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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 13 A
TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE WILLIAM T. HART

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

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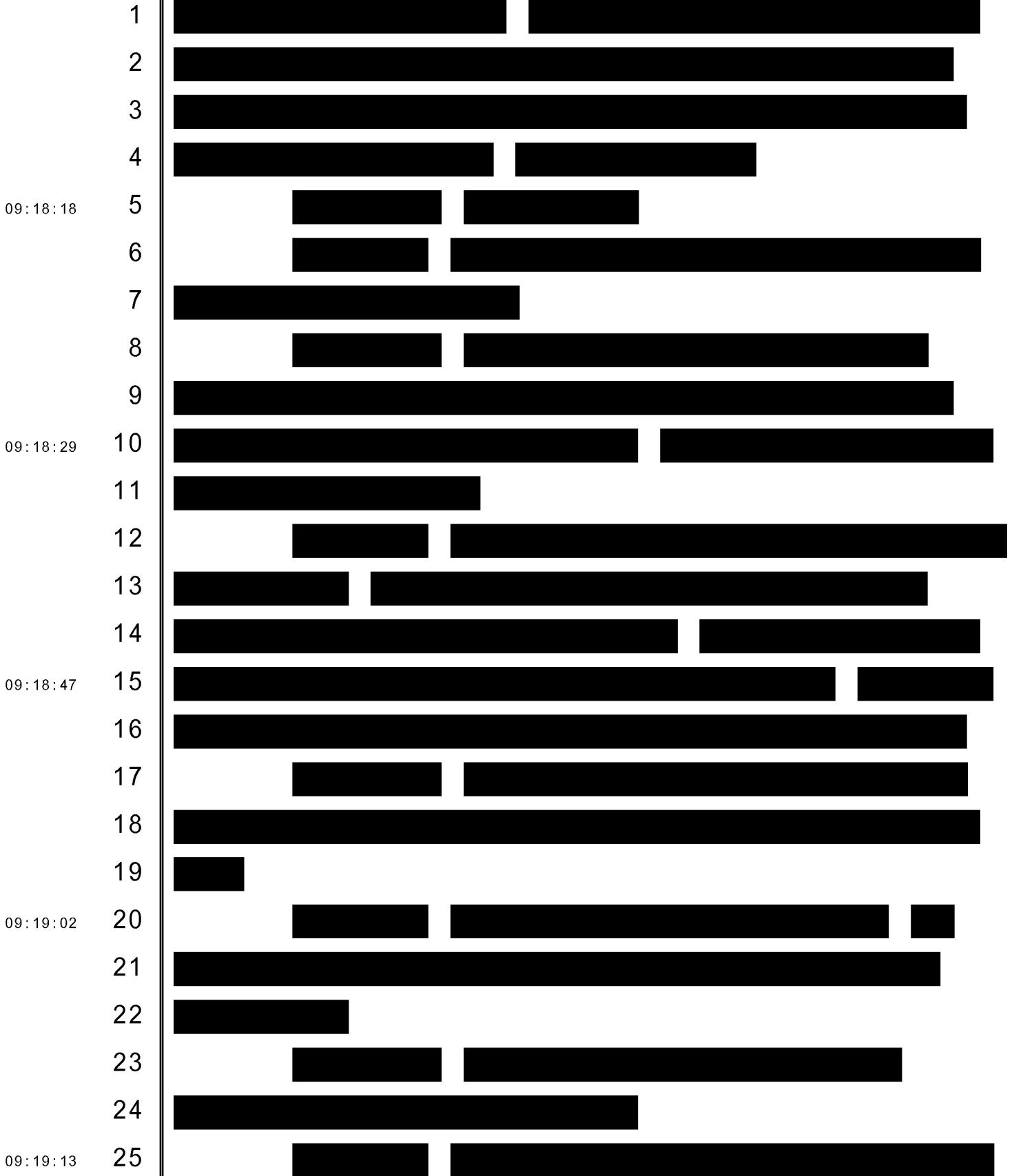
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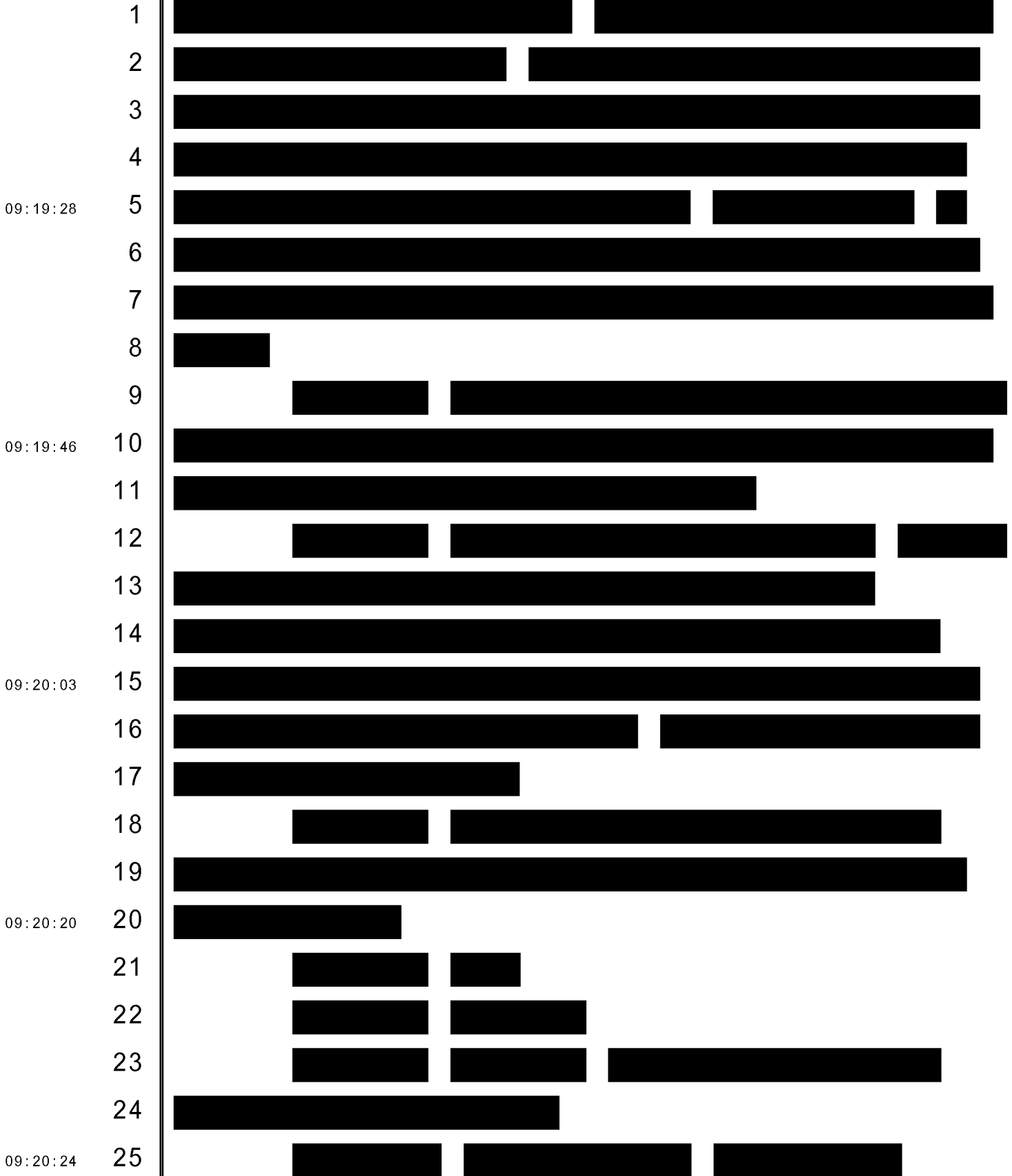
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[REDACTED]





1 [REDACTED]

2 [REDACTED]

3 [REDACTED] [REDACTED]

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

09:30:34

6 [REDACTED] [REDACTED] [REDACTED]

7 [REDACTED] [REDACTED]

8 [REDACTED] [REDACTED]

9 [REDACTED]

09:30:41

10 [REDACTED]

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

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

09:32:03

15 We'll resume.

16 MS. HENNINGER: Thank you.

17 THE COURT: You may proceed, ma'am.

18 MS. HENNINGER: Thank you.

19 If it please the Court, counsel. Good morning, ladies
20 and gentlemen.

09:32:13

21 WENDY DOLIN, PLAINTIFF'S WITNESS, PREVIOUSLY SWORN

22 CROSS EXAMINATION

23 BY MS. HENNINGER:

24 Q. Good morning, Mrs. Dolin.

09:32:15

25 A. Good morning.

1 Q. Yesterday when we ended I asked you if your husband
2 expressed fears to you that he would be fired at Reed Smith,
3 and we're about to look at your deposition.

4 But before we do that, why don't I just ask you again,
5 do you recall your husband expressing fears to you that he
6 would be fired while he was working at Reed Smith?

7 A. Yes.

8 Q. Okay. And when he expressed those fears, you didn't
9 believe they were based in fact, correct?

10 A. Correct.

11 Q. And you recall that he may have expressed similar fears of
12 losing his job while he was at Sachnoff Weaver, correct?

13 A. Yes.

14 Q. Now, your husband was prescribed the generic version of
15 Zoloft, sertraline, in the summer of 2010, correct?

16 A. Yes.

17 Q. And you don't know how many pills or how many days he took
18 that sertraline, correct?

19 A. No, I don't.

20 Q. But you do know, because he told you, that for whatever
21 reason he just didn't feel right on that medication, correct?

22 A. Yes.

23 Q. And he stopped taking it, correct?

24 A. Yes.

25 Q. Okay. In June 2010, you aware that your husband started

1 seeing a Dr. Salstrom, correct?

2 A. Yes.

3 Q. And she is a psychologist, correct?

4 A. Yes.

09:33:36

5 Q. And you were familiar with Dr. Salstrom before your husband
6 started seeing her, correct?

7 A. Yes.

8 Q. But you weren't involved in referring him to see Dr.
9 Salstrom, is that right?

09:33:46

10 A. Yes.

11 Q. Okay. And after your husband passed away, like with Ms.
12 Reed, you wrote to Dr. Salstrom requesting that she summarize
13 her records for you, correct?

14 A. Yes.

09:33:57

15 Q. And you received that summary and you've also reviewed some
16 of her actual notes, correct?

17 A. Yes.

18 Q. And we're not going to go through those today because the
19 jury has seen them, but you know that he started seeing her
20 around June 29, 2010, I can just say late June --

09:34:10

21 A. Yes.

22 Q. -- because he was having some stressors at work, correct?

23 A. Yes.

24 Q. And now you told the jury yesterday that you believe your
25 husband started taking Paxil, or the generic version of Paxil,

09:34:24

1 on July 10th, correct?

2 A. Yes.

3 Q. And that was a Saturday?

4 A. Yes.

09:34:32

5 Q. Okay. And you never saw him take his medication, correct?

6 A. Yes.

7 Q. And that would include Paroxetine?

8 A. Yes.

09:34:46

9 Q. Now, you don't recall anything memorable that your husband
10 did on Saturday, July 10, correct?

11 A. No.

12 Q. It was kind of a normal day. He took the dog for a walk
13 and you went out to dinner with friends, correct?

14 A. Yes.

09:34:56

15 Q. Okay. And you don't remember any kind of strange behavior
16 or anything different about him on Saturday, correct?

17 A. No.

18 Q. All right. Now Sunday, which was July 11th, was a pretty
19 normal Sunday, correct?

09:35:10

20 A. Yes.

21 Q. And you went to a friend's house for dinner, I believe you
22 told the jury, correct?

23 A. Yes.

09:35:19

24 Q. And your husband was not acting strange on Sunday night,
25 correct?

1 A. I think he started to not feel quite right that day.

2 Q. Okay. Did you notice -- well, let me ask you to look at
3 your deposition on page 295, please, Mrs. Dolin.

4 I left it up there for you.

09:35:41

5 A. Yeah. Thank you very much.

6 (Brief pause).

7 BY MS. HENNINGER:

8 Q. And when you get there, let me know. I'm going to direct
9 you to lines 8 and 9.

09:35:53

10 (Brief pause).

11 BY THE WITNESS:

12 A. Yes, I see that.

13 BY MS. HENNINGER:

14 Q. I asked -- I didn't take your deposition but somebody asked
15 you:

09:36:05

16 "... did he act strange Sunday night?"

17 And your answer was:

18 "No."

19 Correct?

09:36:10

20 A. Yes.

21 Q. So, the next day was Monday, July 12th. And I recall your
22 testimony yesterday about your husband pacing while he was on a
23 phone call that evening, correct?

24 A. Yes.

09:36:21

25 Q. And the pacing that you noticed -- well, let me back up a

1 little bit.

2 I believe you testified that normally he would sit on
3 the chair or on the sofa and take work calls, correct?

4 A. Yes.

09:36:32

5 Q. But you noticed that he got up and he was pacing during
6 some telephone calls, going up and down the stairs?

7 A. Yes.

8 Q. Now, you had seen your husband pace at times before during
9 his career when he was anxious and depressed, correct?

09:36:46

10 A. No.

11 Q. Okay. I can get you to look at page 114 of your
12 deposition, please, Mrs. Dolin.

13 (Brief pause).

14 BY THE WITNESS:

09:37:03

15 A. Yes.

16 BY MS. HENNINGER:

17 Q. If you look at lines 23 through 25, please.

18 And the question was:

09:37:11

19 "... would his behavior indicate to you that he
20 was anxious or depressed, pacing or agitated?"

21 And your response was:

22 "Sometimes."

23 A. I see that, but that's kind of a misleading question,
24 because it says:

09:37:27

25 "... would his behavior indicate to you that he

1 was anxious or depressed, pacing or agitated."

2 There's a bunch of words in there. So I think I was
3 most likely referring to anxious or depressed at that time.

09:37:43

4 Q. And that's fair enough, but it's not your testimony that
5 you never saw your husband pace until the evening of Monday
6 night, is it?

7 A. I don't remember.

09:37:59

8 Q. Okay. Now, on that phone call or phone calls -- well,
9 first of all, let me ask you, do you know if he had one phone
10 call that evening or more than one?

11 A. I don't remember.

12 Q. Okay. And you don't know who he was talking to, correct?

13 A. No.

14 Q. Or what they were discussing, correct?

09:38:07

15 A. No.

16 Q. Okay. But you do know that he had that phone call and you
17 noticed that behavior?

18 A. Correct.

19 Q. But he never told you what the conversation was about?

09:38:15

20 A. No.

21 Q. All right. Now, Tuesday morning you actually saw your
22 husband, I believe you told Mr. Rapoport, before he left for
23 work?

24 A. Yes.

09:38:24

25 Q. And you recall him saying that he didn't want to go to work

1 that day?

2 A. Yes.

3 Q. But he said he would go and he would end up feeling better,
4 correct?

09:38:32 5 A. Correct.

6 Q. And he went to work. And you don't recall speaking to him
7 during the day on Tuesday, correct?

8 A. No.

9 Q. But you did see him Tuesday night when he got home from
10 work because you and Dr. Sachman and your husband went to
11 dinner and to a memorial service, correct?

12 A. Yes.

13 Q. For a friend's father, I believe.

14 A. Yes.

09:38:53 15 Q. Okay. And you spent about two-plus hours with Dr. Sachman
16 that night, correct?

17 A. Yes.

18 Q. Now, during the time you spent with Dr. Sachman during
19 dinner or at the memorial service, did you raise with him at
20 all the fact that your husband was pacing?

21 A. No.

22 Q. Did you raise with him at all the fact that, I believe you
23 described it, as him being weepy on Tuesday morning?

24 A. Your question? I'm sorry.

09:39:16 25 Q. Sure. Did you raise --

1 A. Oh, yeah. No, no.

2 Q. Okay. You didn't raise any unusual behavior that you
3 noticed with Dr. Sachman, correct?

4 A. No.

09:39:26 5 Q. Okay. So we're at Wednesday, and you didn't get to see
6 your husband before he left for work Wednesday morning?

7 A. Correct.

8 Q. Now, as we discussed briefly yesterday, that was kind of
9 normal?

09:39:41 10 A. Yes.

11 Q. He was an early riser.

12 A. Yes.

13 Q. And but you know your husband contacted Ms. Reed on that
14 Wednesday, correct?

09:39:49 15 A. I did find that out, yes.

16 Q. Because he called you, I believe, and said he was going to
17 be a little bit late for dinner, correct?

18 A. I don't remember that, but --

19 Q. That's fair.

09:39:59 20 A. -- it probably makes sense.

21 Q. But you know that he went to see Ms. Reed. And when he
22 came home from Ms. Reed, he talked about a relaxation tape or
23 meditation --

24 A. Meditation tape.

09:40:10 25 Q. A meditation take.

1 And you noticed that when he came home from the visit
2 with Ms. Reed that Wednesday night, that he was very, very,
3 very anxious about the meeting with the Miniatt family Friday,
4 correct?

09:40:23 5 A. Yes.

6 Q. Okay. And he told you he was concerned about that meeting,
7 correct?

8 A. Not in great detail, just that he was concerned.

09:40:37 9 Q. And that's fair because that was going to be my next
10 question, Mrs. Dolin. He didn't tell you the details of why --
11 what was going on at that meeting or anything?

12 A. I don't remember the specifics.

13 Q. Okay. But you knew the meeting was scheduled for that
14 Friday, correct?

09:40:47 15 A. I believe so.

16 Q. Okay. And I believe it was you that suggested that your
17 husband go to his law partner, Mr. LoVallo, who the jury heard
18 from yesterday, and ask Mr. LoVallo to attend that meeting with
19 him, do you remember that?

09:41:01 20 A. Yes.

21 Q. And your husband thought that was a good idea, correct?

22 A. Yes.

23 Q. Okay. Now, the meditation tape, you told the jury
24 yesterday, that he did in fact listen to that meditation tape,
09:41:13 25 correct?

1 A. Yes.

2 Q. He suggested you listen to it, but you do that all the time
3 with work, so you didn't, correct?

4 A. Correct.

09:41:20

5 Q. Okay. Now, Wednesday night, you told the jury yesterday,
6 that he was tapping his leg during dinner, correct?

7 A. Uh-huh.

8 Q. But you didn't notice any pacing Wednesday night, correct?

9 A. No.

09:41:33

10 Q. Okay. So the unusual behavior that you recall from that
11 Wednesday was him tapping his leg at dinner?

12 A. And that he said, "I still feel so anxious," I think that
13 was significant.

14 Q. Okay. That he still felt so anxious, correct?

09:41:51

15 A. Right.

16 Q. Okay. So I want to move to Thursday, Mrs. Dolin, and I'm
17 only going to briefly touch on Thursday.

18 But you talked to your husband on the way to work, we
19 heard about the dog; correct?

09:42:04

20 A. Yes.

21 Q. And you know that he exercised that morning, I think you
22 told the jury, because you found some sweaty clothes next to
23 the laundry machine, correct?

24 A. Yes.

09:42:15

25 Q. And when you spoke with your husband about the dog that

1 morning, he didn't seem very -- I mean, his voice sounded fine,
2 there was nothing unusual about that conversation?

3 A. He said he felt better.

09:42:36

4 Q. Okay. Now, the week that your husband passed away, you
5 knew that he was having some issues with Standard Parking and
6 the Miniat meeting on Friday, correct?

7 A. I don't know the -- I knew about the meeting on Friday, I
8 didn't know what the date was for Standard.

09:42:56

9 Q. Okay. But he told you that he was in fear, or was at least
10 concerned, that he would lose Standard Parking as a client,
11 didn't he?

12 A. Yes.

09:43:14

13 Q. The jury heard a little bit earlier during Dr. Glenmullen's
14 testimony that your husband had something called sleep apnea,
15 is that correct?

16 A. Yes.

17 Q. And do you remember approximately when he was diagnosed
18 with sleep apnea?

19 A. I think in maybe the early 2000's.

09:43:33

20 Q. Okay. And he went like a sleep center at Northwestern to
21 get studied?

22 A. Yes.

23 Q. And he ended up to having to wear, what is it, a CPAP
24 machine?

09:43:41

25 A. Yeah.

1 Q. And it's a little mask that has some straps that you wear
2 when you sleep?

3 A. Yes.

09:43:49

4 Q. Okay. And he wore that -- or he took that with him when
5 you would travel and things like that?

6 A. Yes.

7 Q. Okay. Now, after your husband passed away, you moved from
8 Glencoe down to the Water Tower, correct?

9 A. Yes.

09:44:02

10 Q. And you also started your own therapy group called Wendy
11 Dolin Therapy, correct?

12 A. Correct.

13 Q. And the work that did you did at Wendy Dolin Therapy is
14 about three days a week, correct?

09:44:15

15 A. It's actually more four days a week now.

16 Q. But when you were back at the Family Service Center you
17 were working three days a week, correct?

18 A. Yes.

09:44:36

19 Q. Okay. Now, the night your husband passed away, the police,
20 unfortunately, came to your house to talk with you, correct?

21 A. Yes.

22 Q. And they asked some questions whether or not you noticed
23 anything unusual, correct?

24 A. I don't remember.

09:44:48

25 Q. Okay. I'm not -- I'm going to hand you, if I may, the

1 police report.

2 Have you reviewed the police report, Mrs. Dolin?

3 A. No.

4 MS. HENNINGER: This is Defense Exhibit 3153, Your
5 Honor.

09:45:03

6 Do you need a copy, Mr. Rapoport?

7 MR. RAPOPORT: I'd be happy for one. Thanks.

8 (Document tendered.)

9 MS. HENNINGER: If I may approach?

09:45:22

10 THE COURT: Yes.

11 (Document tendered to the witness).

12 BY MS. HENNINGER:

13 Q. And I don't intend to go through this with you in any great
14 detail --

09:45:40

15 A. I appreciate that.

16 Q. -- Mrs. Dolin.

17 But on the back, the very -- it's on both sides of the
18 page, the front and back, but the last page and a half you'll
19 see that there is some summary notes from the police officer.

09:45:58

20 And I just want to direct your attention to this --
21 it's actually page 7 of 8, ma'am.

22 A. Okay.

23 Q. And if you look down, it talks about a conversation that
24 the police had with you. And I just want you to read that to
25 yourself.

09:46:14

1 (Brief pause).

2 BY MS. HENNINGER:

3 Q. There's a paragraph about has "... told Wendy Dolin..."
4 and then down at the bottom as well.

09:46:35 5 A. Are you referring to the second to the last paragraph?

6 Q. Yes, Mrs. Dolin.

7 A. I've read that.

8 Q. Okay. Great. And do you recall now seeing this, that you
9 didn't report any unusual behavior to the police officers the
10 evening your husband passed away?

09:46:42 11 A. No, I was in a total -- I think why I'm having difficulty
12 responding to this question is that I was in a total state of
13 shock.

14 Q. And I understand that, Mrs. Dolin. That's why I only
15 wanted to show you that one paragraph.

09:47:03 16 A. I appreciate your sensitivity, but I also think you need to
17 understand what I had just been told.

18 Q. Yes. I understand.

19 And you ended up having a group of friends and family
20 that evening, correct?

09:47:16 21 A. Ah --

22 Q. If you can even remember the events of that night. I'm
23 sure it's kind of --

24 THE COURT: What's your question, ma'am?

09:47:24 25 BY THE WITNESS:

1 A. I guess what I want to know --

2 THE COURT: We're kind of going off the track now.

3 What's your question?

4 BY MS. HENNINGER:

09:47:32

5 Q. Well, let me just change topics and I'll move on from the
6 police report, ma'am.

7 The evening that your husband passed away, you
8 e-mailed Dr. Salstrom, correct?

9 A. I think so, yes.

09:47:42

10 Q. And that morning, when she responded to you on July 16, you
11 told her that you thought that Paroxetine had something to do
12 with your husband's death, correct?

13 A. Yes.

09:47:59

14 Q. So as of the very next day you were concerned that
15 Paroxetine may be implicated --

16 A. Yes. Sorry for shaking my head "yes."

17 Q. And you had the bottle of Paroxetine in your home, correct?

18 A. Yes.

09:48:16

19 Q. And that was kept -- your husband kept that in the
20 bathroom?

21 A. Yes.

22 Q. And after he passed away and after you e-mailed Dr.
23 Salstrom, at some point you threw away the Paroxetine pills,
24 correct?

09:48:25

25 A. Yes.

1 Q. And you did that, you threw them in the garbage because you
2 wanted them out of the house because you thought they were
3 poison, correct?

4 A. I did.

09:48:36

5 Q. All right. Now, after your husband's death, Reed Smith
6 gathered his things from his office. I believe you talked
7 about some pictures, and his briefcase, et cetera, right?

