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,	April 5, 2017
Defendant.	9:20 o'clock a.m.

VOLUME 14 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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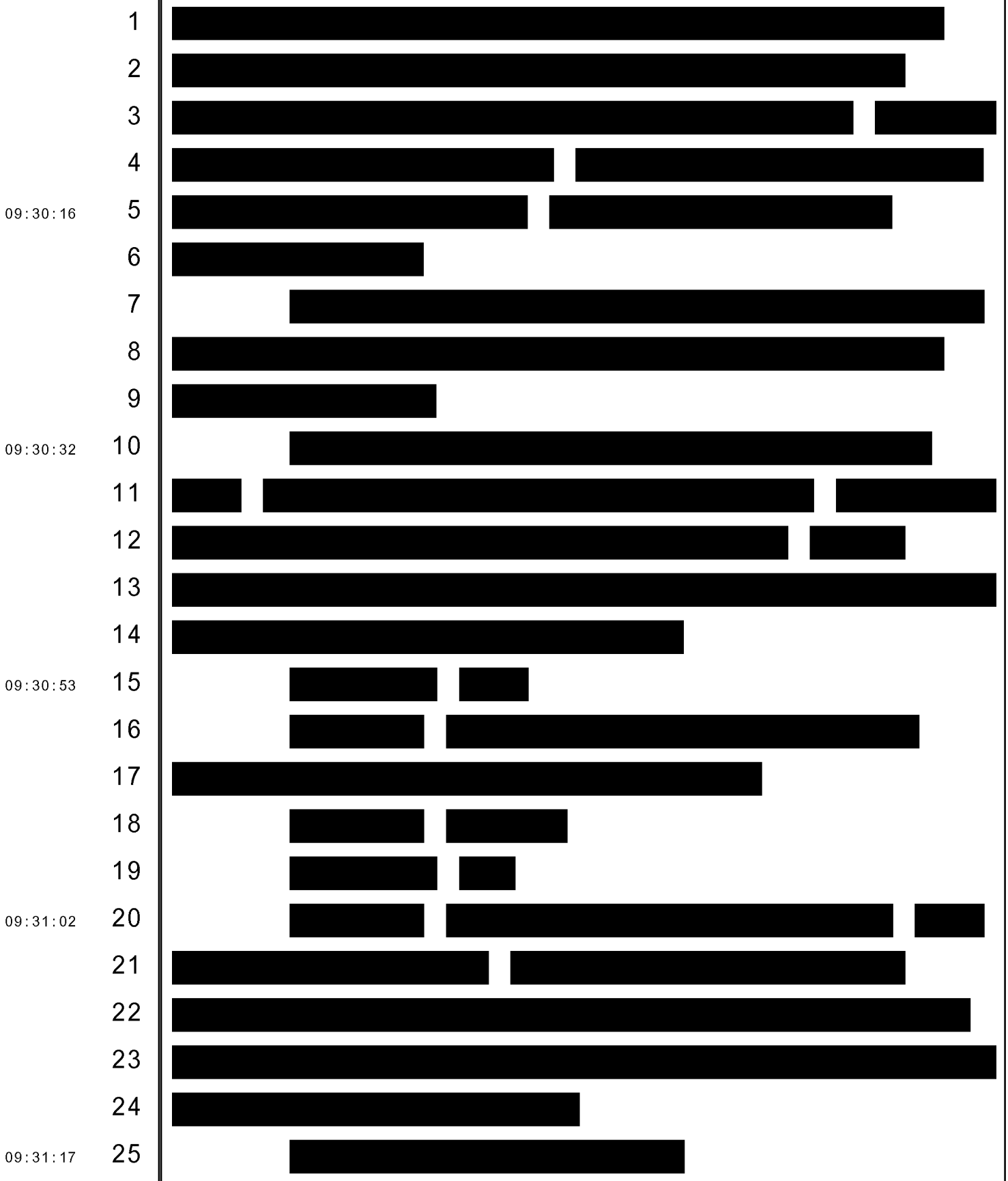
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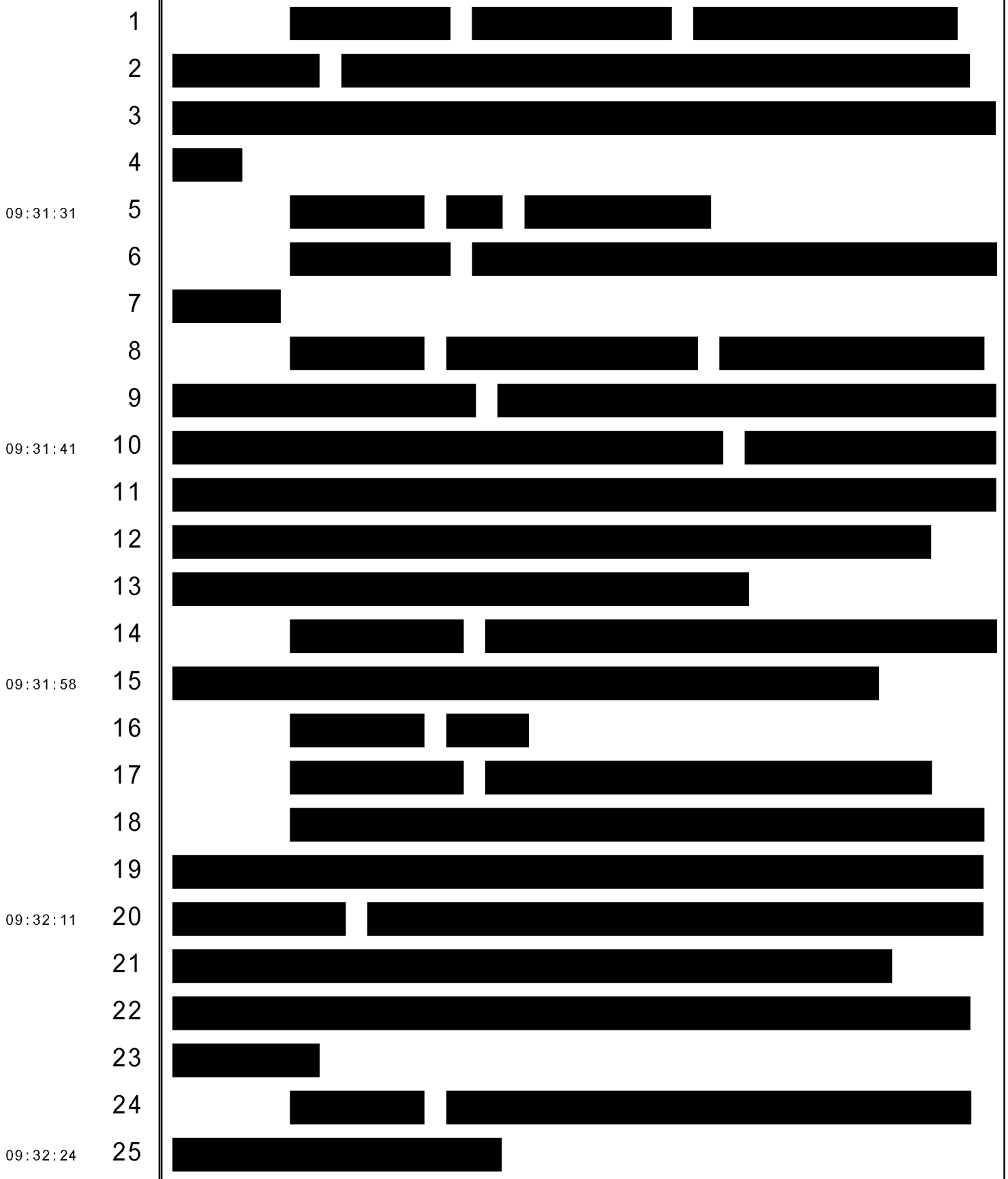
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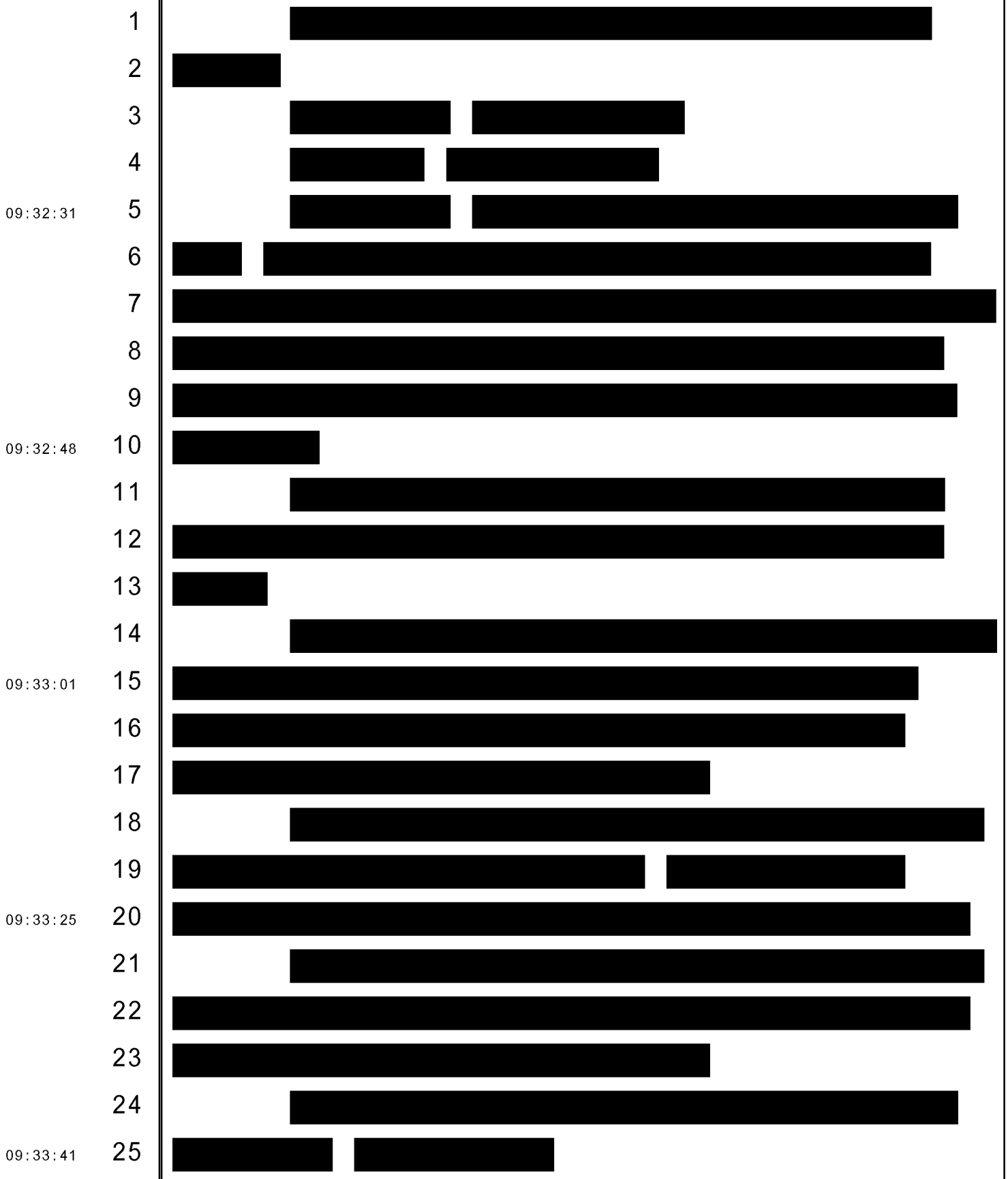
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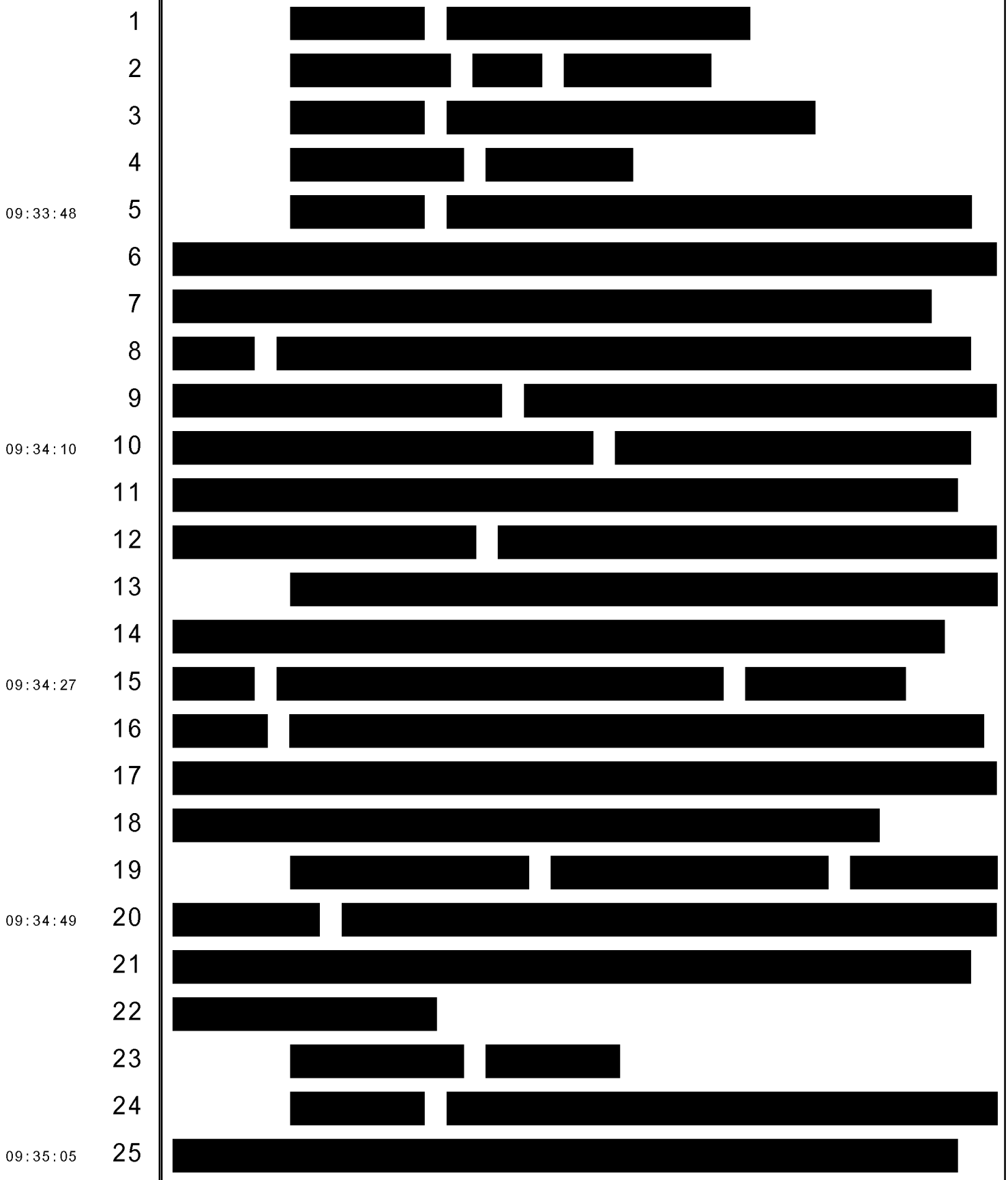
