2 the home he shared with his estranged wife and
3 shot her, he then turned the gun on himself,"
4 right?

10:23:49 5 A. Yes, that's what it says.

6 Q. A male, 46 years old?

7 A. Yes.

8 Q. Turn to the next one.

9 ID number 670, and then we don't know the middle
10 number, and it's 01046, do you see that?

10:24:05

11 A. Yes, I see it. I'm on it now.

12 Q. Okay. It's a male who's 40 years old, right?

13 A. Yes.

14 Q. And on June 28, 1999, he committed suicide?

10:24:25

15 A. Yes.

16 Q. Turn to the next patient.

17 650.307.06282; do you see that, Doctor?

18 A. Can you point me to where the patient's number is on this
19 form?

10:25:00

20 Q. Sure. Let's keep it simple. Let's just use the incident
21 number B0233651A, right?

22 A. It could be "851A." I can't read it on this copy, but
23 we're probably on the same one.

24 Q. Okay. "8" or "65," it's hard to tell.

10:25:28

25 If you look at the bottom, it looks like it says "6"

1 but at the top it looks like it says "8."

2 In any event, this individual was a male who is 35
3 years old, right?

4 A. Yes.

10:25:38

5 Q. Went to his car and shot himself, correct? March 30th,
6 2000?

7 A. Right.

8 Q. Turn to the next page.

9 Male, 19 years old; do you see that?

10:26:05

10 A. Yes.

11 Q. His ID number is 211, right?

12 A. Yes.

13 Q. Committed suicide by gun in December of 2003, correct?

14 A. Yes.

10:26:20

15 Q. And finally, Doctor, patient number 2206.005; do you see
16 that?

17 A. Yes, I do.

18 Q. We don't have the date of her suicide, but she was a
19 48-year old female, correct?

10:26:43

20 A. I'm on maybe a different tab, 58.

21 Q. Oh, did I say 48? I'm sorry. This illness.

22 She was a 58-year old female, correct?

23 A. Yes; according to the document I have.

24 Q. And she committed suicide by hanging, right?

10:27:03

25 A. Yes.

1 Q. So, Doctor, I've marked all the completed suicides for
2 these individuals in the GSK Paxil trials. This is out of the
3 2009. Are you aware of any additional people who killed
4 themselves while taking Paxil in GSK's clinical trials after
5 that?

10:27:28

6 A. I'm not aware of that, no.

7 Q. Have you looked?

8 A. I have not looked.

9 Q. And would you agree that Plaintiff's Exhibit 342 reflects
10 the various ages of those individuals that we just went
11 through?

10:27:36

12 A. It does.

13 Q. And is it true, Doctor, that all but a single one of the
14 people that we went through were not counted in your 2006
15 analysis?

10:27:51

16 A. That's correct. And again, for very good reasons.

17 Q. What's that reason, Doctor?

18 A. The reason is, what you're investigating in the 2006
19 analysis, both GSK and FDA, is the question of whether or not
20 there's an association of suicidal behavior or ideation with
21 treatment versus the absence of treatment.

10:28:07

22 And what you're seeing here is suicides occurring
23 during treatment of a disease for which suicide ideation and
24 behavior and suicide itself occur.

10:28:28

25 It's like having a chart in a Statin study of heart

1 attacks and attributing them to drug even though it's part of
2 the disease.

3 So, because there is no control, you're unable to make
4 conclusions about treatment versus no treatment.

10:28:43

5 Q. So, not relevant to your analysis, Doctor?

6 A. They were not contributory to our analysis because we were
7 looking at a very specific scientific question.

10:29:02

8 Of course they're relevant in terms of having
9 committed their time to a clinical trial, in terms of their
10 helping us help understand the drug, and in terms of a very
11 serious outcome of a very serious disease, suicide, they're all
12 important, but they didn't contribute to this analysis.

13 Q. Did you ever go back and talk to their families about what
14 happened to these people?

10:29:16

15 MR. BAYMAN: Objection, Your Honor. Argumentative.

16 THE COURT: Overruled.

17 BY THE WITNESS:

18 A. We, as a sponsor, we do not speak directly with patients in
19 clinical trials.

10:29:24

20 BY MR. WISNER:

21 Q. So that's a "no"?

22 A. No.

23 Q. In any of your clinical trials, for example those suicide
24 attempts, did you ever sit down with the person who tried to
25 killed themselves while taking Paxil and asked them what

10:29:34

1 they've actually personally experienced?

2 A. No, I did not.

3 Q. So, all of the analysis that you testified to didn't
4 include these people who killed themselves, and it didn't
5 involve a single conversation with an actual person who tried
6 to kill themselves, is that right?

10:29:48

7 A. That's all true, but it doesn't change the validity and
8 outcome of our analysis.

9 Q. Fair to say then, Doctor, these people, they don't matter?

10:30:03

10 A. That's not fair to say. I already said these people
11 matter. These people don't contribute to the scientific
12 analysis that we did, but they matter.

13 Q. They matter, but you never counted them, right?

14 A. We obviously collected their data. You have it in hand.
15 They weren't included in the analysis because they wouldn't
16 have helped us address the question of whether paroxetine
17 versus no medicine could contribute to increased risk of
18 suicidal ideation or behavior.

10:30:19

19 Q. To be clear, Doctor, every one of those people that we've
20 marked up on this board, Plaintiff's Exhibit 347, committed
21 suicide while taking Paxil, correct?

10:30:42

22 A. I -- I didn't read the narratives, but I would suspect that
23 that's correct, but I'd have to look back at all the narratives
24 to ensure that.

10:30:58

25 Q. And to be clear, when you look at the age plot we created,

1 the vast majority of these completed suicides were over the age
2 of 30, right?

3 A. Right. As the vast majority of the patients in the
4 clinical trials were over the age of 30, 80 percent of them.

10:31:12

5 MR. WISNER: With the Court's indulgence.

6 (Brief pause).

7 MR. WISNER: No further questions, Your Honor.

8 THE COURT: All right. Redirect.

9 MR. BAYMAN: Yes, Your Honor.

10:31:37

10 REDIRECT EXAMINATION

11 BY MR. BAYMAN:

12 Q. Good morning, Doctor.

13 A. Good morning, Mr. Bayman.

14 Q. You recall Mr. Wisner yesterday asking you about whether
15 you owned any stock in GSK?

10:32:10

16 A. Yes, I do.

17 Q. I believe you said you had options but you would sell them
18 as soon as they vest?

19 A. I do.

10:32:19

20 Q. Did your GSK stock options prevent you from analyzing the
21 adult suicidality data in 2006?

22 A. Actually, when I analyzed the data in 2006, I had no stock
23 options. You have to be there a period of time. I wasn't
24 there long enough.

10:32:33

25 Q. Did your stock options prevent you or GSK from submitting

1 the results of the data to FDA?

2 A. No, they -- none of that was in consideration.

3 Q. Did your stock options prevent you from issuing a Dear
4 Healthcare Provider letter or labeling change to disclose the
5 results of the analysis in 2006?

10:32:52

6 A. No. When I signed that letter I had no options; nothing.

7 Q. Did your stock options influence you or prohibit you from
8 repeatedly asking FDA to include the Paxil-specific analyses in
9 the Paxil labeling after FDA announced what it wanted in the
10 Paxil labeling in 2007?

10:33:16

11 MR. WISNER: Objection; leading.

12 BY THE WITNESS:

13 A. No. No.

14 MR. BAYMAN: It's a yes or no question.

10:33:20

15 THE COURT: It's leading, but it's a yes or no
16 question --

17 BY THE WITNESS:

18 A. No.

19 THE COURT: -- so I'll let him answer.

10:33:26

20 BY MR. BAYMAN:

21 Q. And did your stock options prevent you or your colleagues
22 at GSK from publishing two separate articles on the results of
23 the 2006 adult suicidality analyses?

24 A. No.

10:33:37

25 Q. You recall Mr. Wisner asking you yesterday a number of

1 questions about the run-in events from the early -- late '80s
2 and early 1990's?

3 A. Yes.

10:34:01

4 Q. And you recall him showing you documents from 1989 and 1991
5 and 1992, 1995, and 1999 discussing the run-in events?

6 A. Yes, I do.

7 Q. Were the reanalysis of the 1991 suicides and suicide
8 attempts data submitted to the FDA over 14 years ago?

9 A. Yes, they were.

10:34:21

10 Q. And following that submission to FDA, did FDA ask GSK to
11 make any changes in its label?

12 A. No, they did not.

13 Q. Now, Mr. Wisner showed you pages from DX 305, which is
14 Dr. Brecher's report. It's at Tab 16 in your notebook.

10:34:56

15 A. If I might --

16 (Brief pause).

17 BY THE WITNESS:

18 A. Sorry. I got it.

19 BY MR. BAYMAN:

10:35:09

20 Q. Turn, if you would, to I think it's page 23 -- well, first
21 of all, what is that document?

22 A. This is Dr. Brecher's clinical review of the clinical trial
23 data from the paroxetine initial.

24 Q. What is a clinical review?

10:35:27

25 THE COURT: Where are we now? In what book are we on?

1 MR. BAYMAN: We're in the thick, the one from
2 yesterday, that Dr. Kraus book. And we're on Tab 16, Your
3 Honor, which is Defendant's Exhibit 305.