8 A. Yes.

9 Q. And they sent that to you, correct?

09:48:48

10 A. Yes.

11 Q. And I believe yesterday you said that there was -- that his
12 wallet was in the briefcase and some pens but nothing
13 significant?

14 A. Nothing significant.

09:48:55

15 Q. When you opened that briefcase you did see, however, a
16 worksheet that your husband started to prepare with his therapy
17 sessions with Dr. Salstrom?

18 A. Yes.

19 Q. Okay. And you actually called Dr. Salstrom to discuss what
20 that worksheet was about, correct?

09:49:09

21 A. Yes.

22 Q. And you seen that she has notes in her records about that
23 conversation, correct?

24 A. Yes.

09:49:17

25 MS. HENNINGER: If we can show JX1003. It's already

1 been admitted.

2 And, Mr. Rapoport, I'll find you a copy, if you would
3 like.

4 MR. RAPOPORT: That's okay.

09:49:29

5 (Brief pause)

6 BY MS. HENNINGER:

7 Q. Mrs. Dolin, I'll bring you a hardcopy if you would like,
8 because sometimes -- can you see it on the screen?

9 MS. HENNINGER: If I may approach, Your Honor?

09:49:39

10 THE COURT: Yes.

11 (Document tendered to the witness).

12 (Exhibit published to the jury.)

13 BY MS. HENNINGER:

14 Q. And actually this was a phone call you had with Dr.
15 Salstrom on 8/4, correct?

09:50:00

16 A. (No response.)

17 Q. Maybe I should -- I misspoke. You called her on
18 August 4th, if you see what's up there that's highlighted, and
19 she returned your call on August 5th.

09:50:14

20 A. Thank you. Okay.

21 Q. And if we can go down to the body, it says:

22 "Former client's wife called to ask about a
23 worksheet" 'values and goals'.... "

24 And that's the worksheet you found in your husband's
25 briefcase, correct?

09:50:28

1 A. Yes.

2 Q. (Reading:)

3 "... that she had found in his briefcase and
4 asked about a certain phrase he had written 'I
5 don't want to' as a banner to a task such as
6 calling a client. She asked a therapist had a
7 copy of the worksheet."

8 Do you recall asking if Dr. Salstrom had a copy of
9 that worksheet?

10 A. No.

11 Q. Okay:

12 "... explained to her that the worksheet was at
13 least partially completed in session"
14 and then there's a paren:

15 "...she asked as she thought maybe he had
16 written it in his office just before killing
17 himself."

18 Do you see that?

19 A. Yeah.

20 Q. And that worksheet, after you had that call with Dr.
21 Salstrom, you threw that worksheet in the garbage, correct?

22 A. Yes.

23 Q. Okay. Now, August 13th, 2010, you recall is a date that
24 you decided to file the lawsuit, correct? Or to pursue legal
25 action, correct?

1 A. August 13th was the day I found some information out. I
2 don't recall that being the date.

3 Q. Okay. And the information you found out was a friend of
4 yours, Joanne, is it Moffet Silver?

09:51:54

5 A. Yes.

6 Q. Called you and said that she had talked to the law firm of
7 Baum Hedlund and wanted you to Google Paxil and akathisia,
8 correct?

9 A. Yes, Paxil, akathisia, and suicide.

09:52:10

10 Q. Okay. And you did that Google search, correct?

11 A. Yes.

12 Q. And at that point, that's when you decided to pursue this
13 lawsuit, correct?

14 A. To start to think about it, yes.

09:52:17

15 Q. And Joanne Moffett Silver, is she an attorney as well?

16 A. Yes.

17 Q. Okay. None of your husband's therapists or Dr. Sachman
18 told you that your husband had akathisia, correct?

19 A. Correct.

09:52:33

20 Q. Mrs. Dolin, thank you very much for your patience.

21 A. And I appreciate your sensitivity. Thank you.

22 THE COURT: Any redirect?

23 MR. RAPOPORT: Yes, Your Honor, a little bit.

24

09:52:46

25

1 REDIRECT EXAMINATION

2 BY MR. RAPOPORT:

3 Q. First question, I think we'll pick up on this last topic
4 that we talked about.

09:52:52

5 You have seen over the course of this litigation the
6 questionnaire that Stewart filled out with Dr. Salstrom,
7 correct?

8 A. Yes.

09:53:06

9 Q. Was that any different than what you saw that night, that
10 was just referred to?

11 A. No.

12 Q. Okay. Was there anymore written on that?

13 A. I don't remember.

14 Q. What was your thinking when you tossed it?

09:53:15

15 A. I got an answer to the question, she explained it, and that
16 was the end of it.

17 Q. Okay. You were asked a series of questions about
18 suspicions really about Paroxetine that came to your mind
19 early; why?

09:53:30

20 A. What time period are we talking about?

21 Q. In other words, shortly after you found out what happened,
22 I don't know whether it was the next day or whenever, but soon
23 after you were suspicious about the drug.

24 A. Yes.

09:53:45

25 Q. And my question for you is why.

1 A. Well, what happened was, I believe almost instantly someone
2 wanted -- people were saying, "well, what was different, what
3 was different in that he had started Paxil."

09:54:12

4 And then Joanne went back to the Chicago CBOE, and
5 Stewart had done some work for the CBOE, and she very early on
6 thought it was Paxil. And at that time there was some woman in
7 the office, I don't know what her role was at the CBOE, but she
8 said she --

09:54:34

9 MS. HENNINGER: Objection. I'm sorry, Mrs. Dolin, I
10 apologize.

11 A conversation with somebody else is what I'm trying
12 --

13 THE COURT: The objection is sustained.

09:54:44

14 MR. RAPOPORT: Okay. Just trying to follow up on what
15 drove her interest. They brought this up.

16 THE COURT: I know, but that's --

17 BY MR. RAPOPORT:

18 Q. Okay. So just continue your story but bypass whatever
19 about the woman you were going to say.

09:54:54

20 A. And then on August 13th I received that phone call about
21 the word "akathisia" and that's when I looked it up.

22 Q. Now, you were asked some questions about that Tuesday night
23 time spent together with Dr. Sachman.

24 A. Yes.

09:55:15

25 Q. And you were asked particularly, "did you raise the things

1 you had been noticing with him," and you said you did not.

2 A. Yes.

3 Q. Please address why not.

4 A. At that time I just thought that Stewart was going through,
09:55:30 5 you know, some anxiety and stress. And I felt it was Stewart's
6 place to talk to Dr. Sachman, he was with him.

7 Q. Was a suicide note ever found?

8 A. Oh, God no.

9 Q. And was one looked for?

09:55:50 10 A. Yeah. It's a very strange reaction I had because Stewart
11 and I used to write each other notes all the time. We were a
12 big hard family. I mean, at one point, I know this sounds
13 funny, but we had a rabbit and a dog. And whenever we had