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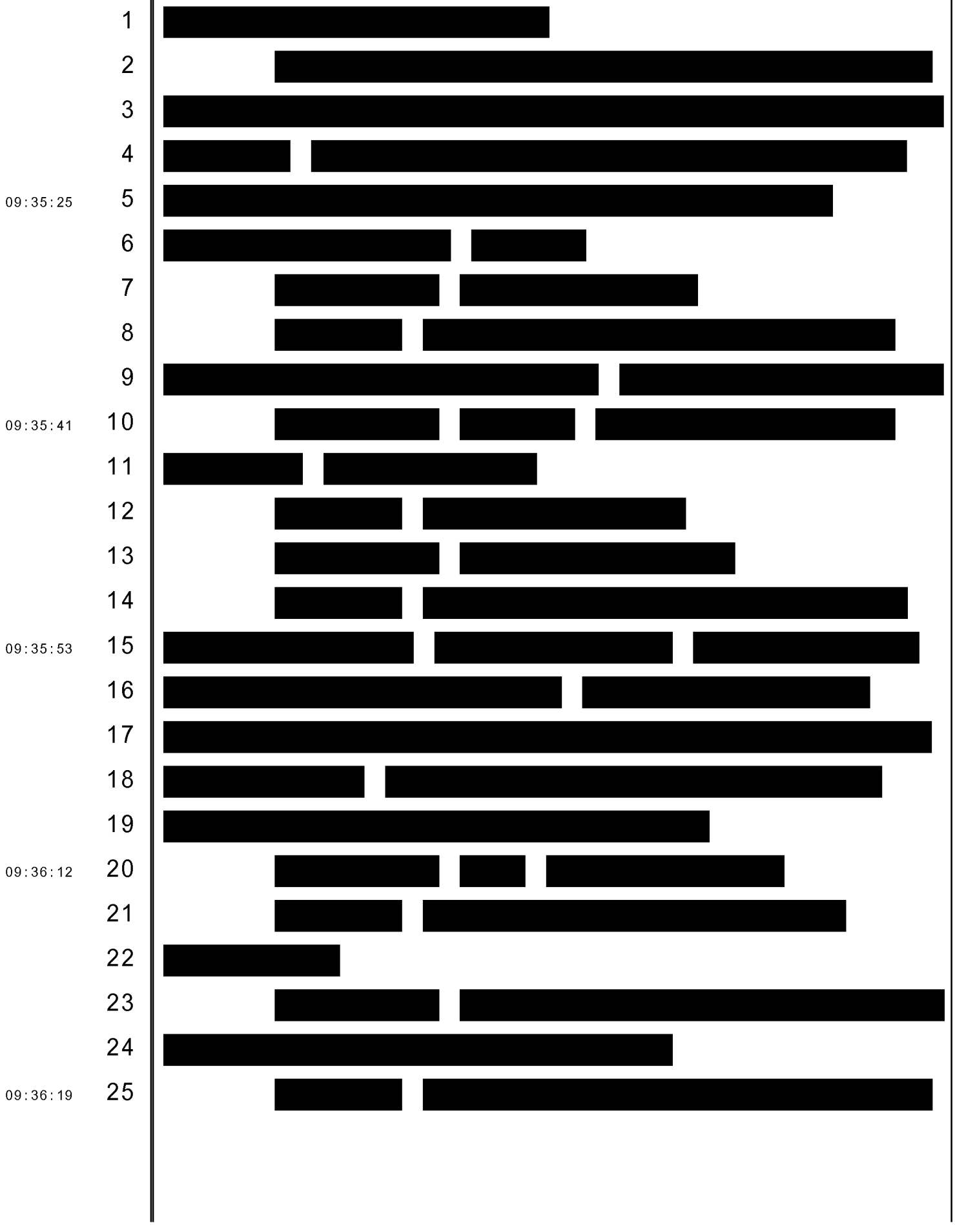
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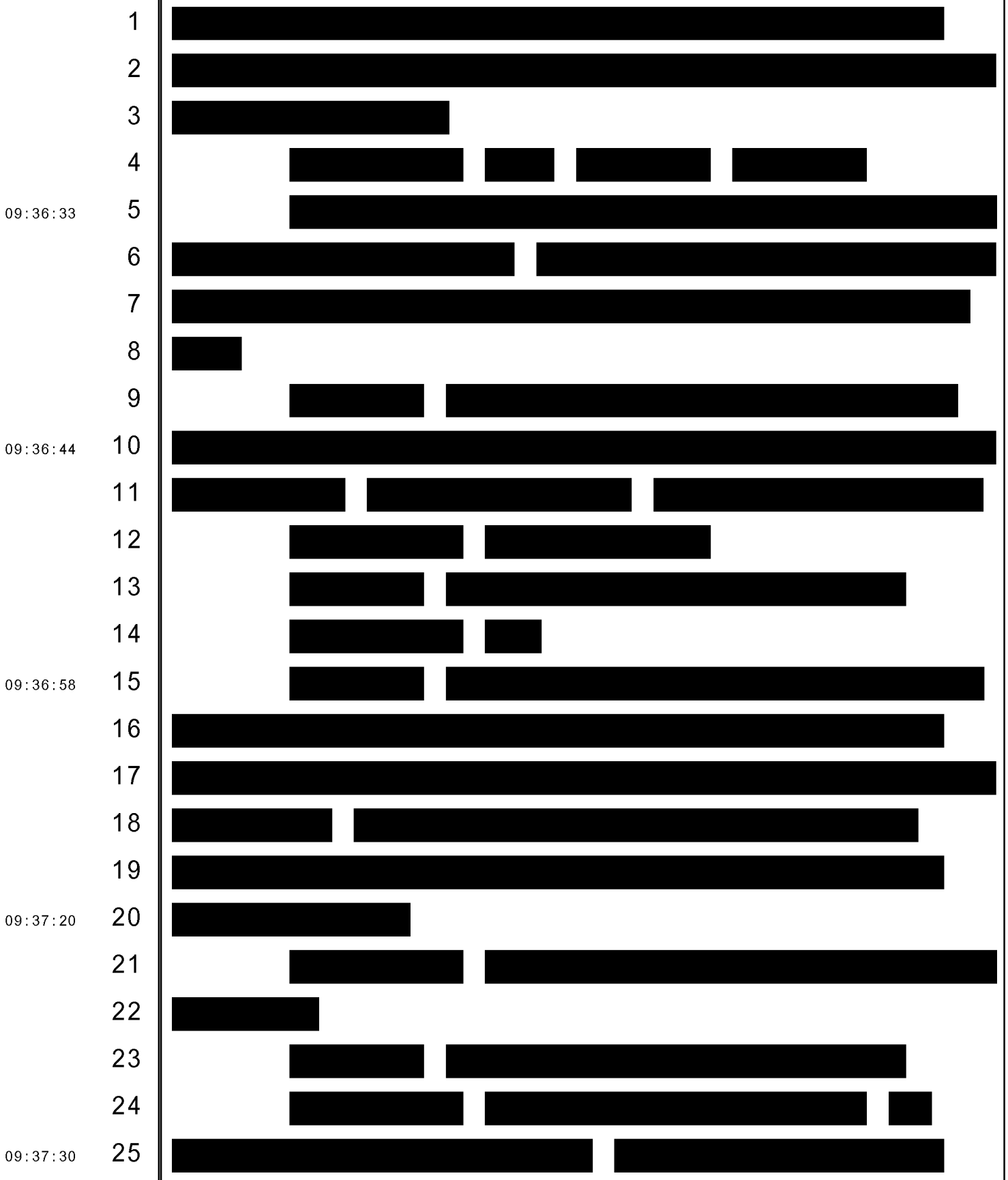
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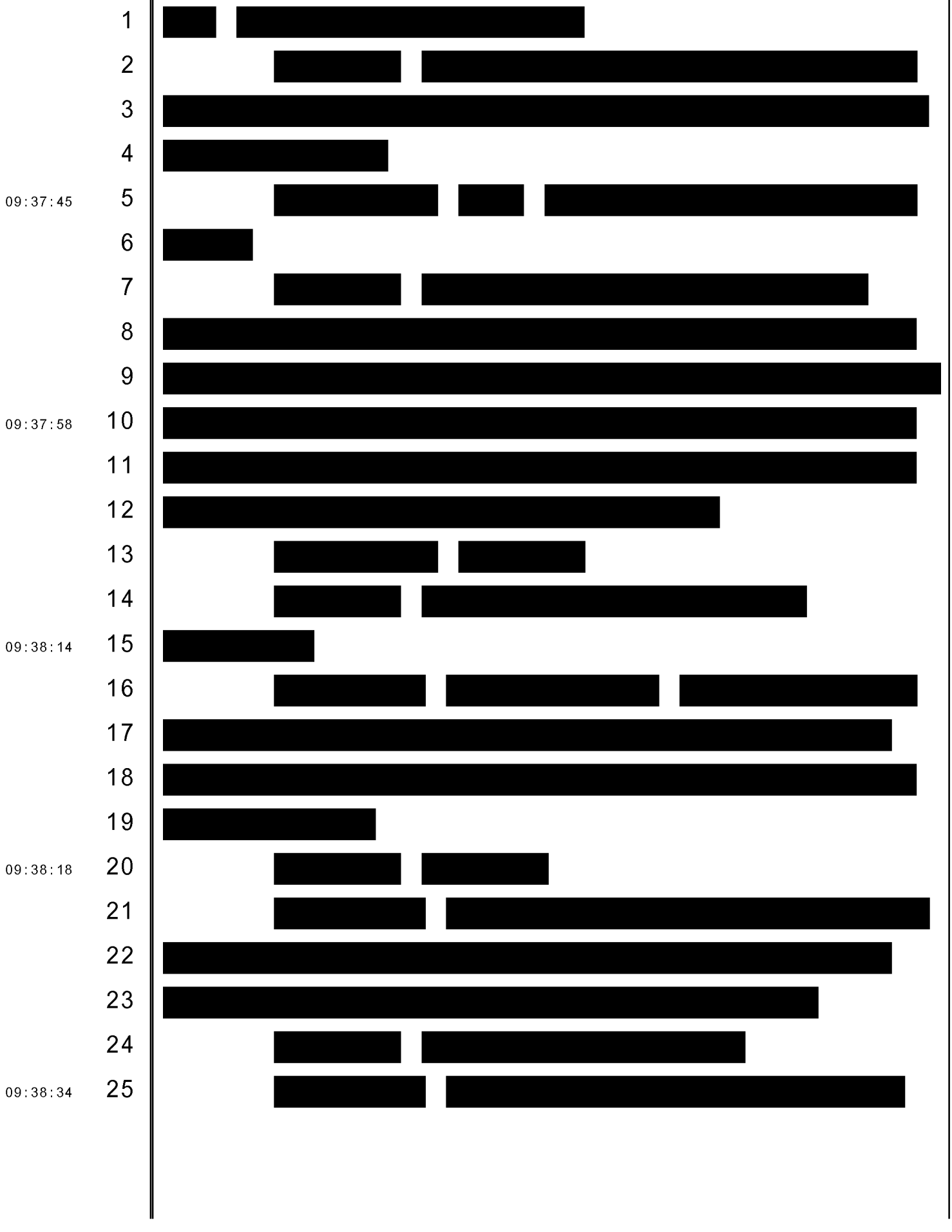
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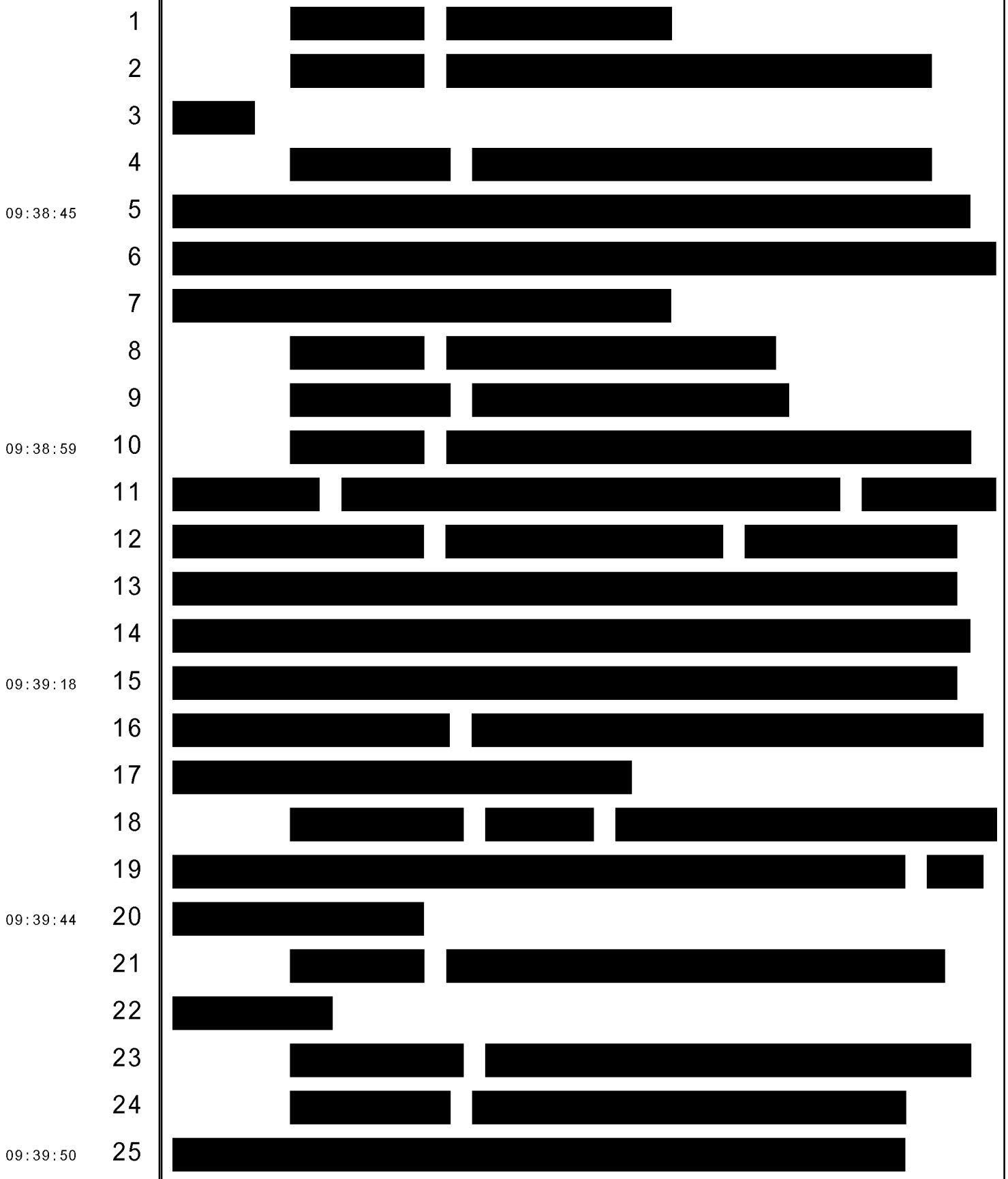
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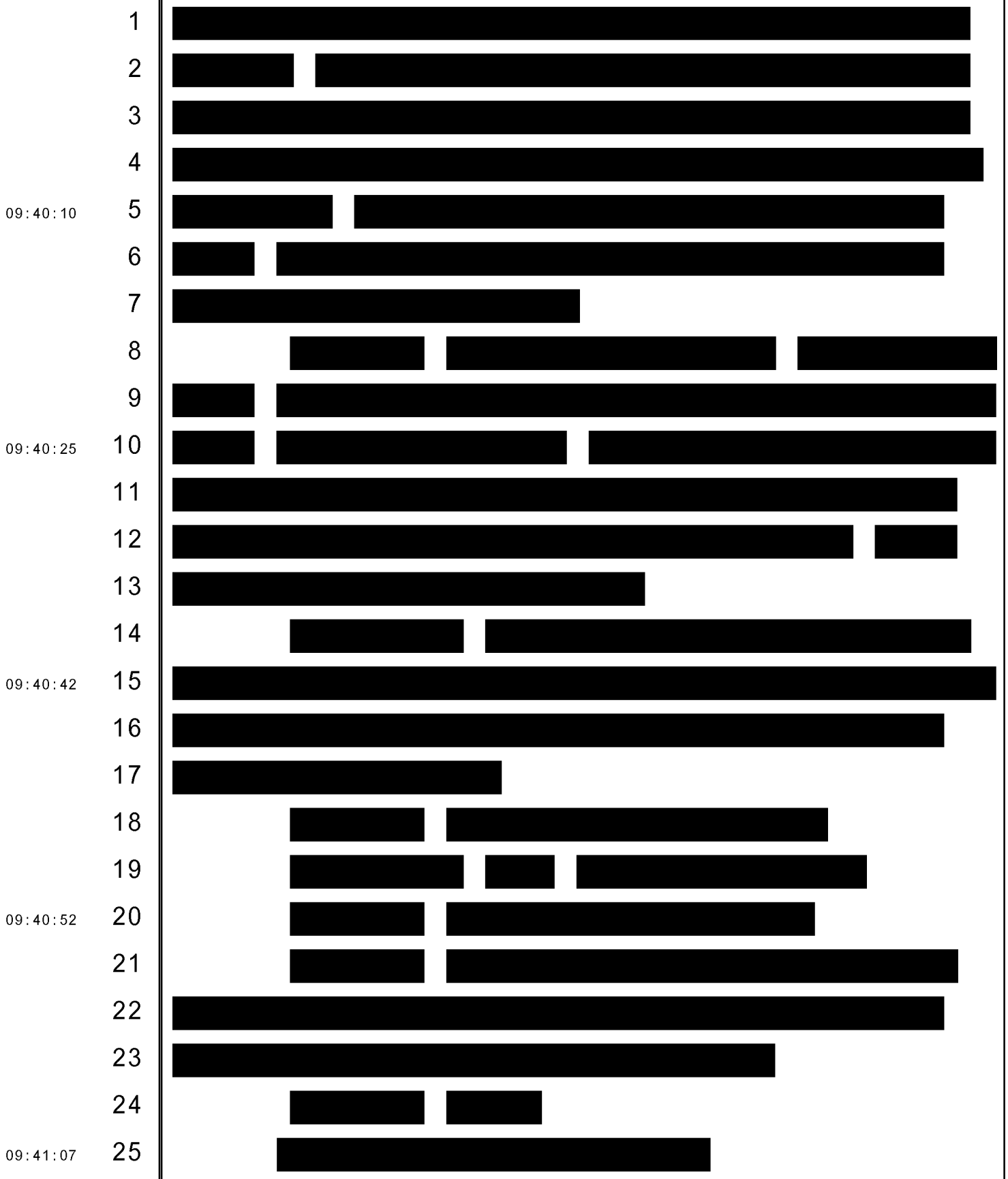
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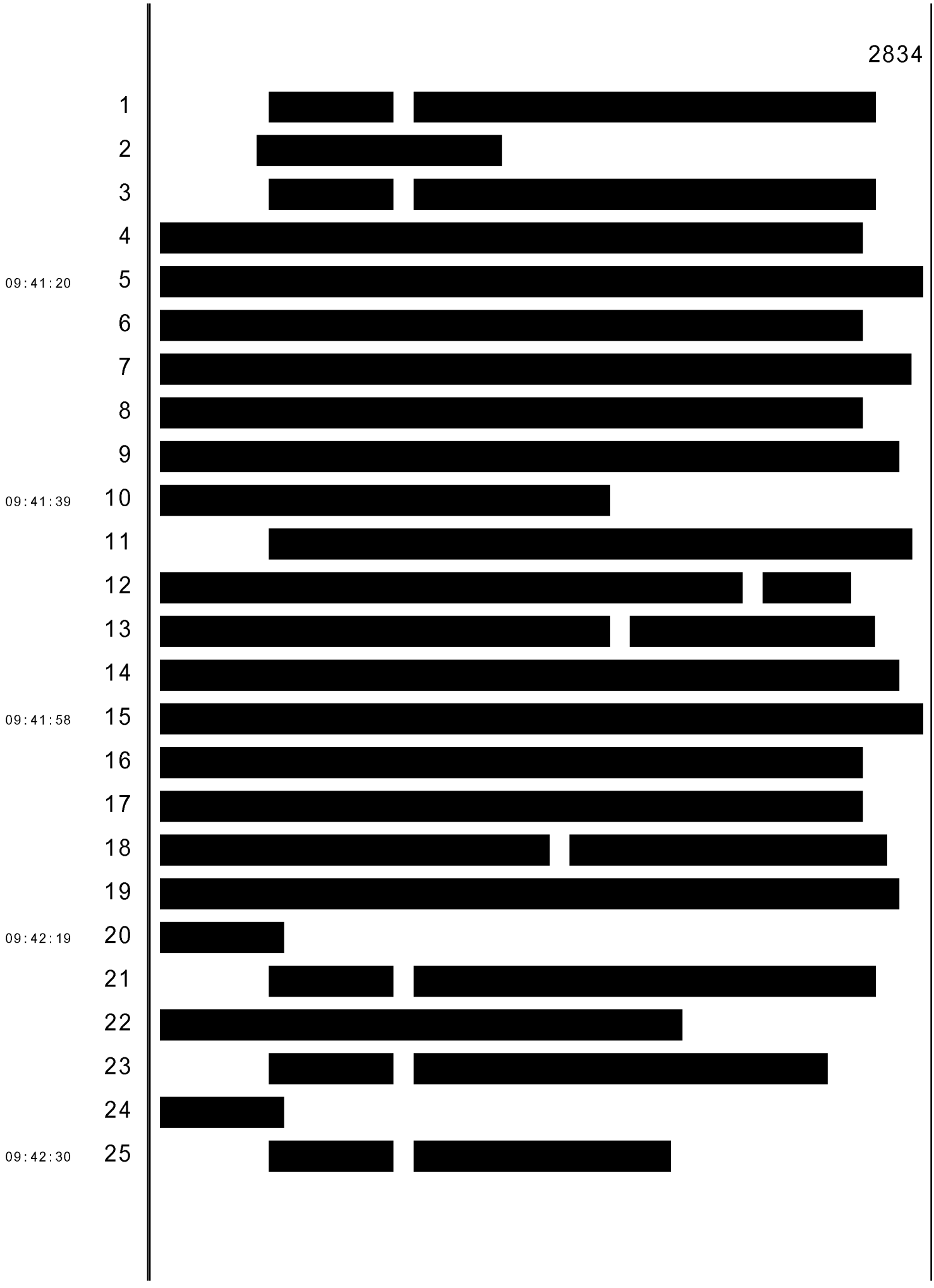