4 BY THE WITNESS:

10:35:50

5 A. And the clinical review is the, in this case, the clinical
6 reviewer, the physician, Dr. Brecher, looking at these safety
7 and efficacy data and making a judgment as to the overall
8 balance.

9 BY MR. BAYMAN:

10:36:03

10 Q. Turn, if you would, to what is page 23 of that document.

11 A. Okay.

12 MR. BAYMAN: Your Honor, permission to publish.

13 THE COURT: Let me get to this.

14 MR. BAYMAN: Sure.

10:36:26

15 (Brief pause)

16 THE COURT: This is Dr. Brecher's report?

17 MR. BAYMAN: Yes, sir.

18 THE COURT: Okay.

19 MR. BAYMAN: Thank you.

10:36:37

20 (Exhibit published to the jury.)

21 BY MR. BAYMAN:

22 Q. Looking at Dr. Brecher's review, does it indicate that
23 Dr. Brecher reported that there were suicides that occurred
24 during the placebo run-in?

10:36:51

25 MR. WISNER: Objection, Your Honor. This is

1 cumulative. They actually went through this already on their
2 direct.

3 MR. BAYMAN: Actually we did not, Your Honor. And
4 Mr. Wisner didn't show this to Dr. Kraus yesterday.

10:37:00

5 MR. WISNER: I believe it was -- he showed this, and
6 then I showed the missing table, and now they're showing it
7 again. This is cumulative and also leading.

8 MR. BAYMAN: He showed him the GSK document on direct.

10:37:11

9 THE COURT: Well, you know, I'm going to start to come
10 down on both sides for cumulative problems, but I don't
11 remember this well enough to remember whether it's so, so I'm
12 going to let do it.

13 MR. BAYMAN: Thank you.

14 BY THE WITNESS:

10:37:21

15 A. So, Dr. Brecher summarized the suicide and suicide attempts
16 and indicated that the suicides here occurred in the run-in
17 phase. So he was aware.

18 Q. Okay. Thank you.

10:37:49

19 So, Doctor, no matter how the run-in events in the New
20 Drug Application data set from the late '80s and early '90s are
21 analyzed, whether you count all the events in any phase of the
22 trials or whether you just look at the placebo-controlled
23 phases of the trials, do the NDA clinical trials show an
24 increased risk of suicidal behavior in patients taking Paxil or
25 paroxetine?

10:38:10

1 A. No, they don't.

2 Q. For a patient who was first prescribed Paxil or paroxetine
3 in 2005 for the first time, what effect, if any, does the data
4 from the NDA or the 1991 analysis have on the label in 2005?

10:38:23

5 A. In 2005 the label had been updated substantially from the
6 original approval. So, the drug label is a living document,
7 it's updated as new data came in. So, 2005 at that time
8 reflected the most recent data.

10:38:48

9 Q. And what did the labeling say about whether patients should
10 be monitored for signs of emerging suicidal thoughts or
11 behavior after the medication was started where the dose was
12 changed?

13 A. It recommended close vigilance during those times because
14 potential risk of these sorts of events we've been discussing.

10:39:04

15 Q. Do you remember being asked by Mr. Wisner questions about
16 coding dictionaries?

17 A. Yes, I do.

18 Q. And you recall Mr. Wisner questioning you about your
19 testimony on direct examination that the dictionary GSK used
20 did not have a coding term, referred term of "suicide attempt"?

10:39:17

21 A. That's right.

22 Q. And you said it did not, and then Mr. Wisner showed you
23 some documents that suggested it did?

24 A. Yes, I remember that.

10:39:31

25 Q. Do you recall Mr. Wisner showing you a document in which

1 Russell Katz of the FDA referred to the possibility that
2 suicides have been hidden under the term "emotional lability"?

3 A. I do remember that.

10:39:53

4 Q. And that was Plaintiff's Exhibit 27, which was a June 3rd,
5 2003, e-mail chain?

6 A. Plaintiff's Exhibit 27?

7 Yes, I've got it.

10:40:13

8 Q. Following that period in time, did GSK submit to FDA in
9 2004 a detailed explanation of the dictionaries that it used
10 and why it used the term "emotional lability"?

11 A. Yes, it did. As I explained to the jury, it was similar to
12 that explanation.

13 Q. Do you remember all the details of that explanation sitting
14 here today?

10:40:25

15 A. I don't remember all the details, but if I saw the document
16 I could obviously refresh my memory.

17 MR. BAYMAN: Permission to publish, Your Honor?
18 (Document tendered to the Court and the
19 witness.)

10:40:53

20 BY MR. BAYMAN:

21 Q. Handing you what's been marked Exhibit DX 7041 and would
22 ask you to take a look at the second to the last page of that
23 document, which is at the bottom, page 18.

24 A. Yes, I see it.

10:41:20

25 Q. Is DX 7041 the submission that was made to the FDA in

1 response to their question about asking for a rationale for
2 coding suicide attempts and other forms of self-injurious
3 behavior under the term "emotional lability"?

4 A. Yes; submitted to Russell Katz.

10:41:53

5 Q. Does that refresh your recollection as to GSK's explanation
6 to the FDA of the dictionaries it used?

7 A. Yes, it does. And it's similar to my testimony, but I
8 didn't name all the dictionaries when I was talking to the
9 jury.

10:42:06

10 Q. You mentioned yesterday that GSK used a dictionary called
11 ADEX?

12 A. That's correct.

13 Q. Does the ADEX dictionary have the coding term "suicide
14 attempt" as a preferred term?

10:42:20

15 A. It does not.

16 Q. And --

17 MR. BAYMAN: Your Honor, permission to pull up a
18 section of the 1992 label that Mr. Wisner showed the witness
19 yesterday.

10:42:34

20 THE COURT: Yes.

21 MR. WISNER: Plaintiff's Exhibit 48.

22 MR. BAYMAN: Yes. Thank you.

23 (Exhibit published to the jury.)

24 BY THE WITNESS:

10:42:48

25 A. Oh, wow.

1 MR. BAYMAN: We'll blow it up.

2 THE COURT: You'll have trouble with that.

3 MR. BAYMAN: We'll blow it up.

4 (Brief pause).

10:42:56

5 BY THE WITNESS:

6 A. I could see it better.

7 BY MR. BAYMAN:

8 Q. Here we go.

10:43:07

9 Now, do you recall some discussion yesterday with
10 Mr. Wisner saying GSK used COSTART and you recall saying that
11 GSK used a COSTART based dictionary?

12 A. Right. And ADEX is a COSTART based dictionary.

13 Q. So who was correct, you or Mr. Wisner?

14 A. I've been correct, yes.

10:43:24

15 Q. When did the COSTART dictionary start including suicide
16 attempt as a preferred coding term?

17 A. It was not until 1994.

18 Q. Why did GSK continue to use the term "emotional lability"?

10:43:49

19 A. The reason was is it had been in the dictionary from the
20 trials from the beginning. So it was to allow consistency of
21 collection of adverse events as more information came through
22 the studies to build those integrated safety databases for
23 submissions and be able to compare it across time.

24 Q. And when did those Paxil or paroxetine studies begin?

10:44:08

25 A. Which ones?

1 Q. Well, when were the earlier trials for paroxetine or Paxil?

2 A. Wow. They would've started in the early to mid '80s.

3 Q. After getting the explanation from GSK about why coded
4 suicide events, or the preferred term of "emotional lability"
5 as reflected in Defendant's Exhibit 7041, did FDA tell GSK to
6 stop using that term in its label?

10:44:30

7 A. No.

8 Q. Did FDA say, hey, you're using an inappropriate coding term
9 to hide adverse events?

10:44:44

10 MR. WISNER: Objection; hearsay.

11 THE COURT: Sustained.

12 BY MR. BAYMAN:

13 Q. Did FDA ever in correspondence to you or in any of the
14 discussions that you had with the FDA, indicate that "emotional
15 lability" was an inappropriate coding term used to hide adverse
16 events?

10:45:01

17 A. No.

18 MR. WISNER: Objection.

19 MR. BAYMAN: Your Honor, at this time I move for
20 admission of Defendant's Exhibit 7041.

10:45:09

21 THE COURT: Which one now?

22 MR. BAYMAN: The one I just showed the witness, 7041.
23 The one I just handed to your clerk.

24 MR. WISNER: Oh, absolutely not, Your Honor. This
25 document was used to refresh his recollection. They have not

10:45:21

1 laid proper foundation for its admission.

2 BY MR. BAYMAN:

3 Q. Well, Dr. Kraus, take a look at Exhibit 7041.

4 A. Okay.

10:45:33 5 Q. Is that a letter to Dr. Katz of the FDA in response to a
6 question the FDA posed to GSK?

7 MR. WISNER: Objection; leading.

8 THE COURT: Sustained.

9 BY MR. BAYMAN:

10:45:47 10 Q. What is the letter?