14 Mother's Day, day, Father's Day, my birthday, anniversary, not
09:56:18 15 only did I get a card from him, I got one from the dog and the
16 rabbit separately.

17 And so we -- and when -- and this is what's so
18 significant to me, when I left him his dinner at night, when I
19 was working, I always put a little Post-It note on his plate,
09:56:34 20 "see you later," things like that, and I signed it "XX00 me."
21 And most people write "XOXO," but our special thing with us was
22 "XX00." So the fact that he didn't write a note was
23 staggering, just staggering. I mean, because he wasn't
24 planning on killing himself, but there was no note, ever.

09:56:55 25 Q. Now, concerning his weight loss. I want to come back for a

1 minute to this moment you've heard about where he was eating
2 salad at lunch. Why would he be eating salad at lunch?

3 A. You know, because he was trying to lose weight. You know,
4 he was watching his health. I mean, this sounds -- there's
5 nothing funny at all about what happened that day, but Stewart
6 had gout and he couldn't eat meat.

7 And so sort of the joke of our family was, you know,
8 you're kind of "this is your last day on earth, if you're going
9 to the chair what's your meal." And he was going to go to Lou
10 Malnati's, I mean, my kids looking forward to this, and have
11 sausage and pepperoni pizza, followed by going to Superdawg,
12 our other favorite place, and have Whoopercheesies.

13 So, for our family, I mean there's nothing funny about
14 it, but there is sort of an irony that he had a chicken salad
15 with we believe the dressing on the side and an ice tea, which
16 wouldn't have been his first choice of meals.

17 Q. Now, in evidence are the various records of physicals where
18 Dr. Sachman weighed Stewart or his staff weighed Stewart over
19 the years. And all of the numbers are somewhere between a low
20 of 200 and high of 209. He was about the 5/10?

21 A. Yes.

22 Q. And what is your best estimate of his weight just shortly
23 before he died?

24 A. 190.

25 Q. Was he looking good?

1 A. Yeah. He looked thinner, yeah.

2 Q. And was he feeling good about that thinner-self?

3 A. Yes.

09:58:54

4 Q. All right. I'm going to approach you with what we've
5 marked as Exhibit 332 for the plaintiff.

6 There was testimony about retirement plans or
7 possibilities. And you've seen the various average income
8 figures, correct?

9 (Document tendered to the witness).

09:59:16

10 BY THE WITNESS:

11 A. Yes, I have.

12 BY MR. RAPOPORT:

13 Q. Is exhibit 332 a fair summary of that you believe the loss
14 of earning capacity in this case is in total?

09:59:25

15 A. Are you looking at?

16 Q. You'll see the bottom line on the right.

17 A. Oh, I'm sorry. I'm looking at the left.

18 MS. HENNINGER: Your Honor, there's an objection to
19 this exhibit with this witness.

09:59:36

20 THE COURT: I haven't seen the exhibit.

21 (Document tendered to the Court.)

22 (Brief pause).

23 MS. HENNINGER: The objection is related to
24 foundation. It's calling for an expert opinion. It's beyond
25 the scope of cross-examination. We've had other witnesses

10:00:01

1 cover Mr. Dolin's earnings. This has projections that are only
2 within the scope of an expert witness, Your Honor.

3 THE COURT: All these numbers are in evidence already?

10:00:21

4 MR. RAPOPORT: They are. So the assumptions are --
5 the foundation is provided by Mr. LoVallo and Mrs. Dolin. And
6 the Illinois Supreme Court in the LaFever case makes clear that
7 expert testimony is not required, and the Air Crash case in the
8 Seventh Circuit also allows no expert.

10:00:40

9 THE COURT: Well, it's all in evidence. She may
10 testify.

10:00:56

11 MS. HENNINGER: Your Honor, the portion to the lower
12 left is not in evidence and that's what I'm objecting to as
13 being speculative, calling for an expert opinion. And also
14 pointing out that this is on redirect rather than direct, and
15 this was completely outside the scope of cross which was not
16 even touched.

17 THE COURT: Well, let's reserve on this.

18 MR. RAPOPORT: All right.

19 BY MR. RAPOPORT:

10:01:04

20 Q. So, in any event, we will show ruling reserved. I don't
21 have further questions other than the one I asked, which is is
22 this a fair and accurate, the bottom line there, is that a fair
23 and accurate calculation of what you believe the loss of
24 earning capacity would be?

10:01:19

25 A. Yes.

1 MR. RAPOPORT: That was my last question, Your Honor.
2 Other than seeking to play Plaintiff's Exhibit 2 as we had
3 reserved yesterday.

4 THE COURT: All right.

10:01:28

5 MR. RAPOPORT: And while they're having that set up, I
6 was reminded --

7 THE COURT: Can we excuse this witness?

8 MR. RAPOPORT: We can excuse the witness, yes.

9 THE COURT: All right. You may step down, ma'am.

10:01:39

10 THE WITNESS: Thank you.

11 (Witness excused.)

12 THE WITNESS: Excuse me. Do you need this back
13 (indicating)?

10:01:49

14 MS. HENNINGER: You can leave it up there. I'll get
15 it, Mrs. Dolin.

16 THE COURT: Leave everything there, ma'am.

17 MR. RAPOPORT: This is just about read, but yesterday,
18 Your Honor, you admitted into evidence life expectancy tables,
19 I would just like to publish the life expectancy of a 57-year
20 old male at this time. Takes one second.

10:02:06

21 THE COURT: All right.

22 MR. RAPOPORT: All right. According to a table of
23 mortality, admitted in evidence, the life expectancy of a male
24 person aged 57 years is 24 years.

10:02:17

25 Thank you, ladies and gentlemen.

1 Now Exhibit 2.

2 (Exhibit published to the jury.)

3 MR. RAPOPORT: Your Honor, ladies and gentlemen, we
4 rest our case.

10:15:15

5 THE COURT: All right. Ladies and gentlemen, we will
6 take a brief recess now. You may step into the jury room, if
7 you will.

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

10:16:00

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

10:16:17

15 [REDACTED]

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19 [REDACTED]

10:16:32

20 [REDACTED]

21 [REDACTED]

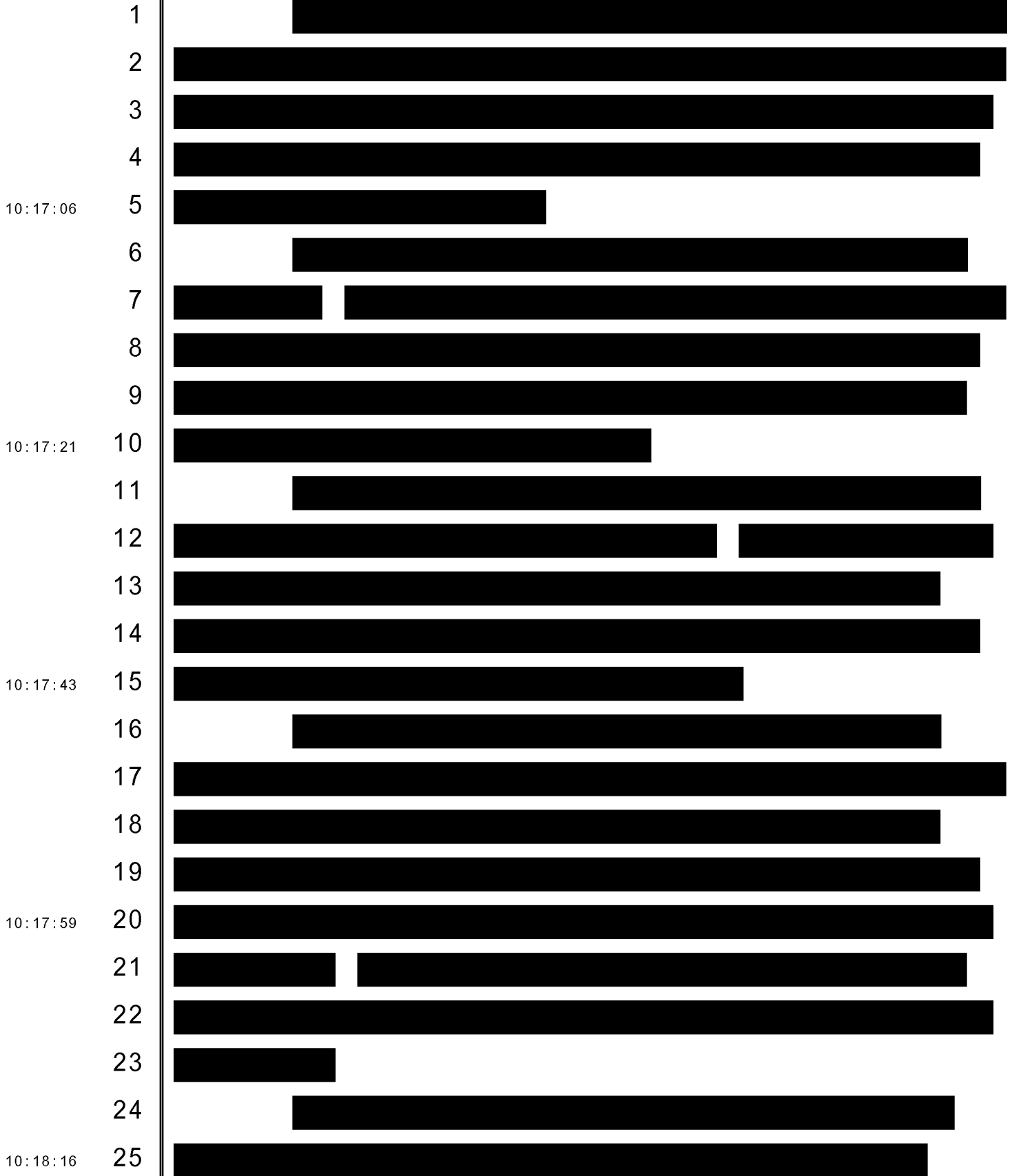
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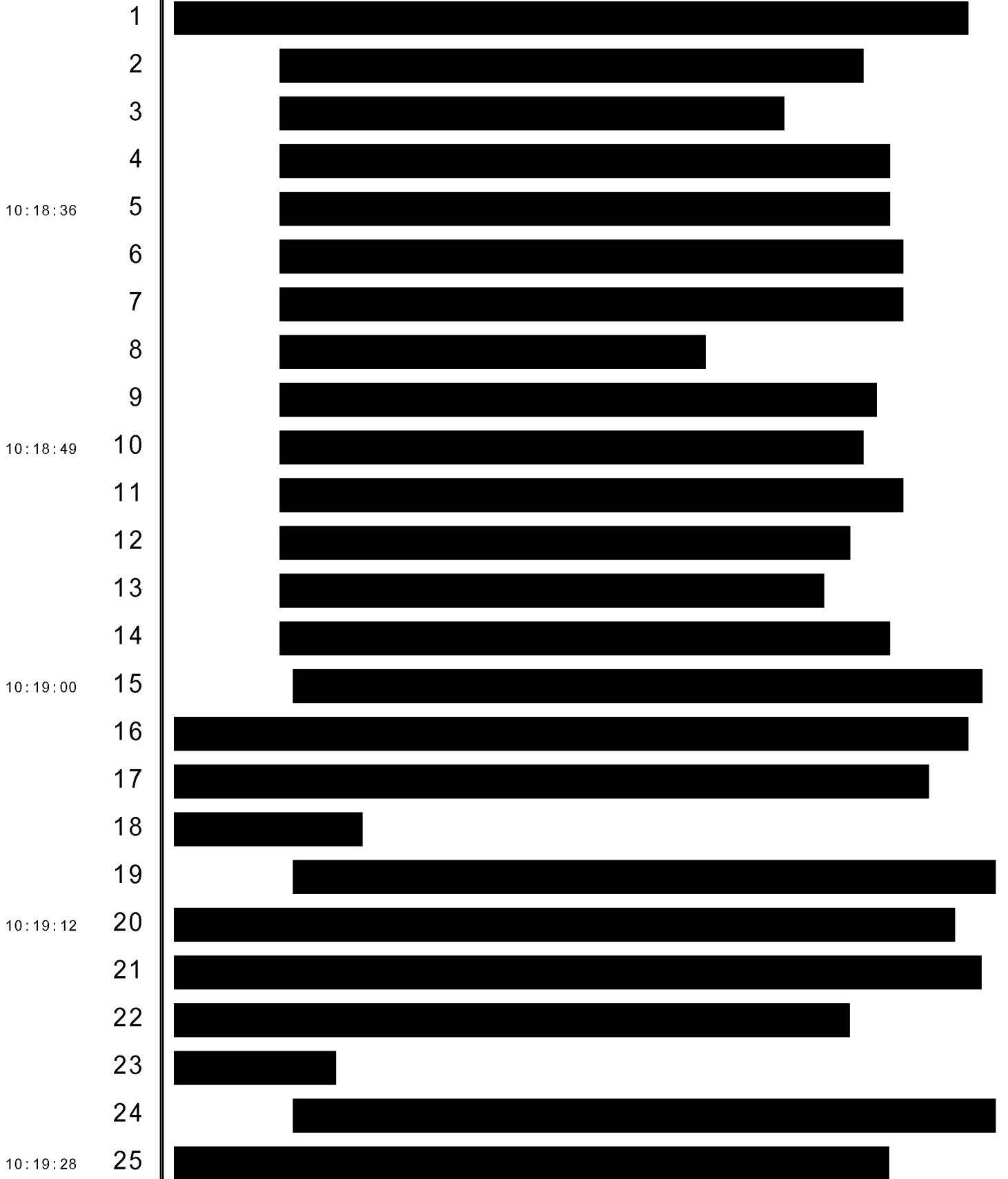
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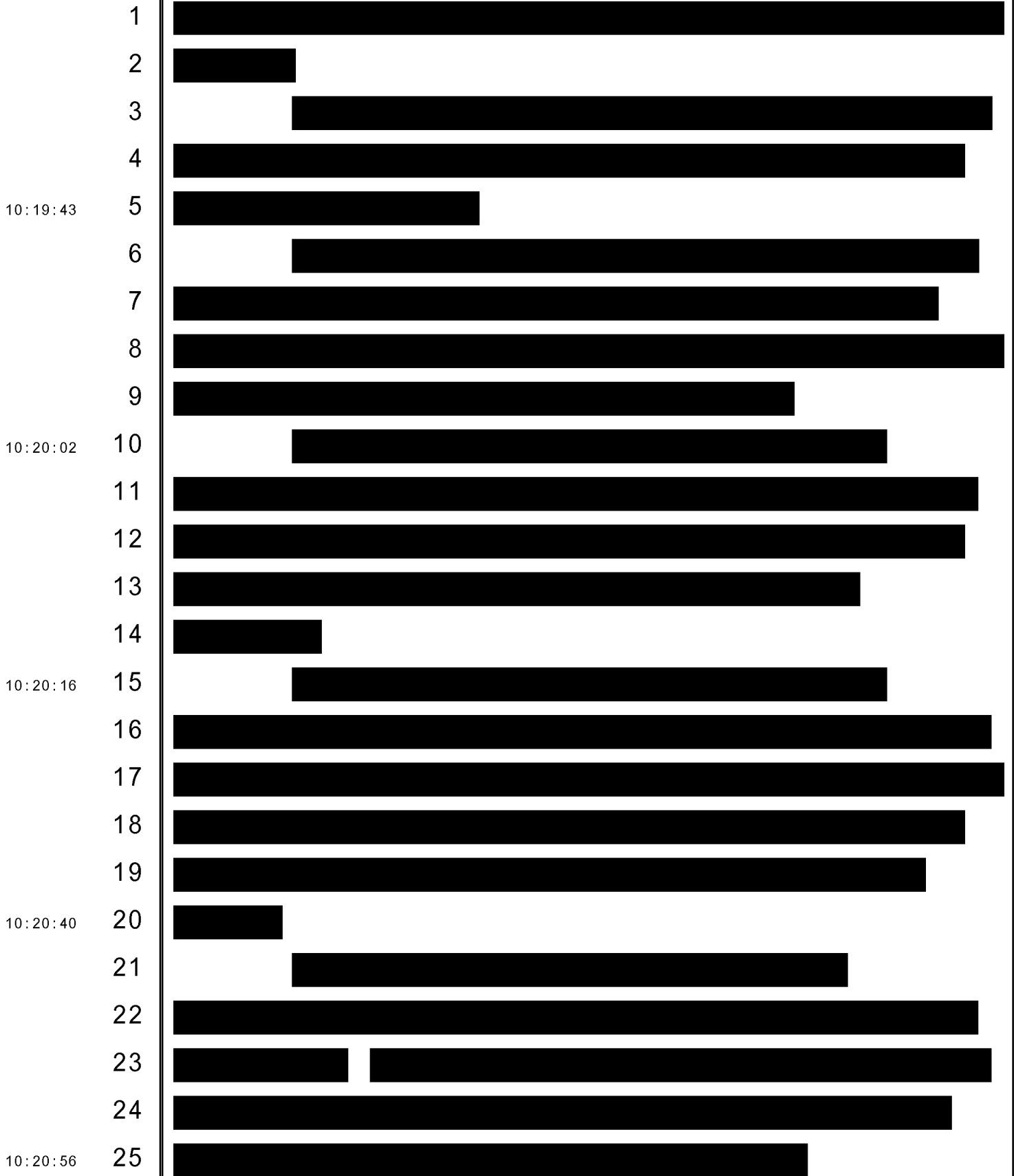
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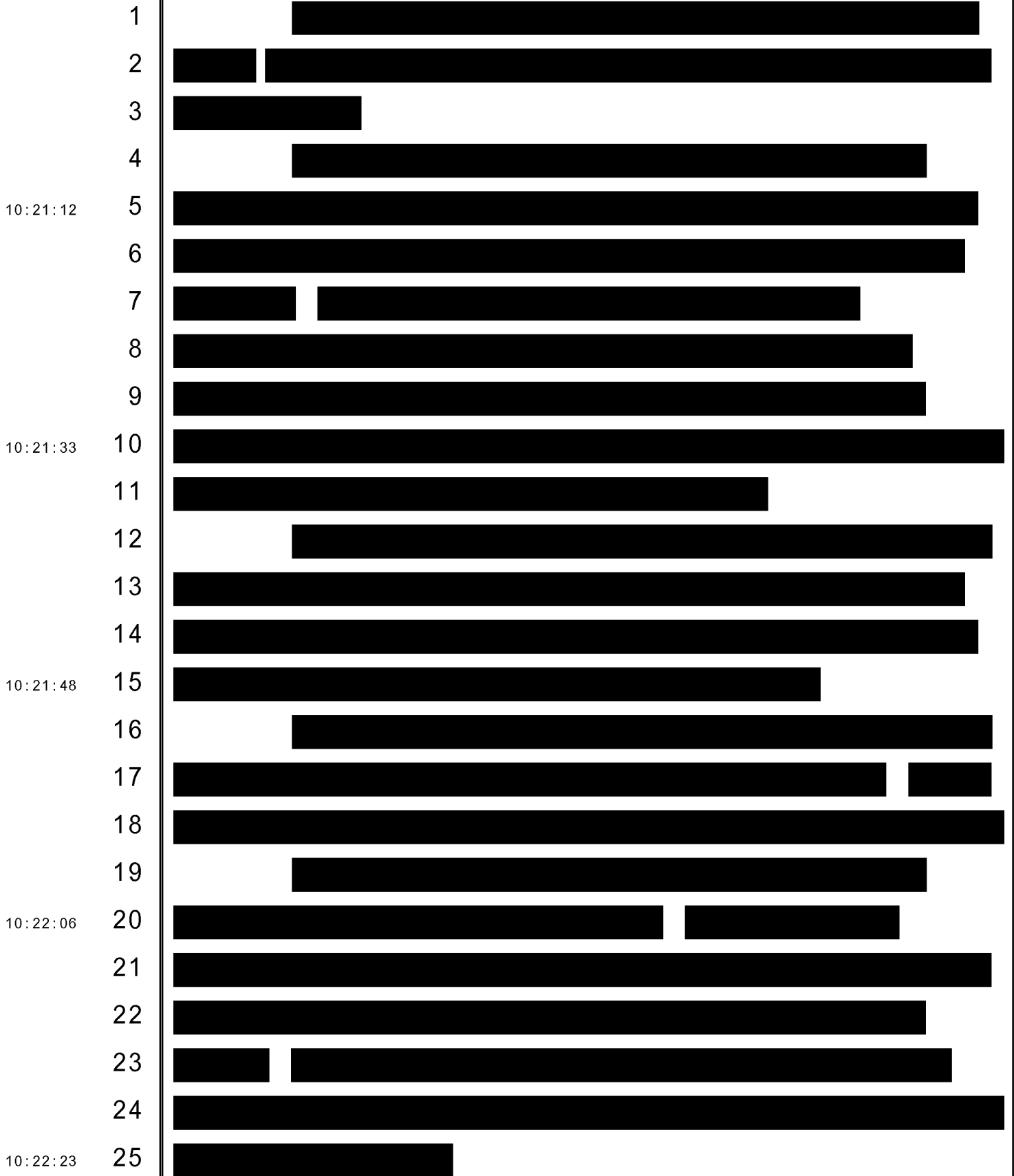
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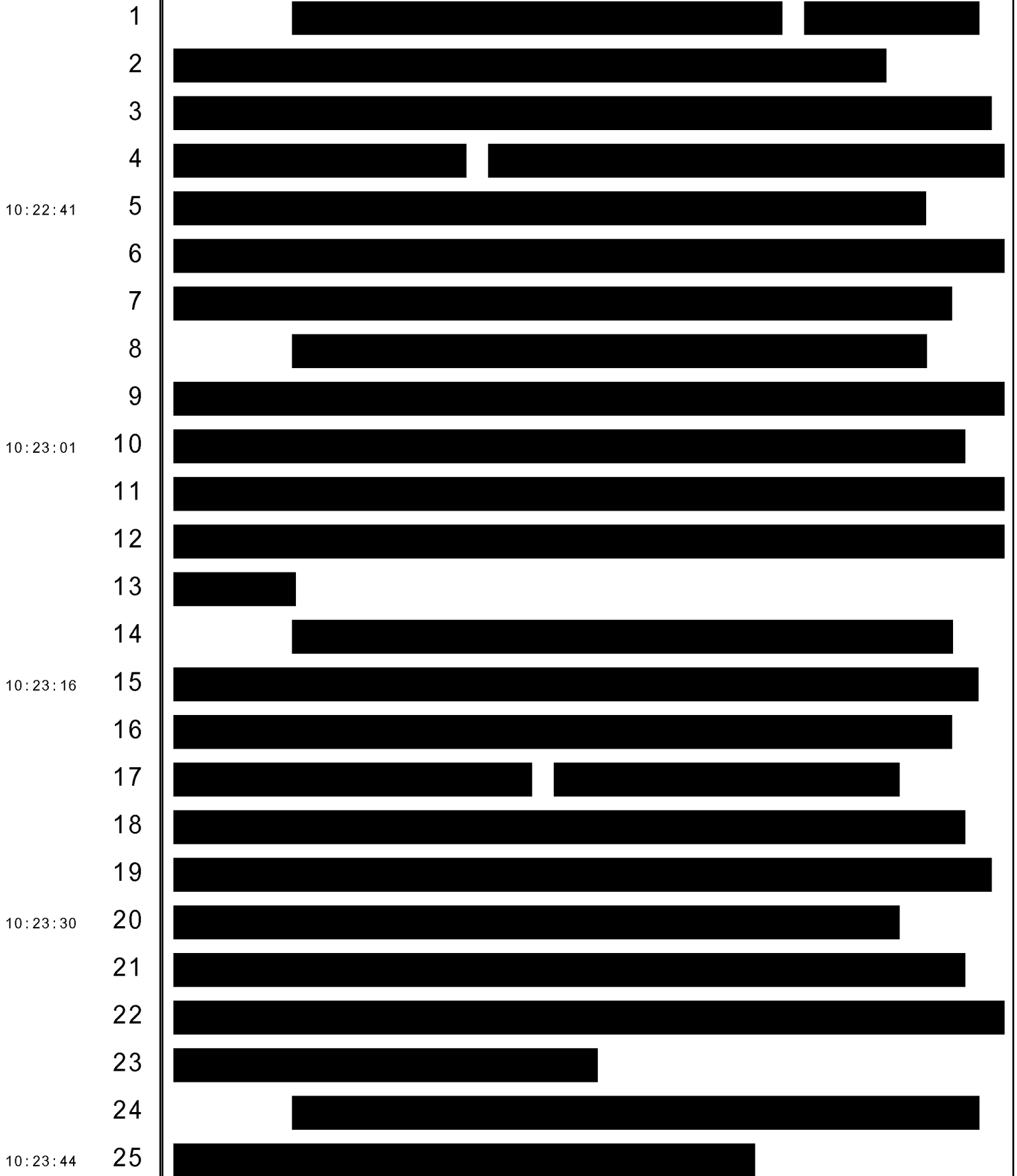
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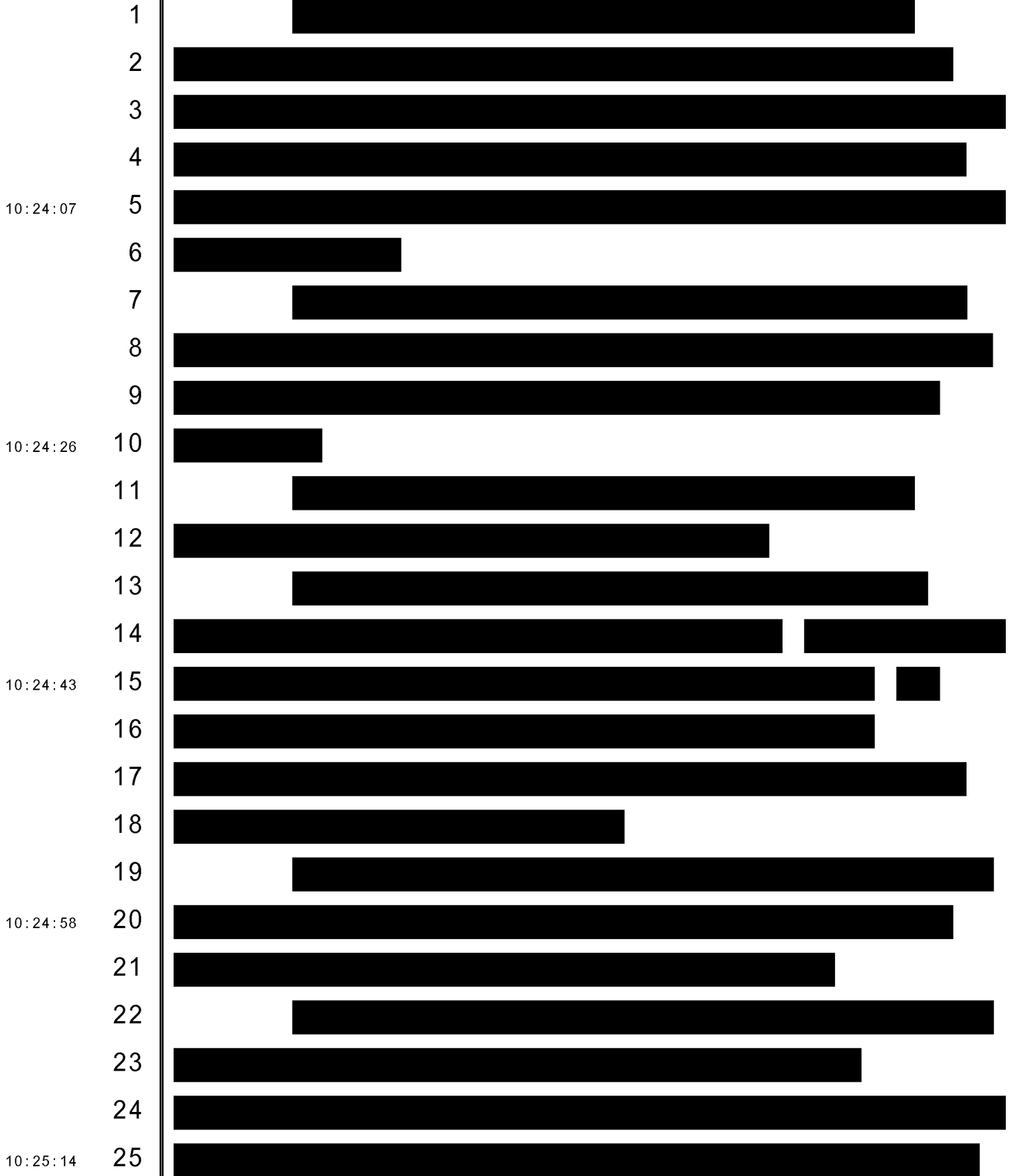