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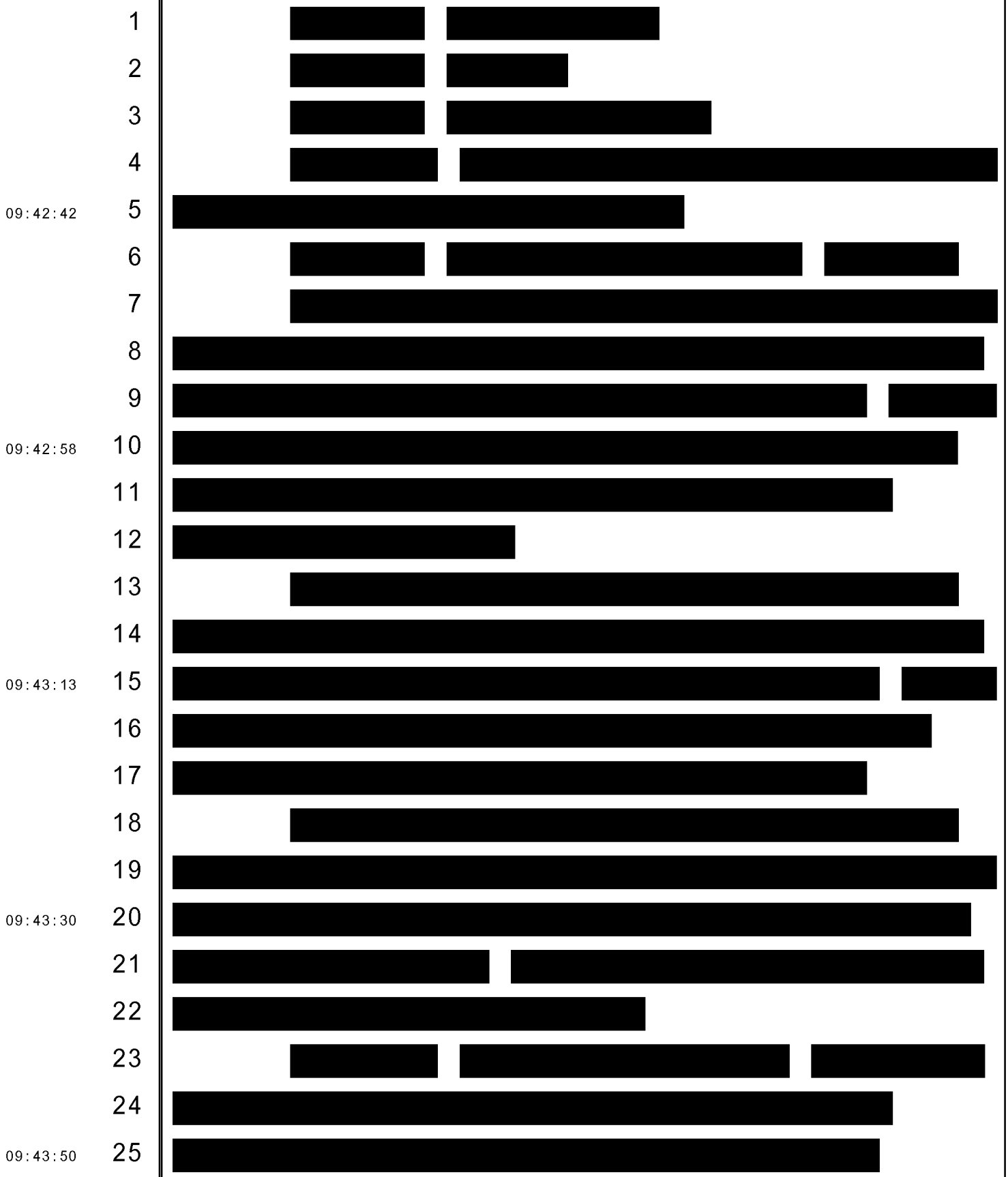
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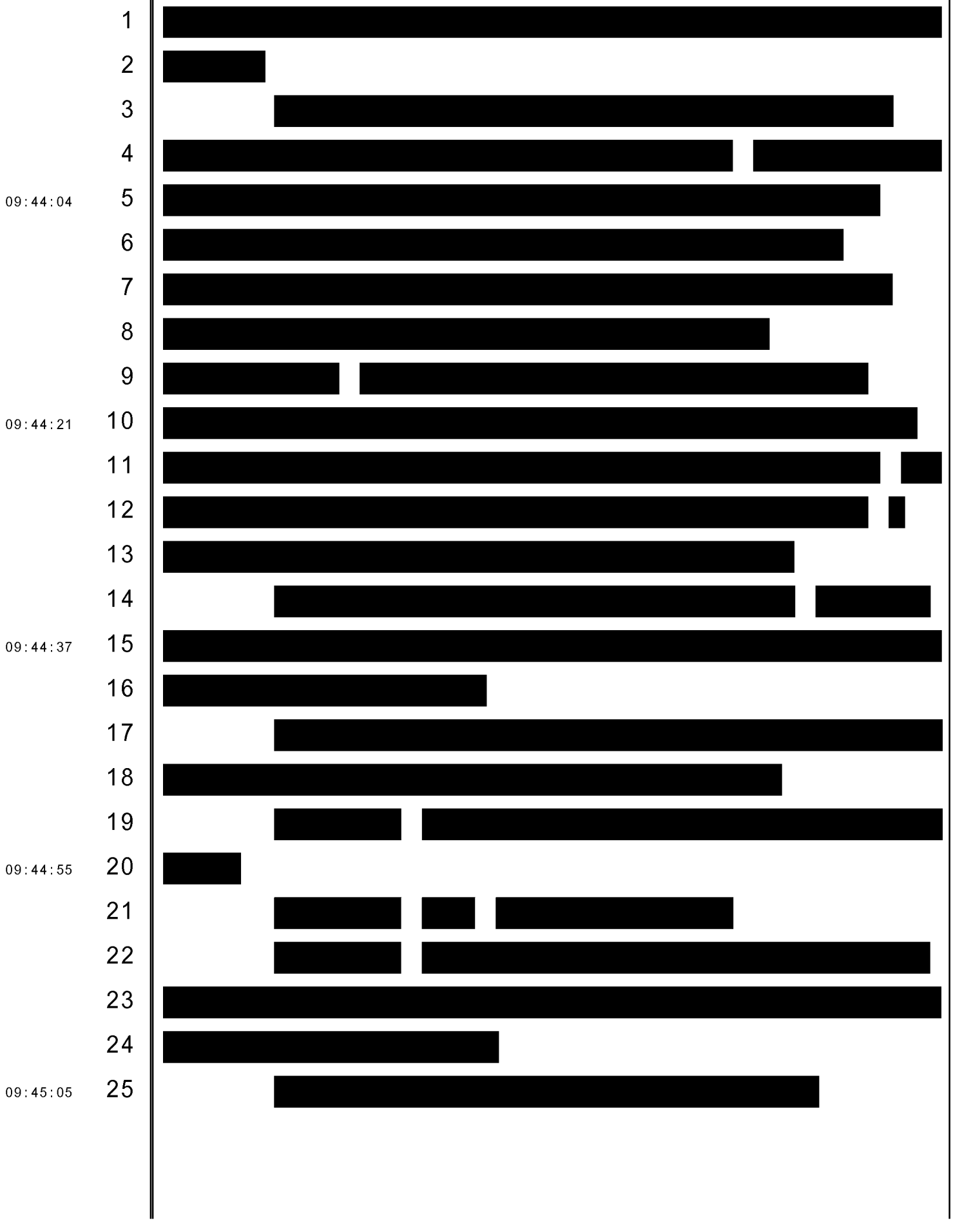
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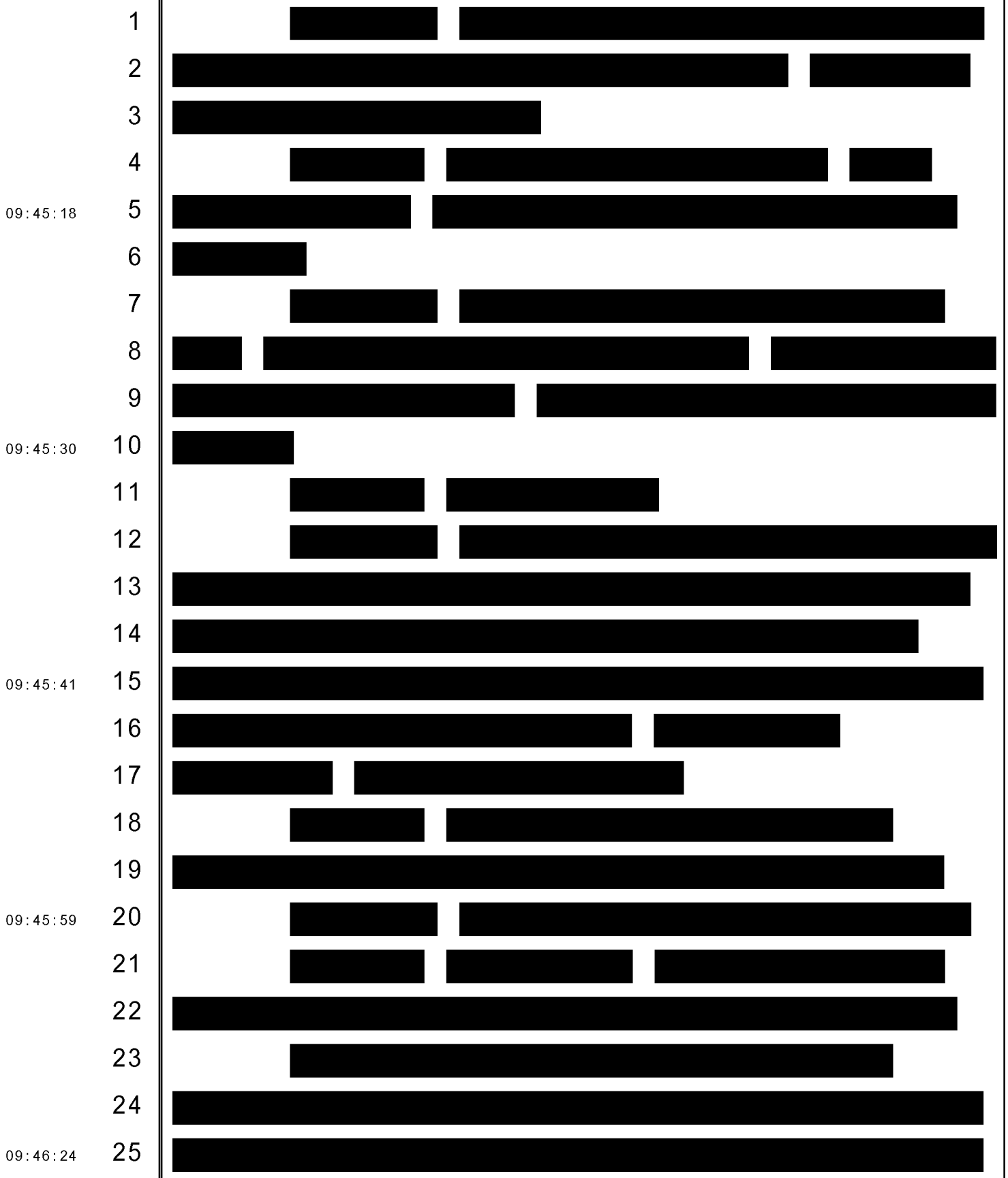
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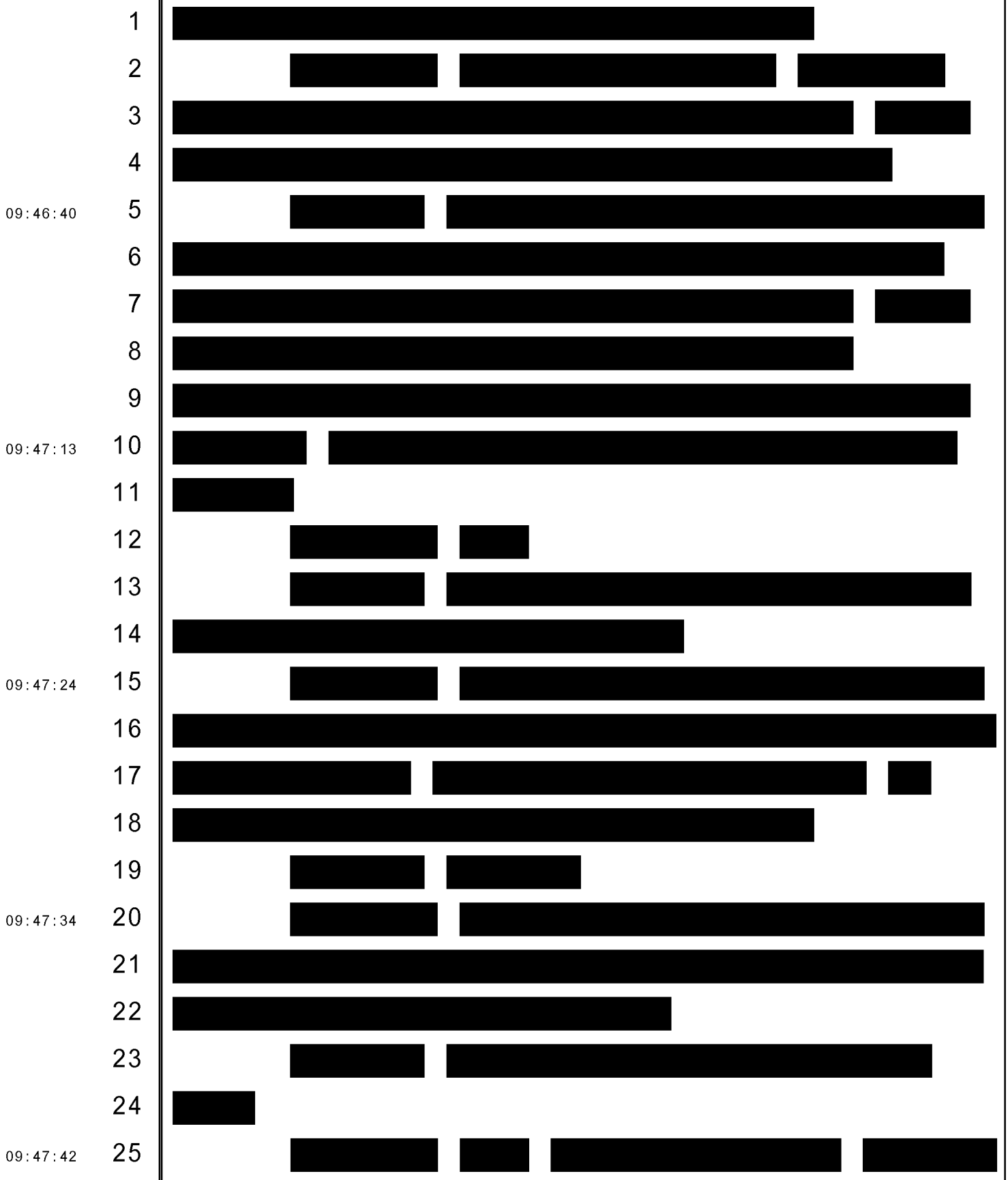
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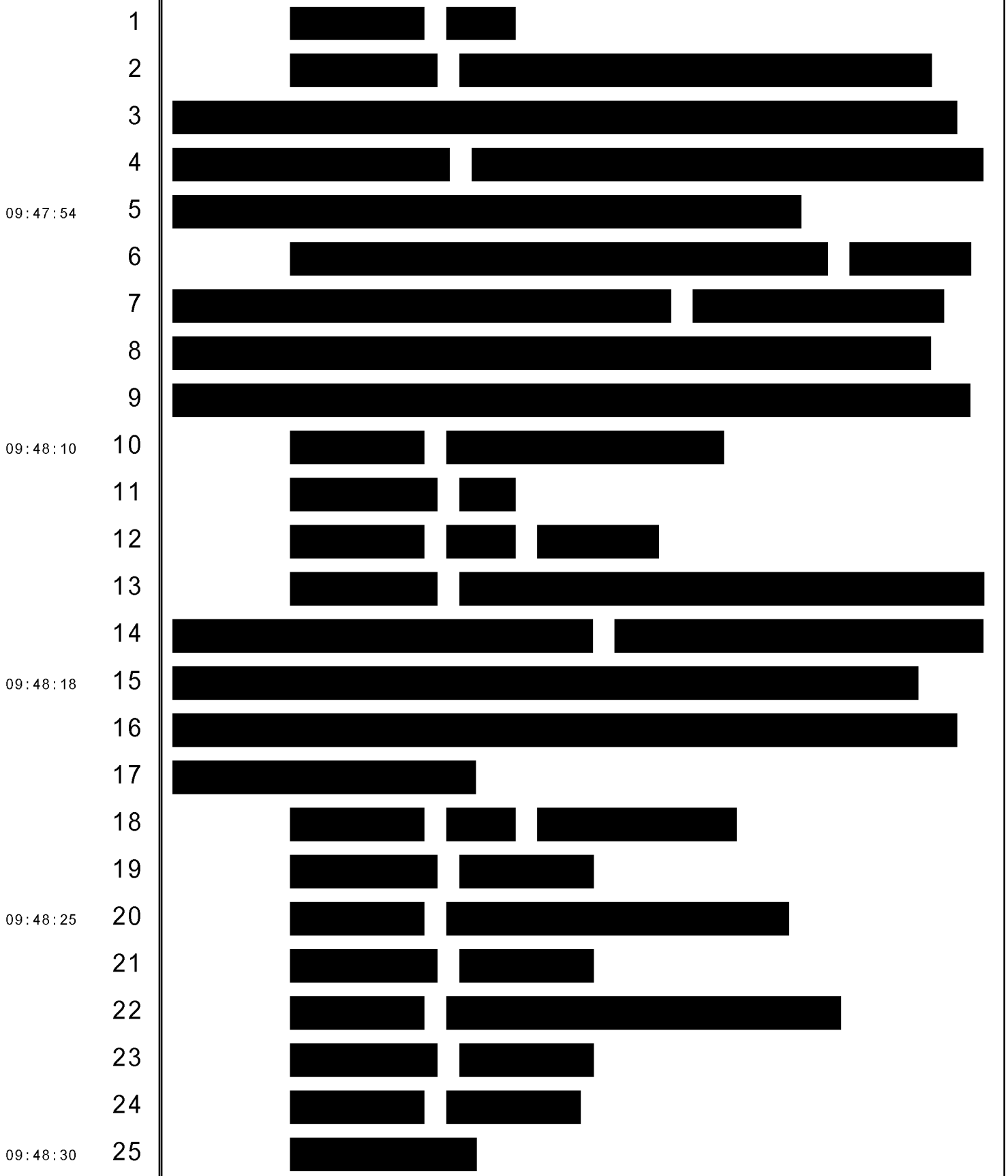
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(The following proceedings were had in the presence of the jury in open court:)