11 A. This is a letter from GSK regulatory to Dr. Katz, a cover
12 letter and an explanation as to the use of emotional lability
13 in the label.

14 Q. In your experience in GSK, does GSK respond to inquiries
10:46:07 15 from the FDA in writing?

16 A. Yes, we do.

17 Q. And does GSK maintain the correspondence with the FDA back
18 and forth in its regulatory files?

19 A. We do.

10:46:21 20 Q. Are those maintained in the ordinary course of business?

21 A. Absolutely. Yes.

22 Q. And are you familiar with this correspondence?

23 A. Yeah, I've seen this in the past.

24 MR. BAYMAN: Your Honor, at this time I move for
10:46:31 25 admission of Defendant's Exhibit --

1 MR. WISNER: Renew my objection; hearsay.

2 THE COURT: Objection sustained.

3 BY MR. BAYMAN:

10:46:40

4 Q. Do you recall being asked some questions about the studies
5 in patients with intermittent brief depression or what is IBD?

6 A. Yes, I recall.

7 Q. And I believe those studies were studies 057 and 106?

8 A. That's right.

10:47:09

9 Q. I'm just going to cut to the chase. In terms of whether
10 paroxetine or Paxil increases the risk of suicidal behavior or
11 ideation in adults, does it matter one way or the other whether
12 those studies are included in the analysis?

13 A. No, it didn't.

14 Q. Were they included in the GSK 2006 analysis?

10:47:27

15 A. They -- they were included as part of the analysis,
16 correct.

17 Q. Were they included in the FDA's 2006 analysis?

18 A. No, we did not submit that.

10:47:45

19 Q. On the primary end point of suicidal behavior and ideation,
20 did either of the GSK or FDA analysis show an increased risk?

21 A. No.

22 Q. So, given that the result is the same whether the IBD
23 studies are included or not, what is your opinion as to whether
24 including them skews the data?

10:47:59

25 A. My opinion is, it does not. And again, it's important that

1 you look at our analysis. We pulled out each of the
2 indications in addition to the combined. So, we had
3 opportunity to look with or without those. So, it did not make
4 a difference.

10:48:13 5 Q. Do you recall being asked some questions by Mr. Wisner
6 yesterday about a 1999 deaths analysis?

7 A. I do.

8 Q. Can you turn to DX 25 in your black notebook.

9 A. Okay.

10:48:42 10 Q. Is this the December, 1999 response to the FDA's request for
11 information about death -- deaths in controlled clinical
12 trials?

13 A. Yes.

14 Q. Turn, if you would, to page 7, Section 2.

10:49:16 15 A. I may be in the wrong place here.

16 Oh, I've got it. Yes, Section 2.

17 THE COURT: Where are the page numbers?

18 MR. BAYMAN: Down in the lower right corner. It's
19 25-07.

10:49:31 20 THE COURT: 007?

21 MR. BAYMAN: Yes, Your Honor.

22 THE COURT: Okay.

23 MR. BAYMAN: Your Honor, permission to publish to the
24 jury.

10:49:41 25 THE COURT: Any objection?

1 MR. WISNER: No, Your Honor. I believe this is in
2 evidence. To the extent it goes too far, I will object to
3 scope, but for now, no objection.

4 THE COURT: Okay. Proceed.

10:49:56

5 BY MR. BAYMAN:

6 Q. Do you see Section 2?

7 A. Yes, I do.

8 Q. Which is headed "incidents of deaths in depression trials
9 in the paroxetine central database"?

10:50:06

10 A. Yes.

11 Q. And down below, do you see Table 1?

12 A. I do.

13 Q. In Table 1 is there information for paroxetine and for
14 placebo?

10:50:17

15 A. Yes.

16 Q. And are there ends reflecting the number of patients who
17 got paroxetine and placebo in the trials?

18 A. Yes, there are.

19 Q. And are there calculations of the frequency of non-suicides
20 and suicides in each of the groups?

10:50:32

21 A. Yes.

22 Q. Now, look at the bottom of the page. You see the start of
23 that next section, "deaths in depression trials not in
24 paroxetine central database"?

10:50:47

25 A. Yes, I do.

1 Q. And can we go to the top of the next page. There's another
2 table.

3 Do you see that?

4 A. Yes.

10:50:55

5 Q. And that has some information about the paroxetine in the
6 label groups?

7 A. Yes, it does.

8 Q. Does it have the ends indicating the total number of
9 patients in each group?

10:51:12

10 A. No, it does not.

11 Q. Does it have the calculation of the frequency of
12 non-suicides and suicides?

13 A. No, it does not.

10:51:26

14 Q. Do you recall me asking you on direct examination if
15 studies 513 and 559 were in this death analysis and you
16 answered "no"?

17 A. Yes.

10:51:42

18 Q. Let me ask you a more precise question now. Were 513 and
19 559 included in the part of the deaths analyses where an actual
20 analysis was done and frequency of events were calculated?

21 A. They were not included in the analysis, section. That's
22 what I was addressing.

23 Q. Is that what you had in mind when you answered "no" to my
24 question?

10:51:54

25 A. Yes, that's correct.

1 Q. Thank you.

2 Now, Mr. Wisner showed you some documents yesterday
3 and asked you if people lied; do you recall that?

4 A. Yes, I recall that.

10:52:15

5 Q. Did he show you any e-mail or any internal company document
6 where someone from GSK indicated that they lied or
7 intentionally misrepresented any Paxil data to the FDA?

8 A. No.

10:52:36

9 Q. When you drafted the revised language with respect to adult
10 suicidality in 2006 following GSK's analysis to the data, did
11 you do your very best to accurately describe the results of the
12 analysis?

13 A. Absolutely yes.

10:52:50

14 Q. Did you do your very best in the letter that you signed
15 that went to healthcare professionals to provide the
16 information they needed to know to safely and effectively treat
17 their patients with Paxil or paroxetine?

18 A. Yes, I did.

10:53:08

19 Q. Did anyone from the marketing department influence you in
20 any way at all with respect to that analyses and the
21 communications about that analyses?

22 A. Absolutely not.

10:53:20

23 Q. In doing the analysis that you and your colleagues did in
24 2006, including revising the labeling, sending the Dear
25 Healthcare Provider letter, interacting with FDA, were you

1 influenced by any commercial concerns at all?

2 A. No.

3 Q. Do you believe the language you drafted, which was in the
4 label until the class labeling was implemented, accurately
5 convey your best understanding of the relationship between
6 Paxil or paroxetine use in suicidal thinking and behavior in
7 adult patients?

10:53:34

8 A. Yes. It was, in my view, the correct interpretation of the
9 data, yes.

10:53:46

10 Q. Now, on cross-examination you were asked to tell the jury
11 the reason there were a number of suicide attempts in all the
12 Paxil clinical trials; do you remember that?

13 A. The reason why there were suicide attempts?

14 Q. Well, you were asked about suicide attempts --

10:54:14

15 THE COURT: You don't mean that, do you?

16 MR. BAYMAN: No, sir.

17 BY MR. BAYMAN:

18 Q. You were asked about suicide attempts in the clinical
19 trials?

10:54:19

20 A. Yes, I was.

21 Q. And you were being questioned about whether you believed it
22 would be burdensome to collect the number of suicide attempts,
23 and you responded that that was an inaccurate characterization
24 and you wanted to read paragraph 9 --

10:54:32

25 A. That's right.

1 Q. -- of Mr. Davis declaration to explain?

2 A. I did. I wanted the full context of that reply.

3 Q. Well now I'm going to give you your chance. What does
4 paragraph 9 say?

10:54:44 5 A. Paragraph 9 says:

6 The results of such --"

7 So, again, this is a collection of suicide attempts
8 throughout all those studies that we've talked about that are
9 noncentral database:

10 "... the results of such an undertaking would
11 not yield much scientifically useful information
12 for several reasons: First, it would be
13 impossible to determine the total population of
14 patients in the clinical trials from which the
10:55:13 15 suicide attempts were identified. Thus, it
16 would be impossible to calculate a rate of
17 suicide attempts for patients taking paroxetine.
18 Second, because this analysis would include
19 uncontrolled or active controlled clinical
10:55:27 20 trials, it would be impossible to determine the
21 rate of placebo or other control group suicide
22 attempts. Thus, there would be nothing against
23 which to compare the rate of paroxetine suicide
24 attempts if one could be determined. It is now
10:55:42 25 generally accepted that the most rigorous and

1 scientifically reliable method for assessing
2 associations is to utilize randomized
3 placebo-controlled trials rather than a
4 conglomeration of uncontrolled, nonrandomized,
10:55:57 5 open-label, and various other types of clinical
6 trials, because it would time-consuming,
7 expensive, and burdensome and because the
8 information would not be scientifically useful,
9 the cost and burden of conducting the searches
10:56:10 10 outweigh any potential benefit."

11 Q. Explain what that means?

12 A. It basically means even if you collected all of that data,
13 it wouldn't provide information to address the question at
14 hand:

10:56:22 15 Do SSRIs, or paroxetine, compared to no treatment
16 result in an increase of suicidal ideation and behavior. Since
17 they would not contribute to addressing that question, again
18 collecting that data would not provide information that would
19 be useful.