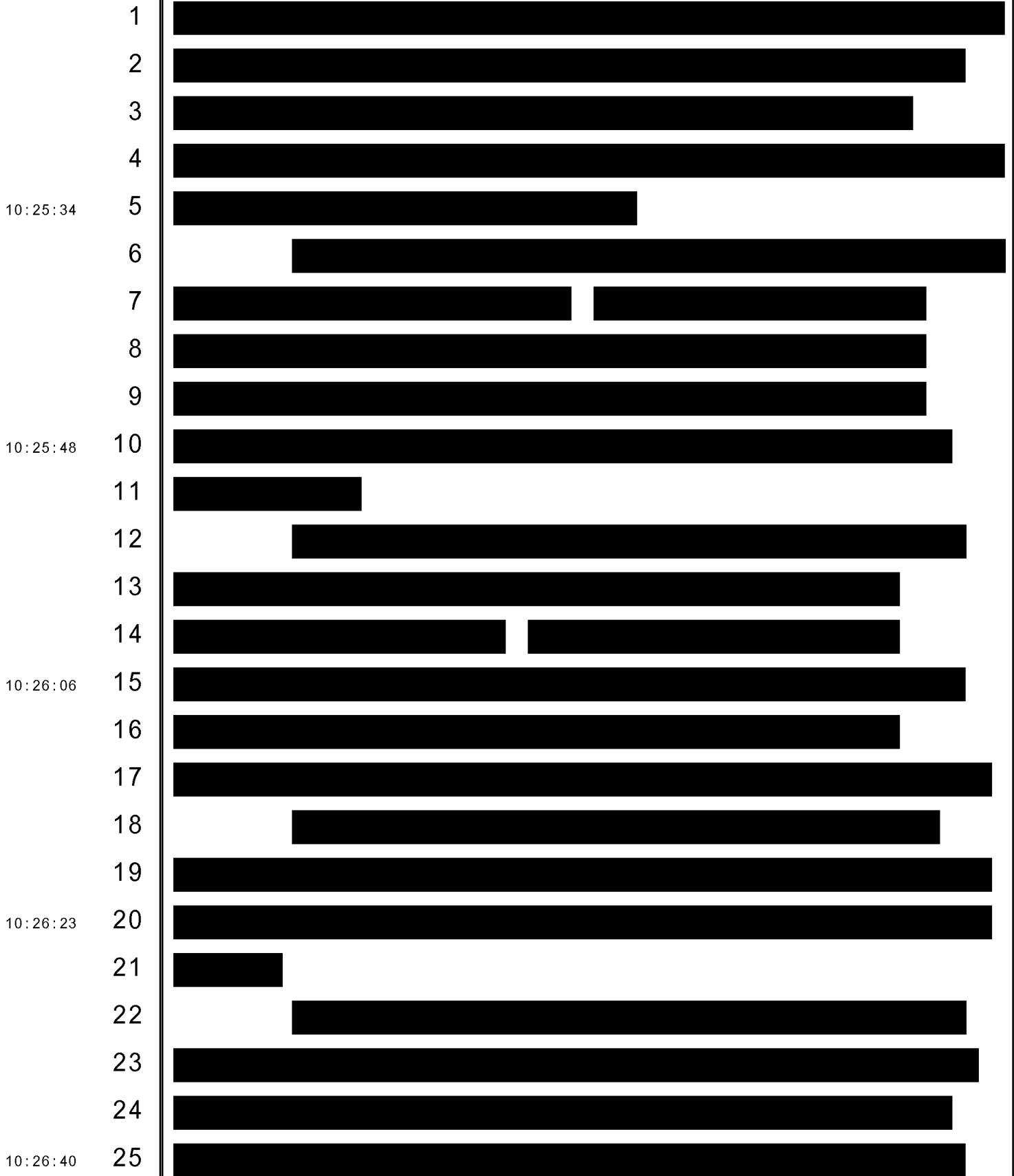


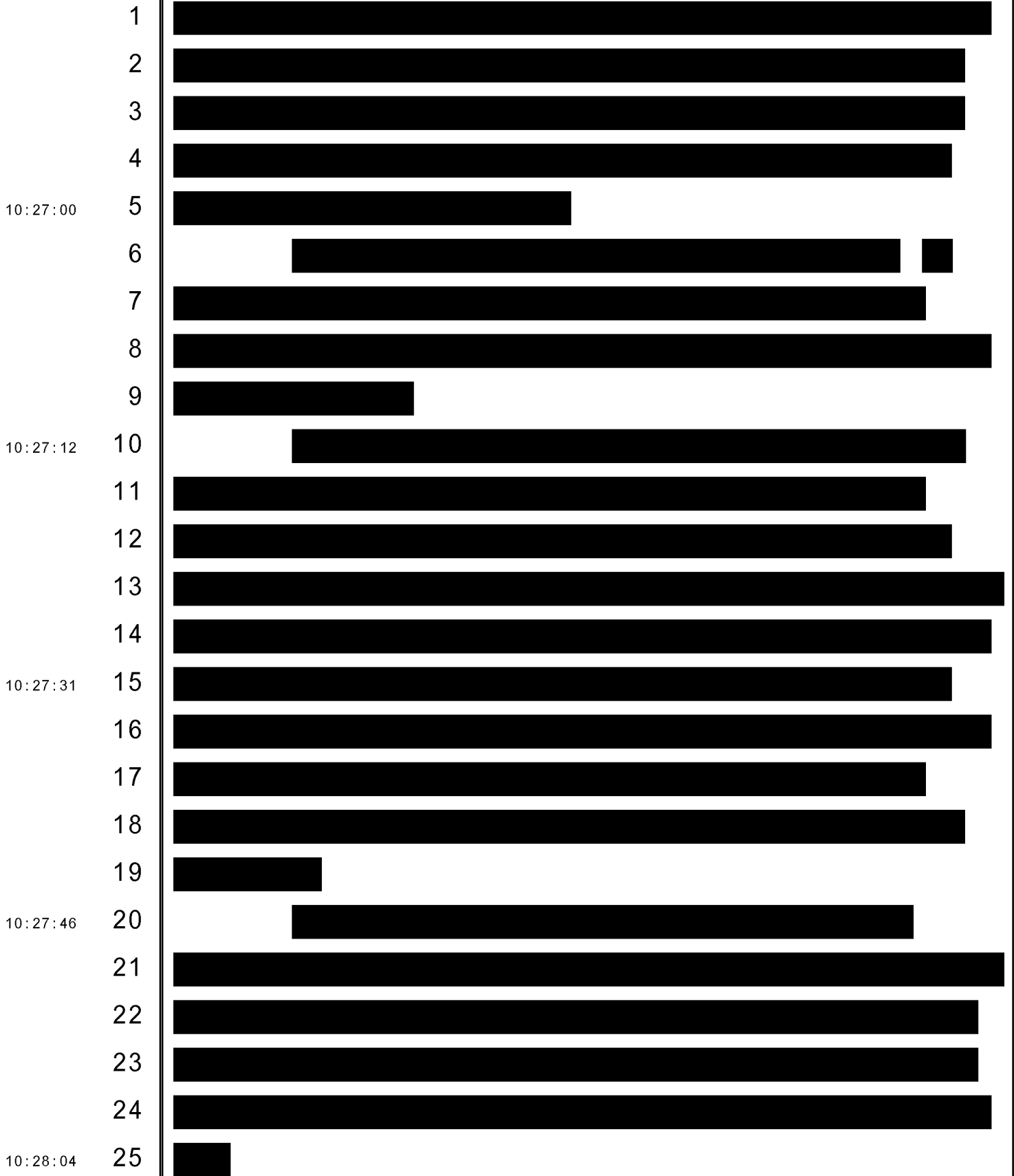


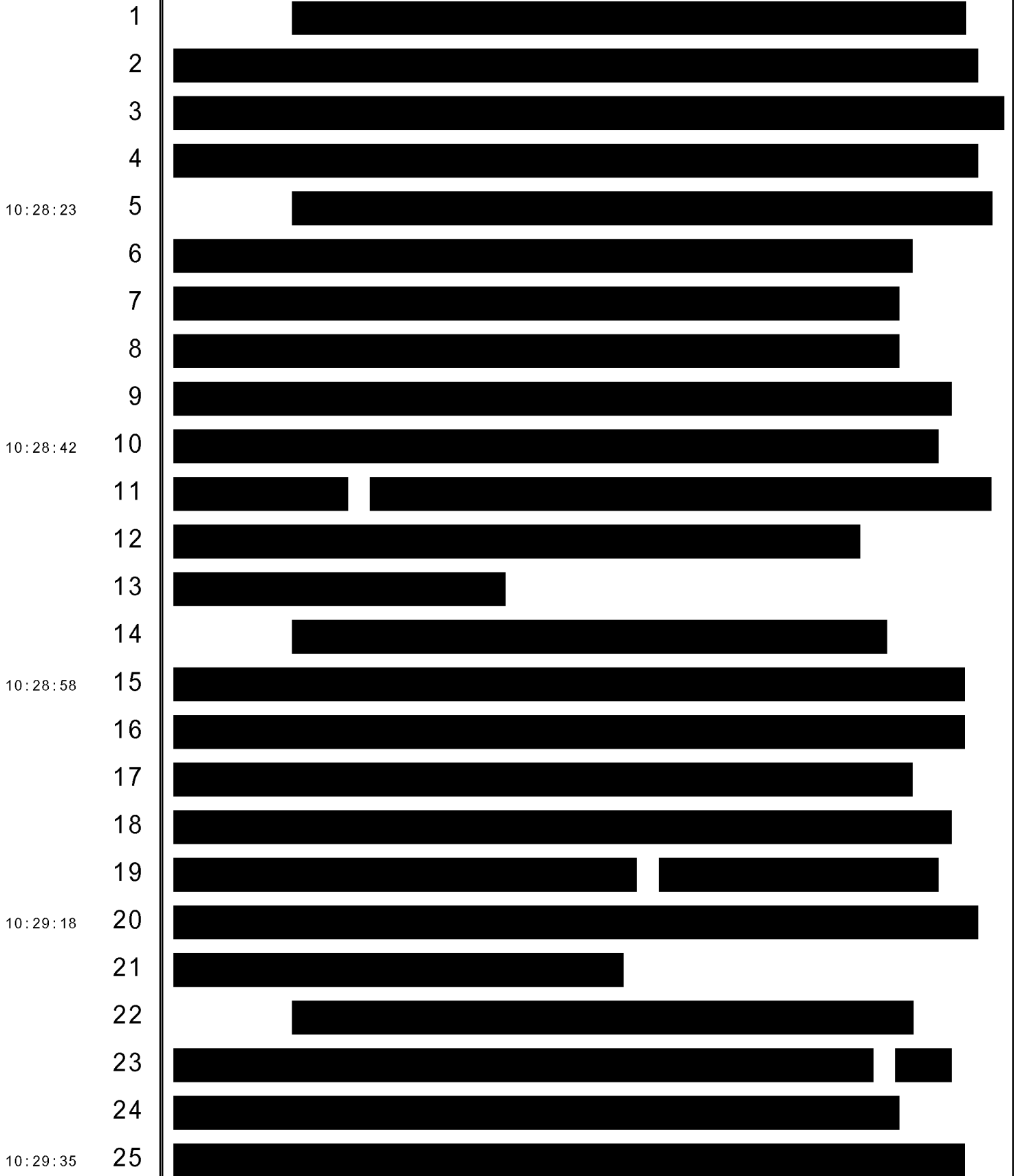


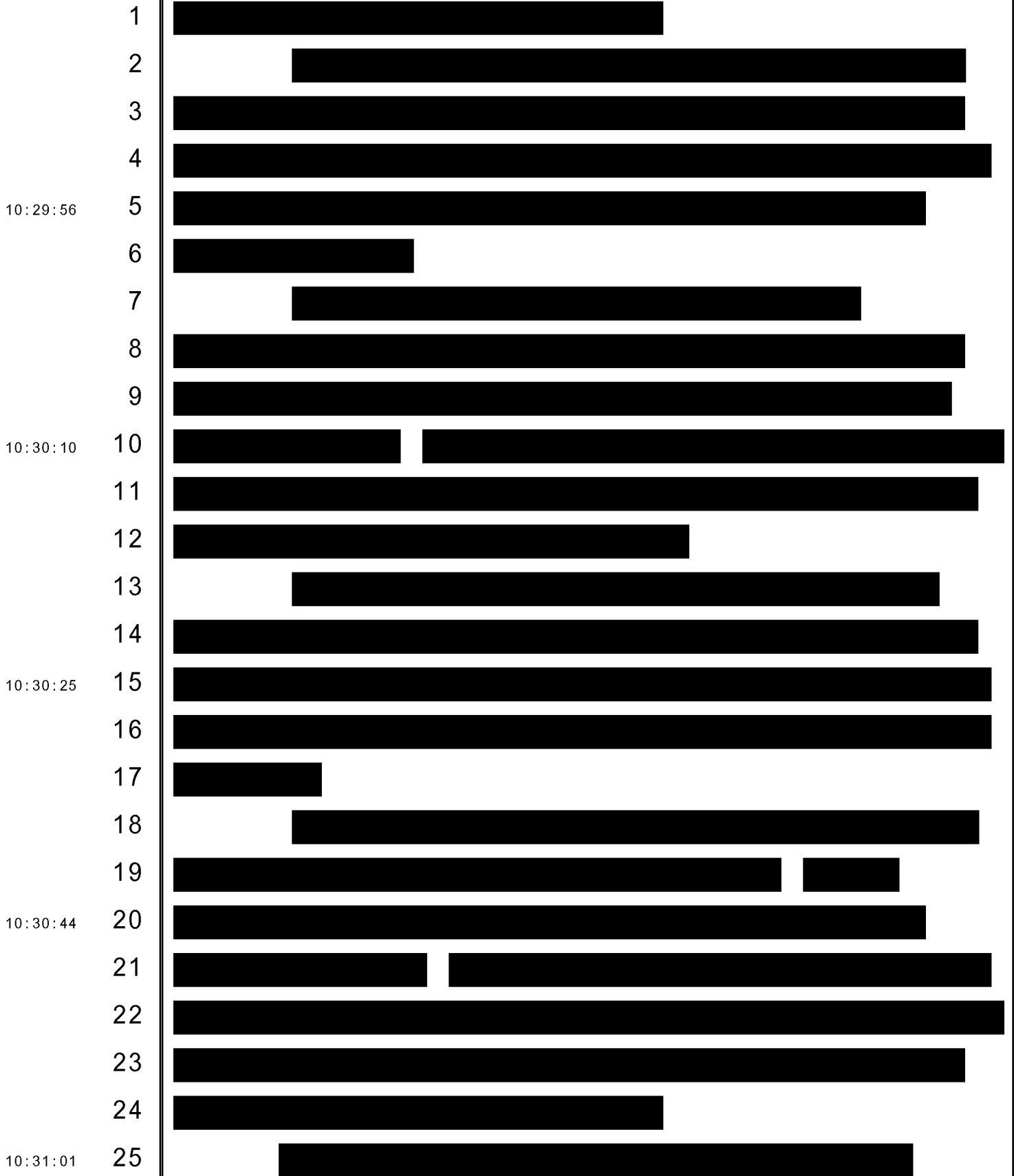


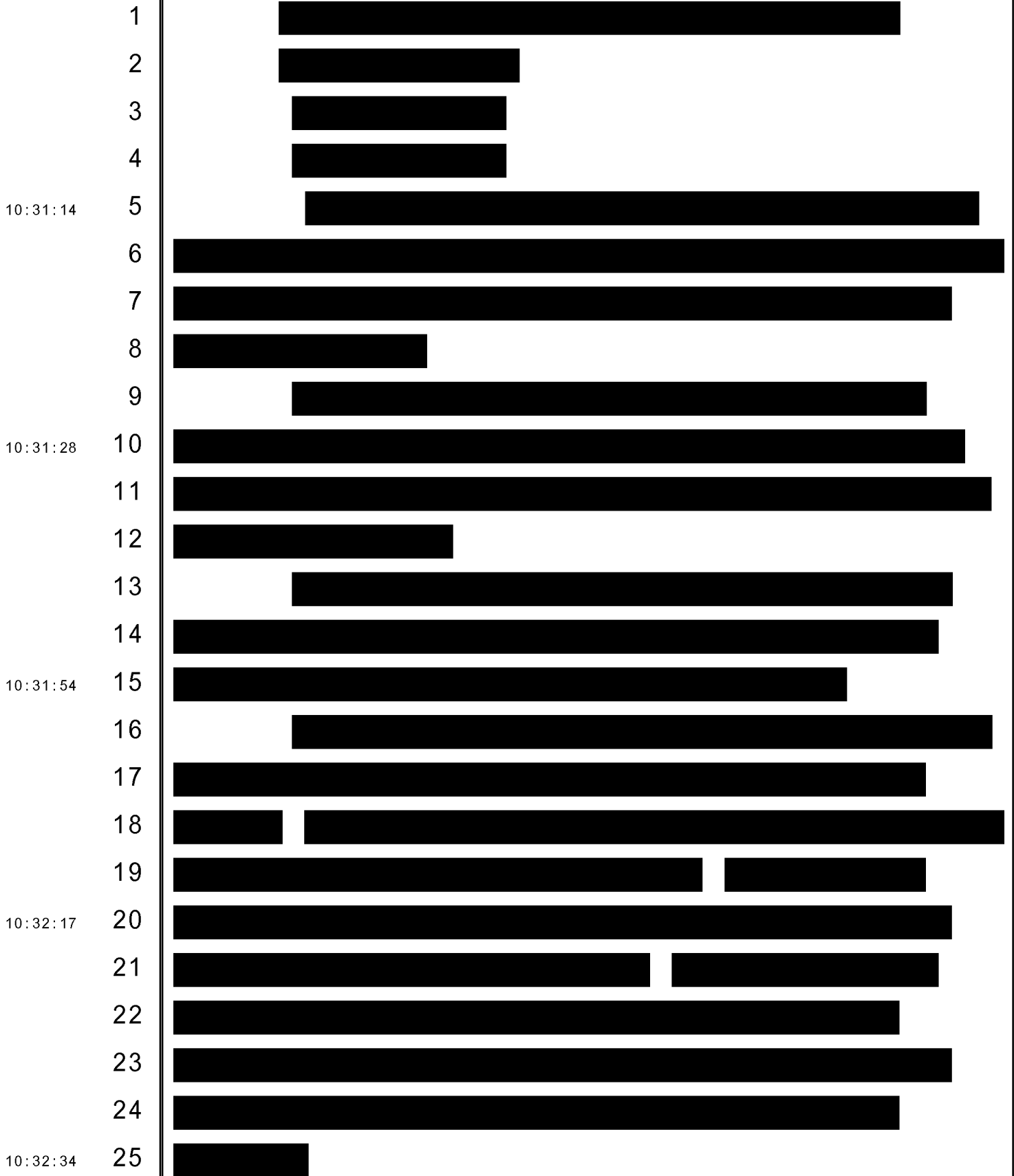


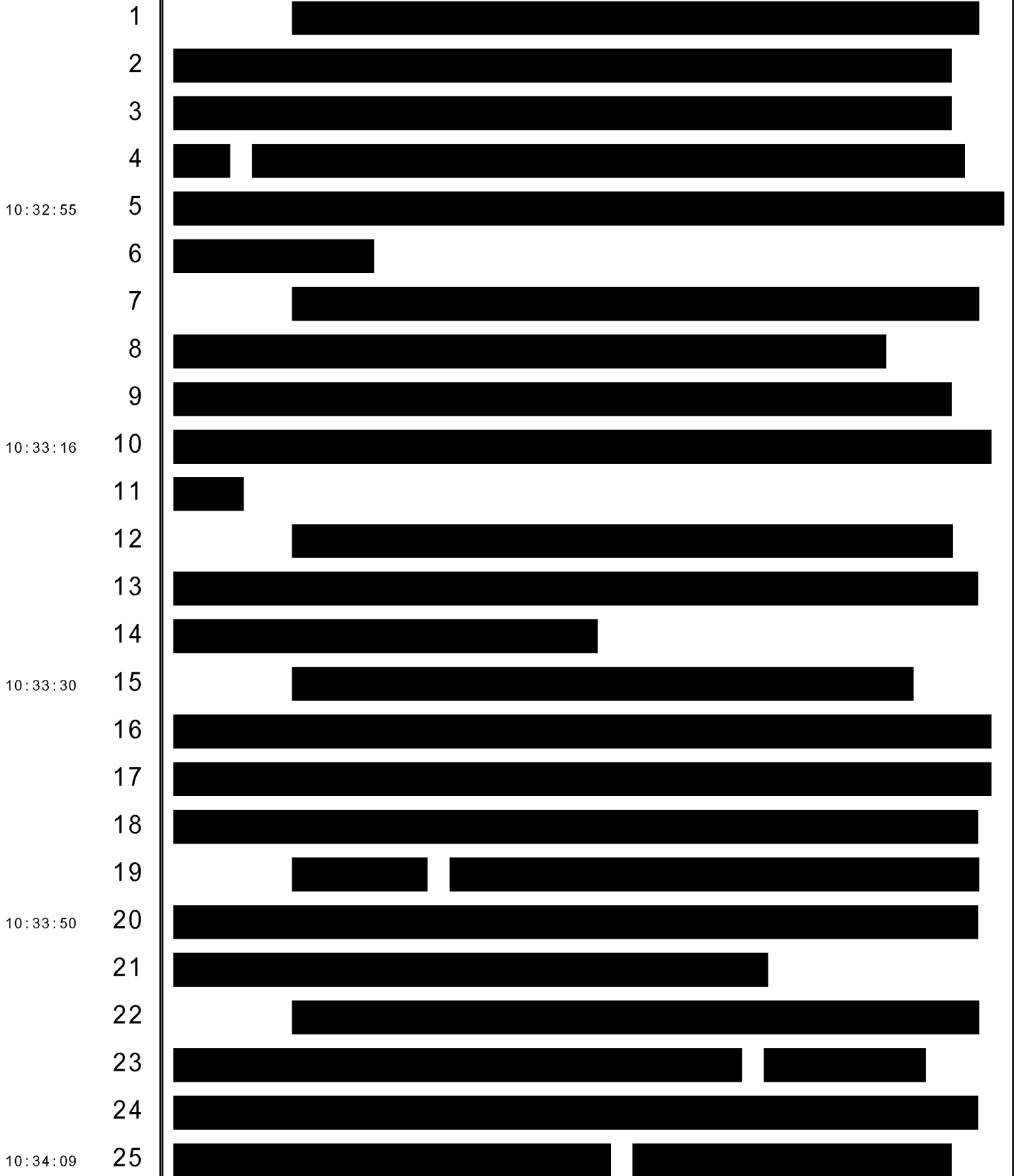


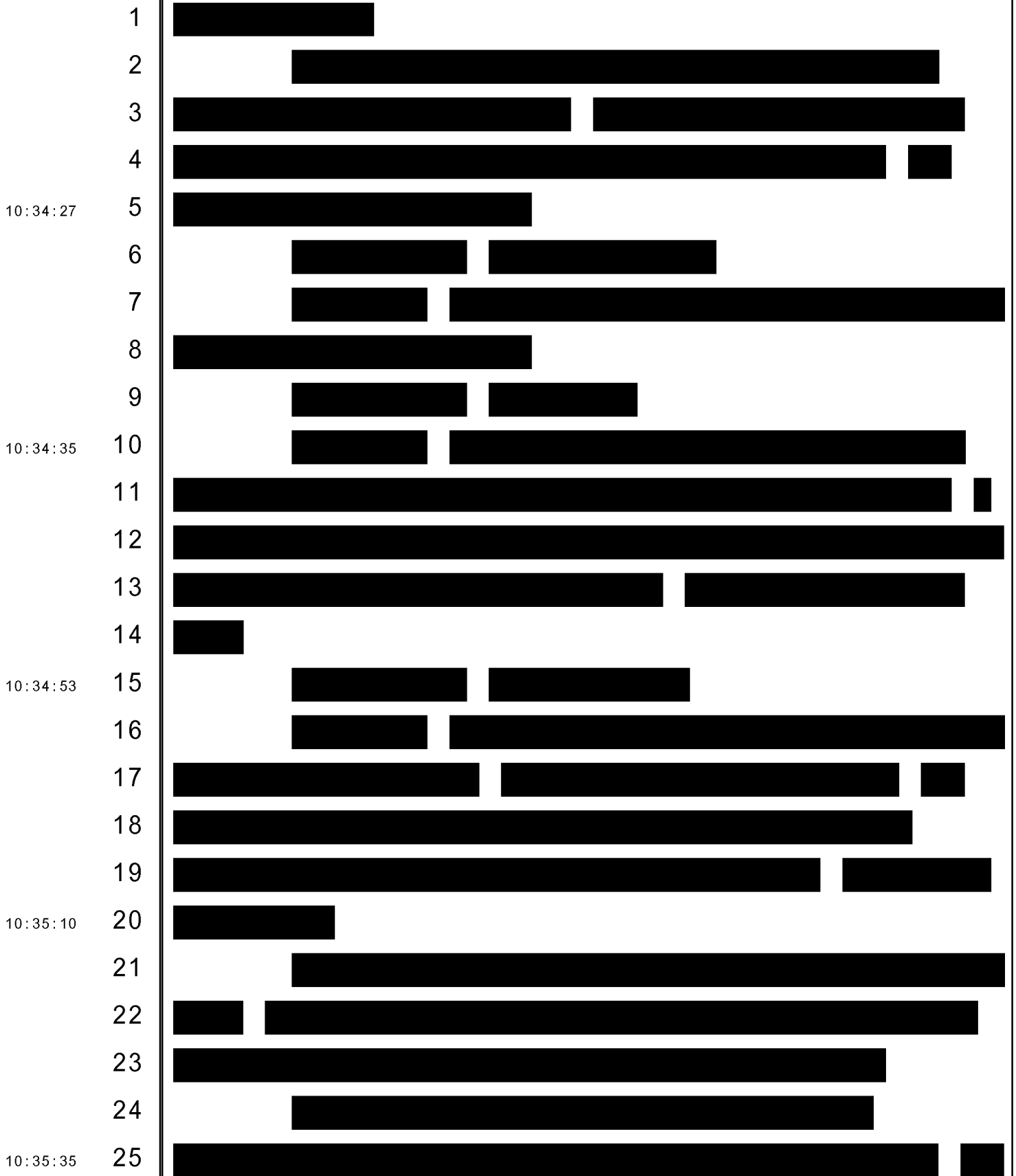


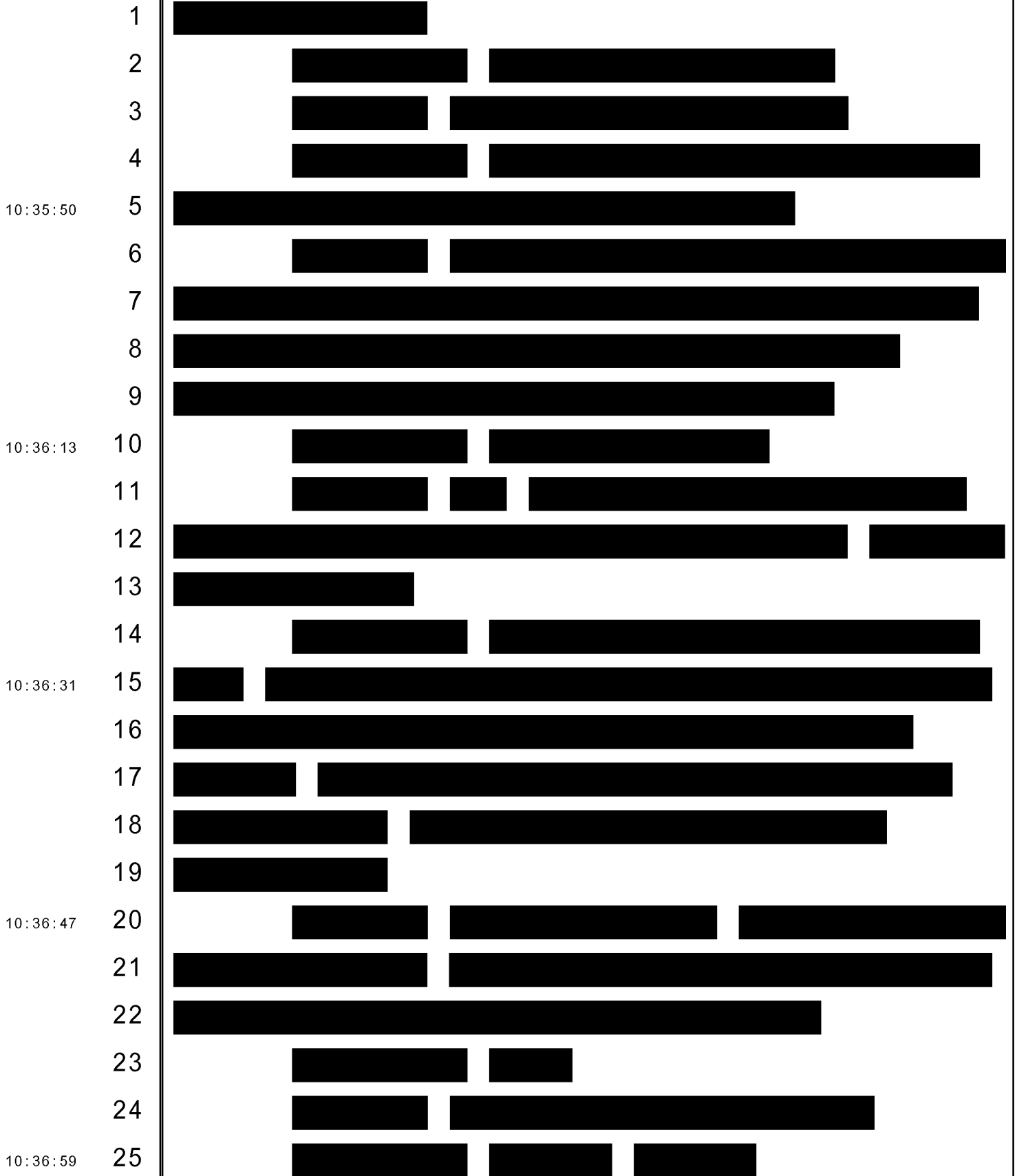