THE COURT: All right, Doctor.

Thank you very much, ladies and gentlemen. Please be seated. We will resume.

I'm sorry you didn't get your cream cheese. I was told about that. I keep track of you.

All right, proceed.

MR. DAVIS: May it please the Court, ladies and gentlemen, good morning; counsel.

ROBERT GIBBONS, DEFENDANT'S WITNESS, PREVIOUSLY SWORN

DIRECT EXAMINATION (resumed)

BY MR. DAVIS:

Q. Dr. Gibbons, good morning.

A. Good morning.

Q. We left off yesterday talking about the Healy-Fergusson article and its analysis and FDA's analysis of that particular piece of literature.

So, if we can kind of turn our attention back to that particular article. For the category that was described as fatal suicide attempts in the Healy-Fergusson article, what did that analysis find as to all SSRIs --

THE COURT: Which article are we referring to?
MR. DAVIS: This is -- it's PTX165.
THE COURT: Okay.
MR. DAVIS: Here, Your Honor, I have a copy.
09:50:50 THE COURT: All right.
(Document tendered to the Court.)
MR. DAVIS: Permission to publish PTX165.
THE COURT: Yes, you may proceed.
MR. DAVIS: Thank you.
09:51:06 (Exhibit published to the jury.)
BY MR. DAVIS:
Q. With respect to the category of looking at all SSRIs combined and the category of fatal suicide attempts, Dr. Gibbons, what was the findings?
09:51:15 A. Which tab? I just want to make sure that --
Oh, I'm sorry.
Q. It's up on the screen.
A. There was no statistically significant association.
Q. Given this finding of no association between fatal suicide
09:51:32 attempts, and then you compare that to their finding on suicide attempts, what does that tell you about how you interpret those two results?
A. It lacks consistency.
Q. So, is there anything that you take away from the numbers
09:51:49 in the Healy-Fergusson articles from those two different

categories to make an assessments of whether or not SSRIs are increasing the risk of suicide attempts?
A. No, my -- my take away would be that they're not increasing the risk of suicide attempts.
09:52:03 Q. Are you familiar with the FDA's analysis of the Healy-Fergusson article?
A. Yes.
MR. DAVIS: Your Honor, permission to publish Defendant's Exhibit 435.
09:52:21 THE COURT: You may proceed.
MR. WISNER: Objection; lacks foundation as to what this relates to.
THE COURT: Okay. Is it in evidence?
MR. DAVIS: It's been shown before, Your Honor. It's
09:52:28 been published before the jury.
MR. WISNER: What article is this, Todd?
MR. DAVIS: This is DX435 which is the Dr. Laughren memo of November 16 --
MR. WISNER: I was confused. You said the FDA memo.
09:52:42 Okay.
(Exhibit published to the jury.)
MR. DAVIS: Mr. Holtzen, could we pull back page 4, last paragraph. I'm sorry, pull up page 4, the discussion. Here we go.
09:52:49 BY MR. DAVIS:

Q. Is this the FDA's analysis of the Healy-Fergusson article?
A. Yes, it is.
Q. Were there any limitations of the Healy-Fergusson analysis that the FDA discussed, and if so, what were they?
09:53:08 A. The FDA pointed out several serious limitations of the Healy-Fergusson article. The first is that 58 percent of the data were missing --

MR. WISNER: Objection, Your Honor; hearsay. This isn't his opinion. He's talking about the FDA's thinking. If
09:53:25 he can give his own opinion, that's one thing, but this is --

THE COURT: Yeah. You have to stay with what the information is.

BY MR. DAVIS:
Q. Let me see if I can tab this. Given that the FDA's
09:53:34 analysis, as shown on Defendant's Exhibit 435 says, that there was no -- that there were serious limitations in this review, most important being a lack of any information on adverse events for 58 percent of the patients eligible for the analysis, what is your takeaway about that statement?
09:53:54 A. I think it's a correct statement. As I indicated in my expert report, there were several limitations of this study, including the majority of data being missing.

And also, and quite significantly, the ratio between suicide attempts to completed suicides was 2 to 1. We would
09:54:15 expect it to be 10 to 1, or 20 to 1. Suicides are much rarer

than suicide attempts. So it suggests that the ascertainment, the finding of those suicide attempts may well have been biased.

Q. By "biased" what due you mean by that?

09:54:35 A. Incorrect, misleading.

Q. So, how does that -- the fact that the 58 percent of the patients were not analyzed for this analysis, how does that affect the reliability of the Healy-Fergusson article?

A. It makes it unreliable.

09:54:48 Q. Are you familiar with an earlier by the name of--and I'm going to have some difficulty pronouncing the gentleman's name--Aursnes, A-u-r-s-n-e-s, did he publish an article in 2006?

A. Yes.

09:55:00 Q. Now did you review and consider that article for purposes of forming your opinions in the case?

A. Yes.

Q. And if we could call up PTX 217.

Is this the article we're talking about, Doctor?

09:55:16 A. Yes, it is.

Q. Does this particular article provide any new data that -- that had not already been analyzed by the FDA?

A. No.

Q. So in terms of any information entered about Paroxetine, is

09:55:30 there anything new or different in that that's not already --

not already not been analyzed?
A. Nothing whatsoever.
Q. This article used a Bayesian statistical model. Are there any problems or issues with using that kind of analysis?
09:55:44 A. Well, there's nothing with Bayesian statistics. There were problems with the analysis in terms of choosing a prior distribution, and also being able to preserve the fact that these data came from multiple studies, which was not included in the analysis either in terms of adjusting for the
09:56:08 differences in the background rate or allowing the effect of treatment to vary from study to study.
Q. Do you believe that that affected the reliability of any findings that are in the Aursnes article?
A. Yes; it's not a proper meta-analysis.
09:56:21 Q. Let's turn our attention to two studies conducted by Dr. Greg Simon.

Did you review and rely upon those analyses to form your opinions in this case?
A. Yes, I did.
09:56:35 Q. Are those the type of data that experts in your field would reasonable rely upon to form opinions?
A. Yes, they do.
Q. For purposes of what we're talking about here today, do you consider those two articles to be authoritative?
09:56:47 A. Very much so.

Q. So, if we could call up -- excuse me.

THE COURT: Permission to publish DX1345, Your Honor.

MR. WISNER: I just -- this is not a sequence. He has to show the witness. He can say what -- just throwing numbers out doesn't help me follow what's going on.

09:57:04

MR. DAVIS: It's behind Tab 8.

MR. WISNER: So, can the witness identify this document as to what you're talking about?

MR. DAVIS: Sure.

09:57:13

MR. WISNER: So we know the record is preserved.

MR. DAVIS: I'm happy to do that.

BY MR. DAVIS:

Q. What is DX1345 behind Tab 8, Dr. Gibbons?

A. It's the Simon article published in the American Journal of Psychiatry in 2006.

09:57:27

Q. Can you give us some information about how the study was conducted?

A. This was a large-scale study that looked at 82,000 episodes of antidepressant treatment.

09:57:44

And what was interesting about this study is they characterized the rates of suicide both before and after the initiation of antidepressant therapy.

Q. What time period did this particular study assess?

A. It was 6 -- 3 months before and 6 months after the initiation of treatment.

09:58:02

Q. And in terms of the total type of data that was collected, what years were involved?
A. These data were collected between 1992 and 2003.
Q. This Simon study, is that one of the large well-controlled observational studies that you discussed yesterday?
A. Yes, it is.
MR. WISNER: Your Honor, I renew my objection. This is data that we specifically ruled out pretrial. This is national suicide rate data.
MR. DAVIS: Your Honor, we've already discussed this.
THE COURT: But we haven't heard that yet.
MR. WISNER: He just testified to that, Your Honor.
MR. DAVIS: You may proceed, Your Honor?
THE COURT: Yes. To the extent that we have previously ruled out national suicide data, the objection is sustained.
MR. DAVIS: Your Honor, I would like to publish DX1345.
THE COURT: You may proceed.
MR. DAVIS: Thank you.
BY MR. DAVIS:
Q. I told us just a few moments ago, Dr. Gibbons, that this study analyzed information before patient starts on the medication and also the window of time after the patient starts on the medication; do you remember that?