10:56:42 20 Q. In looking at the issue of whether Paxil or paroxetine
21 increases the risk of suicidality in adult patients, what, in
22 your opinion, is the better dataset to look at, the dataset
23 from 1989 and 1991 or the dataset from 2006?

10:57:05 24 A. The dataset from 2006 where we have 15,000 patients we're
25 looking at.

1 Q. And how many patients were there in the approximately NDA
2 trials?

3 A. I don't know. 4,000 level, something like that.

4 Q. So was the dataset in 2006 significantly larger?

10:57:19

5 A. Yes; much larger.

6 Q. Okay. Now, Mr. Wisner, I believe, asked you yesterday how
7 many patients have been in Paxil or paroxetine clinical trials
8 since they were first started.

9 A. He did.

10:57:37

10 Q. And you said you didn't have an estimate?

11 A. I don't know the answer, yes.

12 Q. Is it fair to say that there could've been 100,000 patients
13 in those trials?

14 MR. WISNER: Objection; leading.

10:57:48

15 THE COURT: Sustained.

16 BY MR. BAYMAN:

17 Q. Do you have an estimate of how many patients have been in
18 paroxetine trials since the beginning?

10:58:02

19 A. I don't have an estimate, but a very large number, and
20 millions post-marketing.

21 Q. And today -- I believe you said that the Paxil clinical
22 trial started in the 1980's?

23 A. If not earlier, but yes, at least in the 1980's.

24 Q. And then how many --

10:58:18

25 THE COURT: All right. We'll take a recess now,

1 ladies and gentlemen.

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

4 [REDACTED]

10:58:50

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

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

11:17:07

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

13 You may proceed, sir.

14 MR. BAYMAN: Thank you, Your Honor.

11:17:14

15 BY MR. BAYMAN:

16 Q. Dr. Kraus, when we broke I was asking you about patients in
17 the Paxil clinical trials. Do you know, roughly, how many
18 clinical trials on Paxil or paroxetine GSK has sponsored?

19 A. Yes, well over 200.

11:17:30

20 Q. I want to turn your -- and do you know about, on average,
21 how many subjects in a clinical trial?

22 A. Depending on the study, anywhere from 300 to 400 subjects.

23 Q. So 200 trials with, on average, 300, 400 subjects?

24 A. Right. Over 60,000.

11:17:49

25 Q. I want to turn your attention to the board --

1 A. Okay.

2 Q. -- that Mr. Wisner showed.

3 Of the patients that were enrolled in the various
4 Paxil or paroxetine trials, whether controlled or uncontrolled,
5 did those patients have depression and other anxiety disorders?

11:18:15

6 A. Yes. They all had mental illness.

7 Q. A why is that significant?

8 A. As we've talked about during the course of my testimony,
9 these illnesses themselves are characterized by an increased
10 risk of suicidal thinking and behavior. So that can be part of
11 these diseases.

11:18:33

12 Q. So given the number of trials that were conducted, the
13 number of patients, on average, per trial, does it surprise you
14 that there were 21 suicides in all of the paroxetine or Paxil
15 clinical trials, as well as some in non-GSK's sponsored
16 trials?

11:18:50

17 A. It's -- it's not surprising, except maybe in the sense that
18 the number could be considered low because of the diseases
19 under investigation and the fact that these events occur as
20 part of the disease.

11:19:07

21 Q. Now, you said GSK did not ignore these patients who
22 committed suicide?

23 A. No; absolutely not.

24 Q. Explain what you meant by that.

11:19:20

25 A. So, as we've talked about, every adverse event in clinical

1 trials are captured and reported. And clearly, completed
2 suicide is what we call serious adverse event. These events go
3 to our central safety division where they are analyzed,
4 narratives are constructed, and, of course, they are filed with
5 regulatory authorities as well, FDA.

11:19:41

6 Q. Would this kind of analyses that Mr. Wisner did meet the
7 FDA's criteria in 2006 or did they, for that matter, to answer
8 the question of whether paroxetine or Paxil causes suicidal
9 thoughts, suicidal behavior, or completed suicides in adult
10 patients?

11:20:03

11 MR. WISNER: Objection. I didn't do any analysis. I
12 just told their story. Misstates --

13 THE COURT: Objection sustained.

14 BY MR. BAYMAN:

15 Q. The story that Mr. Wisner told, would that meet the FDA's
16 criteria in 2006, or today for that matter, to answer the
17 question of whether Paxil causes or induces suicidality in
18 adult patients?

11:20:10

19 A. No. As we've discussed before, FDA, GSK, and accepted
20 within the scientific community, is that the best way to look
21 it is the possible association of drug with an outcome is in
22 those placebo-controlled phases.

11:20:29

23 Q. And why is that?

24 THE COURT: I think we've heard that. Let's go on.

25 BY MR. BAYMAN:

11:20:40

1 Q. Does this story that Mr. Wisner presented, does this change
2 your opinions that paroxetine does not cause suicidal thoughts
3 or behavior in adult patients?

4 A. No, it does not.

11:20:55

5 Q. Did Mr. Wisner show you any scientific evidence relating to
6 the risk of either suicidal thoughts or behavior on paroxetine
7 or Paxil that, based on everything you know, the FDA did not
8 know about when it issued the class labeling in 2007?

9 A. No, it did not.

11:21:15

10 MR. BAYMAN: No further questions, Your Honor.

11 THE COURT: All right. Very narrow redirect.

12 RECROSS EXAMINATION

13 BY MR. WISNER:

14 Q. You talked about emotional lability, Doctor, right?

11:21:25

15 A. Yes.

16 Q. Throwing yourself out of a four-story window, is that
17 emotional lability?

18 MR. BAYMAN: Objection. Argumentative, Your Honor.

19 THE COURT: Overruled.

11:21:32

20 BY THE WITNESS:

21 A. That's a completed suicide and it was captured as a
22 completed suicide.

23 BY MR. WISNER:

24 Q. Sorry, Doctor. That's not my question.

11:21:37

25 Jumping out of a four-story window, is that emotional

1 lability?

2 A. I would say no, it's a suicide.

3 Q. Going into your car and shooting yourself with a gun,
4 that's not emotional lability, right?

11:21:48

5 MR. BAYMAN: Objection. Argumentative, Your Honor.

6 THE COURT: Overruled.

7 BY THE WITNESS:

8 A. These are all captured under suicide. So it's a suicide.

9 BY MR. WISNER:

11:21:55

10 Q. So it's "no," it's not emotional lability?

11 A. Yeah, that's correct.

12 Q. Okay.

13 A. There was a preferred term available to map those events.

11:22:07

14 Q. And to be clear, throwing yourself in front of a train,
15 that's not emotional lability either, correct?

16 A. Assuming a death that would be a suicide and there was a
17 preferred term that could be mapped to it, that's correct.

18 Q. You told this jury that in 2004 GSK explained why they used
19 "emotional lability" as an opposed to a "suicide attempt," is
20 that right?

11:22:21

21 A. As opposed to a suicide attempt, that's correct. That's
22 why we used that preferred term. But, of course, as you've
23 seen in the evidence, we've always reported suicide attempts as
24 well.

11:22:35

25 Q. At that point in 2004. In 2004 and 2010, GSK never

1 attempted to change the "emotional lability" term in the label
2 to suicide attempt, correct?

3 A. The term was not changed, correct.

11:22:54

4 Q. And you admit, in fact you agreed yesterday that GSK, you
5 guys were the ones responsible for the label, right?

6 MR. BAYMAN: Objection.

7 THE COURT: That's covered.

8 BY MR. WISNER:

11:23:05

9 Q. You mentioned the FDA, on redirect, the FDA not taking any
10 action, is that right?

11 A. Any action as regards to what?

12 Q. Well, you said that the FDA has never taken any enforcement
13 actions against GSK, is that right?

11:23:19

14 MR. BAYMAN: Objection; that wasn't the question. I
15 said in response to the analysis, not the label change.

16 THE WITNESS: I don't understand the question, Judge.

17 BY MR. WISNER:

18 Q. Let me ask a simple --

11:23:25

19 THE COURT: You don't have to answer if you don't
20 understand it, Doctor.

21 Put another question.

22 MR. WISNER: Yes, Your Honor.

23 BY MR. WISNER:

11:23:32

24 Q. Doctor, GSK has not always complied with FDA regulations,
25 correct?

1 MR. BAYMAN: Objection, Your Honor. I think we're
2 getting into the matter we discussed this morning at the
3 beginning of the day.

4 THE COURT: Oh, I don't think so. Don't go into that
5 matter.

11:23:40

6 MR. WISNER: I'm not.

7 BY MR. WISNER:

8 Q. MR. WISNER: Yes or no, Doctor.

9 A. There had been times when that's true, correct.

11:23:47

10 Q. The Paxil, correct?

11 A. That was one of the compounds, yes.

12 Q. Mr. Bayman didn't talk to the jury about any of those
13 times, did he?

14 A. I don't know.

11:23:57

15 MR. BAYMAN: Objection. Argumentative.

16 THE COURT: Sustained as to what he talked to the jury
17 about.

18 BY MR. WISNER:

19 Q. You mentioned that there's potentially millions of people
20 who have taken Paxil but you used the word post-market, is that
21 right?