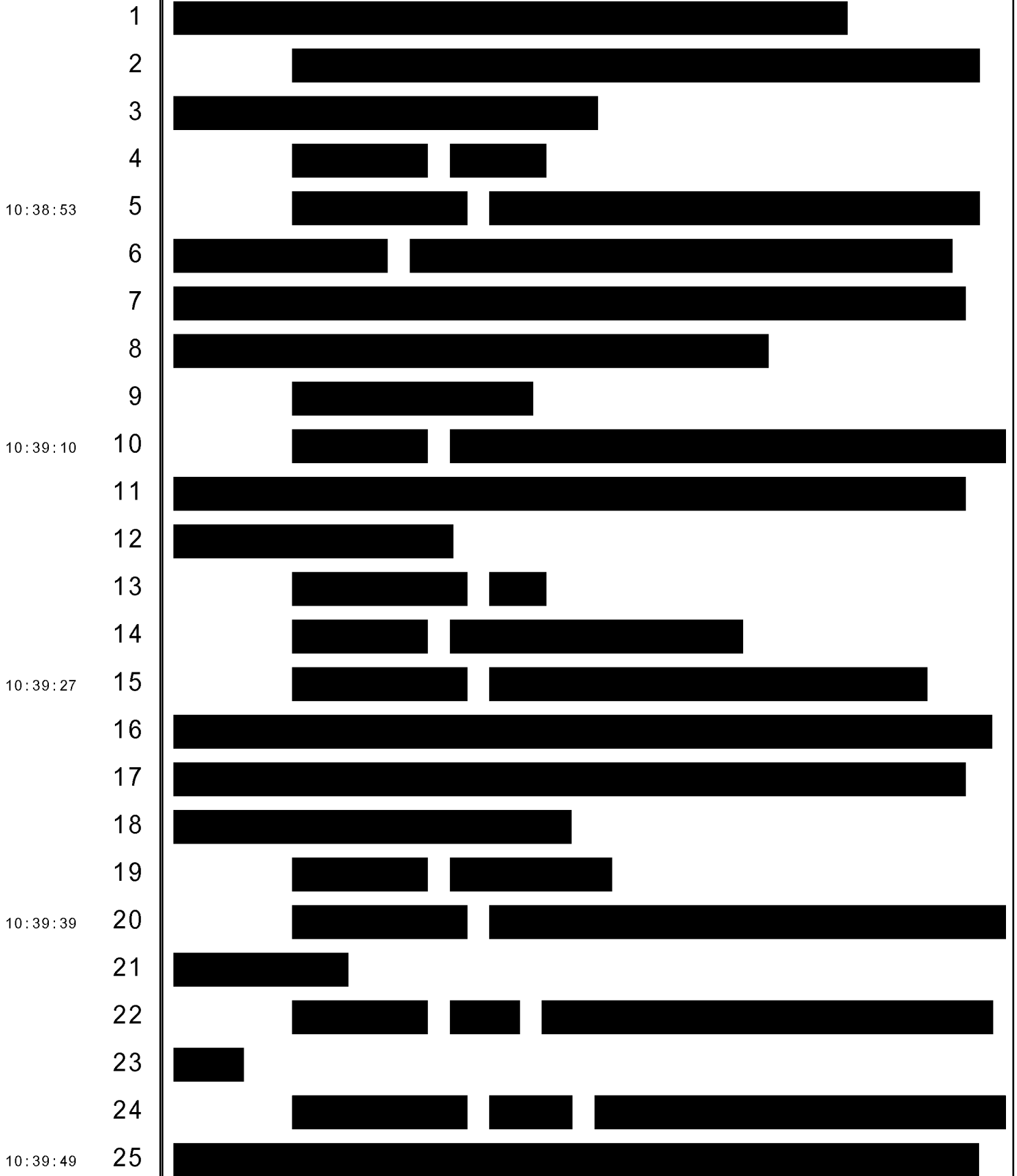


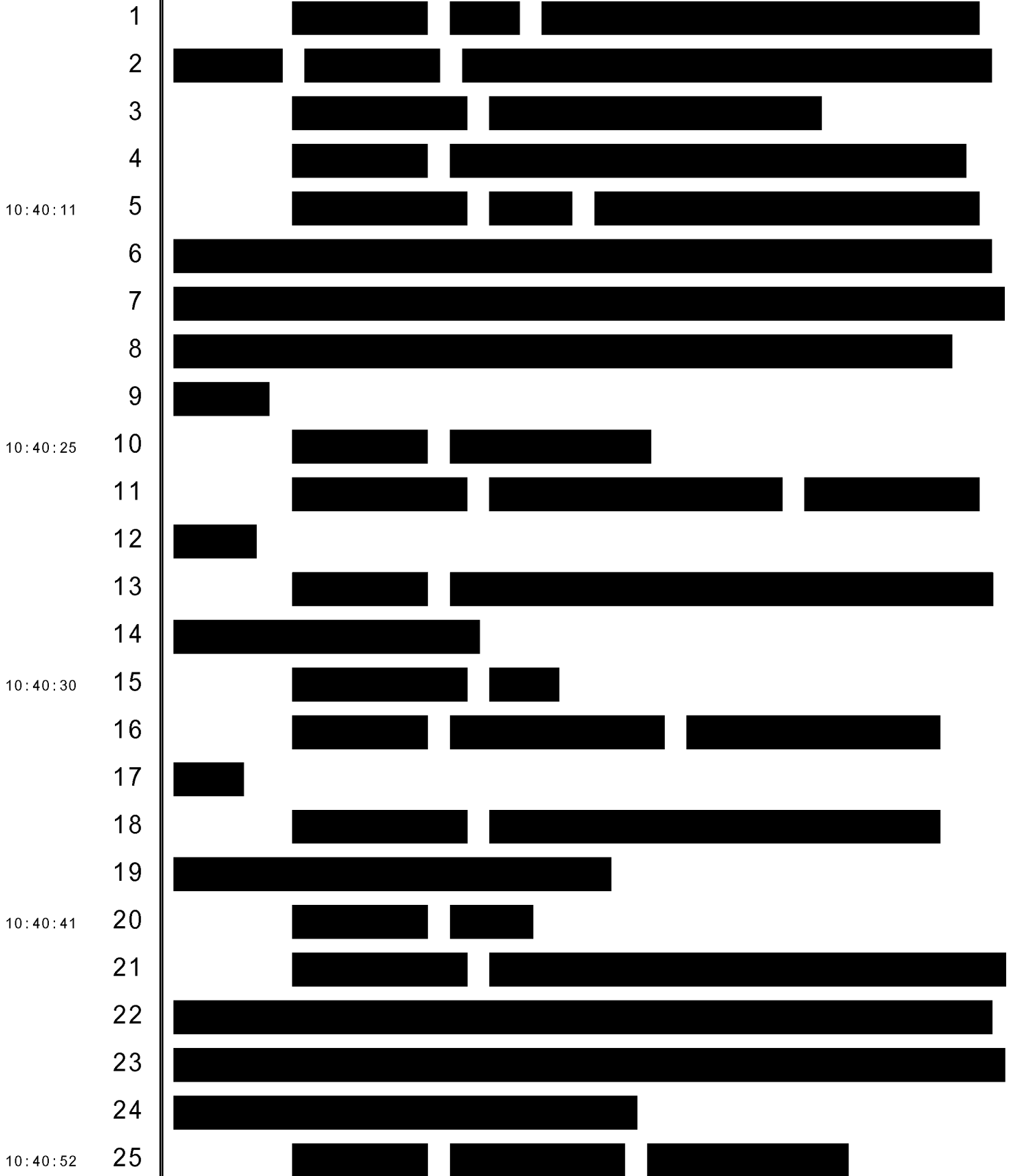


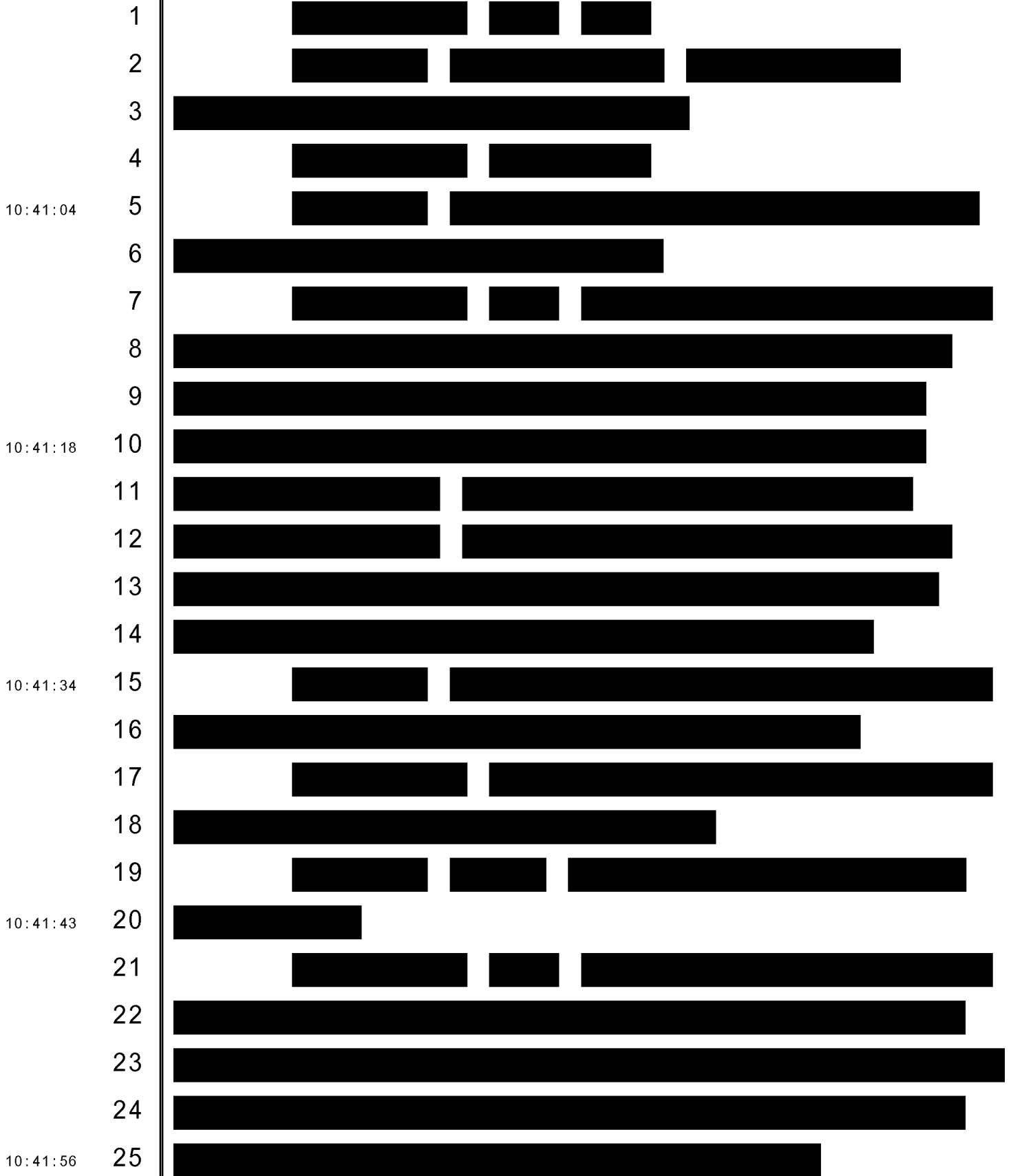


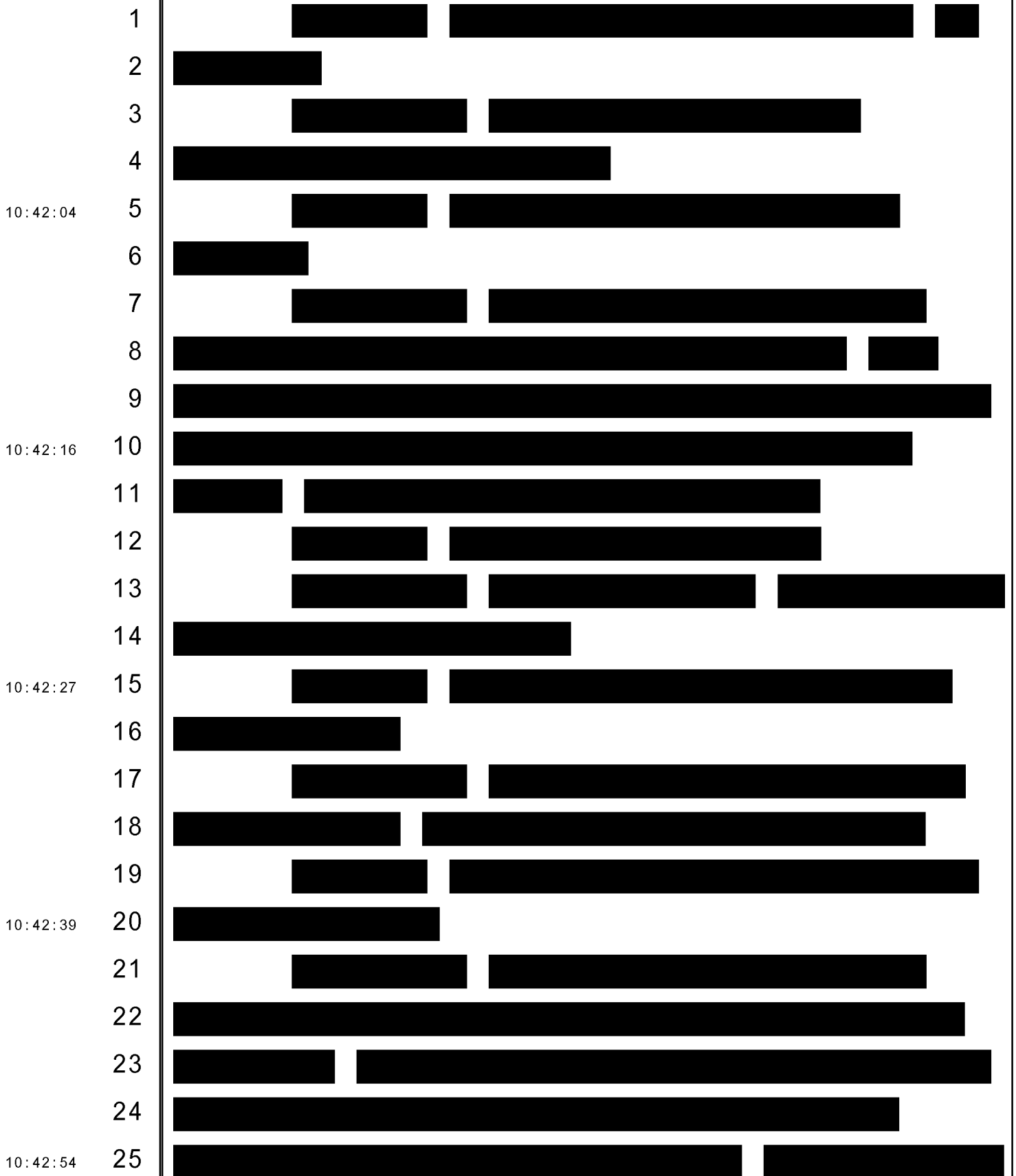


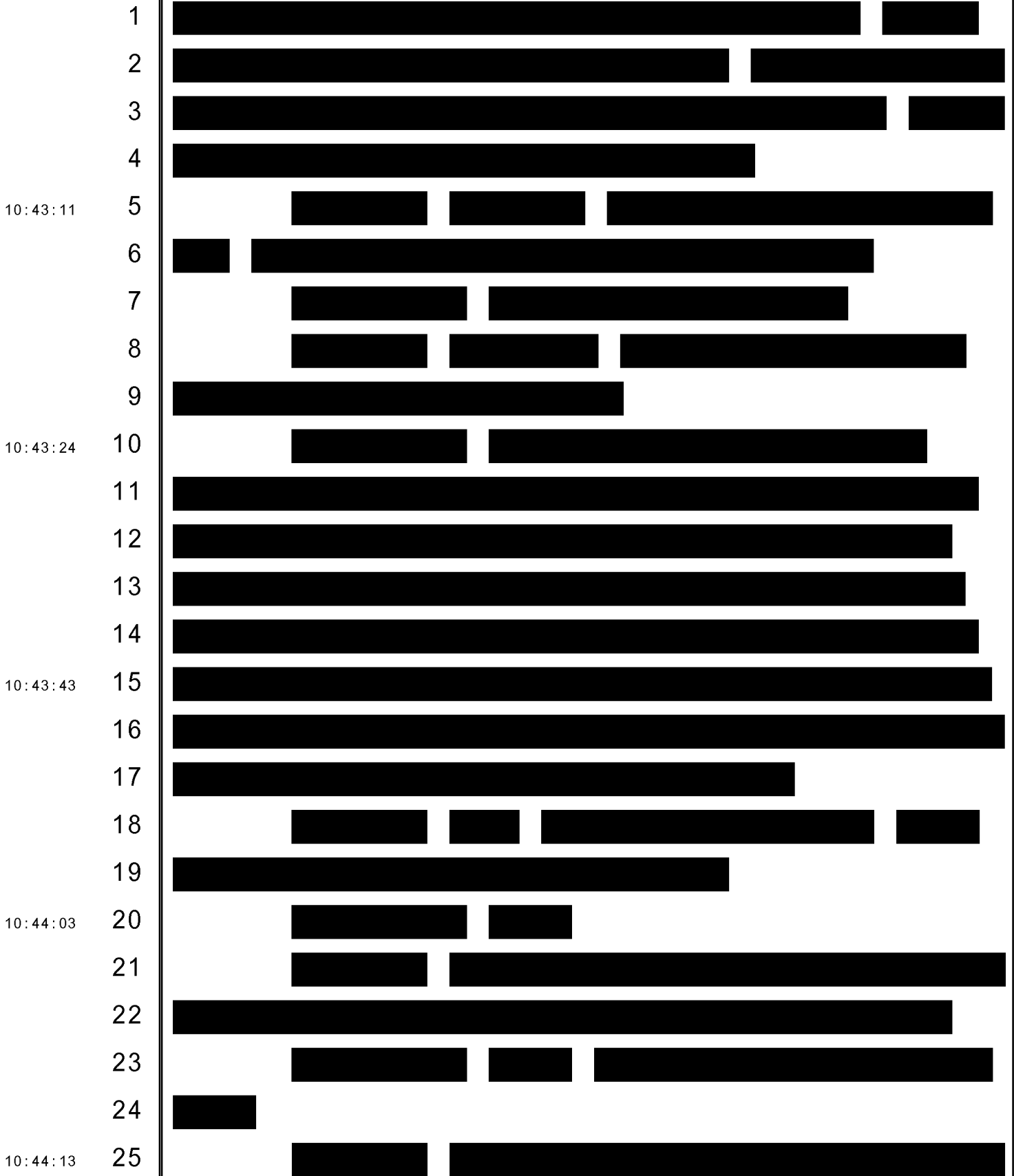
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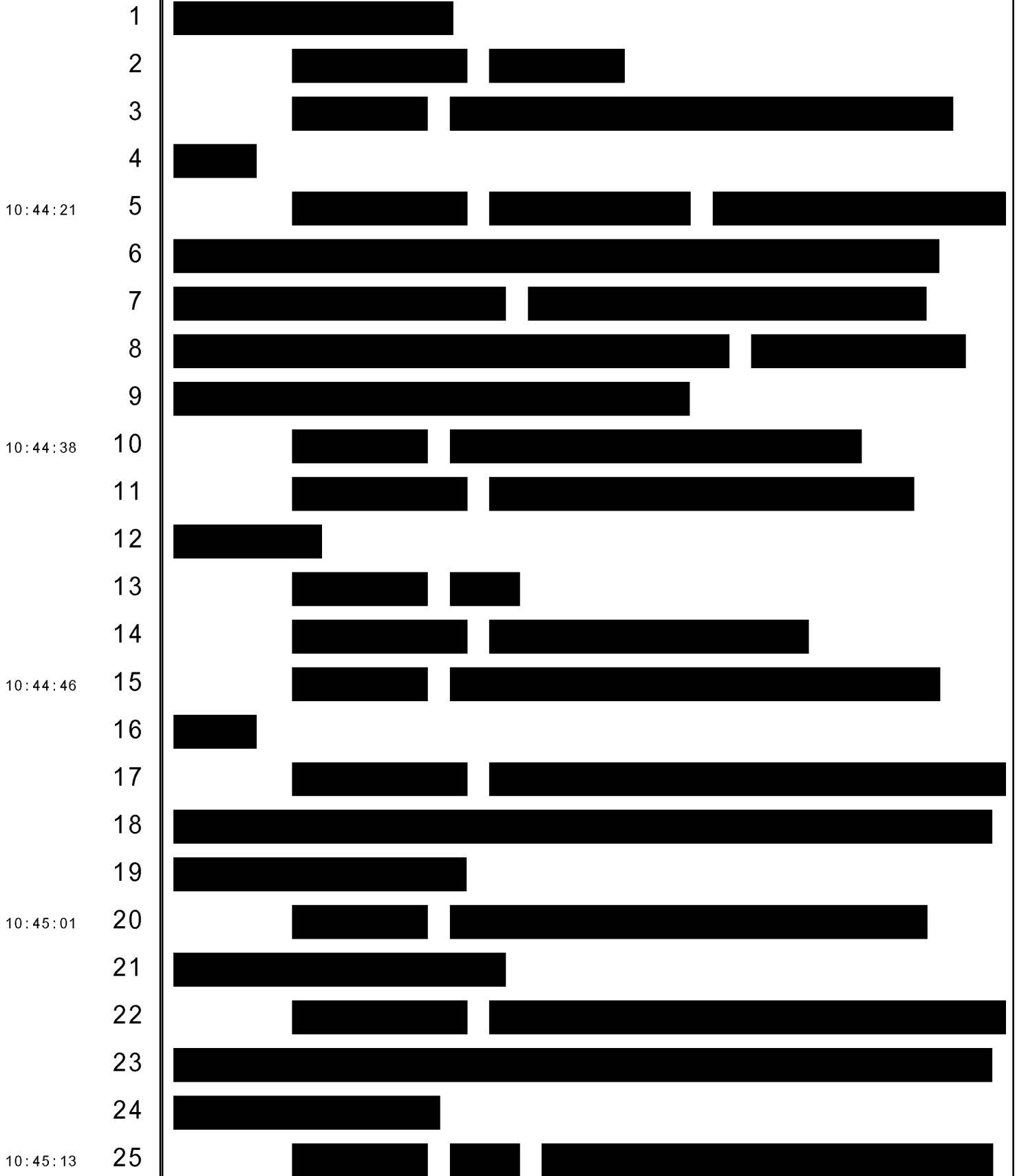