A. Yes.
Q. All right.
MR. DAVIS: So if we could call up Figure 6 on page 45, Mr. Holtzen.
09:59:18 And if you can call up -- make the figure -- there we go.
BY MR. DAVIS:
Q. Doctor, can you help us understand what we are looking at here in this particular figure in the Simon article.
09:59:33 A. The importance of this figure, and in particular the left side of this figure on newer antidepressants, shows that the highest period of risk is prior to the initiation of antidepressant therapy, and that it drops off and then slowly declines thereafter.
09:59:51 The importance of this is that the high risk period even after, if we hadn't looked at the data before, we would've thought, well, in the first month there's an increased risk of suicide, what were seeing here is a tailing off of the prior high risk of suicide into the first month following the
10:00:13 initiation of suicide --
MR. WISNER: Objection, Your Honor.
THE WITNESS: -- the initiation of antidepressant.
MR. WISNER: Sorry.
Are you done, sir?
10:00:19 THE WITNESS: Not yet.

MR. WISNER: Okay.

THE WITNESS: And so what we're seeing is that the highest risk period is prior to the initiation of treatment, and that risk goes down significantly with the initiation of treatment.

MR. WISNER: At this time, Your Honor, I move to strike the witness's testimony under relevance. The increased risk of suicidality prior to initiation of therapy has no relevance in this case, and is, in fact, just a common-sense understanding. In comparing before therapy and after therapy for the first month is entirely misleading. So, we move to strike his testimony, Your Honor.

THE COURT: You may inquire on cross-examination and then we'll deal with that.

BY MR. DAVIS:

Q. And so we are clear, the left side is looking at SSRIs which are newer antidepressants?

A. Yes.

Q. Okay. And so in terms of -- from a statistical analysis and someone who's spent his career looking at these kinds of studies, what does this finding tell us from the standpoint of a biostatistician and expert in this field?

A. It tells us that the initiation of antidepressant therapy is not increasing the risk of suicide, it's decreasing the risk of suicide.

Q. Now, did the Simon study, the authors, did they publish their convolutions from this particular analysis?
A. Yes, they did.
MR. DAVIS: All right. If we can call those up, please, Mr. Holtzen.
BY MR. DAVIS:
Q. What were the findings, Dr. Gibbons?
A. They indicated that their data did not suggest increased risk of suicide death or serious suicide attempt during the first month of antidepressant treatment.
Q. Do you agree with that assessment?
A. I do.
MR. DAVIS: If we could also look at the next conclusion, Mr. Holtzen.
BY MR. DAVIS:
Q. What was their other conclusion, Dr. Gibbons?
A. They concluded that the risk was highest in the month before the initiation of antidepressant treatment, before the initial prescription, probably because of the fact that suicide attempts may prompt initiation of treatment.
Q. Do you agree with that?
A. I do.
Q. All right. Let's turn or attention to the second article by Dr. Simon. If you can turn behind Tab 9.
And can you tell us what -- that's DX1346. That's the

second article by Dr. Simon?
A. Yes, it is.
Q. What year was it published and where was it published?
A. It was published in the American Journal of Psychiatry, in
10:02:58 the same journal, and it was published the following year, in 2007.
Q. How was this study conducted?
A. So, this was a similar study that looked at the time sequence of suicide events before and after the initiation of
10:03:12 treatment, but one of the things that this study added to the prior study, which was incredibly important, was the comparison between medications like SSRIs, like Paroxetine, to psychotherapy in the absence of those medications.
Q. So in terms of the time period, the years that this
10:03:33 particular controlled study looked at, what periods of time were assessed?
A. I believe they were the same periods of time.
Q. If you can look at -- if you look -- can you turn to the second page under "methodology."
10:04:01 It's actually the first page, last paragraph, turning over to the next page on 1030?
A. The period of time was 1996 through 2005.
Q. In terms of when the patient started the medication, did this study also assess what the risk was before the patient
10:04:27 started medication and after they started the medications?

A. Yes.
Q. And what were the results.
MR. DAVIS: And if we could show Figure 1 in DX1346.
And permission to publish that, Your Honor.
10:04:44 THE COURT: Yes.
MR. WISNER: I mean, understanding my continuing objection to this, no objection, Your Honor.
THE COURT: You may proceed.
(Exhibit published to the jury.)
10:04:47 BY MR. DAVIS:
Q. Again, Doctor, what are we looking at here with respect to the second Simon study?
A. So, this is an enormously slide in contribution to this literature. The second two panels, the middle says, 10:05:05 "antidepressant prescriptions from a psychiatrist." So, this is in the hands of a psychiatrist.
Were seeing the same pattern that we saw in the 2006 paper where the highest rate of suicide, suicide attempts was -- suicide attempts were before the initiation of 10:05:23 treatment, and then it goes down, and continues to go down through the course of treatment.
What's really important about this slide is the next panel, the third panel of that individual psychotherapy for depression. These people did not receive an SSRI. They did 10:05:39 not receive Paroxetine. They did not receive any

pharmacotherapy for the treatment of their depression. They received talk therapy, yet we see exactly the same pattern.

What's important about this slide is, if there really was an effect of antidepressants on increasing suicide attempts and suicide, we'd see a very different pattern between those that received pharmacotherapy, like an SSRI, like Paroxetine, versus those that received talk therapy.

10:05:58

MR. WISNER: Objection; move to strike this witness's testimony what you'd expect to see with psychotherapy. He is not a psychotherapist and cannot offer that opinion.

10:06:16

MR. DAVIS: He's just talking about the statistical analysis.

MR. WISNER: He is saying you would expect to see, that is what you -- that's a medical opinion, Your Honor.

10:06:26

MR. DAVIS: It's not a medical opinion. It's a statistical --

THE COURT: I say to the extent that he's testifying based on the statistics, he may testify.

MR. DAVIS: Thank you.

10:06:34

BY MR. DAVIS:

Q. So, let's turn to what the conclusions of this particular study.

MR. DAVIS: If we could call up DX1346, Mr. Holtzen.

BY MR. DAVIS:

10:06:45

Q. What was the conclusion of this particular study,

Dr. Gibbons?
A. First, as in the earlier paper, that the incidents of suicide attempt was highest in the month before starting treatment and declined steadily over the next 6 months.
10:06:58 Q. So, do either of the Simon studies that we've talked about, do either of them support the claim that the use of Paroxetine or other SSRIs result in a greater number of suicide attempts in the first month of treatment in adult patients?
A. No, they do not.
10:07:13 Q. I want to outline for you a claim that's been made about statistical analyses and get your opinion about it, Dr. Gibbons.

The claim is that if the results of the statistical analyses that have been conducted on SSRIs or Paroxetine, 10:07:35 including the GSK analysis in 2006 and the FDA analysis in 2006, that if you look at those studies, that those studies can't rule -- can't rule out if there's a decrease risk in some patients if there's an odds ratio of less than 1, that you can't rule out that some patients who received the medication, 10:08:01 it may be increasing the risk but at the same time it also may be increasing the risk in others?

MR. WISNER: Objection; move to strike.

THE COURT: Yeah. You are leading him. You are asking him if he agrees with you. You got to ask him the 10:08:14 question. Let him testify to what he thinks.

MR. DAVIS: Sure.

BY MR. DAVIS:

Q. I want you to assume that there's a claim in statistical analyses, that if the odds ratio is less that 1.0, that the results show there could be a decrease risk in some patients and an increase risk in others, do you believe that's a valid way to analyze statistical analyses such as these?

A. Well, I don't believe that's a valid way to interpret the results of statistical analyses.

Q. Why not?

A. Well, first of all, it's a conjecture. It's a hypothesis that the overall effect that may be in the direction of benefit is restricted to a subset of the population and that there's another subset of the population that is going in the opposite direction.

I think that it's a hypothesis. It may be true. I think you could say it about anything. You could say it about any drug and any adverse effect. You could say it about the benefit of any particular treatment as well. It lacks specificity.

If there is a reason and you can identify people who may be subject to increased risk, then you should identify them and conduct a study and analyze those data and draw scientific conclusion.

I do think that they is evidence that we've seen here

today, in fact we just seen it, that supports the idea that there isn't such a subgroup, and the reason is is that we don't see a difference in the temporal pattern in the 2007 Simon paper between people who are treated with pharmacotherapy versus people who are treated with psychotherapy.

10:09:50

If there was a subset, we would see a very different ratio between the month before initiation of treatment and the month after the initiation of treatment in people who were treated with pharmacotherapy than we do in people who are treated with psychotherapy, those temporal patterns are virtually identical.

10:10:09

Q. So to form your opinions in this case, Dr. Gibbons, did you review analyses done by GSK in -- which assess placebo-controlled studies and whether there was increased risk in suicide, suicide attempts, and suicide related events in adult patients?

10:10:30

A. Yes, I did.

Q. Did those analyses -- were those analyses that you looked at just limited to the GSK 2006 analysis that we discussed?

A. No, looked at all of the analyses.

10:10:45

Q. And so did that -- did the analyses that you looked at, did they include the re-analyses of adult data that GSK had conducted -- let me back up.

Did those analyses that you looked at include GSK's re-analyses of the 1991 suicide and suicide attempt data?

10:11:05

A. Yes.
Q. Did those analyses in any way change your views that you have expressed over the last two days?
A. No.
10:11:16 Q. To form your opinions in this case, did you review analyses of GSK's healthy volunteer studies?
A. Yes, I did.
Q. Did those analyses show that any healthy volunteer had suicidal thoughts or behavior on Paroxetine?
10:11:36 A. No, they did not.
Q. So does the healthy volunteer analysis that you looked at, does that support the claim that Paroxetine increases the risk of suicidal thoughts or behavior on Paroxetine?
A. No, it doesn't.
10:11:47 Q. Based upon your review and assessment of the worldwide scientific literature and controlled studies, are there any randomized placebo-controlled studies or observational studies that show that adult patients exposed to Paroxetine develop irresistible urges or impulses to harm themselves or commit
10:12:13 suicide?
A. No, I've seen no such evidence in the literature.
Q. In forming that opinion, did you assess GSK's adult analyses on Paroxetine, as well as FDA's analysis of Paroxetine in adult patients?
10:12:28 A. Yes, I did.

Q. Based upon your review and assessment of the worldwide scientific literature and controlled studies, are there any randomized double blind placebo-controlled studies or observational studies which show that treatment emergent agitation, or acathexia, or any other symptoms lead to suicidal thoughts, suicidal behavior, or suicides in adult patients taking Paroxetine?

A. No, I found no such evidence.

MR. DAVIS: Let's go back, if we could publish slide 79 again, Mr. Holtzen.

MR. WISNER: Todd, what is that? What exhibit number?

MR. DAVIS: It's just the ranking of scientific information.

MR. WISNER: Yeah. But we have to have an exhibit number.

(Brief pause)

MR. WISNER: I'll find it.

(Brief pause)

MR. DAVIS: 79.

MR. WISNER: Oh, 79.

(Brief pause)

MR. WISNER: It's Defendant's Exhibit 70035 I.

BY MR. DAVIS:

Q. Doctor, given that we have data from meta-analyses of randomized controlled trials and observational studies, have

the questions raised by case reports such as the Teicher and Cole article been investigated?
A. Yes, they have.
Q. So, and terms of -- so given the scientific evidence -- so, in terms of knocking the case reports, such as challenge, rechallenge and de-challenge uncontrolled healthy volunteer study, can we take those off the list for consideration given the fact that they're controlled studies that are investigating the issue?
10:14:28 10:14:46
A. Yes, we can.
Q. And given the scientific evidence available today from randomized double blind placebo-controlled trials and large-scale observational studies, where do we end up n whether Paroxetine increases the risk of either suicidal thoughts, suicidal behavior or completed suicide in adult patients?
10:15:01
A. We end up with the conclusion that there is no association (coughing) excuse me. That there is no association between Paroxetine and increased risk of suicidal attempts, ideation, behavior or completion.
Q. For each of the opinions that you've offered, do you hold them to a reasonable degree of scientific certainty?
10:15:19
A. Yes.
Q. Thank you, Doctor.
THE COURT: All right. You may inquire.
10:15:41

CROSS EXAMINATION

BY MR. WISNER:

Q. Good morning, Dr. Gibbons.

A. Good morning.

10:16:12 Q. We met previously yesterday, right?

A. Yes.

Q. So we've actually never had a pleasure of engaging in a question and answer, have we?

A. No.

10:16:23 Q. My name is Brent Wisner and I represent the plaintiff Wendy Dolin in this case.

You have never spoken with Wendy Dolin or any of the fact witnesses in this case, correct?

A. That's correct.

10:16:33 Q. All right. So just before you got off -- just before I came up here, you actually testified that there is no association between Paxil ingestion and adult suicidal behavior, is that right?

A. Yes.

10:16:48 Q. Are you familiar with Dr. Kraus?

A. Yes.

Q. He works for GSK?

A. That's my understanding.

Q. You understand he's going to be testifying in this case for

10:16:57 GSK, right?

A. I believe he will, yes.
Q. And, in fact, before you took your deposition in this case, you actually read his depression, didn't you?
A. I may have.
10:17:08 Q. That's what you testified to in your depression, right?
A. Sitting here right now I don't recall, but --
Q. Well, do you recall that Dr. Kraus testified that there was a statistically significant association between Paxil and adult suicide?
10:17:25 A. Sitting here right now, I don't recall.
Q. Would you like to take a look at the deposition to refresh your recollection?
A. If you'd like me to.
MR. WISNER: May I approach?
10:17:41 BY MR. WISNER:
Q. Doctor, I'm handing you a copy of Dr. Kraus's deposition. Why don't you take a look at the section highlighted on page --
MR. DAVIS: My objection is, I don't believe the foundation has been laid to impeach or utilize this testimony
10:17:55 with Dr. Gibbons.
MR. WISNER: I'm not impeaching. I'm refreshing his recollection.
THE COURT: You have Dr. Gibbons's deposition?
MR. WISNER: Yes. But he said he reviewed Dr. Kraus's
10:18:08 depression and so I just want to refresh his recollection about

what Dr. Kraus said.

MR. BAYMAN: He hasn't said he's relied upon it, Your Honor.

THE COURT: Overruled. He may inquire.

10:18:14 BY MR. WISNER:

Q. So why don't you just read that orange section and let me know when you're done; to yourself.

(Document tendered to the witness).

MR. DAVIS: May I have a copy, please? I don't think

10:18:35 I've been handed a copy.

MR. WISNER: I only got one.

BY MR. WISNER:

Q. Are you done, Doctor?

MR. DAVIS: Your Honor --

10:18:43 MR. WISNER: I'm going to hand it to you in a second. Just waiting until he's done, Mr. Davis.

(Brief pause)

BY THE WITNESS:

A. Yes, I'm done.

10:18:49 (Brief pause)

BY MR. WISNER:

Q. So, Doctor, does that refresh your recollection that Dr. Kraus, a psychiatrist working for GSK, testified that there was a statistically significant association between Paxil ingestion

10:19:02 and adults?

A. Yes, it does.
Q. Okay. You disagree with him, right?
A. I don't disagree that the P-value was around .05 and that the lower confidence limit didn't include the value of 1. What
10:19:20 I disagree with is that this is one of numerous subgroup analyses. And so the statistical significance of one of many subgroup analyses no longer applies.
Q. So that sounds like a bunch of words, but from my understanding you disagree with Dr. Kraus that there is a
10:19:40 statistically significant increased risk of adult suicidal behavior, correct?
A. Again, as I said, I certainly see the same statistic that Dr. Kraus looked at. As a psychiatrist, he looked at that statistic and said, "oh, it is statistically significant."
10:19:59 We're talking about the MDD subpopulation for Paroxetine, but given the multitude of tests, both the FDA and I come to the same conclusion, that it is consistent with the large number of repeated subgroup analyses that were conducted, and I would not view that as statistically significant
10:20:23 evidence.
Q. I'll ask you again. Maybe we can get a yes or no out of that. Yes or no --
MR. DAVIS: Objection.
BY MR. WISNER:
10:20:28 Q. -- do you disagree --

MR. DAVIS: Excuse me.

I object to the argumentative nature of the question.

MR. WISNER: I asked a yes-or-no question. He hasn't answered yes or no to my question, Your Honor. He keeps talking about the FDA. I didn't even talk about the FDA. I said does he agree with Dr. Kraus or not yes or no, and he gives me a two-paragraph answer.

10:20:38

THE COURT: All right. You may answer if you can, sir.

10:20:47

BY THE WITNESS:

A. So my answer is, I agree with Dr. Kraus seeing that the value 1.0 is not in the confidence interval. I disagree that it is statistically significant given the multitude of tests that needed to be performed in order to find that subgroup.