11:24:05

22 A. That's correct.

23 Q. That means people out in the regular world taking Paxil,
24 right?

11:24:14

25 A. Yes, that's right.

1 Q. Do you know how many of those people killed themselves
2 while taking Paxil?

3 A. We get what's called post-marketing reports if those were
4 to occur, and they go also to our same central database where
5 these can be analyzed.

11:24:26

6 Q. What's the number?

7 A. I don't have the number at hand right now.

8 Q. You do know about a couple of them, don't you, Doctor?

9 A. How do you mean, sir?

11:24:38

10 Q. You know about a Catholic priest who shot --

11 MR. BAYMAN: Objection. This case is now in
12 litigation. You ruled this out.

13 MR. WISNER: He opened the door and talked about
14 post-marketing.

11:24:47

15 MR. BAYMAN: I did not.

16 THE COURT: No, objection is sustained. We won't go
17 into that.

18 MR. BAYMAN: I ask the jury disregard that, Your
19 Honor.

11:24:52

20 THE COURT: Yes, the jury will disregard that.

21 BY MR. WISNER:

22 Q. Without going into any details, Doctor, you are aware of
23 specific instances where people killed themselves while taking
24 Paxil?

11:25:04

25 MR. BAYMAN: Same objection.

1 THE COURT: Overruled.

2 BY THE WITNESS:

3 A. Yes, that's part of the reason I'm here today.

4 MR. WISNER: No further questions.

11:25:14

5 MR. BAYMAN: One question, Your Honor?

6 THE COURT: Sure.

7 MR. WISNER: Sorry, Your Honor. Before this witness
8 gets discharged, we'd like to do an offer of proof outside the
9 presence of the jury on the issue we addressed this morning.

11:25:27

10 THE COURT: Go ahead with your redirect.

11 FURTHER REDIRECT

12 BY MR. BAYMAN:

13 Q. When GSK reported suicide events under the preferred term
14 "emotional lability," did they also report the verbatim terms,
15 the terms that the investigators were using, such as hanging,
16 overdose, suicide attempts?

11:25:42

17 A. Yes. And that's what I was saying, they were described as
18 well.

19 MR. BAYMAN: Thank you, Your Honor.

11:25:51

20 THE COURT: All right.

21 All right. Doctor, you may step down.

22 THE WITNESS: Okay. Am I done or --

23 THE COURT: I think so.

24 THE WITNESS: Okay. Thanks.

11:26:07

25 THE COURT: I think they want you to stay in the

1 building, though, for a while.

2 THE WITNESS: Oh, okay. That's what I was asking.

3 Thank you.

4 (Witness exited the courtroom).

11:26:19

5 THE COURT: Let's go to sidebar.

6 (Proceedings heard at sidebar on the record.)

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11:26:55

10 [REDACTED]

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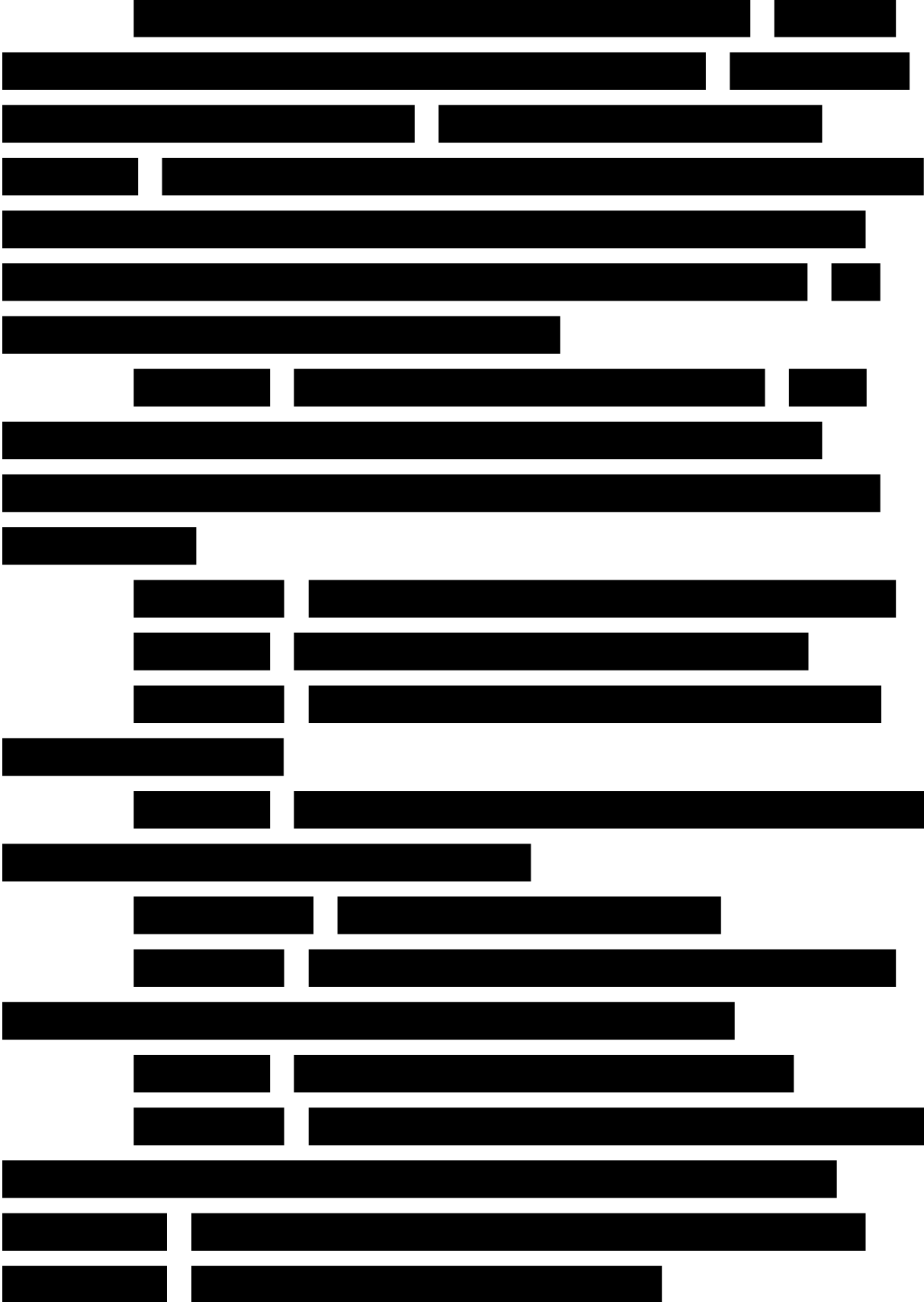
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11:29:15

11:29:31

10 (Proceedings resumed within the hearing of the
11 jury).

12 THE COURT: The last witness is excused.

13 MR. BAYMAN: Thank you, Your Honor.

14 (Witness excused.)

11:30:02

15 MR. BAYMAN: Your Honor, for our next witness we're
16 going to read the deposition of Ms. Laura Krueger.

17 THE COURT: Okay.

18 (Reading of deposition of Laura Krueger by Ms.
19 Henninger and Mr. Davis.)

11:30:45

20 MR. DAVIS: Thank you, ladies and gentlemen of the
21 jury; counsel.

22 (Reading:)

23 "Would you please tell us your full name, ma'am.

24 A. Laura L. Krueger.

11:30:53

25 Q. And you're employed at Reed Smith as an administrative

1 assistant?

2 A. That is correct.

3 Q. And how long have you been a legal secretary?

4 A. About -- about 20 -- 20 some years.

11:31:02

5 Q. And is that how you met Mr. Dolin?

6 A. Yes.

7 Q. And once you started working for Mr. Dolin as his secretary
8 in 1993, did that continue on through the time that he passed
9 away in July of 2010?

11:31:14

10 A. Yes.

11 Q. In 2010, what were your job responsibilities at Reed Smith?

12 A. I was a legal secretary to three individuals.

13 Q. After the merger between Reed Smith and the Sachnoff Weaver
14 firm, did Mr. Dolin serve as a deputy team leader for the U.S.
15 corporate and securities group --

11:31:32

16 A. Yes.

17 Q. -- for Reed Smith? He did.

18 And was the group of lawyers and staff that he had to
19 manage as part of his job larger than what he had to manage
20 when he was at the Sachnoff & Weaver firm?

11:31:42

21 A. Yes; it was much larger.

22 Q. Much larger. Was it -- are we talking about a 2 or 3 times
23 difference in terms of the number of people whom he had to
24 manage?

11:31:55

25 A. I would say at least 2 or 3 times.

1 Q. Did he ever talk to you about any concerns or anxieties
2 that he had about managing that large group of people as part
3 of his job responsibilities at Reed Smith?