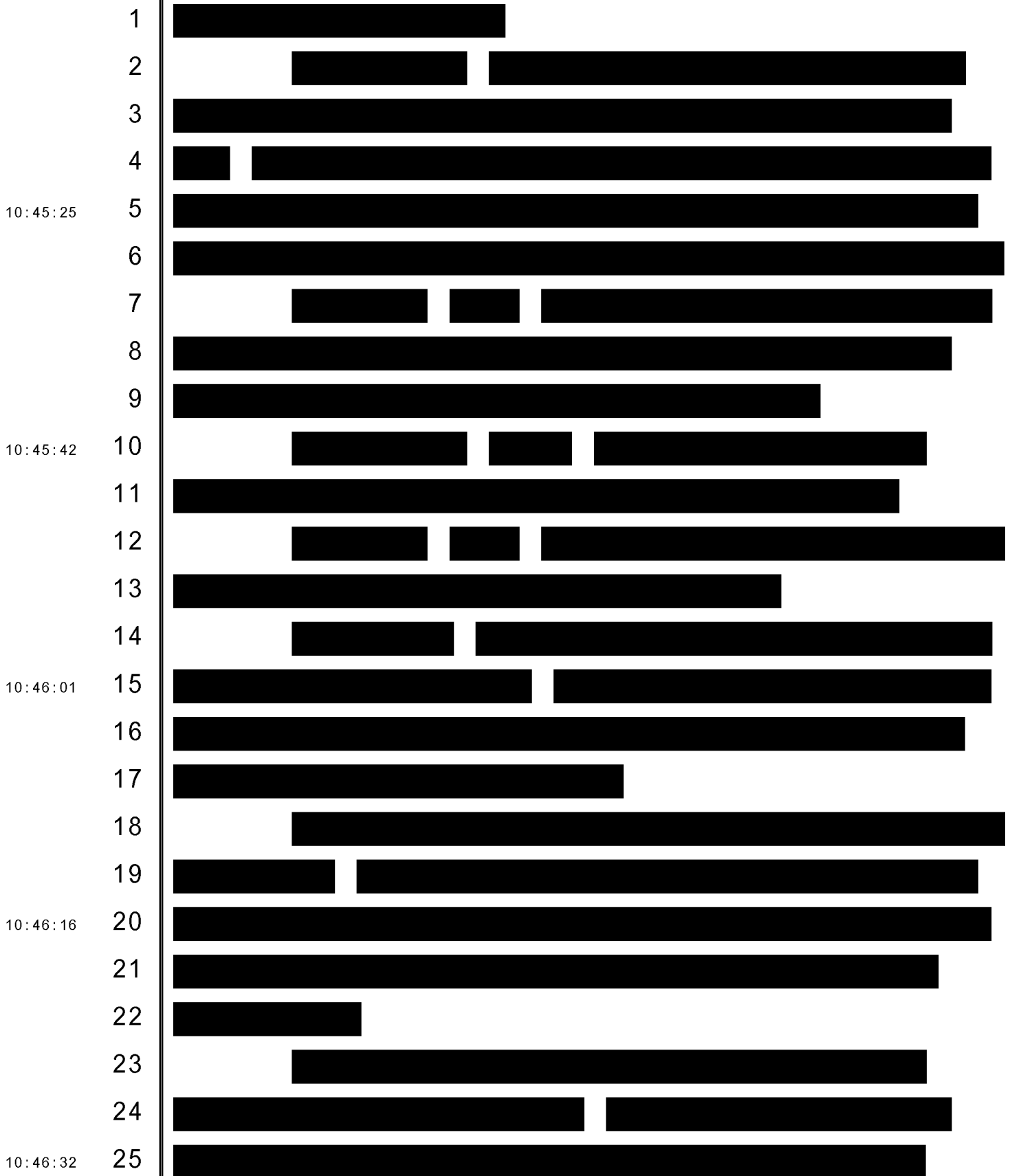


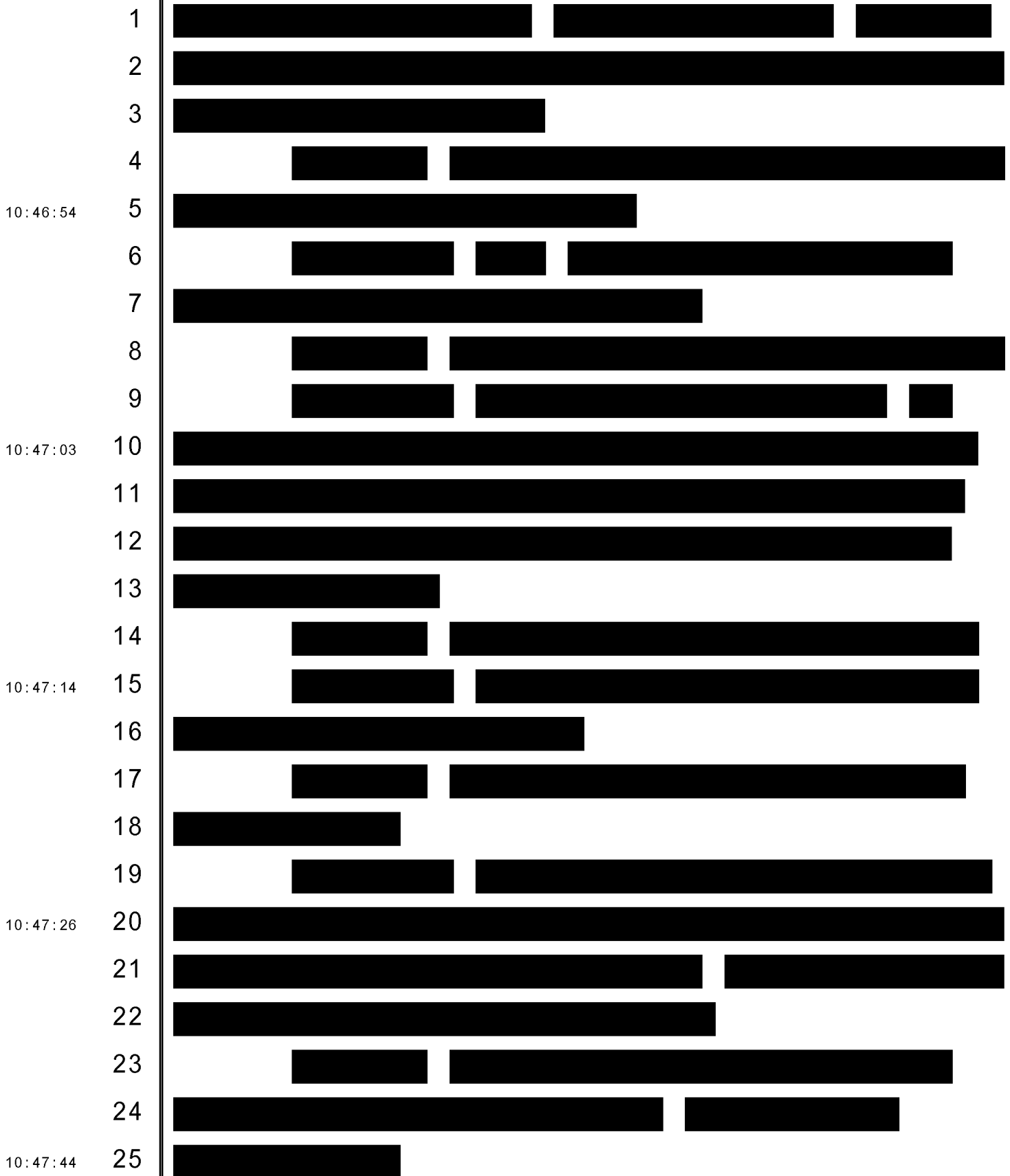




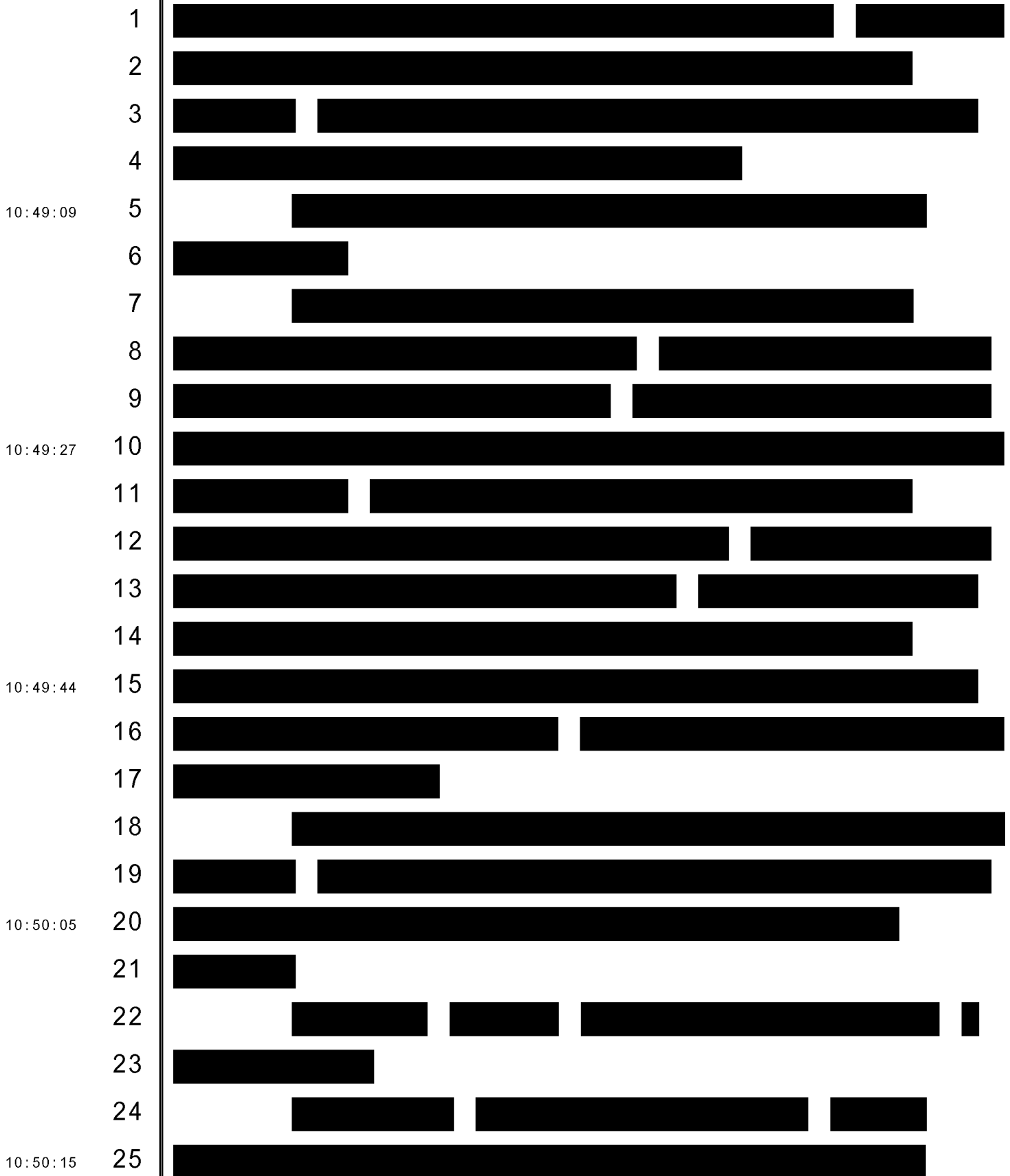


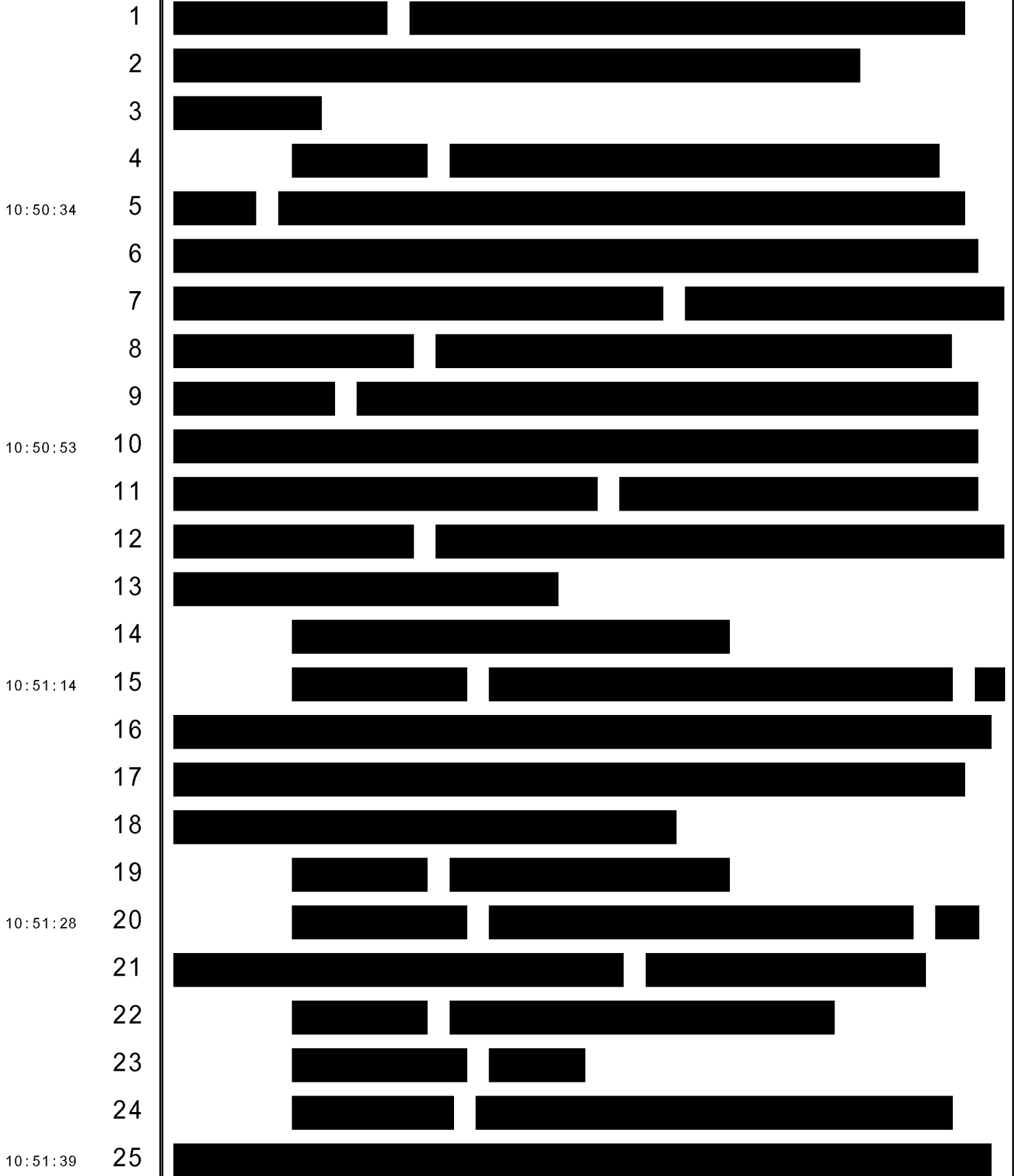






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10:52:39	25	(Recess.)

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

3 [REDACTED] [REDACTED]
4 [REDACTED] [REDACTED]
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6 [REDACTED] [REDACTED]
7 [REDACTED] [REDACTED] [REDACTED]
8 [REDACTED]

11:13:09

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

11:14:09

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

13 Step up here, please, doctor.

14 Please raise your right hand.

11:14:19

15 (Witness duly sworn.)

16 THE COURT: You may take the witness stand.

17 You may proceed, sir.

18 MR. DAVIS: Thank you, Your Honor.

19 ROBERT GIBBONS, DEFENDANT'S WITNESS, SWORN

11:14:31

20 DIRECT EXAMINATION

21 BY MR. DAVIS:

22 Q.

23 Ladies and gentlemen of the jury, counsel:

24 GlaxoSmithKline calls as its first witness Dr. Roberta

11:14:39

25 Gibbons.

1 Dr. Gibbons is the Blum-Riese Professor of
2 biostatistics at the University of Chicago. Dr. Gibbons
3 conducts scientific research and analyses that assess whether a
4 medication or other exposure causes side effects, including
5 suicidal thoughts or behavior.

11:14:55

6 He gives lectures, teaches classes, presents papers to
7 fellow statisticians, as well as to the medical community,
8 particularly psychiatrists, and publishes scientific research
9 in various scientific and medical journals on these issues and
10 other scientific issues about public health.

11:15:11

11 He is a fellow of the American Statistical
12 Association, a fellow of the International Statistical
13 Institute, and a fellow of the Royal Statistical Society.

14 Dr. Gibbons obtained a Bachelor's Degree from the
15 University of Denver in 1976 where he majored in chemistry and
16 mathematics.

11:15:28

17 In 1981, he obtained a Ph.D. in statistics and
18 psychometrics from the University of Chicago.

19 In 2010, after teaching for many years at the
20 University of Illinois as professor of biostatistics, with
21 joint appointments in departments of statistics and psychiatry,
22 Dr. Gibbons joined the faculty of the University of Chicago
23 where he continues to teach and conduct research as a professor
24 of biostatistics.

11:15:43

25 He also continues to hold a position at the University

11:15:58

1 of Illinois as professor Emeritus of biostatistics.

2 In addition to his position as professor of
3 biostatistics, Dr. Gibbons currently works at the University of
4 Chicago as the Director of Center for Health Statistics, a
5 Professor of Medicine, as Professor of Public Health Sciences,
6 and as a Professor of Psychiatry. A major focus of Dr.
7 Gibbons's research has been in the area of drug safety.

8 His statistical work and the methods he has developed
9 have been applied thousands of times in the biological
10 behavioral and social sciences.

11 Dr. Gibbons's worked in the subject of drug safety in
12 general, and suicide in particular, dates back over 30 years.

13 After the leaving the University of Chicago as a
14 graduate student in 1981, he joined the faculty of the
15 University of Illinois at Chicago and had joint appointments at
16 Rush Medical School here in Chicago at both the School of
17 Medicine and the School of Public Health.

18 At Rush he worked with one of the leading researchers
19 in suicide, Dr. Jan Fawcett. And while he worked with Dr.
20 Fawcett they concentrated their research on identifying risk
21 factors and causes for suicidal thoughts and behavior.

22 The Institute of Medicine of the National Academy of
23 Sciences retained Dr. Gibbons to work on a national committee
24 to assess suicide risk and prevention. As part of is work for
25 that National Committee Dr. Gibbons used his expertise in

1 evaluating the scientific literature and data to assess both
2 risk factors and causes for suicidal thoughts and behavior.

3 In 2010, he coauthored a report on these issues. The
4 Institute of Medicine of the National Academy of Sciences are
5 the leading advisers to the federal government on issues
6 relating to our public health. It recruits leading scientists
7 who participate --

8 MR. WISNER: Your Honor, I'm going to object. He's
9 discussing facts about other institutes. This is supposed to
10 be credentials. He has four more pages.

11 THE COURT: Just credentials, sir.

12 MR. DAVIS: Sure.

13 THE COURT: Just go back and give us his credentials.

14 MR. DAVIS: Sure.

15 Dr. Gibbons is one of the statisticians who works with
16 the Institute of Health. And as part of his work for the
17 Institute of Health Dr. Gibbons developed and designed the
18 statistical methods for the analyses of suicidal events --

19 THE COURT: Sir, that will come out later. Give us
20 his background.

21 MR. DAVIS: Yes, sir.

22 THE COURT: Where did he graduate and what are his
23 credentials.

24 MR. DAVIS: Yes. And his --

25 THE COURT: Just that. Then you can bring these other

1 matters out as they may develop on direct.

2 MR. DAVIS: All right. Thank you.

3 Dr. Gibbons is a member of the American College of
4 Neuropsychopharmacology that leading professional organizations
5 that assesses the risk of psychiatric medications.

11:18:37

6 He has been an invited speaker of the American College
7 of Neuropsychopharmacology, to speak at that organization's
8 meetings about his research and his work in the area of
9 antidepressants and whether they cause the risk of suicidal
10 thoughts or behavior --

11:18:56

11 MR. WISNER: Your Honor, can we move this along? I
12 mean, we're about to learn the name of his children and his
13 dogs.

14 MR. DAVIS: I'm not sure this has to do with children
15 and dogs, but I'll move it along.

11:19:03

16 Dr. Gibbons has authored and co-authored over 290
17 peer-reviewed publications which have appeared in various
18 well-regarded journals in the field of medicine, psychiatry,
19 public health and statistics. Those include the Journal of
20 Clinical Psychiatry, the Journal of American Medical
21 Association, the American Journal of Public Health, and the
22 Journal of Statistics in Medicine, and the Journal of American
23 Statistical Association.

11:19:20

24 In addition to authoring hundreds of scientific
25 articles, Dr. Gibbons has also served in the editorial boards

11:19:32

1 of scientific journals that are charged with the responsibility
2 of reviewing the work of other scientists to make sure it's
3 worthy of publication.

11:19:47

4 Those journals include the American medical
5 Association for Psychiatry and the Health Services and Outcome
6 Research Journal.

11:19:59

7 He has also published five leading textbooks on
8 statistical methods, including how to assess and interpret
9 scientific information in the areas of medicine and public
10 health.

11:20:11

11 His most recent book is called Statistical Methods For
12 Drug Safety which was published in 2016, and is the only
13 statistical textbook devoted exclusively to assessing drug
14 safety.

15 This textbook analyzes how to interpret and assess
16 scientific studies, including randomized placebo-controlled
17 trials, metaanalyses, observational studies, and other
18 scientific information so as to make determinations of
19 whether --

11:20:25

20 MR. WISNER: Objection, Your Honor. He's talking
21 about the content of a textbook.

22 MR. DAVIS: Just background information.

23 MR. WISNER: This is not credentials. This is just
24 full-on argument.

11:20:33

25 THE COURT: That is argument, sir.

1 MR. DAVIS: I'm sorry.

2 THE COURT: That may come out later in your inquiry,
3 I'll be surprised if it doesn't, but tell us now about his
4 background credentials.

11:20:41

5 MR. DAVIS: Yes.

6 THE COURT: Where did he go to school and all that
7 sort of thing --

8 MR. DAVIS: Yes, sir.

9 THE COURT: -- please.

11:20:47

10 MR. DAVIS: Over the course of his career, Dr. Gibbons
11 has been honored many times by academic and professional
12 organizations, and I will bring that out with the question.

13 THE COURT: I'm sure you will.

14 BY MR. DAVIS:

11:20:59

15 Q. Dr. Gibbons --

16 MR. WISNER: Your Honor, I object.

17 THE COURT: I haven't heard his credentials yet.

18 MR. DAVIS: Yes, Your Honor. He went to --

19 THE COURT: Tell me where --

11:21:08

20 MR. DAVIS: He went was in --

21 THE COURT: That's what I want to hear.

22 MR. DAVIS: He went to the University of Colorado in
23 1981. He joined the faculty.

24 THE COURT: Okay. Is he an M.D.?

11:21:10

25 MR. DAVIS: No, sir, he's not.

1 THE COURT: A Ph.D.?

2 MR. DAVIS: Yes, sir.

3 THE COURT: Okay. Any other degrees?

4 MR. DAVIS: Biostatistics.

11:21:23

5 THE COURT: Biostatistics, okay, fine.

6 MR. WISNER: Your Honor, at this time we move to
7 strike this witness's testimony in its entirety. He is an
8 admitted not an expert in suicide, as well as not being a
9 medical doctor. He's being offered to offer testimony about a
10 drug he cannot prescribe to treat conditions he cannot treat.

11:21:39

11 THE COURT: Overruled, sir.

12 MR. DAVIS: Thank you, Your Honor.

13 BY MR. DAVIS:

14 Q. Dr. Gibbons, would you please introduce yourself to the
15 jury.

11:21:50

16 A. Hi. My name is Robert Gibbons and I'm a professor at the
17 University of Chicago.

18 Q. Dr. Gibbons, what type of doctor are you?

19 A. I have a Ph.D. in statistics from the University of Chicago
20 which I received in 1981, and I have been a professor of
21 biostatistics since that time.

11:22:01

22 Q. How long have you lived in the Chicago area?

23 A. 61 years.

24 Q. And what do you do for a living?

11:22:14

25 A. I'm a professor of biostatistics at the University of

1 Chicago. I'm the Blum-Riese Professor of Medicine and
2 Biostatistics at the University of Chicago.

3 Q. Have you done research in the area of drug safety?

4 A. Extensively, yes.

11:22:27

5 Q. And have you done -- does your work include whether
6 medications cause suicidal thoughts or behavior?

7 A. Yes, that is one of the fundamental areas of my work. Not
8 only suicide, but a wide variety of adverse effects.

11:22:48

9 Q. Have you done any research and work in the area of mental
10 health and the prevention of suicide?

11 A. Yes. Mental health has always been a major focus of the
12 application of my statistical work. I founded the mental
13 health statistic section of the American Statistical
14 Association, which now I understand has over 700 members.

11:23:05

15 Q. How long have you been involved in research and
16 investigating causes of suicidal thoughts or behavior?

17 A. The early work with Jan Fawcett from Rush Medical School.
18 Jan was the chairman of the Department of Psychiatry and
19 absolutely delightful clinician and scientist. He was a part

11:23:29

20 of the National Institute of Mental Health, collaborative study
21 of psychobiology of depression which established a large cohort
22 of about 1,000 patients that were followed for over 27 years.

23 And so early on we were trying to determine if there
24 was a way we could identify symptoms that people had that might
25 lead to suicidal thoughts and behavior, and that was really the

11:23:48

1 primary focus of our work at that time. This is probably in
2 1981 through 1985.

3 Q. Dr. Gibbons, have you worked at all with the National
4 Institute of Mental Health?

11:24:03

5 A. Yes, we receive continuous funding from the National
6 Institute of Mental Health of mental health for many, many
7 years in a variety of areas related to statistical developments
8 in the area of mental health in general. And also a lot of
9 work and separate grants for looking at drug safety, what are
10 the methods by which we can determine whether or not there's a
11 causal association between a particular exposure, like taking a
12 drug, and an adverse event, like suicidal thoughts, behavior
13 and completion.

11:24:28

14 Q. Have other federal government -- other federal agencies
15 reached out to you to retain your expertise in assessing
16 scientific information and how to analyze studies to assess
17 whether a medication or other exposure causes an outcome?

11:24:45

18 MR. WISNER: Objection; Compound and leading.

19 THE COURT: Yes, it has those.

11:25:04

20 MR. DAVIS: I'll rephrase.

21 THE COURT: Rephrase.

22 MR. DAVIS: Sure.

23 BY MR. DAVIS:

24 Q. Dr. Gibbons, have other federal agencies retained your your
25 services on the issues of analyzing scientific data?

11:25:10

1 A. Yes, they have.

2 Q. Have some of those agencies specifically retained you for
3 purposes of assessing the risk and causes of suicide?

4 A. Yes, they have.

11:25:23

5 Q. Has that included the study and analysis of whether
6 medications, such as selective serotonin reuptake inhibitors or
7 SSRIs, cause suicidal thoughts or behavior?

8 A. Yes.

11:25:38

9 Q. Okay. Can you explain to the jury, please, who those
10 federal agencies are and what you did in connection with your
11 work for them.

12 A. So, there have been a variety of experiences and
13 participation I've had with different federal government
14 agencies.

11:25:52

15 I was on the psychopathology advisory board of the
16 FDA, Food and Drug Administration, and a member of the
17 committee that led to the black box warning for antidepressants
18 and suicide in children.

11:26:13

19 I was also brought in before that meeting to review
20 the statistical work that the FDA had done that was to be
21 presented at that meeting of the psychopharm advisory board.

11:26:38

22 I've also been an adviser to now two secretaries of
23 the Veterans Administration. I was a member of the Blue Ribbon
24 panel about 5 years ago on the question of veteran suicide and
25 I'm an adviser to the brand new and delightful Secretary

1 Shulkin who is the new SECRETARY of Veterans Administration.
2 I'm one of a small handful advisers to help with their number
3 one priority, which is the reduction of veteran suicide, and we
4 are developing methodologies to help achieve that very
5 important goal.

11:27:06

6 Q. Thank you, Dr. Gibbons.

7 Could you move your mike a little bit closer to help
8 us hear you. Or move closer to the mike. Thanks.

9 Dr. Gibbons, how many peer-reviewed scientific
10 articles have you published?

11:27:21

11 A. Over 290 and 5 books.

12 Q. Have any of those dealt with the issue of antidepressants
13 or SSRIs and suicidality?

14 A. A large number of publications in that specific area,
15 probably over 30.

11:27:36

16 Q. Now, in terms of recognition for your work as someone who's
17 done research either in biostatistics or on the issue of
18 assessing suicidality, have you received any awards?

19 A. Yes.

11:28:02

20 Q. What awards have any received?

21 A. I was given the -- well, for one, I was elected to the
22 membership of the National Academy of Medicine of the National
23 Academy of Sciences for contributions to the statistical
24 underpinnings of drug safety.

11:28:24

25 I was given the American Statistical Association's

1 Outstanding Statistical Application Award for the explication
2 of the relationship of antidepressants and suicide.

3 I've been given the Harvard award for contributions to
4 Psychiatric Epidemiology and Biostatistics.

11:28:47

5 The American Public Health Association's Rema Lapouse
6 award for contributions to psychiatric epidemiology.

7 The health policy statistics section of the American
8 Statistical Association for work in the measurement of mental
9 health constructs, including suicidality.

11:29:08

10 Q. Dr. Gibbons, have you ever been invited to come and speak
11 at a group of, you know, professional organizations that focus
12 on psychiatric medications?

13 A. Yes.

14 Q. And what groups have invited you to come and speak?

11:29:23

15 A. I -- I gave a lecture on the statistical methods of drug
16 safety invited by the Department of Statistics at Harvard
17 University.

18 I was the keynote speaker at the last two World
19 Congresses of Suicide Research.

11:29:42

20 And there have been several others at different
21 universities.

22 I, a week ago, gave the grand rounds at the University
23 of Colorado on the statistical methods for drug safety.

11:29:58

24 Q. Are you a member of the American College of
25 neuropsychiatrists?

1 A. Yes, I am.

2 Q. Have you been invited by the American College of
3 Neuropsychopharmacology to come and speak on the issues of
4 antidepressants and whether or not they cause suicidal thoughts
5 or behavior?

11:30:10

6 A. Yes; several times over the last decade.

7 Q. And just for the jury's benefit, what is the American
8 College of Neuropsychopharmacology?

9 A. It's a very long title, but it is the leading psychiatric
10 organization involved in the research and practice of
11 psychiatry and biological underpinnings of mental health
12 disorders.

11:30:26

13 Q. Dr. Gibbons, what were you asked to do for this particular
14 case?

15 A. I was asked to review the literature on the relationship
16 between antidepressants in general, and suicidal thoughts,
17 behavior and completion, and Paroxetine in particular, and to
18 determine whether or not there's a causal association between
19 taking Paroxetine and the development of suicidal events,
20 suicidal thoughts, behaviors and completion.

11:30:43

11:31:13

21 Q. And for the purpose of this case, were you asked to
22 specifically focus your attention and opinions on whether or
23 not Paxil or Paroxetine cause suicidal thoughts or behavior in
24 adult patients?

11:31:27

25 A. Yes; that's correct.

1 Q. What have you done to prepare to give those opinions in
2 court today?

3 A. I've reviewed the entire literature. The scientific
4 peer-reviewed published literature. I've reviewed the FDA
5 reports on their large scale research synthesis of these data.
6 I've reviewed expert reports in this case of plaintiff experts.
7 And just the proceedings of -- of this case -- of this --

8 THE COURT: You got to keep your voice up, Doctor.

9 THE WITNESS: I'm sorry.

10 BY MR. DAVIS:

11 Q. How much time did you spend working on this case in order
12 to prepare to deliver your opinions that you would give in the
13 case?

14 A. Someplace in the order of 100 to 150 hours.

15 Q. And do you get paid for your time?

16 A. I do.

17 Q. How much do you charge for your time?

18 A. \$850 an hour for the preparation of this work and \$1,000 an
19 hour for deposition and courtroom testimony.

20 Q. What accounts for the difference between the 850 for the
21 review and the \$1,000 for testimony?

22 A. During testimony and deposition I -- I -- my schedule is --
23 has to be kept completely open for the schedules of the court.

24 And also, I have to be very careful not to think about lots of
25 other things so that I can really focus on the issues related

1 to this particular trial.

2 Q. Have you been an expert in other lawsuits where you are
3 asked to assess the scientific information available on whether
4 a medication or an exposure causes a medical condition or
5 outcome?

11:33:04

6 A. Yes.

7 Q. And in cases not involving Paroxetine or Paxil, have you
8 worked as an expert where there's an issue about whether the
9 medication caused or increased the risk of a medical condition
10 or suicidal thoughts or behavior?

11:33:18

11 A. Yes.

12 Q. And who retained you in those cases?

13 A. I've been retained by the U.S. Department of Justice, I've
14 been retained by Wyeth Pharmaceuticals, Pfizer Pharmaceuticals;
15 there are a few others.

11:33:39

16 Q. Have you testified at a trial?

17 A. Yes, I have.

18 Q. What trial was that?

19 A. This was the Giles trial. This was a trial about the drug
20 Effexor, the Wyeth drug. This was a suicide and antidepressant
21 trial similar to this one.

11:33:52

22 Q. Other than this case, have you been retained by
23 GlaxoSmithKline to work on any other cases?

24 A. Yes; there's a case in the United Kingdom, in London, that
25 I have participated in related to a potential adverse effect of

11:34:08

1 Paroxetine.

2 Q. Is that particular proceeding involve suicidal thoughts or
3 behavior?

4 A. No, not directly.

11:34:22

5 Q. Okay. And what percentage of your time do you spend
6 working as an expert in litigation?

7 A. Maybe 10 percent of my time.

8 Q. So what do you do with the other 90 percent of your time on
9 a day-to-day basis?

11:34:34

10 A. I teach students, I do research, I run a center at the
11 University of Chicago and play tennis.

12 Q. Based on your own research and your review of research by
13 others, have you reached opinions to a reasonable degree of
14 scientific certainty regarding whether Paroxetine or Paxil use
15 causes suicidal thoughts or behavior in adult patients?

11:34:57

16 A. Yes.

17 Q. For each of the opinions that you're going to offer today,
18 do you hold them to a reasonable degree of scientific
19 certainty?