10:21:03

BY MR. WISNER:

Q. Dr. Kraus was so concerned about that result, he actually sought to include a warning about that issue in the Paxil label, didn't he?

MR. DAVIS: Your Honor, now we're talking about

10:21:16

Dr. Kraus's state of mind and also the labeling issues.

THE COURT: Sustained.

BY MR. WISNER:

Q. Dr. Kraus included a warning in the label about that exact risk, correct?

10:21:23

MR. DAVIS: Outside the scope.

THE COURT: Outside the scope, yes. This witness is not testifying on the label or anything in it.

BY MR. WISNER:

Q. So, to be clear, Doctor, you disagree with the psychiatrist that works for the company that's paying your bills today, right?

MR. DAVIS: Objection; that's argumentative.

THE COURT: Yes. Sustained.

BY MR. WISNER:

Q. All right. Well, let's go through some of these studies.

Now, you went through a series of studies on your direct examination that you say support your opinion there's no association. Do you recall that, Doctor?

A. Yes.

Q. All right. I actually went through them as well. And I noticed a section in all of the articles that is called "conflicts of interest." Are you familiar with that section, Doctor?

A. Yes.

Q. In fact, when you publish, you have to fill out that section, right?

A. Yes, I do.

Q. And in that section, you disclose financial relationships that you may have with drug companies, right?

A. Yes.

Q. And, in fact, in all these articles, these authors who you rely upon, they make that disclosure, don't they?
A. Yes, they do.
Q. First one was Dr. Simon. Do you recall we just talked about that?
10:22:28
A. Yes.
Q. Dr. Simon, he's a consultant for drug companies, right?
A. Dr. Simon does a lot of things, including apparently being a consultant for drug companies.
10:22:38
Q. A lot of them, isn't that true?
A. I don't know how many.
Q. Let's look.
I'm going to show you the first article you showed this jury. This is Defendant's Exhibit 1346.
10:22:51
Do you see that, Doctor?
A. Yes, I do.
Q. All right. If you look at the --
A. This is the second one.
Q. I'm sorry, this is the second one. Let me show you the
10:22:54
first one.
(Brief pause).
BY MR. WISNER:
Q. This is the first one. This is 1345, do you see that?
A. Yes.
10:23:02
Q. All right. We got "Simon" up here, do you see that

(indicating)?
A. I do.
Q. And a bunch of other names, including Phillip Wang, do you see that?
10:23:10 A. Yes.
Q. All right. So, let's look at the disclosure.
Talking about Dr. Simon, do you see that, Doctor?
A. Yes.
Q. And it goes on to read:
10:23:21 "During the past 3 years, Dr. Simon has received a research grant from Eli Lily Company, manufacturer of Fluoxetine ..."
That's Prozac, right?
A. Yes, it is.
10:23:34 Q. All right:
"... and has received consulting fees for contributions to a patient education program developed by Pfizer Pharmaceuticals, manufacturer of Sertraline ..."
10:23:44 That's Zoloft, right?
A. Yes.
Q. And you actually have worked for Pfizer as well too, right?
A. I have been an expert witness in cases involving Pfizer Pharmaceuticals.
10:23:52 Q. And Zoloft?

A. Yes.
Q. Okay. And then it goes on to say:
"... Dr. Wang has provided expert testimony regarding Paroxetine and the risk of suicide."
10:24:03 Do you see that?
A. Yes, I do.
Q. So according to that, Dr. Wang actually is a paid expert testifying in suicide trials for them?
A. It's actually "Dr. Wang" is the way you pronounce that. He
10:24:14 is -- he was the assistant to the director of the National Institute of Mental Health.
Q. That really wasn't my question. My question was, he's a paid testifying expert for them (indicating)?
MR. DAVIS: How does the witness know that, Your
10:24:33 Honor?
MR. WISNER: It says right here (indicating).
BY MR. WISNER:
Q. I'm sorry, Doctor, is he a paid testifying expert? Do you know that or not?
10:24:45 A. Well, all I know it is what it says here, that Dr. Wang has provided expert testimony regarding Paroxetine and risk of suicide.
Q. Paroxetine, that's the chemical name for Paxil?
A. Yes, it is.
10:24:55 Q. Okay. And so this study that you relied upon, the Simon

study, it has at least two authors, including Dr. Wang, who consults with pharmaceutical companies, correct?
A. Yes, he does.
Q. In fact, one of the authors --
10:25:11 MR. DAVIS: Your Honor, I believe this is mischaracterizing what the witness said.
MR. WISNER: He just said "yes," Your Honor.
THE COURT: He said "yes." It's covered.
BY MR. WISNER:
10:25:22 Q. All right. So, the second study also has Dr. Simon, do you see that?
A. Yes.
Q. And if we could go to the CME disclosure, he continues to say he works for Eli Lily, Pfizer, and Wyeth, and consulting
10:25:37 fees from Wyeth Pharmaceuticals, do you see that?
A. It says that he received a research grant from these pharmaceutical companies to conduct research studies, and he received consulting fees from Wyeth Pharmaceuticals, it doesn't say what those consulting fees were for.
10:25:57 Q. Okay. But he worked for drug companies, correct? Gets paid by them?
A. He's paid for his time.
Q. Okay. Like you?
A. Yes.
10:26:06 Q. Okay. Now, in the study, I was actually sort of intrigued.

You said just before I got up here that -- that this graph was really important, right?
A. Yes, I did.
Q. And you said that it shows, and if you see here, the negative 1. That's one month before starting treatment, right?
A. Yes.
Q. Okay. And in the month before -- let's look at this blue one first because this is sort of interesting. This is from primary care physicians, right?
A. Yes.
Q. That's non-psychiatrist, right?
A. Correct.
Q. Family doctors?
A. Could be.
Q. Okay. And in the month before starting an SSRI or an antidepressant prescription, that's when the highest rate of suicide attempts are, right?
A. Yes.
Q. And this isn't a completed suicides, obviously, because if you completed a suicide you wouldn't be able to get started on a therapy, right? You'd be dead?
A. That's correct.
Q. So for attempted suicides in a month before intimation of treatment, that's the highest time when you see it occurring,

right?
A. In this data, yes.
Q. Now, you agree, Doctor, that if someone goes and attempts suicide and they fail, they get sent to a doctor, right?
10:27:21 A. Yes, that could happen.
Q. And get treated for whatever might've precipitated that suicide attempt, right?
A. Yes.
Q. And so you would expect following that point that they'd be
10:27:32 started on drugs like antidepressants, right?
A. Yes.
Q. So by looking at the month just before the initiation of treatment, that's kind of a bias number, because that's not what the baseline is for all people out in society, those are
10:27:46 people selected to start treatment, right?
A. Well, these are medical claims data. So the medical claims data would indicate when the treatment occurred for a particular suicide attempt. This doesn't indicate the date of the suicide attempt, it's the claim for treatment for the
10:28:07 suicide attempt.
So one potential source of bias in these kinds of studies is that, on the same day, you can have a claim (coughing) excuse me, for a suicide attempt, you can have a new diagnosis of depression, and you can have the initiation of
10:28:26 treatment for that.

We have conducted numerous analyses of these kinds of data using sensitivity analyses where we exclude those events where it's clear that the suicide attempt itself led to the initiation of treatment, and we find the same general pattern.

10:28:45 Q. I'm not talking about what you did. I'm talking about what this article says. They didn't do that, did they?

A. I don't know. I'd have to re-read the article.

Q. Okay. Well, here's the thing that I found interesting, Doctor. Look at "minus 2" there, do you see that?

10:29:02 A. Yes.

Q. Not a lot of suicide attempts two months before starting treatment, is there?

A. No.

Q. Now, if you compare two months before treatment to

10:29:14 one month after treatment, do you see that, Doctor?

A. I do.

Q. That month after treatment is significantly higher than two months prior, isn't it?

A. I wouldn't -- I don't know if it's significantly higher.

10:29:27 It's certainly higher.

Q. Actually, we do know, because there's confidence intervals on there, isn't there?

A. Well, I see confidence intervals.

Q. And the confidence interval for the one, all of it, is

10:29:41 above the confidence interval for the two?

A. The appropriate analysis would adjust for the number of comparisons that are being done throughout three. It wouldn't be a simple comparison between the two.
Q. You keep talking about adjusting for multiple comparisons. Doctor, isn't it your testimony that when it comes to drug safety, you almost never do that?
A. That's for adjusting for multiple comparisons of looking at different adverse events. This is just given that we have multiple time points, that's a kind of multiple comparison as well, and that comparison would be adjusted for multiplicity.
Q. All right. So, looking at this right now, from what we can tell, the confidence interval for the month after starting treatment is all above the confidence interval for the two months prior to treatment?
A. I see that in the graph.
Q. Okay. Let's focus on some more of these studies that you showed the jury.

Now, you remember Mark Olfson. You talked about two studies from there?
A. Yes.
Q. I'll show it to you right there. This is Defendant's Exhibit 1273.

Do you see that, Doctor?
A. Yes, I do.
Q. And up here we have Mark Olfson and Steven Marcus, do you

see that?
A. Yes.
Q. And this is one of the studies that you told the jury about, right?
10:30:59 A. Yes, it is.
Q. All right. So, look at the disclosure statement, and I it highlighted here. It says:
"Dr. Olfson has received grant support and has served on the advisory boards of Eli Lilly &
10:31:16 company, Bristol-Myers Squibb, has been consultants to Pfizer, Inc., and Ortho-McNeil, Inc., and has been on the Speakers Bureau from Janssen L.P."
Do you see that?
10:31:26 A. I do.
Q. Now, going on to the Speakers Bureau, that means they go out and talk to doctors about their drugs, right?
A. I don't know what they do.
Q. Okay. Great.
10:31:37 Now, I don't see anything here about Dr. Marcus, do you?
A. No, I don't.
Q. Okay. Well, let's look at the next one by Olfson and Marcus. This was also a study that you referenced, right?
10:31:52 I'm sorry, this is Defendant's Exhibit 1275.

Did you see that, Doctor?
A. Yes.
Q. Okay. This is another one that you cited as well?
A. Yes.
10:31:57 Q. All right. So here we do have both of them discussed. It says:
"Dr. Olfson has served as a consultant for McNeil ...."
That's a pharmaceutical company?
10:32:08 A. I don't know.
Q. Okay. "Eli Lilly," that's a pharmaceutical company, right?
A. Yes.
Q. Okay:
10:32:15 "... Bristol-Myers Squibb and Pfizer has received grant/research support from Bristol-Myers Squibb, Eli Lily, and as AstraZeneca, and has served on the speaker/advisory board for Janssen. Dr. Marcus has served as a consultant for McNeil, Eli Lily, Bristol-Myers Squibb, Pfizer, and as AstraZeneca."
Do you see that?
A. I do.
Q. So, again, the authors, Olfson and Marcus, both of them
10:32:38 work in a consulting capacity with pharmaceutical companies

that manufacture SSRIs, correct?
A. Well, some of these are grant support. So they're -- they're not consulting for a pharmaceutical company. Instead of a grant coming from the National Institute of Mental Health it might be coming from a pharmaceutical company.
10:33:04
Some of this is consultancy. So the ones that say "consultancy" I assume that these pharmaceutical companies have paid them for their time or for their opinion.
Q. It says right here that Dr. Olfson has served on speakers and advisory board for Janssen. Do you know what an advisory board is, Doctor?
10:33:23
A. I don't know what an advisory board is for Janssen. I mean, I'm not an expert in that.
Q. Have you served on an advisory board before --
A. For --
10:33:35
Q. -- for a drug company?
A. No.
Q. Okay. You do understand that Dr. Olfson felt compelled to disclose this as potential conflict of interest, you understand that, right?
10:33:48
A. Oh I -- I understand tremendous amount about academic conflicts of interest. We are to include all conflicts of interests, whether we think they're relevant or not, to provide a complete disclosure so that the reader of the article will know that there is the potential for a conflict of interest.
10:34:05

It doesn't mean there is a conflict of interest, but there could be the potential. And it's important to have that full disclosure whether you're the assistant head of the National Institute of Mental Health, like Dr. Wang, or a full professor of psychiatry at Columbia University like Dr. Olfson.

Q. And you agree that when reviewing the medical literature, it's really important to think about where those opinions and where that research is coming from, right?

A. I'm not sure I understand the question.

Q. Well, you're a statistician, right?

A. Yes.

Q. And as a statistician, your analysis is only as good as the data, right?

A. My analysis is of the data, yes.

Q. And so if the data is false or fraudulent or misleading, that can affect your analysis, right?

A. It could, yes.

Q. And, in fact, you would agree with me that in reviewing the medical literature, you have to consider whether or not the people who are making these representations in the publications have a conflict of interest, right?

A. It's important to be aware of it, but it's also -- the key in reviewing the medical literature is to look at the studies that are conducted, and where the data came from, and the statistically methodologies, and research methodologies, the

design of those studies, and the integrity of the inferences that are drawn from that.

It's important to know whether or not there are potential conflicts of interest, but you can -- it doesn't mean that the -- that that potential conflict of interest would discredit the high-quality scientific work that is published in all of the studies you've just shown me.

Q. So, Doctor, I assume when you publish, you have to disclose that you work for GSK, right?

10:35:59 A. I do.

Q. You have to disclose that you work for Pfizer, right?

A. I have to disclose that I've been paid as an expert for my opinion in cases related to these pharmaceutical companies.

I don't work for Pfizer. I don't go to Pfizer and do work for Pfizer. I'm paid for my time coming here today, and I disclose that as a potential conflict of interest so that the people who read the articles that I publish will know that there is that potential and they'll look carefully at the experimental design and reach their own conclusions based on the analyses that are performed.

Q. You say you don't work for Pfizer, but, you know, when they call you up and ask you to come testify, you do, right?

A. I don't think I've ever been called by Pfizer to come testify.

10:36:47 Q. Or provide a deposition, for example?

A. Again, I don't think I've ever been called by anyone at Pfizer. I've been contacted by lawyers who have been involved in cases representing Pfizer and paid by those lawyers through Pfizer for the time that I've taken to prepare an expert report or to come here, as an example, and provide testimony. And they pay me for my time and I disclose that in my scientific publications.

10:37:09

Q. Whether it's a call from their lawyers or the drug company, the point I'm making, Doctor, is, you do consult for Pfizer, right?

10:37:33

A. I do not consult for Pfizer. I'm paid for my time to be an expert. If they wanted me to consult for Pfizer and give my opinion about how they should design a new experimental trial, or a new design, or to consult with them on how they should analyze their data, I might well do that, that would be consulting. I don't view this as consulting. This is being paid for my time, for my experience, and for my opinion that has been derived from over 30 years of scientific work in this area, long before I ever knew what a Pfizer was.

10:37:48

Q. I'm sorry, Doctor. When did you first start working for Pfizer?

10:38:06

A. As I said, I'm not an employee of Pfizer. I don't work for Pfizer. I provide --

Q. Okay. Sorry. Let me rephrase the question, because it's the semantics here.

10:38:21

When did you first start getting paid for your time and testimony by Pfizer?
A. Ah, probably -- I don't remember the exact date, but maybe it was within the last -- well, within the last 10 years.
10:38:46 Q. You worked in the Neurontin cases, right?
A. That's correct.
Q. Those are filed in 2004?
A. My participation in those cases started probably about 8 or 9 years ago.
10:38:54 Q. Okay. And just to be clear, in the work you've done for Pfizer, what other companies. You mentioned Wyeth, right?
A. Yes.
Q. In your direct you said "and some others," I'm just wondering who are the others?
10:39:09 A. GSK, Pfizer, Wyeth, I can't pronounce it, Bollin- -- Bollinger -- Bollinger Ingersoll. And I've done similar work for the U.S. Department of Justice.
Q. And you mentioned the U.S. Department of Justice. You have never actually been hired by the DOJ to investigate fraud by a
10:39:36 drug company, have you?
MR. DAVIS: Objection, Your Honor. Outside the scope; irrelevant.
MR. WISNER: He brought it up on direct.
MR. DAVIS: Irrelevant.
10:39:43 THE COURT: Overruled. He may answer.