4 A. He never talked to me about it.

11:32:11

5 Q. When you noticed that Mr. Dolin had lost weight, did you
6 raise that issue with him?

7 A. I did.

8 Q. And what did you say to him?

11:32:24

9 A. I asked him if everything was okay because he had lost
10 wait.

11 Q. And to you, can you describe how marked or significance was
12 the weight loss to you?

11:32:36

13 A. Because of his build, I would say maybe 7 to 10 pounds, and
14 it would show because of his build. He wasn't an extremely
15 large man.

16 Q. And when you say "his build," are you talking about there
17 were certain parts of him that looked thinner than normal?

18 A. He just looked thinner, generally.

19 Q. And was that not only his body but also his face?

11:32:51

20 A. I would say so.

21 Q. And would you give anymore -- and could you give any more
22 precision about when noticed this in June or July of 2010?

23 A. I can't. It was just something that I had noticed.

11:33:06

24 Q. Can you give us an estimate of how many weeks before he
25 passed away that you noticed this and said something to him?

1 A. It was something I noticed. I couldn't tell you exactly
2 when. It was just something I noticed and I can't tell you
3 when, I'm sorry.

11:33:22

4 Q. Are you able to say that it was within the last week of his
5 death, 2 weeks before his death?

6 A. I cannot say whether it was within that timeframe, no.

7 Q. And what did you -- " excuse me.

8 "Question: And what did he say in response?

9 A. (No response.)

11:33:36

10 Q. I think you asked him, you said to him, "is everything
11 okay"?

12 A. Correct.

13 Q. What was his response?

14 A. Initially he said he was fine, and we left it at that.

11:33:44

15 Q. Did you --

16 A. And then --

17 Q. Did you come back, did that issue -- again, did you
18 re-raise the issue with him later?

19 A. I did not re-raise it with him, no.

11:33:54

20 Q. Did he re-raise it with you?

21 A. He did.

22 Q. When did that occur?

23 A. The same day, whenever that was. I had gone into his
24 office to either give him something and he had just made
25 mention of it again.

11:34:05

1 Q. What did he say to you?

2 A. He said that there was a lot going on in his life and that
3 he was not able to devote the type of time any one of the
4 matters that he was concerned about.

11:34:18

5 Does that make sense?

6 Q. He was not able to devote?

7 A. The type of time, the amount of time to any one of them.

8 Q. When you had this discussion with him, how did he appear to
9 you?

11:34:30

10 A. He wanted to set me at ease.

11 Q. Why do you say that? Why do you say that?

12 A. Because he's the type of person he was.

13 Q. Did he say anything more to you other than he was not able
14 to devote his time to any one of the matters, or however he
15 phrased it? Did he say any more to you other than what you
16 previously told us in that second conversation?

11:34:45

17 A. Specifically, he made mention of his father-in-law.

18 Q. What did he mention about his father-in-law?

19 A. That his father-in-law was passing. He was ill, very ill.

11:35:01

20 Q. What else did he mention during that second conversation?

21 A. That his clients and his -- the administrative side of his
22 work, those were three issues that he wanted to be able to
23 devote more time to.

11:35:18

24 Q. So his three issues that he wanted to devote more time to
25 were his clients, the administrative work, and this issue with

1 his father-in-law being very ill?

2 A. Yes.

3 Q. How long did the first conversation last?

4 A. My first conversation when I asked him?

11:35:29

5 Q. Yes.

6 A. That -- that was the extent of it.

7 Q. And then, so a few seconds?

8 A. Oh, sure. A couple of seconds.

11:35:39

9 Q. And for the second conversation that you had with him, how
10 long did that last?

11 A. Enough time, three minutes, five minutes.

12 Q. And in terms of his physical appearance during those
13 conversations, how did he look?

14 A. He looked good. He looked good."

11:35:57

15 MS. HENNINGER: Oh, I'm sorry. No, I think this is
16 you.

17 Wait.

11:36:10

18 "... oh, I'm sorry, he did mention that he wanted to
19 start getting prepared for skiing season as well, which was
20 another reason that he was --

21 Q. And I'm just trying to get a sense of whether the
22 conversation you had with him took place before or after the
23 announcement that Mr. Jaskot was coming in.

24 A. Oh, it would've been before.

11:36:22

25 Q. Before the announcement about Mr. Jaskot?

1 A. About -- yes.

2 Q. Did Mr. Dolin ever tell you or say in your presence why he
3 was -- Mr. Jaskot had come in to serve as co-practice group
4 leader?

11:36:35 5 A. Yes.

6 Q. What do you remember Mr. Dolin saying about that?

7 A. That the amount of -- he was not going to be able to handle
8 the amount of administrative -- administration matters because
9 the group was so large.

11:36:46 10 Q. Did you ever hear anybody make any criticisms or complaints
11 about Mr. Dolin's work as a practice group leader?

12 A. No.

13 Q. After the announcement came out that Mr. Jaskot was going
14 to be sharing co-practice group leader responsibilities with

11:37:01 15 Mr. Dolin, did Mr. Dolin appear more relieved or less stressed
16 in any way to you?

17 A. Yes.

18 Q. In what way?

19 A. Exactly what you stated, less relieved, less stressed.

11:37:12 20 Q. More relieved, less stressed?

21 A. More relieved, less stressed.

22 Q. Did you enter Mr. Dolin's time in 2010?

23 A. I did.

24 Q. Did he have time sheets?

11:37:21 25 A. He did.

1 Q. Did he handwrite out the time sheets?

2 A. Yes, he did.

3 Q. And where the time sheets due at the end of every week?

4 A. Well, Stu handed them in every day.

11:37:32

5 Q. He did. All right.

6 And did -- during the week of his death, the week he
7 passed away, did he complete a time sheet for every day?

8 A. I believe so.

9 Q. Yes. And so the last week of his death, he continued to

11:37:42

10 follow that practice?

11 A. Yes; to my knowledge.

12 Q. Are you aware of any client complaints that came in to

13 Mr. Dolin the last week of his life?

14 A. No.

11:37:50

15 Q. During that entire week, did you notice anything different,
16 unusual, or odd about Mr. Dolin?

17 A. No.

18 Q. When you spoke with him that week, was Mr. Dolin acting
19 coherently to you?

11:38:01

20 A. Yes.

21 Q. When you spoke to him that week, did he sound rational to
22 you?

23 A. Yes.

24 Q. Did you notice any anxious behavior on his part that week,

11:38:10

25 whether that be pacing, or jitteriness of his hands or legs, or

1 hand rigging, anything of that nature?

2 A. Not that I can remember.

3 Q. Did you see him the morning of July 15, 2015?

4 A. I believe so, yes.

11:38:22

5 Q. Anything about Mr. Dolin's behavior that day that was odd,
6 unusual, or out of the ordinary in any way?

7 A. I did not notice anything.

8 Q. Did you speak with him that day?

9 A. I'm sure I did.

11:38:34

10 Q. Was he -- did he sound as if he was speaking clearly and
11 coherently?

12 A. Yes.

13 Q. Anything about his speech or his pattern of speech that was
14 unusual or out of the ordinary in any way?

11:38:48

15 A. Not that I can remember.

16 Q. Your last interaction with him on July 15, 2010, was
17 sometime before he left for his lunch?

18 A. Sometime before I left for my lunch, yes.

19 Q. Sure. Based upon your observations and interactions, how
20 did the economic downturn in 2009 affect Mr. Dolin?

11:39:02

21 A. I don't know how it affected him personally.

22 Professionally, I can say that he tried to keep everybody
23 upbeat about it.

24 Q. When you interacted with Mr. Dolin during the week of July
25 12, did he -- was he his normal friendly self?

11:39:18

1 A. Yes.

2 Q. Are you aware of any instance where Mr. Dolin reported to
3 somebody else that he didn't believe that he had the abilities
4 or the experience to work at a law firm like Reed Smith?

11:39:32 5 A. Can you rephrase that?

6 Q. Sure. Was there ever an occasion where you learned that
7 Mr. Dolin had reported to somebody else that he didn't feel
8 qualified or didn't feel like he had the expertise to work at a
9 law firm such as like Reed Smith?

11:39:46 10 A. That Stu didn't feel he had the expertise or that Stu felt
11 that the person he was reporting to didn't have the expertise.

12 Q. That Stu felt like he didn't have the experience or
13 expertise to work at a law firm like Reed Smith?

14 A. No.

11:40:01 15 Q. Was Standard Parking a major firm for the Chicago office?

16 A. It was a major client for Stu.

17 Q. And did you know of any situation over Mr. Dolin's career
18 where he faced the possibility that he would lose a major
19 client?

11:40:17 20 A. Not that I can remember.

21 Q. Did Wendy frequently call him at his office?

22 A. Yes, she did.

23 Q. About how many times a day do you think she called him?

24 A. Once a day.

11:40:26 25 Q. And what about his children? Did they frequently call him

1 as well?

2 A. They would call. As they grew older, they called less, but
3 they would call.

11:40:37

4 Q. Okay. You mentioned that you had a conversation with Mr.
5 Dolin at some point regarding his loss of weight. Do you
6 remember that?