11:35:08

20 A. Yes, I do.

21 Q. Did you and I work on a collection of slides that would
22 help the jury understand your opinions?

23 A. We did, yes.

24 Q. And do you believe the use of those slides would be helpful
25 to the jury in understanding the scientific evidence on whether

11:35:17

1 Paroxetine or other SSRIs cause suicidal thoughts or behavior
2 in adult patients?

3 A. I do.

4 MR. DAVIS: Your Honor, permission --

11:35:27

5 THE COURT: Why don't you ask the doctor what his
6 opinion is first so we know what you're trying to support.

7 MR. DAVIS: Sure.

8 BY MR. DAVIS:

11:35:38

9 Q. Dr. Gibbons, if you could, please, for the jury's benefit,
10 could you summarize your opinions.

11 A. My opinion is is that SSRIs in general, and Paroxetine in
12 particular, do not increase the risk of suicidal thoughts or
13 behavior or completion. If anything, they decrease the risk of
14 these events.

11:35:53

15 Q. Dr. Gibbons, the jury has heard evidence -- let me back up.

16 The jury has been told that the scientific data
17 actually shows that Paroxetine causes suicidal thoughts or
18 behavior or completed suicide. Is that a fair assessment of
19 where we are today on the science?

11:36:10

20 A. That's not fair at all.

21 Q. Tell us, in your own view, why that's not fair, why that is
22 not a fair assessment of evidence with respect to Paroxetine
23 and other SSRIs in adult patients.

11:36:26

24 A. There's a tremendous amount of data now available on the
25 question of whether or not antidepressants in general, SSRIs in

11:36:51

1 particular, and Paroxetine in particular, increase risk of
2 suicidal thinking, behavior or completion. These include
3 numerous, hundreds and hundreds of randomized controlled trials
4 that have the benefit of randomization to rule out confounding
5 by other factors that might lead one person to seek treatment
6 and another not.

11:37:17

7 Those data are very, very clear. In particular, the
8 FDA synthesis of 372 randomized controlled trials in 100,000
9 patients, that these drugs either decrease the risk of the
10 combination of their primary endpoint of suicidal thinking and
11 behavior or have no effect overall on suicidal behavior,
12 neither increase it or decrease it in the adult population.

11:37:44

13 As we age, as we get to the population of over 65,
14 there are benefits, significant reductions in not only suicidal
15 thoughts but also suicidal behavior. These are the findings of
16 the US FDA.

17 Q. Dr. Gibbons, does that hold true also specifically with
18 respect to Paroxetine?

19 A. Yes, it does.

11:37:54

20 Q. Now, what types of studies have you relied upon for
21 purposes of forming the opinions that you just gave?

22 A. So the importance of randomized controlled trials is that
23 they eliminate bias, bias on things that we can see and
24 measure, and also bias on some things that we can't because of
25 randomization.

11:38:15

1 You can manage with the advances in molecular genetics
2 that we've all seen and read about, that there may be genes
3 that would influence whether or not someone would have suicidal
4 thoughts or behavior.

11:38:28

5 The advantage of randomized controlled trials is even
6 if there are genes we can't measure, we will balance those
7 people who receive placebo or sugar pill or an active
8 medication like Paroxetine in terms of all of those observed
9 and unobserved findings or potential confounders. So those
10 data are terribly important for deriving an inference about
11 whether or not there is any relationship between
12 antidepressants and suicide.

11:38:49

13 Now, the people who get into randomized controlled
14 trials may not be totally representative of the people who
15 ultimately take the drugs, and the amount of time that these
16 studies go on for may not be representative to the experiences
17 of individuals in the real world. For that reason, it's
18 extremely important to also not only look at randomized
19 controlled trials but to well-controlled observational studies
20 conducted in hundreds of thousands, and in some cases millions
21 of people, for the ultimate end users of these products to see
22 whether or not the findings from a randomized controlled trial
23 do, in fact, generalize to the real world of real people who
24 take these drugs.

11:39:05

11:39:25

11:39:41

25 Those are the two main streams of data that I have

1 focused my attention, not only in the context of this case but
2 in my academic work.

11:39:55

3 Q. Why is it that we need that specific type of scientific
4 evidence to figure out whether or not a medication such as
5 Paroxetine causes suicidal thoughts or behavior?

6 MR. WISNER: Objection; vague as to what scientific
7 evidence he's referring to. He's testified about two of them.
8 I don't know which one he's talking about.

11:40:10

9 MR. DAVIS: I believe it's the randomized control
10 trials he talked about and the observational studies that he
11 mentioned, Your Honor.

12 THE COURT: All right. You may proceed.

13 MR. DAVIS: Thank you.

14 BY THE WITNESS:

11:40:15

15 A. With respect to the randomized controlled trials, they are
16 the gold standard because they eliminate the potential for
17 bias.

11:40:28

18 We can imagine that patients who are sicker are more
19 likely to be treated with the more novel treatments, the newer
20 kinds of treatments. And that sickness may be confounded with
21 adverse events they might experience, including suicide.

22 All of that potential bias is eliminated in randomized
23 controlled trials, that's why they're so important.

11:40:45

24 But equally important is the idea that what we observe
25 in a well controlled laboratory setting actually generalizes to

1 the population of potential users of these drugs, and that's
2 why the observational studies are important.

3 The observational studies are also much larger. It's
4 easy for us to obtain medical claims data on the experiences of
5 millions of Americans to be able to identify whether or not
6 even rare events like suicide attempts and even suicide
7 actually are related to exposures to different kinds of drugs,
8 antidepressants, antiepileptic drugs, different kinds of drugs.

9 Q. Dr. Gibbons, you mentioned randomization. Later on, are we
10 going to talk about randomization and how that process works to
11 try to get to the right answer in terms of how studies need to
12 be done?

13 A. Yes.

14 Q. All right. So we're going to park that to the side briefly
15 and we'll come back to it.

16 The jury has heard a lot about two terms, one of those
17 terms is "association," and the other term is "causation." Are
18 they the same?

19 A. Oh, absolutely not.

20 Q. Have you and I prepared a slide that helps explain the
21 difference between association and causation?

22 A. Yes, we have.

23 MR. DAVIS: Your Honor, permission to publish slide 5,
24 which is DX7035E.

25 MR. WISNER: I'd like a copy of these things before he

1 tries to publish them to the jury.

2 MR. DAVIS: I'm getting them, Your Honor.

3 MR. WISNER: Don't ask to publish before you have
4 shown them to me.

11:42:12

5 (Binder tendered).

6 MR. WISNER: All of these (indicating).

7 MR. DAVIS: Your Honor, do you need a set?

8 Permission to approach.

9 (Binder tendered to the Court.)

11:42:37

10 MR. WISNER: Your Honor, it appears to be over a
11 hundred pages here.

12 THE COURT: Why haven't these been shown to counsel
13 before?

14 MR. DAVIS: Your Honor, I gave him a copy. He's got a
15 copy.

11:42:48

16 THE COURT: He has a a copy now, but it's 100 pages.
17 Why didn't you show them to him before?

18 MR. DAVIS: I apologize.

19 THE COURT: I don't know if that's going to take care
20 of it.

11:42:58

21 (Brief pause).

22 THE COURT: You want to go through these first,
23 Mr. Wisner?

24 MR. DAVIS: It's the fifth one. It's the DX7035D.

11:43:12

25 THE COURT: All right. Well, start with that one,

1 then.

2 MR. WISNER: No objection to that one, Your Honor.

3 MR. DAVIS: Thank you.

4 (Exhibit published to the jury.)

11:43:23

5 BY MR. DAVIS:

6 Q. Dr. Gibbons, using this slide can you help us understand
7 the difference between association and causation.

11:43:40

8 A. Of course. So this is a very simple toy example, but it
9 illustrates the point. People who wear helmets have a greater
10 incident of broken bones. It's not because wearing the helmet
11 is causing the broken bones, it's because the people who wear
12 helmets engage in risky behaviors like motocross racing or
13 skiing, aerial skiing, or snow boarding. And people who engage
14 in those riskier sports or behaviors have an increased risk of
15 broken bones.

11:44:11

16 So the association between wearing a helmet and broken
17 bones is not a causal association, it's mediated by the
18 participation in risky behaviors that increases the likelihood
19 of having broken bones. So it's an indirect effect rather than
20 a direct effect.

11:44:27

21 The causal effect is a direct effect. Putting on the
22 helmet somehow increases the likelihood of a broken bone not
23 because their -- regardless of the behavior. So we know that
24 putting on a helmet is not increasing broken bones.

11:44:50

25 Q. Did you and I also work on a slide to show how the

1 scientific community assesses whether a medication causes an
2 adverse effect or a medical condition such as suicidal thoughts
3 or behavior?

4 A. Yes, we did.

11:45:02

5 MR. DAVIS: Permission to publish DX7035E, Your Honor,
6 which is the next slide, slide 6.

7 THE COURT: All right.

8 MR. WISNER: No objection, Your Honor.

9 (Exhibit published to the jury.)

11:45:16

10 BY MR. DAVIS:

11 Q. Dr. Gibbons, can you help us understand what this slide is
12 showing in terms of how one goes about from a scientific
13 standpoint to determine causation.

14 A. So we begin with randomized controlled trials. They're the
15 gold standard of scientific inference for drawing causation.

11:45:31

16 And I've mentioned already the reason they work so
17 well is that we balance all of the potential biases and
18 confounders both that are observable and that are unobservable
19 or unmeasured.

11:45:52

20 We next look to see whether or not the results from a
21 randomized controlled trial replicate across a large number of
22 randomized controlled trials. And we do that with different
23 approaches to research synthesis sometimes called

24 meta-analysis. It's the combining of evidence from multiple

11:46:13

25 studies that have all studied the same phenomenon in a similar

1 way.

11:46:30

2 Comparison of placebo to Paroxetine in terms of
3 suicidal ideation and/or behavior across multiple studies to
4 see are we getting a consistent effect, how much variability is
5 there in that effect, and overall, what is the magnitude of
6 that effect.

11:46:46

7 The magnitude of that effect is the third point, that
8 is the strength of the association. Is the increase in risk a
9 very tiny increase in risk that may be statistically
10 significant because we have such large sample sizes or is there
11 an appreciable risk, are we seeing a doubling of the risk or a
12 tripling of the risk. How strong is the association between
13 the exposure, the taking of a medication and the outcome of
14 interest that we're investigating.

11:47:03

15 Fourth, what I mentioned before about the importance
16 of observational studies, how well do those randomized
17 controlled trials under very precise laboratory conditions
18 generalize to the population of real people who take these
19 medications, of people in the real world who take them for
20 short periods of times or very long periods of time. Do we see
21 the same kind of findings out in the real world environment.

11:47:22

22 These are less rigorous data, because there not
23 randomized. So, it may be that sicker patients are actually
24 receiving the medication more frequently than less sick

11:47:39

25 patients, but we still should be able to see that. We see the

1 similar effect in the real world.

2 And then finally, it's important to also show that
3 there is a dose response relationship. The more you take of a
4 drug, or at the higher concentration, the greater the effect of
5 that drug on the outcome of interest.

11:47:54

6 Q. Now, when you have a medical condition such as anxiety or
7 depression, and also -- which also cause suicidal thoughts or
8 behavior --

9 MR. WISNER: Objection; move to strike. Mr. Davis nor
10 this man on the stand is a medical doctor and can testify about
11 this.

11:48:07

12 MR. DAVIS: Your Honor, I think this has already been
13 addressed.

14 MR. WISNER: He cannot say. He's not a doctor, nor is
15 this guy (indicating).

11:48:16

16 THE COURT: Sustained.

17 BY MR. DAVIS:

18 Q. Let me back up.

19 Dr. Gibbons, are you familiar with the -- with both
20 depression and anxiety and what are risk factors for depression
21 and anxiety?

11:48:23

22 A. Risk factors for depression and anxiety, yes.

23 Q. Yes. And have you researched and investigated what -- what
24 risk -- whether depression and anxiety or risk factors for
25 suicidal thoughts or behavior?

11:48:44

1 A. Yes.

2 Q. Have you -- and as part of your work and research, are
3 anxiety or depression risk factors for suicidal thoughts or
4 behavior?

11:48:55

5 MR. WISNER: Objection; lacks foundation and proper
6 opinion. If I may voir dire the witness, Your Honor, I believe
7 I can lay the foundation that he's not qualified to offer this
8 testimony.

11:49:07

9 MR. DAVIS: Your Honor, I don't believe that's
10 necessary. I can go -- he's free to ask him those questions on
11 cross-examination.

12 THE COURT: I'll let you proceed.

13 MR. DAVIS: Thank you.

14 MR. WISNER: With voir dire?

11:49:17

15 THE COURT: When we break I'll let you ask some
16 questions.

17 MR. BAYMAN: Okay.

18 THE COURT: Outside the presence of the jury.

19 MR. WISNER: Yes, Your Honor.

11:49:25

20 MR. DAVIS: May I proceed with that question, Your
21 Honor?

22 THE COURT: Yes.

23 Read it back, please.

24 (Question read.)

11:49:29

25 BY MR. DAVIS:

1 Q. Did you get that?

2 A. Yes.

3 THE COURT: You better put another question. That's
4 not clear.

11:50:17

5 BY MR. DAVIS:

6 Q. Are -- is anxiety and depression, both individually, risk
7 factors for suicidal thoughts or behavior?

8 MR. WISNER: I renew my objection, Your Honor.

9 THE COURT: Yes. Sustained.

11:50:26

10 Has he studied it, is the issue, not whether he can
11 make a diagnosis of it.

12 MR. BAYMAN: Oh, I'm not asking for individual
13 diagnosis.

14 THE COURT: You got to confine him to what he studied.

11:50:36

15 MR. DAVIS: Sure.

16 BY MR. DAVIS:

17 Q. Based upon your research and investigation, and looking at
18 risk factors for suicidal thoughts and behavior, is depression
19 or anxiety a risk factor for suicidal thoughts or behavior?

11:50:50

20 A. Yes; we established extensively on this question. So we --
21 we looked at 41 --

22 MR. WISNER: Objection; move to strike as
23 nonresponsive at the word "yes."

24 MR. DAVIS: Your Honor, I believe he's allowed to
25 explain --

11:51:04

1 THE COURT: Put another question.

2 BY MR. DAVIS:

3 Q. Doctor, given the answer was "yes," why is it then
4 important to look at placebo-controlled data or other
5 controlled data to assess whether a medication either increases
6 the risk or separately causes suicidal thoughts or behavior?

11:51:15

7 A. Because the severity of depression is one of the greatest
8 drivers of suicidal thoughts and behavior and completion. And
9 if we don't control for the severity of depression, and then,
10 in essence, make it identical on average in the placebo group
11 and in the active treatment group, then we will see imbalances
12 in the rate of suicidal thoughts and behavior produced by the
13 differences in the severity of depression.

11:51:36

14 In adults, severity of depression is the greatest
15 driver of suicide.

11:52:01

16 MR. WISNER: Your Honor, I move to strike this
17 witness's answer. This is an opinion about the driver of
18 suicidality. Again, he is not a medical doctor. He cannot be
19 making this testimony.

11:52:11

20 THE COURT: No, as I understand it, he's made a study
21 of what these things are. So, on that basis, I'll let him
22 testify.

23 MR. DAVIS: Thank you, Your Honor.

24 BY MR. DAVIS:

11:52:18

25 Q. For that reason, what you just described, is that the role

1 and purpose of doing randomization?

2 A. It is certainly a good illustration of why it's so
3 important to do randomization, so that we can balance things
4 like the severity of depression across the treated and
5 controlled conditions of an experimental study.

11:52:35

6 We've illustrated this in the Journal of the American
7 Medical Association in a peer-reviewed publication that I
8 authorized.

9 Q. Now, the jury has heard a lot about the term "statistical
10 significance." Is that a term you familiar with?

11:52:53

11 A. Intimately.

12 Q. Okay. And did you and I work on a slide together to help
13 the jury understand what statistical significance means and
14 when results are not statistically significant?

11:53:06

15 A. Yes, we did.

16 MR. DAVIS: All right. Your Honor, permission to
17 publish DX 7035X

18 MR. WISNER: Your Honor, I have one objection and it's
19 a continuing objection to these slides, and that is, Mr. Davis
20 keeps saying that he and the expert put them together together.
21 I think foundation needs to be laid about who did what, because
22 I don't believe Mr. Davis is allowed to testify.

11:53:15

23 MR. DAVIS: Your Honor, I think that foundation has
24 already been laid.

11:53:26

25 THE COURT: Well, you can't -- technically, the

1 objection is correct. It's the witness who has to put it
2 together, not you.

3 MR. DAVIS: Okay. I'll just ask the question.

11:53:41

4 THE COURT: So, rely on the witness's testimony as to
5 what was done.

6 MR. DAVIS: Sure.

7 MR. WISNER: No objection to that slide, though, Your
8 Honor.

9 MR. DAVIS: Okay. Thank you.

11:53:45

10 THE COURT: Okay.

11 BY MR. DAVIS:

12 Q. Let's go to the next slide.

13 Dr. Gibbons, help us understand the scientific term
14 and evaluation of statistical significance.

11:53:57

15 Looking at this, tell us what -- tell us what this
16 means and whether the results are statistically significant or
17 not.

11:54:17

18 A. So, the first thing you need to look at here is that we're
19 talking about statistical significance now of something like an
20 odds ratio or a relative risk. You probably have heard this in
21 the connection of this case. And what that basically means is,
22 what is the relative risk of an event like a suicidal thought
23 or behavior in the treated patients, patients who got
24 Paroxetine versus the controlled patients, patients who got
25 placebo.

11:54:38

11:55:00

1 And the bars that you're seeing, the midpoint of that
2 bar is what we call the point estimate of the odds ratio. It's
3 sort of the average. It's sort of the mean. It's the relative
4 risk. If it's a value of about 2, it means there's a doubling
5 of the risk.

11:55:18

6 The length of the bar, if you focus on the one that's
7 in the upper right corner, that's the uncertainty. That's what
8 we call a confidence interval. Typically, it's a 95 percent
9 confidence interval. What that means is that 95 percent of the
10 time the true population value is going to lie within that
11 interval.

11:55:34

12 Now, there's truth in the universe, and then there's a
13 sample of data that where people who participated in a trial,
14 and that's an estimate of that truth. So the width of that
15 interval is telling us something about the uncertainty in our
16 estimate around what is really true. And if we have a very
17 small sample size in a very rare event, that the width of
18 interval is going to be very large.

11:55:53

19 So with that basic introduction, the idea of
20 statistical significance is, how likely are the data given the
21 known hypothesis, the hypothesis we're trying to test.

11:56:11

22 In this case, the known hypothesis is that the odds
23 ratio or the relative risk is 1.0. It's that middle line on
24 this chart.

25 So what does that mean? What does the relevant risk

1 of 1 mean? It means that there's equal chance of observing
2 this on drug or on placebo.

11:56:27

3 MR. WISNER: Your Honor, I'm going to object to
4 narrative. He's actually literally asking himself questions
5 and then answering them. I'd like it to be broken up with some
6 questioning by the attorney.

7 MR. DAVIS: Your Honor, I don't believe this is any
8 different than what Dr. Glenmullen and Dr. Healy did.

9 THE COURT: You may proceed.

11:56:37

10 MR. DAVIS: Thank you.

11 BY THE WITNESS:

11:56:48

12 A. So in the upper right corner, the top one, we see that that
13 95 percent confidence interval does not include the value 1.
14 That means it's statistically significant. It's beyond what we
15 would expect by chance alone. And that it is in the direction
16 of increased risk for the experimental condition versus the
17 control condition.

11:57:09

18 The relative risk is greater than 1, the confidence
19 interval, that band, that 95 percent confidence interval does
20 not include the value 1, and so it's statistically significant.

11:57:37

21 The middle two bars include the value 1, and they are
22 not statistically significant. One is moved over to the right,
23 so our point estimate is greater than 1, but the data are still
24 consistent with the known hypothesis. And the other is moved
25 over to the left, so it's in the protective direction, but the

1 data are still consistent with the known hypothesis.

2 The bottom left-hand corner we see as an example of a
3 statistically significant protective effect. Now the entire
4 confidence interval is less than the value 1, so there is a
5 significant reduction in the risk associated with the treatment
6 relative to the control.

11:57:56

7 BY MR. DAVIS:

8 Q. Thank you.

9 So if the horizontal bars that go across this
10 demonstrative touch or cross over the 1.0 vertical line, what
11 does that mean?

11:58:10

12 A. So if the bars include the 1.0, it means they're not
13 statistically significant. If they exclude it, they are
14 statistically significant either in direction of increased harm
15 or decreased harm.

11:58:29

16 Q. What role does the statistical significance play in
17 assessing whether or not an association exists in a study
18 result?

19 A. Well, statistical significance is one of the important,
20 probably three important factors when we review a result.

11:58:47

21 So, statistical significance is important if a study
22 has been well controlled, particularly if it's a randomized
23 study, if we're looking at the primary end point, and we want
24 to say something how plausible the data are given the known
25 hypothesis, which in this case is that the drug has no effect,

11:59:06

1 no increase, no benefit, no risk in terms of the outcome of
2 interest.

11:59:22

3 So statistical significance is a key factor in
4 determining whether or not we can conclude that there is an
5 effect that we need to explore more -- in more detail.

11:59:43

6 We also need to know, look at the point estimate, how
7 big is the effect, what's the magnitude of the effect, and we
8 also need to explore the confidence interval to see how precise
9 is our estimate of that, how plausible are -- what are the
10 range of plausible values.

11:59:56

11 Q. So, do you just look at statistical significance alone?

12 A. No. No. We look at statistical significance, we look at
13 the point estimate, we look at the confidence interval. And
14 then we also look at how is the study designed. If this is a
15 study relating wearing a motorcycle helmet to -- to injury to
16 to -- to bone breaking, then we might say, "well, this really
17 wasn't a very good study in the first place" and statistical
18 significance may -- you know, really doesn't matter.

12:00:17

19 Q. Now, if there's a statistical association in one study or
20 analysis, or sometimes may even -- more than one study or
21 analysis, does that alone mean that causation has been
22 established?

12:00:35

23 A. No. The scientific process is about drawing inferences
24 from multiple streams of data. It's about replication. It's
25 about validation. It's about seeing the same consistent

1 effect. It's about looking for dis-confirming evidence. It's
2 looking at controlled studies, randomized studies, and well
3 controlled observational studies and synthesizing that into a
4 coherent statement about the process that's going on in the
5 world.

12:00:57

6 MR. WISNER: Objection, Your Honor. Move to strike
7 his testimony about what constitutes causation. Again, he's a
8 medical expert. He's not not Bradford Hill analysis. He
9 cannot testify about biological plausibility or the mechanics
10 of a serotonin system. He is well outside of his wheelhouse as
11 an expert and I move to strike his answer.

12:01:09

12 MR. DAVIS: Your Honor, I believe we've already been
13 over this.

14 THE COURT: The objection is sustained.

15 MR. DAVIS: Your Honor, may we have a sidebar?

12:01:21

16 THE COURT: No, let's go on. We'll take a break in a
17 few minutes.

18 BY MR. DAVIS:

19 Q. In assessing statistical analyses, Dr. Gibbons, when you're
20 looking at whether or not there is an association or an
21 increased risk or not, what role does consistency play?

12:01:33

22 A. Consistency is extremely important. If we have a primary
23 endpoint and a secondary endpoint, we should be seeing a
24 consistent pattern between them. We should be seeing, if there
25 is an effect, it should be an effect that generalizes to the

12:01:53

1 real world. It should be an effect that's seen with -- in
2 people who have similar kinds of diagnosis. Consistency is
3 extremely important in the scientific process.

12:02:13

4 Q. Doctor, before we look at the scientific evidence on
5 Paroxetine and other SSRIs and the types of studies that you've
6 described, I want to briefly discuss with you the suicide rate
7 in the United States.

12:02:24

8 As an expert in the field of drug safety, have you
9 studied, and are you familiar with, the suicide rate in the
10 United States for white males of Mr. Dolin's makeup --

11 MR. WISNER: Objection.

12 BY MR. DAVIS:

13 Q. -- and age?

12:02:32

14 THE COURT: The objection is sustained. We're not
15 going into suicide rates in this case. I thought I made that
16 clear before.

17 MR. DAVIS: Your Honor, this is on a totally separate
18 issue.

19 THE COURT: No, we're not going into that, sir.

12:02:42

20 MR. DAVIS: Okay.

21 BY MR. DAVIS:

22 Q. Dr. Gibbons, are you familiar with the frequency by which
23 suicides in the United States are by violent means in males of
24 Mr. Dolin's age?