BY THE WITNESS:
A. No, I was asked to provide a similar opinion or to review literature related to the question of whether or not an antidepressant exposure, in fact Paxil, Paroxetine, was related to suicide.
BY MR. WISNER:
Q. And this was in the context of med-mal case against the government for improperly treating a patient, is that right?
A. I don't know if it was -- I don't think this was about improperly treating. I think this was a case related to a psychiatrist in the Veterans Administration who prescribed an antidepressant and the patient ultimately committed suicide.
Q. I mean, I just want to make clear that, you've never been employed or hired by the Department of Justice or any state U.S. Attorney General to investigate fraudulent conduct by a drug company as it relates to a pharmaceutical product, correct?
MR. DAVIS: This has been covered, Your Honor.
THE COURT: I think it's been covered, hasn't it?
MR. DAVIS: He already answered that question.
MR. WISNER: I didn't ask about attorney generals.
BY MR. WISNER:
Q. No attorney generals either, right?
A. No.
Q. And just to be clear, in all the time that you've consulted

with Pfizer, and Wyeth, and that one you mentioned, you have never once testified that there was a statistical association between a drug and an adverse effect, right?

A. I don't think that's true.

10:41:25 Q. Neurontin you said didn't cause suicide, right?

A. I believe there were cases in which I did testify about an association.

Q. With suicide?

A. Not with suicide. You said an adverse event.

10:41:43 Q. Okay. Okay. Let's back up then.

Neurontin, you testified that that doesn't cause suicide, right?

A. Yes.

Q. You testified?

10:41:51 MR. DAVIS: Your Honor, excuse me. I think we're far afield from what we're here to talk about today. And Mr. Wisner objected to the issues along the same lines with -- or Mr. Rapoport did with either Dr. Healy or Dr. Glenmullen, so I --

10:42:06 MR. WISNER: Let me ask one question that I think will cover it all.

THE COURT: Proceed.

BY MR. WISNER:

Q. You have never in your consulting work with drug companies, 10:42:11 ever testified that there was statistically significant

association between a drug and suicidal behavior, correct?
A. Not to my memory.
Q. All right. Doctor, one of the other articles that you showed to the jury was Defendant's Exhibit 1208. This Leon article.
10:42:34
Do you see that, Doctor?
A. Yes.
Q. All right. And this was another one of those articles that you think supports your opinion that there's no relationship between Paxil and suicidal behavior, right?
10:42:40
A. Yes.
Q. All right. So if we go to the disclosure page again. All right, Potential Conflicts of Interest:
"Dr. Leon was been a member of the psychopharmacological Drug Advisory Committee of the U.S. Food and Drug Administration that examined antidepressants and suicidality."
10:42:56
We're going to that one second, Doctor. I know you have some work there as well:
"... has received research support for the National Institute of Mental Health and goes on to serve as independent data and safety monitoring boards for AstraZeneca, Pfizer, Sunovion, and has been a consultant to the National Institute of Mental Health, MedAvante
10:43:06
10:43:21

and Roche."

Do you see that?

A. Yes, I do.

Q. He also says he has equity in MedAvante, do you see?

10:43:28 A. Yes.

Q. What is MedAvante? Is that a pharmaceutical company?

A. I don't know.

Q. Okay:

"...Dr. Solomon is employed by UpToDate."

10:43:40 Do you see that?

A. Yes.

Q. All right. And we keep going. And it talks about Dr. Endicott. He has support from Cyberonics.

A. She.

10:43:50 Q. I'm sorry. Thank you:

"... has support from Cyberonics, and has served as a consultant or advisory board member to AstraZeneca, Bayer Shering, Cyberonics, Forest, GlaxoSmithKline, Eli Lilly, Otsuka, and

10:44:03 Wyeth-Ayerst."

Do you see that?

A. Yes.

Q. And:

"... Dr. Keller has received

10:44:08 consulting/honoraria fees."

Do you know what an honoraria fee is?
A. An honoraria is typically if I go to the University of Colorado and I give a lecture, they might give me $500 as an honorarium for giving that lecture.
10:44:27 Q. Okay. It says he:
"... received consulting/honoraria fees from Medtronic ..."
That's a medical device company?
A. I believe so, yes.
10:44:32 Q. Okay:
"...and Sierra Neuropharmaceuticals ..."
Do you see that?
A. Yes.
Q. And then:
10:44:41 "..... received research funding from Pfizer."
Do you see that?
A. Yes.
Q. Okay. So, again, this is one of the articles that you relied upon that you think support your opinion, right?
10:44:51 A. Yes.
Q. You also discussed some articles that didn't support your opinion but you thought, and I believe testified, were unreliable, right?
A. Yes.
10:45:01 Q. Okay. You mentioned the articles by Ivar-can't pronounce

his last name-Aursnes? Aursnes?
A. I'll trust you on the pronunciation.
Q. All right. But you testified about this one, right?
A. Yes, I believe this is the one.
10:45:20 Q. And you said that this was not reliable, right?
A. Yes.
Q. And if --
A. I'm sorry. I -- I think I said that this article was -- did not have any additional new data. It was just simply
10:45:38 another analysis of those same data. And -- and sitting here -- so, I didn't testify it was unreliable. Sitting here right now, that article is specifically about the MDD subpopulation and presents it as if it was not one of numerous subgroup analyses and focuses just on that.
10:46:03 Q. So you --
A. So, for that reason, I think it's unreliable, but I didn't say it was unreliable before.
Q. Okay. But you just said it was, right?
A. Just now.
10:46:13 Q. All right. Let's look at the conflict of interest.
The authors declared that they have no competing interest, do you see that?
A. I see that.
Q. So none of these authors work for drug companies?
10:46:21 A. I see that.

Q. Okay. Well, let's look another one that you criticized. This is another one by Ivar Aursnes, do you see that?
A. Yes.
Q. And a bunch of other people as well.
10:46:34 This was published later, right? This is the later publication?
A. Yes.
Q. And this is actually responding to criticisms that GSK had made to them about their analysis, right?
10:46:44 A. Yes.
Q. Okay. And then they responded. We went over this with Dr. Healy, so I'm not going to belabor your time, Doctor.
But I will point out again that, by this point, there still is no conflicts of interest, is there?
10:46:56 A. Well, the people who are the authors of these articles are not the leading people in the field. And the leading people in the field are often asked to consult for pharmaceutical companies, and the National Institute of Mental Health, and the Food and Drug Administration.
10:47:12 So I think if you were to open up any leading medical journal, JAMA, the New England Journal of Medicine, you would find that there are authors who have potential conflicts of interest and they appropriately list them on their acknowledgement section.
10:47:32 Q. So, Doctor, if I got you straight, your testimony to this

jury is, all of the leading experts in the field, they all work for drug companies?

MR. DAVIS: Objection; misstates the testimony, Your Honor.

10:47:45 BY THE WITNESS:

A. No, I wouldn't say that all the leading people work for drug companies, but if you go through the author list it wouldn't be surprising to find one or two of the authors who have had some contact with pharmaceutical companies.

10:47:57 And I wouldn't characterize it as working for drug companies, but in some cases they're called upon to advise pharmaceutical companies on whether the most interesting new drugs to explore, what are the important research designs, what are the important questions, are there any new analytical

10:48:18 strategies that should be used, are there imaging methods, are there new molecular genetics methods that would be useful in new discovery. Those are the kinds of things that people list as conflicts of interest. They don't list, I went to work, you know, three days a week for Pfizer Pharmaceuticals.

10:48:38 Q. Now, Doctor, you make about $350,000 at the University of Chicago a year?

A. That's correct.

Q. And you charge when you're working for GSK $850 an hour for your time, right?

10:48:53 A. That's correct.

Q. And $1,000 for every hour you on that stand, right?
A. Yes.
Q. Every hour you in a deposition, right?
A. Yes.
10:49:00 Q. It would be fair to say that the amount of money you charge for your work as a legal consultant is significantly higher than the amount you make in your regular job?
A. Well, I work at my regular job all -- all the time. My hourly rate, if you were to take my total salary and break it
10:49:20 down into the hourly rate -- actually, if you broke it down to the real number of hours I work at the University of Chicago, I make about $2.50 an hour.

But no, my hourly rate would probably be higher for this kind of work than it would be if you took my university
10:49:38 salary and broke it into hours.
Q. That's why they put us on salary, right, Doctor?
A. Yes, sir.
Q. Now, that said, 250 an hour, that's what? What percentage of that is 850? I'm just curious. You're the statistician.
10:49:57 A. I don't -- I don't, you know, have the arithmetic down to what my hourly rate is at the University of Chicago, but I suspect it's less than $850 an hour. I'd like it to be $850 an hour.
Q. I'm sure we all would, Doctor.

10:50:14 I guess you can just work more for GSK, right?

A. No, I can't work more for GSK. We're limited in the amount of time that we can work outside of the University of Chicago by the University of Chicago. So I couldn't work for them more even if I wanted to.

10:50:24 Q. Do you want to?

A. Not particularly.

Q. Okay. Plaintiff's Exhibit 259, this was shown to you, Doctor. This is the Dr. Juurlink article, right?

A. Yes.

10:50:35 Q. And again, you testified to this jury that this wasn't reliable, right?

A. Yes.

Q. Okay. Let's look at the conflicts of interest here. It's a little longer one. It says:

10:50:49 "Supported by a grant from the Ontario Mental Health Foundation. Dr. Juurlink was supported by a New Investigator Award from the Canadian Institutes of Health and Research and by the University of Toronto Drug Safety Research

10:51:03 Group. Dr. Mamdani was supported by a New Investigator Award from the Canadian Institutes of Health Research. Dr. Redelmeier was supported by a Career Scientist Award from the Ontario Ministry of Health and a Canada Research

10:51:22 Chair in medical decision sciences."

Do you see that, Doctor?
A. I do.
Q. And they go on to thank a bunch of people in the next paragraph, do you see that?
10:51:30 A. Yes.
Q. All right. And then if you look at the last part, it says.
"Dr. Mamdani began employment at Pfizer, Inc., in January of 2006 after this study was submitted and accepted for publication. His new
10:51:41 position has no bearing on the research presented in this article, which is free of influence from the pharmaceutical industry."
Do you see that?
A. I see it.
10:51:51 Q. So, it would appear, then, that this article that you believe was unreliable was also authored by people who did not have contacts with the pharmaceutical industry?
A. Well, I think, first of all, you're -- you're -- you're misconstruing that I said it was unreliable. I said that this
10:52:05 article was not replicated by other studies of higher quality, randomized controlled trials and large-scale cohort studies.
I also said that there are issues related to case-controlled studies where it's hard to match people on the really most important things like the severity of illness.
10:52:24 I'm not saying that, you know, they fabricated the

data or that they -- they applied bad methods. I'm saying this study did not replicate this one particular finding of the increased risk in the first month of treatment.

Q. Doctor, they used propensity score matching, right?

10:52:41 A. Yes, they did.

Q. And you have written and published that propensity score matching is the classic form of drawing casual inference, haven't you?

A. I don't think I would say that it's the classic form. It

10:52:54 is a tool for drawing causal inferences from observational data. And just like there are many, many different ways to apply propensity score matching, to do anything, propensity score matching can be done in a variety of ways.

Q. Is your testimony to this jury that you have not published

10:53:17 that propensity score matching is the classic form of drawing causal inferences? Yes or not, Doctor.

A. I don't think I would have said it's the classic for it. It is a classic method. It is a reasonable method. It is a reasonable method. It's not the classic method.

10:53:33 The real classic method of drawing causal inference is to do a randomized controlled trial, then you don't need to use propensity score matching.

Propensity score matching is only used in observational data. And I've already testified that I think

10:53:56 for causal inferences, randomized controlled trials trump

observational data. Observational data are useful for seeing how well the results of randomized controlled trials generalize to the population.

And propensity score matching is one of many ways of insulating yourself from bias produced by selection effects and observational data.

Q. Are you done, Doctor?

A. Yes.

Q. Okay. Did you not publish, before you ever started working for GSK, that propensity score matching was a classic approach for drawing causal inferences? Yes or no.

A. You just asked the question in two very different ways.

The first way you asked it was --

THE COURT: Doctor, please, just answer the question.

BY MR. WISNER:

Q. Did you tell us that or not? Yes or no.

A. Your last question -- in response -- if what your question is, is it a classical method? Yes, it is a classical method.

If your question is, is it the classical method? Then, no.

Q. Did you publish, Doctor, the now classic approach is based on propensity score matching? Did you publish that or not?

A. I'm assuming you looking at a publication of mine and reading something from it. I'd have to see what you reading.

Q. Okay. Would you like to look at it?

A. Please.
Q. I'm handing you a binder --
MR. WISNER: May I approach, Your Honor?
(Document tendered to the witness).
10:55:19 BY MR. WISNER:
Q. Go to Defendant's Exhibit 1103.
THE COURT: Let's take a recess, ladies and gentlemen.
(The following proceedings were had out of the presence of the jury in open court:)
10:55:53 [redacted]
10:56:10 [redacted]
11:16:19 [redacted]
(The following proceedings were had in the presence of the jury in open court:)
THE COURT: All right. Thank you very much, ladies and gentlemen. Please be seated.
11:17:28 We will resume.

You may proceed, sir.

MR. WISNER: Thank you, Your Honor.

BY MR. WISNER:

Q. All right. Doctor, did you have a chance to take a look at the article I gave you?

A. I don't think you gave it to me.

Q. Oh, it's in the binder. Defendant's Exhibit 1103.

You got it, Doctor?

A. Yes, I do.

Q. And the title is called The Statistics of Suicide, right?

A. Yes.

Q. And it's written by yourself?

A. Yes.

Q. And there is no co-authors, right?

A. No co-authors.

Q. So it's fair to say, you are the words in this publication, right?

A. I did.

Q. Okay. If you turn to page 128 in the top left corner. The Section 5.3 "causal inference."

Let me know when you're there, Doctor.

A. I'm there.

Q. Okay. Great.

And if you go down, I'm going to start with the second sentence. It reads:

"... to insulate inferences from bias produced by the selection of patients to treatment, either self-selected or selected by their treating physician based on observable characteristics, such as severity of illness, we turn to methods designed to draw causal inferences from observational studies. The now classic approach is based on propensity score matching in which patients who do not receive a particular treatment of interest are matched on a large number of potential confounders, for example age, sex, concomitant treatments, comorbid diagnosis, prior attempts, and the likelihood of receiving treatment, for example an antidepressant."

Did I read that right, Doctor?

A. Yes, you did.

Q. And this was published what year?

A. 2013, I believe.

Q. When did you start consulting with GSK for this case?

A. For this case? I don't recall. I know I was contacted, but did very little work until later.

Q. So, it was after this publication, is that fair to say?

A. Probably.

Q. All right. So, I just want to get a little tally going

here.

I've marked on this sheet of paper as Plaintiff's Exhibit 3. And I'm going to draw two sides okay, Doctor. And on the left side I'm going to put authors who have Pharma connections, okay. And on the right side I'm going to put authors who don't, all right.

So I'm going to put Pharma --

MR. DAVIS: Your Honor, we've been over this already.

MR. WISNER: I want to quickly go through it, Your Honor. It's cross-examination. I don't think this has been covered the way I want to cover it. We haven't finished the authors.

THE COURT: All right.

BY MR. WISNER:

Q. All right. So, in the group that has connections, right, we have a series of people. We have -- I'm just going to refer to them by first author, is that okay, Doctor, to keep it simple.

So it's Olfson, right? On the left?

A. Yes.

Q. Okay. Simon on the left, right?

A. Yes.

Q. Leon on the left?

A. Yes.

Q. All right. Simon again and then more Olfson. Okay.

Great.

Wait. Do we have Simon up there? We have Olfson, we have Leon. Missing anyone?

Okay. Great.

11:20:56 And then on the other side, we have Aursnes articles, right, Doctor?

A. Yes.

Q. Okay. And then we also have Juurlink, right?

A. Yes.

11:21:15 Q. You also discuss an article by Fergusson and Healy?

A. Yes.

Q. And you know that Dr. Healy doesn't consult with pharmaceutical companies, at least not in the last 20 years, right?

11:21:30 MR. DAVIS: Objection, Your Honor. I don't believe that's the testimony that came from Dr. Healy.

MR. WISNER: I'll ask him.

THE COURT: Ask him if he knows.

BY MR. WISNER:

11:21:42 Q. Do you know?

A. I don't know with certainty, but as I recall, Dr. Healy, some other connections, said that he did consult for pharmaceutical companies.