7 A. Uh-huh.

8 Q. And there was -- there was two parts to that conversation,
9 the first one and a longer second one, is that right?

11:40:48

10 A. Yes.

11 Q. He mentioned -- you said earlier that he mentioned he was
12 getting ready for skiing?

13 A. Yes.

14 Q. What do you mean by that?

11:40:57

15 A. He would take -- he would exercise to get his lungs and his
16 legs ready for skiing, so

17 Q. And when you said he looked like he had lost weight, did he
18 look malnourished?

19 A. No.

11:41:10

20 Q. Did he look more fit?

21 A. Yes.

22 Q. Okay. When things were busy at the office throughout the
23 career, not just in 2010 but when things were busy in the
24 office, how did Mr. Dolin generally cope?

11:41:20

25 A. Calmly. When I had already started -- I had worked for him

1 when he had already made -- he was already partner, so I'm
2 trying to remember specifically.

3 He was always calm to me.

4 Q. Did he ever seem emotionally distraught in front of you?

11:41:38

5 A. No.

6 Q. And to the best of your knowledge, how did the other
7 attorneys or staff members look upon him?

8 A. I always thought that they looked favorably upon him, that
9 he was a leader.

11:41:48

10 Q. During the many hours, the many years that you worked with
11 Mr. Dolin, had you ever seen him nervously pacing back and
12 forth?

13 A. No.

14 Q. Had you ever seen him be jittery or tap his leg nervously?

11:41:58

15 A. No.

16 Q. Had he ever repeated statements over and over again?

17 A. No.

18 Q. In the years that you worked with him, had you ever known
19 Mr. Dolin to have a hard time processing information?

11:42:09

20 A. No."

21 MR. DAVIS: That's the end of this witness, Your
22 Honor.

23 THE COURT: All right.

24 MR. BAYMAN: Your Honor, our next witness is by video
25 deposition, Edward Walsh.

11:42:15

1 THE COURT: All right.

2 (Audiotaped deposition of Edward Walsh played in
3 open court).

11:56:13

4 MR. BAYMAN: Your Honor, our next witness we call is
5 Dr. Anthony Rothschild.

6 THE COURT: Okay. I'm going to break early for lunch.
7 So we'll start him -- it's 12:00 o'clock now. So we'll take
8 the luncheon break, but I also want to talk to you before we do
9 that.

11:56:25

10 MR. BAYMAN: Okay.

11 THE COURT: Ladies and gentlemen, we'll take a break
12 now. Thank you very much. Approximately one hour.

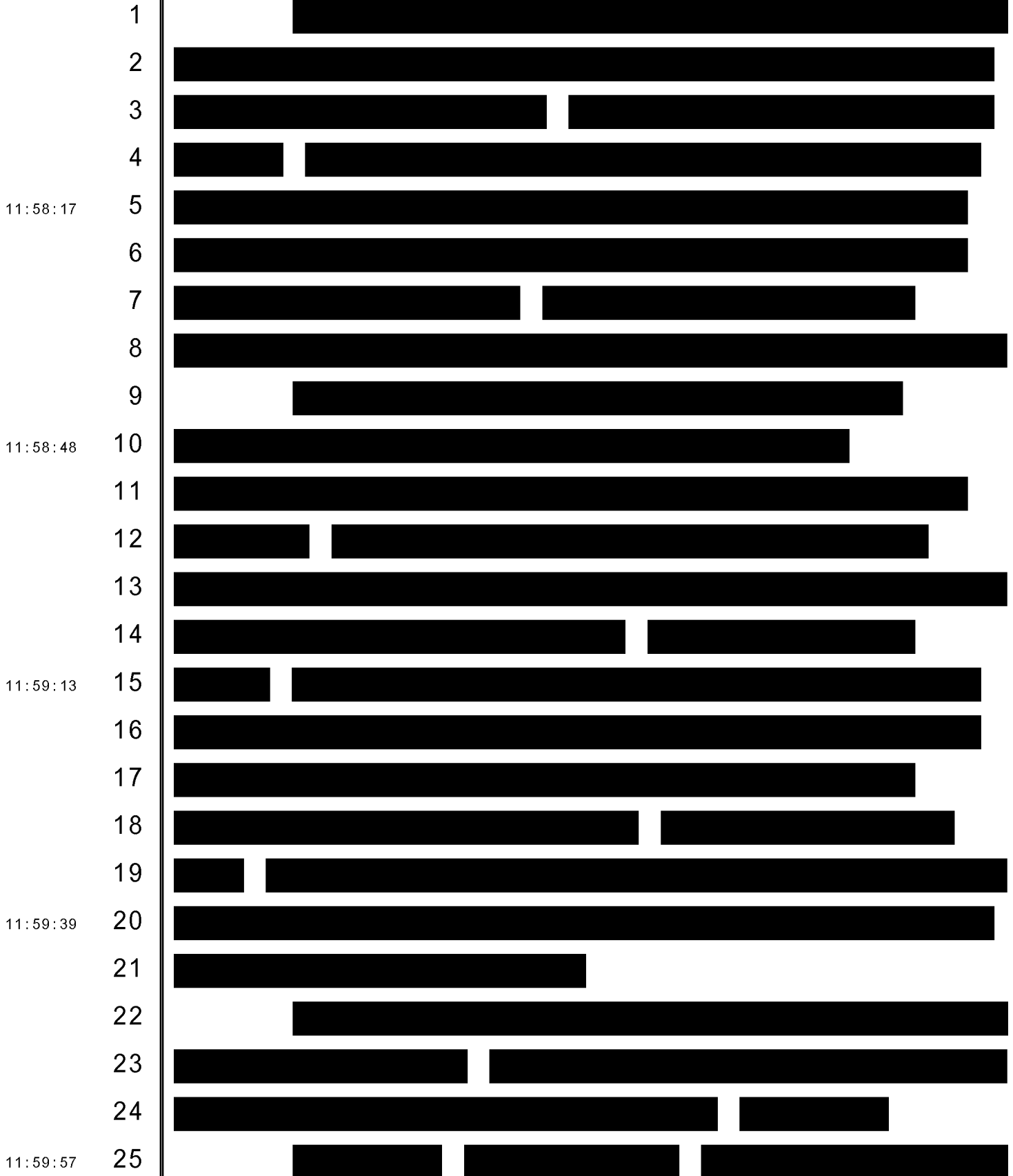
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14 presence of the jury in open court:)