12:03:05

25 MR. WISNER: Objection.

1 THE COURT: Sustained.

2 BY MR. DAVIS:

3 Q. Dr. Gibbons, did you prepare a slide that shows how
4 randomization in placebo-controlled trials actually works?

12:03:17

5 A. Yes.

6 MR. DAVIS: Permission to publish DX7035F, please.

7 MR. WISNER: No objection, Your Honor.

8 THE COURT: You may proceed.

9 (Exhibit published to the jury.)

12:03:27

10 BY MR. DAVIS:

11 Q. All right. Dr. Gibbons, tell us -- tell us where are in
12 terms of how randomized placebo-controlled trials work and what
13 we're seeing up here on the screen.

12:03:47

14 A. So, what were seeing is a run-in period, which is a way of
15 detoxifying patients who might have had prior treatment,
16 perhaps with an antidepressant, before they entered the trial.

17 So there's a period of washout where patients are
18 given placebo prior to the randomization. At this point
19 patients are then randomized into an active treatment arm or a
20 control arm.

12:04:10

21 I think we can see that in the next part of the slide.

22 Q. Let's go to the next slide.

23 Okay. What's happened there where the patients have
24 gone from the run-in phase and they've gone into Group A and
25 Group B, what's going on there?

12:04:19

1 A. So, we've now randomized. Essentially, we've flipped a
2 coin for each patient to decide whether or not that patient
3 should be in the experimental arm, like a Paroxetine arm, or a
4 control arm like placebo.

12:04:30

5 And the thing we notice is, initially in the
6 population we had a fairly equal number of men and women and
7 now we have retained that equal number, that balance of males
8 and females in the control arm and in the -- and in the
9 experimental arm.

12:04:47

10 We actually don't know, we're blinded to the status of
11 what is Group A what is Group B. The investigators don't know
12 that one is Paroxetine and the other is placebo. So that any
13 expectation they may have in terms of whether or not the drug
14 is going to work or produce a side effect is not going to bias
15 the results of the experiment.

12:05:04

16 While we see the difference between the dresses and
17 the non-dresses as being indicative of a balance between males
18 and females in these two arms, randomization ensures that not
19 only those observable characteristics but also the unobservable
20 characteristics are balanced as well.

12:05:26

21 It is only through randomization that we have that
22 kind of complete balance between both observable
23 characteristics and unobservable characteristics.

12:05:41

24 So at this point we have essentially equivalent
25 individuals in terms of their characteristics in these two

1 groups.

2 Q. Then what happens next. If we can go to the next slide.

3 Can you explain what we're now seeing on the screen,
4 Doctor.

12:05:52

5 A. So, the study now is for a particular duration. And we're
6 looking at the benefits of the treatment in terms of efficacy
7 and we're also recording the adverse events that are
8 encountered by patients who are participating in this trial.

9 Q. All right. And so can we go to the next slide.

12:06:10

10 What's happening here with respect to what happens to
11 the patients who are on Paxil?

12 A. So, there's a group of patients who are on Paxil that will
13 now continue on into an unblinded, uncontrolled extension
14 phase of this study.

12:06:26

15 This may be done for a variety of different reasons.

16 It is a phase of the study that is not a part of the
17 randomization portion of the study. In many cases, the
18 patients and also the clinicians are now unblinded to the
19 status that these patients actually are on Paxil. And so our
20 statistical inferences are based solely on the controlled phase
21 of the study.

12:06:43

22 Q. For the extension phase, is there any control group that's
23 taking the sugar pill or a placebo?

24 A. No. So there is no parallel control group for this phase.

12:07:00

25 So, imagine that there are effects that occur later in time.

1 The only people in this study who are measured later in time
2 are those patients on Paxil. So the combination of those data
3 with the controlled portion could lead to bias.

12:07:25

4 Q. And so what is the most important and critical part of a
5 placebo-controlled randomized controlled trial?

6 A. The controlled phase of that trial.

7 Q. So that would be the phase that's in yellow that's in the
8 middle?

12:07:38

9 A. Right. That's the phase that benefits from the
10 randomization in the blinding of both the investigators and the
11 patients to the actual treatment status that they received.

12 Q. Is it scientifically reliable to take patients who had
13 adverse events in the extension phase and include them within
14 the controlled phase to try to make assessments of whether
15 there's a risk factor or an association between Paxil and
16 placebo?

12:07:55

17 A. No.

18 Q. Why not?

12:08:06

19 A. Because it would bias it. We had the benefits of
20 randomization and blindness during the control phase and now
21 we're taking data from another period in time where patients
22 now know what they're receiving and they have expectations
23 about what they might be feeling based on something they've
24 seen, or heard, or 60 Minutes article, or TV show, and that

12:08:26

25 will lead to bias, and it will invalidate the entire benefit of

1 the randomized controlled trial.

2 Q. Have FDA scientists published their views about whether
3 it's appropriate to combine or pull data from the controlled
4 portions of the randomized controlled trial and an open label
5 or extension-phase study?

12:08:46

6 A. Yes, they have.

7 MR. WISNER: Objection.

8 BY MR. DAVIS:

9 Q. And have you considered that information in terms of
10 forming your opinions in this case?

12:08:51

11 A. Yes, I have.

12 MR. DAVIS: Permission to publish slide 10 and 11,
13 Your Honor, which are DX7035H and 7035G.

14 MR. WISNER: I'd object to this as the best evidence
15 rule, Your Honor. These are documents that I believe are
16 Defendant's Exhibits and they're snapshots of them. They're
17 going to talk about an article, put it in the guy's hands, and
18 ask the questions.

12:09:09

19 THE COURT: 10 and 11?

20 MR. DAVIS: Yes, sir. They're part of DX1117.

12:09:24

21 (Brief pause)

22 THE COURT: Yes, I think that that slide doesn't
23 really belong here given that there's a question about the
24 article itself.

12:09:53

25 MR. DAVIS: Would you prefer that I call up the

1 article itself, Your Honor?

2 THE COURT: Well, I don't have any preference except
3 to tell you that this won't work in the form in which you're
4 doing it.

12:10:04

5 MR. DAVIS: Your Honor, I request permission to
6 publish DX1117, which is the article from which those quotes
7 come from. And that's in your exhibit notebook, Your Honor.

8 May I hand it to you?

9 (Document tendered to the Court.)

12:10:20

10 THE COURT: Is it attached to his report?

11 MR. DAVIS: I'm sorry?

12 THE COURT: Is it attached to his report?

13 MR. DAVIS: That article is not attached to his
14 report.

12:10:50

15 THE COURT: Do you have a copy?

16 MR. WISNER: I do. No objection.

17 MR. DAVIS: Thank you.

18 Let's call up DX1117. And can we call up the title
19 and the author at the title, Mr. Holtzen.

12:10:57

20 (Brief pause).

21 BY MR. DAVIS:

22 Q. Dr. Gibbons, what's happened the name of this article and
23 who are the authors?

24 A. Suicide Rates in Short Term Randomized Controlled Trials of
25 Newer Antidepressants. Tarek Hammad, Thomas Laughren and

12:11:09

1 Judith Racoosin.

2 Q. Do you know Dr. Hammad and Dr. Laughren?

3 A. I do.

4 Q. What role do they play at the FDA?

12:11:26

5 A. Tom was the former head of the psychopharmacology division
6 at the FDA. He was the head of it at the time this article was
7 published. And Dr. Hammad was one of the analysts and members
8 of that psychopharm division.

12:11:52

9 Q. Was Dr. Laughren one of the FDA scientists who was involved
10 with the 2006 FDA adult analyses on suicidality?

11 A. Yes, he was.

12 Q. Now, with respect to this particular publication, let's go
13 to --

14 (Brief pause).

12:12:05

15 BY MR. DAVIS:

16 Q. And in this publication by FDA scientists, what is
17 discussed about whether or not it's appropriate to pull data
18 from randomized controlled portions of a trial and open label
19 extension phases?

12:12:25

20 A. There reiterating the point that we just made with the
21 previous slide, that those data from the open label portions of
22 a randomized controlled trial or open label studies, in and of
23 themselves--and by "open label" I mean a study that doesn't
24 have the benefit of randomization and a study where the
25 patients actually know what there receiving in terms of

12:12:44

1 treatment, there isn't a placebo arm, there isn't a comparable
2 arm to compare the active treatment to--should not be pooled or
3 included in these kinds of -- of metaanalyses of randomized
4 controlled trials.

12:13:04

5 Q. Do you grow with these FDA scientists that say when you
6 that and you pull those two different types of studies together
7 that they are subject to bias and could lead to misleading
8 results?

9 A. Yes, I agree with that completely.

12:13:17

10 Q. All right. Now, if an expert such as Dr. Healy or Dr. Ross
11 testified in this case that the analysis that they relied upon
12 or utilized actually combined placebo-controlled data with open
13 label extension phases or even active controlled data, is that
14 scientifically reasonable and appropriate to do for purposes of
15 assessing risk factors for Paxil and whether or not it
16 increases the risk of suicidal thoughts or behavior?

12:13:38

17 A. No.

18 MR. WISNER: Objection; improper opinion. This
19 witness cannot criticize medical doctors and

12:13:49

20 psychopharmacologists who have Ph.D.'s in how these drugs are
21 made and used in real life. This is way beyond his wheelhouse
22 again.

23 MR. DAVIS: Your Honor, the testimony --

24 THE COURT: Let's take the noon recess and see if we
25 can work on this issue.

12:14:01

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

3 [REDACTED]

4 [REDACTED]

12:14:47

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

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9 [REDACTED]

12:15:10

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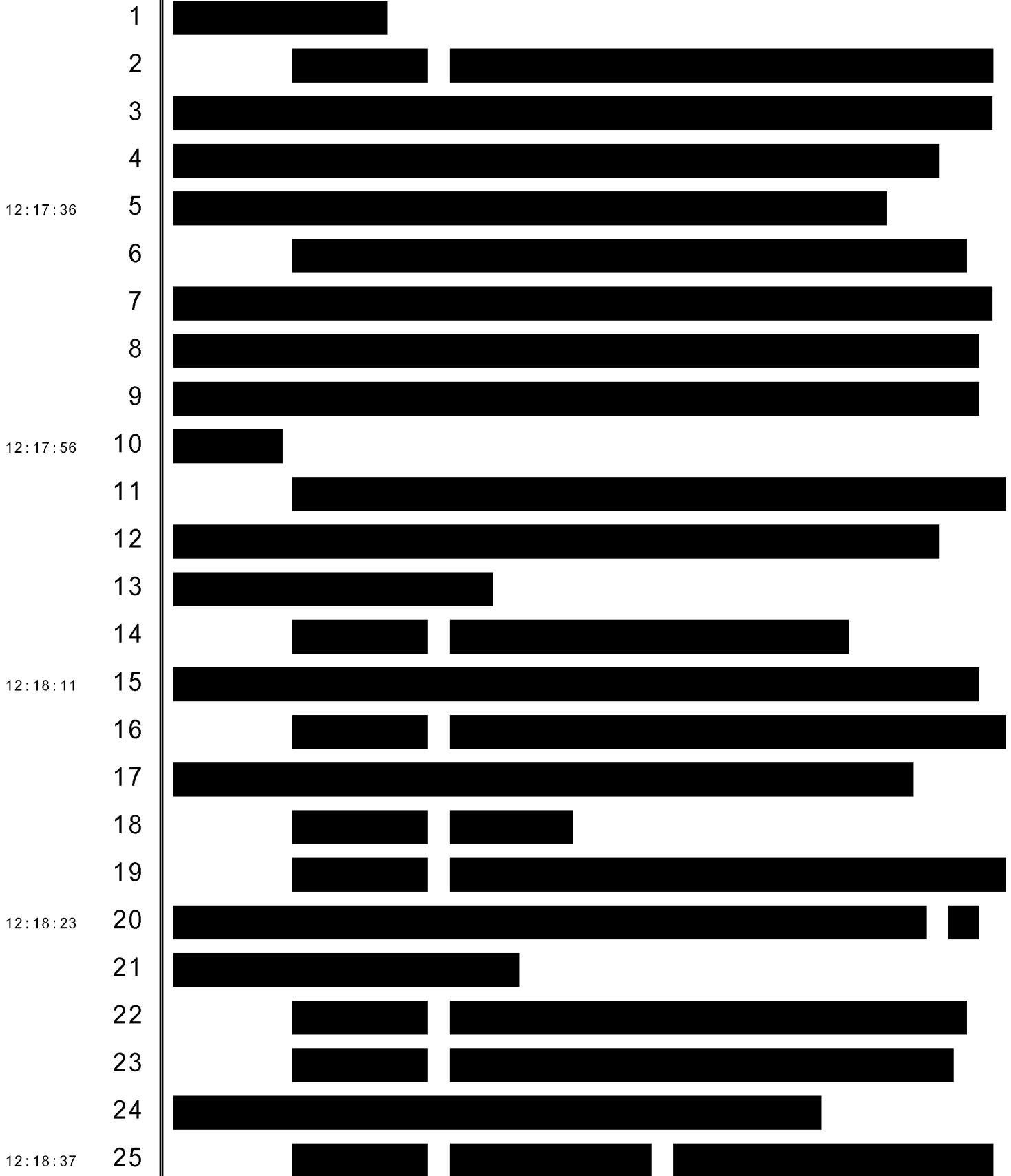
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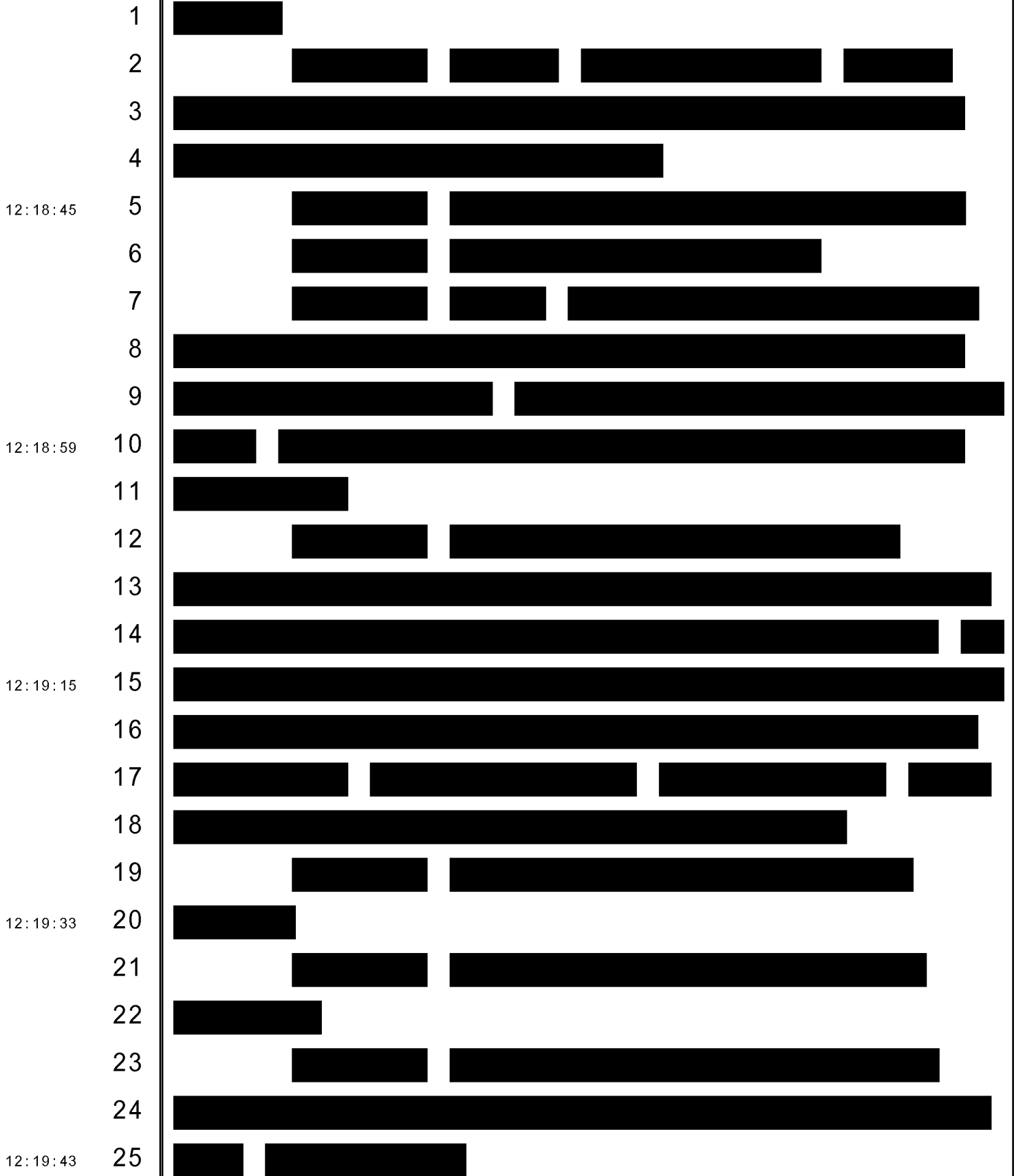
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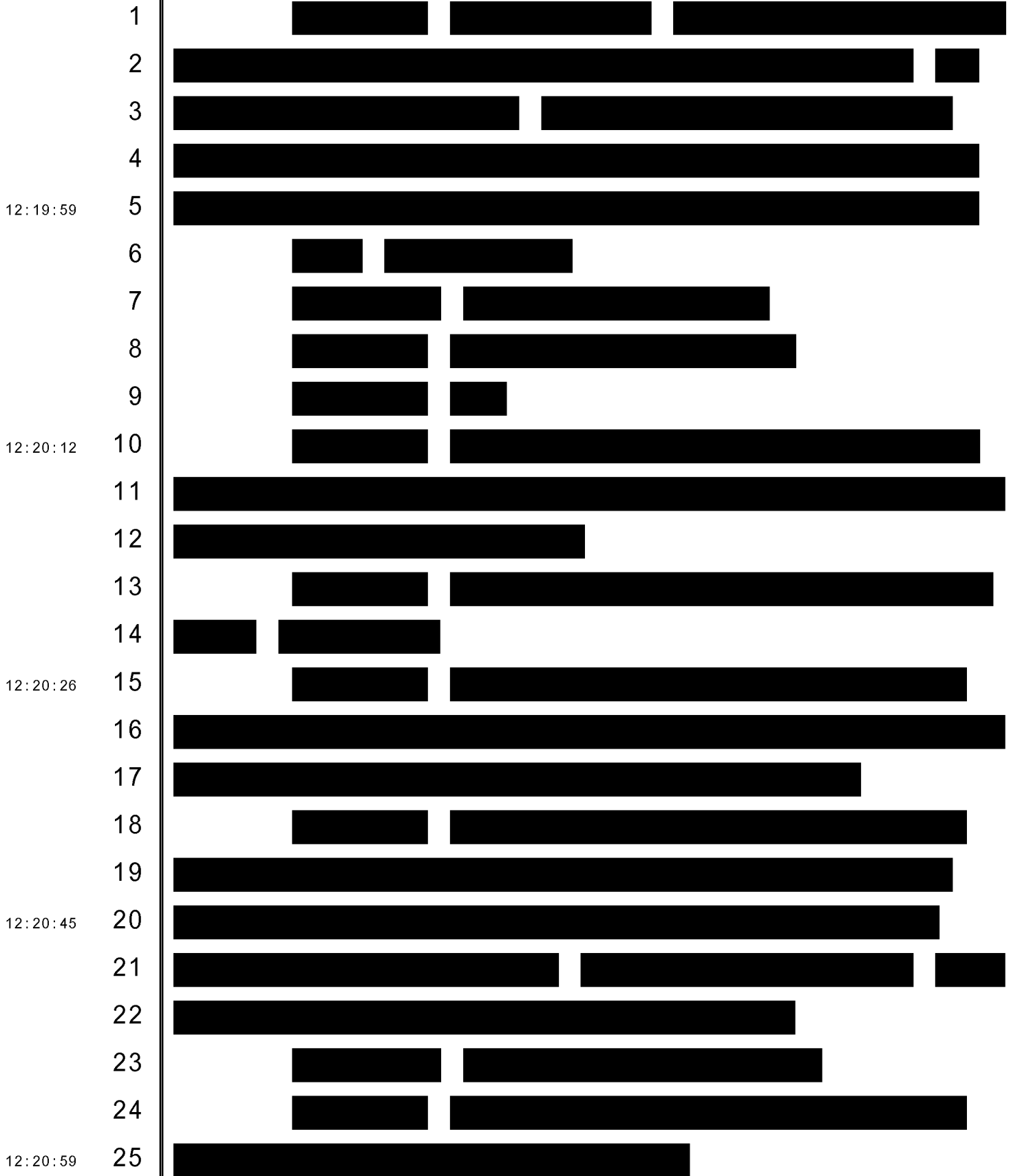
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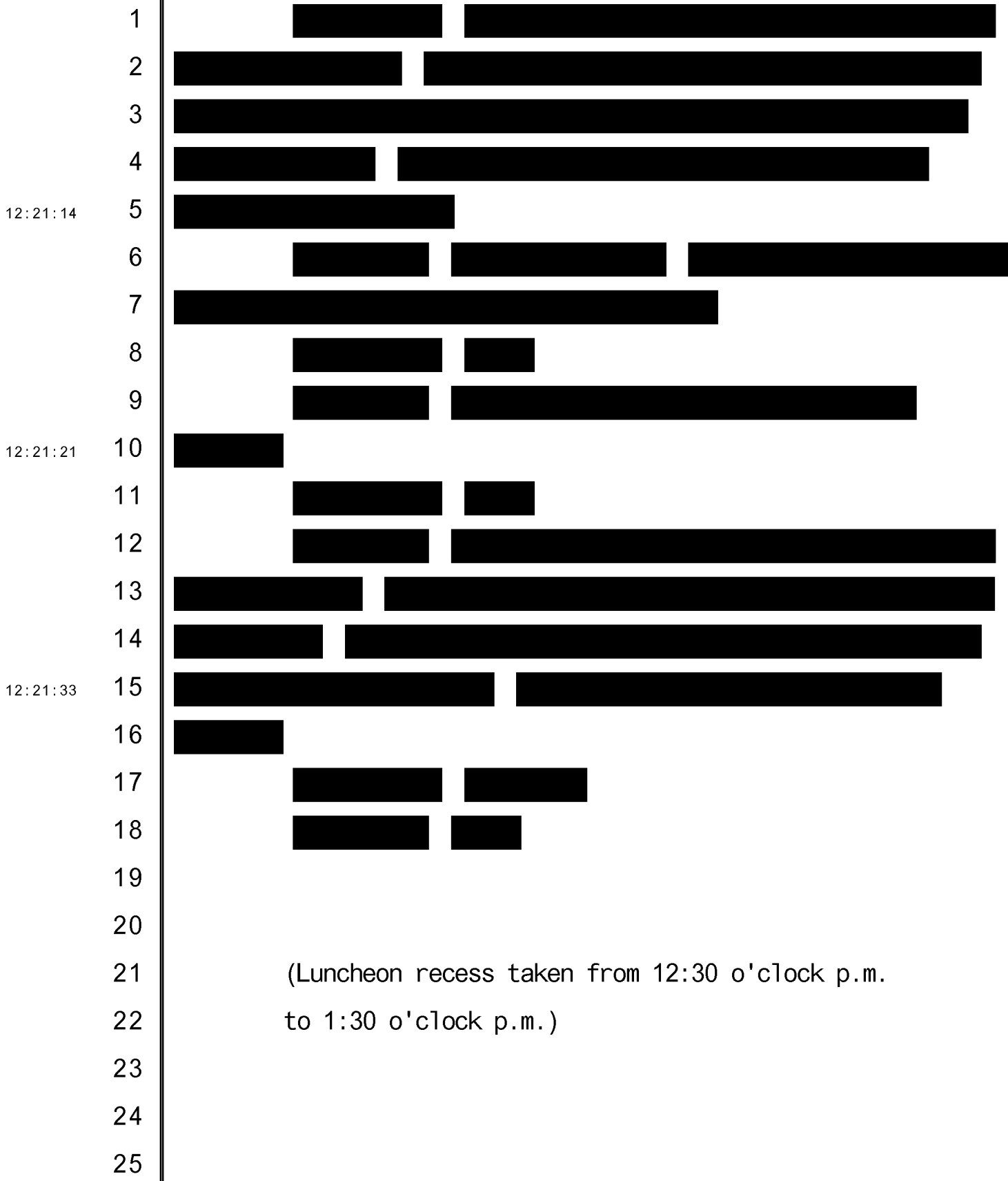
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I CERTIFY THAT THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE
RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER

/s/Blanca I. Lara

April 4, 2017