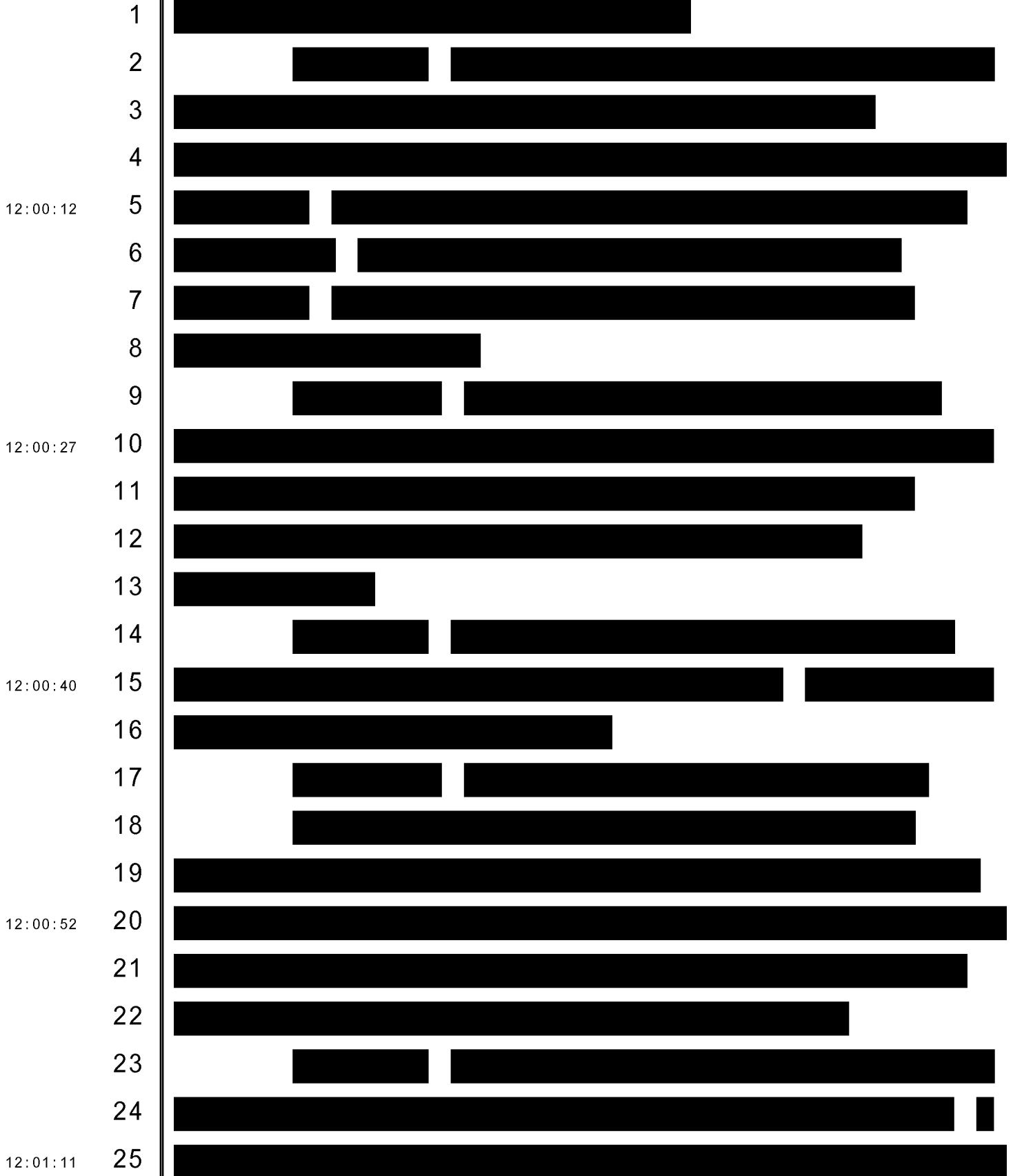
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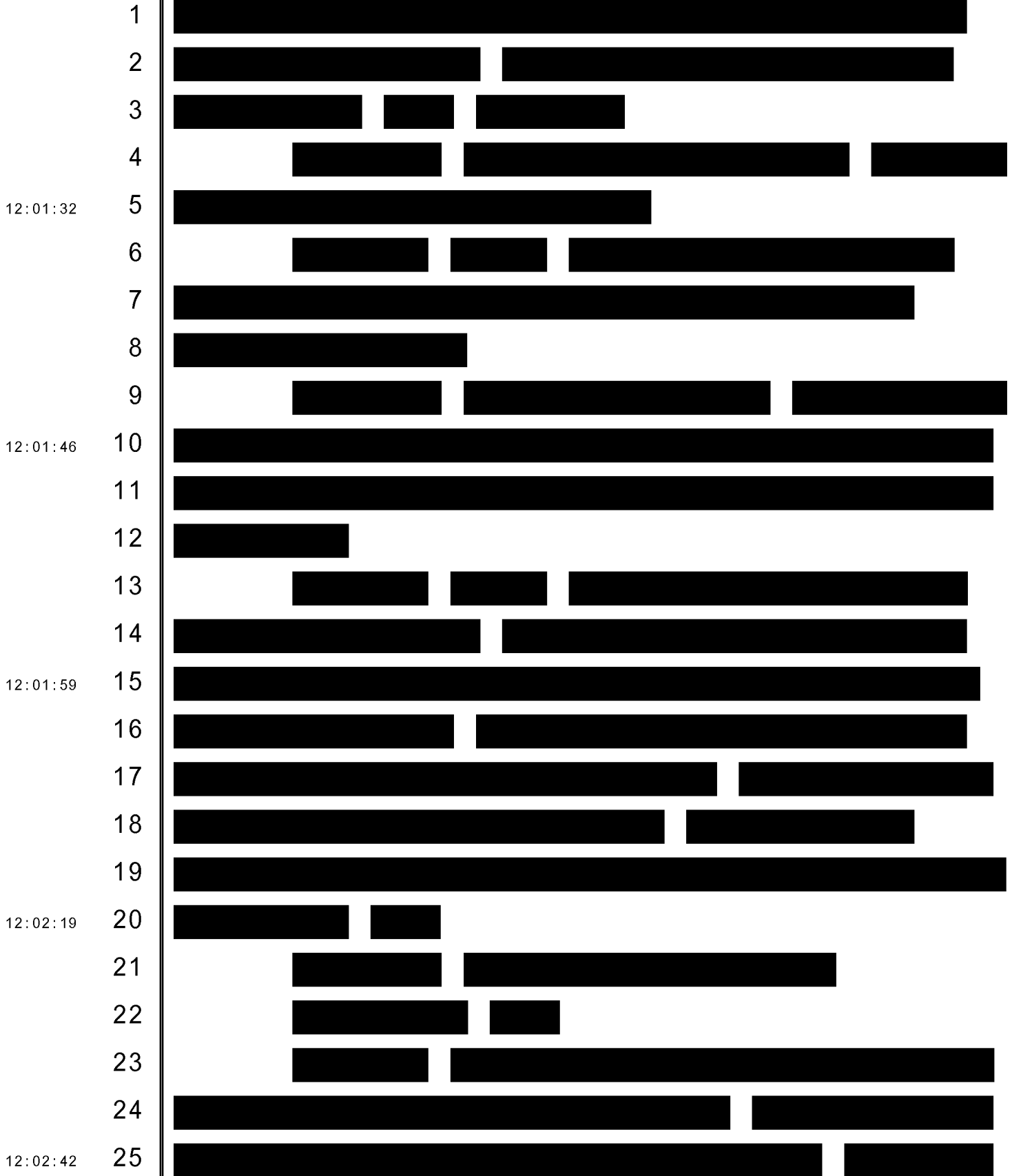
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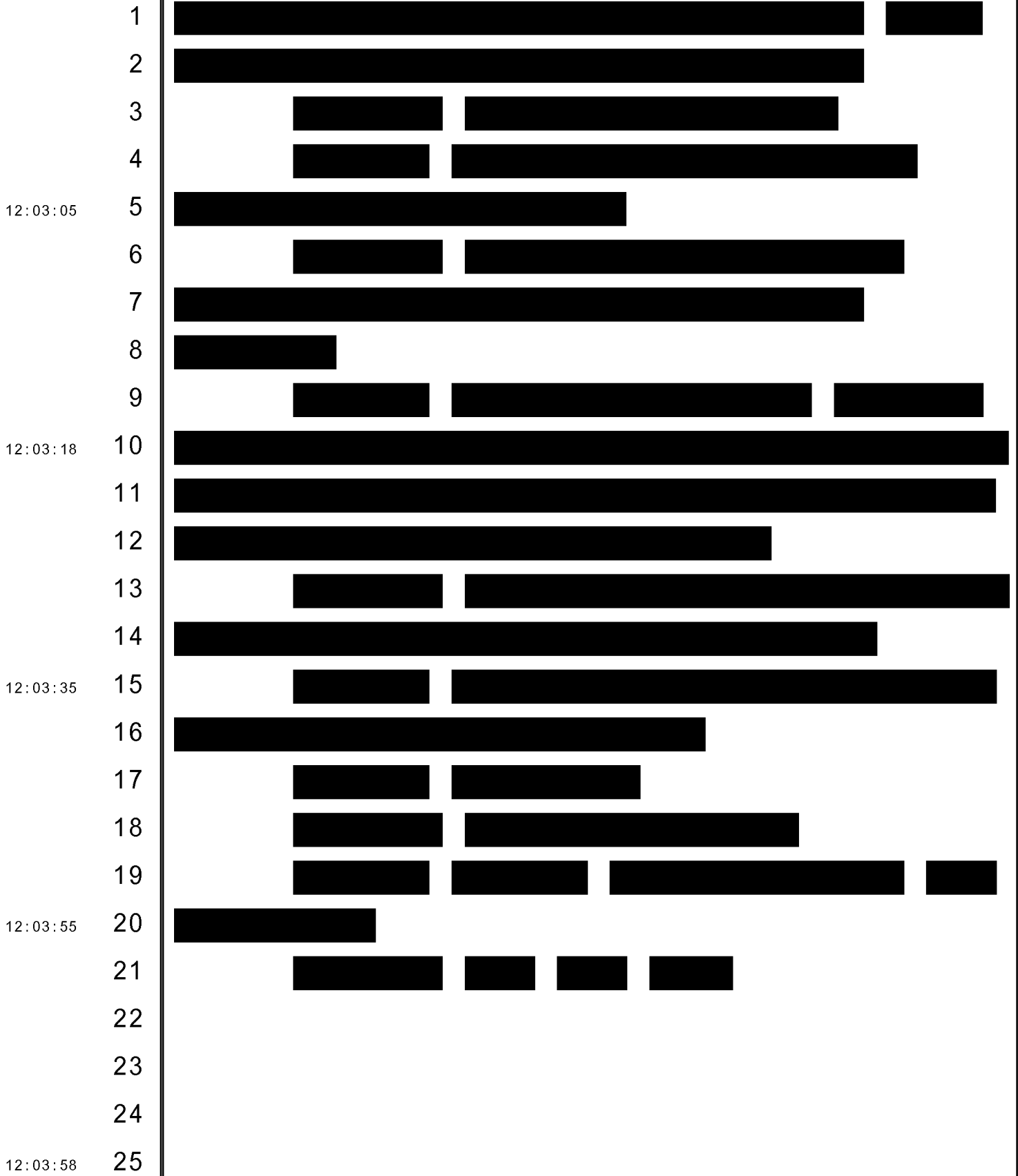
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12:04:05

(Luncheon recess taken from 12:05 o'clock p.m.
to 1:15 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

April 11, 2017