Q. Sure. And I guess my question is, you understand he's a

11:21:56 testifying expert in this case, right?

A. Yes.
Q. And he's testified on the stand that Paroxetine is associated and in fact causes suicidal behavior, right?
A. I -- I didn't hear his testimony, but if that's what you say.
Q. Did they read you his testimony?
A. Ah --
Q. Sir?
A. I don't recall.
Q. In the last couple of days have they read you his testimony?
A. They may have. I don't think so.
Q. Is that a yes or no, Doctor?
A. I don't -- I'm trying to remember if I read his -- no. No.
Q. Okay. I'm going to put "Healy" on the right here, okay, Doctor?
A. Yes.
Q. All right. So we have, on the left we got people who have Pharma connections and on the right we have people who have non-Pharma connections, and everyone on the right you've testified you do not believe --
MR. DAVIS: Your Honor, could we have the volume come down a little bit?
MR. WISNER: I'm sorry. Am I too loud.
MR. DAVIS: I think your mike is pretty loud.

MR. WISNER: My apologies.

(Brief pause).

MR. WISNER: Is that better for you, Mr. Davis?

MR. DAVIS: That's very better. Thank you.

11:23:06 MR. WISNER: Okay.

You let me know if I need to change it again.

MR. DAVIS: Thank you.

BY MR. WISNER:

Q. All right. So, on the left here we have all the studies

11:23:15 you relied upon that have Pharma connections, right?

A. I've relied on many more studies than the studies that you have listed here.

Q. Fair enough. Let me clear up the question.

On the left we have the studies you showed the jury

11:23:28 during your direct examination that support your opinion that there's no association, right?

A. This is a small subset of the studies that I've relied upon.

Q. Okay. Then on the right we have the three articles that

11:23:39 you criticized during your direct, right?

MR. DAVIS: Objection to the form, the characterization of Dr. Gibbons's testimony, Your Honor.

THE COURT: You may inquire.

BY THE WITNESS:

11:23:48 A. I probably criticized other articles in my review that also

have authors that are -- have connections with pharmaceutical companies. And these authors, which is kind of interesting, have connections to plaintiff attorneys in these same cases and receive funding and money for their time and plaintiff
11:24:12 attorney, and I'm not sure why they wouldn't list that as a conflict of interest.

Q. Sir, we're talking about Healy. What are you talking about, Juurlink who works for plaintiff's attorneys? What are you talking about?

11:24:23 A. I don't know. I said some of these, certainly Healy --

Q. So you don't know. You are just making stuff up, Doctor?

A. I'm not making --

MR. DAVIS: Your Honor, argumentative.

MR. WISNER: He just said that these people were
11:24:31 working for plaintiff's lawyers. He's making stuff up, Your Honor.

MR. DAVIS: Your Honor, please. Could we have a question and an answer?

MR. WISNER: All right. I'll ask the question. I'm
11:24:33 sorry.

MR. DAVIS: Thank you.

BY MR. WISNER:

Q. Do you have any evidence that Dr. Juurlink works for plaintiff's lawyers?

11:24:41 A. I don't.

Q. Do you have any evidence that Aursnes works for plaintiff's lawyers?
A. I don't.
Q. Okay. So back to my question, then. Based on this, the
11:24:55 Pharma people on the left, the non-Pharma on the right, the left no association, the right there is association, is that difference statistically significant, Doctor?
MR. DAVIS: Objection to the form of the question.
BY THE WITNESS:
11:25:07 A. Well, certainly I performed no analysis, and it would be statistically significant. And your characterization of Mark Olfson, Greg Simon, and Andy Leon as being Pharma people is completed inaccurate. They have listed conflicts of interest, potential conflicts of interest, because they've had some
11:25:27 association in providing some kind of expert work to pharmaceutical companies. They're not Pharma people.
BY MR. WISNER:
Q. I'm just going to use your word there, Doctor: "Pharma people," that's what you call it?
11:25:40 A. I said they're not Pharma people.
Q. Okay. You don't think they're Pharma people. I don't like to use that word, but that's your word.
Are you a Pharma person?
A. No.
11:25:48 Q. Okay. All right. Now, Dr. Simon, you are aware that after

he published those articles, he then published an editorial where he said "you can't draw any causal association based on my study," correct?

A. I'd have to see that.

11:26:06 Q. You didn't look to see if Dr. Simon had anything to say about the studies that you showed this jury?

A. I'm not sure I'm following your question.

Q. It's okay. We'll continue.

All right. Let's get on with my cross. You are not a

11:26:33 psychiatrist, right?

A. No, I'm not.

Q. Not a psychologist?

A. No.

Q. Not a psychopharmacologist?

11:26:38 A. No.

Q. Not a pharmacologist?

A. No.

Q. You are not a specialist in symptomatology?

A. A specialist in symptomatology? If your question is --

11:26:53 Q. These are your words.

A. -- do I work in this area? We do a lot of work in computerized adaptive testing of mental health measurements. That's a lot of the work I do for the Veterans Administration and involves symptomatology.

11:27:10 I'm not a clinical expert in the symptoms of mental

health disorders. If that's your question, that's what -- I'm not.

Q. During your deposition you said "I'm not a specialist in symptomology," that's what you said, right?

11:27:24 A. I'm expanding on my answer.

Q. Okay. You are not a medical doctor, right?

A. That's correct.

Q. Did not go to medical school?

A. I did not.

11:27:30 Q. And you do not, quote, "hold yourself out to be a suicide expert," correct?

A. I'm an expert in the science of suicide, in the conduct of studies in suicide, in the analysis of data from studies of suicide. I'm not a clinical expert in suicide. I would not be

11:27:49 a person who would treat someone with suicidal ideation or behavior. I would not have those skills or those qualifications.

Q. So that's a "yes," you do not hold yourself out to be a suicide expert, correct?

11:28:02 A. That's a "no." I -- I am a leading suicide expert in terms of the science of suicide. I'm an adviser to the Veterans Administration on the science of suicide. I am not a clinician. I'm not a psychiatrist or a psychologist who treats people who have issues related to suicide, but I'm absolutely

11:28:23 an expert on the science of suicide.

(Cell phone interruption)
BY MR. WISNER:
Q. So, Doctor, to be clear, please turn to your deposition. It's actually in the binder in front of you. It's the first
11:28:40 tab. Please turn to page 80.
Let me know when you're there.
A. I'm there.
Q. Line 1 through Line 7 reads:
"Question: And you are not a suicide expert
11:28:59 beyond the statistical work that you have done, is that correct?
"Answer: That's correct.
"Question: You don't hold yourself out as a suicide expert, do you?
11:29:08 "Answer: No.
MR. DAVIS: Your Honor, I think that's improper impeachment. That's exactly what Dr. Gibbons just explained.
MR. WISNER: And the jury can figure it out for themselves.
11:29:17 THE COURT: Proceed.
MR. DAVIS: Thank you.
BY MR. WISNER:
Q. That's what you testified during your deposition, Doctor?
A. That is my testimony during my deposition, but I believe
11:29:25 that it was expanded at the end to indicate what I've just

said.
Q. You know, it's funny. It was expanded when Mr. Bayman asked you some questions at the end of your deposition, right?
A. Yes.
11:29:36 Q. Did you guys rehearse that answer during the breaks in the deposition?
A. No.
MR. DAVIS: Your Honor, that's argumentive.
MR. WISNER: That's a question. It's a fact.
11:29:43 MR. DAVIS: What's the relevance of it?
THE COURT: He said "no," go on.
MR. DAVIS: Thank you.
BY MR. WISNER:
Q. All right. So moving on, Doctor. You are not authorized
11:29:49 or qualified to treat people suffering from depression, right?
A. That's correct.
Q. You are not authorized or qualified to treat people suffering from anxiety, right?
A. Correct.
11:29:59 Q. You are not authorized or qualified to treat people who are experiencing suicidality, right?
A. Correct.
Q. Depression, anxiety, suicidality, those are conditions that should be treated by a medical professional, right?
11:30:12 A. Could be treated by a psychologist or a social worker,

someone trained in the area of mental health from a clinical perspective. I don't have that training.
Q. And since you lack that training, you in fact are prohibited by law from prescribing drugs to treat patients -- from prescribing drugs to patients, including Paxil, right?
A. I'm not a medical doctor, so it would be illegal for me to prescribe medications, yes.
Q. So you would agree with me then, Doctor, that you are offering an opinion to this jury about whether or not a drug that you are prohibited from prescribing causes a condition that you are prohibited from treating, right?
A. I am providing my opinions about the science of the studies that have been conducted to draw an association between treatment with antidepressants and suicide, much in same way as I have been asked to look at the efficacy of pharmaceuticals that I cannot prescribe. I'm an expert in research methodology and statistical analyses.
Q. You know, when there is a clinical trial, you would agree that there's -- when there's a clinical trial, data is collected in a clinical trial through something called a case report form, right?
A. In some cases, yes.
Q. So that the patients getting into the study and the investigators go through a checklist, ask questions, and they report that information in the case report form, right?

A. In some cases. Not all studies.
Q. In depression studies and psychotropic medications studies, and the studies we are talking about here, there are case report forms, typically, right?
11:32:03 A. Yes.
Q. Okay. And in those case report forms get given to the drug manufacturer and then they input it into a database, right?
A. In the case of the studies we've been reviewing here, those case report forms, or narratives, were blindly adjudicated.
11:32:23 Q. Sure. We'll get to what happened with Columbia University in a second, but as a general matter, before Columbia got involved in the 2000's, generally those case report forms are given to drug companies and they put them into a database, right?
11:32:35 A. They're collected -- if these are sponsored studies by the pharmaceutical company, there collected by the pharmaceutical company and then those data are stored in some way. I don't know the specifics of that.
Q. Okay. And eventually end up in a database, right?
11:32:50 A. I don't know if the entire case report form ends up in a database or if that's maintained in -- I don't know the answer to that.
Q. When you get involved, it's already in the database, right?
MR. DAVIS: Objection.
11:33:00 BY THE WITNESS:

A. I may get involved in the help -- to help design a study for a pharmaceutical company or -- or more typically, for research studies, and that involvement is before any data are collected.

11:33:19 Q. Isn't it true, Doctor, that, in your opinion, you do not have the skills to assess or review a case report form?

A. I would not be analyzing data directly from case report forms. I would be analyzing data from clinical interviews or either the item level or scale level of validated instruments

11:33:44 that are designed to look at, for example, the severity of depression, like the Hamilton Depression Rating Scale. I might have the individual patient responses or the clinician ratings of each of the individual symptoms from those scales, but I would not be analyzing data directly from the case report form.

11:34:05 I might be analyzing terms that were abstracted from the case report form in relationship to adverse events, but no, I wouldn't be working directly with the case report form.

Q. All right. Is that a "yes," you don't have the skills to review case report forms?

11:34:24 A. I don't have the clinical skills to --

Q. Okay.

A. I mean, I can read them. I'm not sure I fully understand the question. If I were to extract something clinically from a case report form, that's not something that I'm -- I would be

11:34:39 doing.

Q. The phrase "I don't have the skills," those are your words, Doctor.
A. I don't think that misrepresents my testimony.
Q. So that's your words? Yes or no? I didn't ask about misrepresenting your testimony. Those are your words, right?
A. Where -- where are you saying those are my words?
Q. I don't want to spend more time on this.
Have you ever conducted a clinical trial on Paxil with suicidal behavior or suicidal ideation as an end point?
A. When you say "conducted," have I been like an investigator on it?
Q. Yes.
A. No, I certainly helped design and analyzed them, but I'm not a clinical investigator. I've never conducted studies.
Q. Doctor, if you could just limit your answer to my question, that would be really helpful. I think we could get you off the stand quicker and save your client a couple of bucks.
MR. DAVIS: Your Honor, I believe that's an issue, Mr. Wisner should direct that to the Court and not to the witness.
MR. WISNER: I would ask Your Honor to admonish --
THE COURT: Proceed. Proceed. Proceed.
BY MR. WISER:
Q. Have you ever participated yourself in placebo-controlled clinical trials of antidepressants which involve suicidal

behavior?
A. No.
Q. You have never conducted a clinical trial for Paxil, correct?
11:35:51 A. Correct.
Q. You have never, in fact, quote, conducted any real world experiments or controlled clinical trials whatsoever, right?
A. I'm -- I've never conducted studies. I've been a part of studies as a statistician.
11:36:07 Q. You are not an expert in labeling, right?
A. I'm not.
Q. According to you, you only do data, right?
A. I said that to Congress.
Q. I believe you said to Congress, "I only do math." I think
11:36:19 in this case you said "I only do data." But it's the same thing, right?
A. If you look at the congressional record, it says only do data, sir.
Q. All right. Now that brought up the congressional record.
11:36:32 You, in fact, served on a committee with the FDA, right?
A. Yes.
Q. And actually during your direct, part of your credentials was that you served on a pharmacological committee for pediatric suicide warning issue, right?
11:36:50 A. Yes.

Q. And during that committee, people voted, right?
A. Yes.
Q. You voted?
A. I did.
11:36:56 Q. And you voted that there was, in fact, a causal relationship between the drugs and pediatric suicide, right?
MR. DAVIS: Your Honor, I believe this is outside the scope of the direct and we're also now beyond the scope of what we're here to talk about.
11:37:11 THE COURT: The door has been opened. He may answer.
BY THE WITNESS:
A. I voted that there -- because the studies that were conducted between the -- between SSRIs and suicidal ideation predominantly showed statistically significant differences,
11:37:33 that that -- because they were randomized controlled trials indicated a causal relation.
I also indicated in my testimony that there were alternative explanations for that statistically significant association.
11:37:52 Q. Sure, Doctor. So you voted for the "yes," that there was a statistical association, right?
A. Yes.
Q. And at the end of the hearing the committee, as a whole, recommended putting a black box warning smack on the top of the
11:38:08 antidepressant labels for pediatric use, right?

A. The vote was 15 to 8. I voted against it.
Q. You voted against putting a black box warning?
MR. DAVIS: Excuse me. I believe he's cut the witness off, Your Honor.
11:38:19 MR. WISNER: I apologize.
BY MR. WISNER:
Q. You voted against the black box warning, Doctor?
A. I did.
MR. DAVIS: Your Honor, if the witness could complete
11:38:25 his answer?
THE COURT: He said "yes." He may certainly answer if he has something else to say.
BY THE WITNESS:
A. The vote was 15 to 8 in favor of a black box warning. I
11:38:34 voted against the black box warning. The -- the vote for the black box warning was largely to encourage doctors, pediatricians and general practitioners to do a better job of following up their patients. And those of us who voted against the black box warning were concerned that there would be a lack
11:38:57 of treatment of those patients. And, in fact, we would have far worse than --
MR. WISNER: Objection. He's gone way past the yes-or-no question. He's getting into stuff that's been excluded.
11:39:08 MR. DAVIS: Can he finish his answer, Your Honor?

MR. WISNER: I believe "yes" was the answer, the rest of it was nonresponsive.

THE COURT: He may finish then we'll decide whether it's responsive.

11:39:23 Ant hying else, Doctor? Finished, sir.

THE WITNESS: I haven't finish.

THE COURT: All right. Go ahead.

BY THE WITNESS:

A. Just to complete that. There was a concern that doctors
11:39:31 would stop prescribing or treating depression in children and we'd have a large-scale epidemic of completed suicide in the United States, that was essentially the vote.

My vote was also added because the clinician-based ratings of the suicidality in children actually went in the
11:39:52 opposite direction and showed a protective effect.

And I believe that these prospective measures were of higher quality than the spontaneous reports that the children had given to their clinicians, for a variety of reasons which I articulated in the FDA hearings.

11:40:10 BY MR. WISNER:

Q. So you voted against the black box warning?

A. Yes, sir.

Q. After you did that, you began working for a drug company as a legal expert, correct?

11:40:20 A. I may have done that -- I don't remember the timeline.

Q. Certainly worked for Pfizer.
A. That's correct.
Q. You worked for Pfizer to testify about certain drugs were not associated with suicide, correct?
11:40:53 A. In adults.
Q. Now, you focused on the data. Well, actually let's back up one second before I get there.
You mentioned an article written by Dr. Hammad from the FDA, do you remember?
11:41:08 A. Yes.
Q. And that was in your direct examination?
A. Yes.
Q. And one of the authors on there was Dr. Laughren, right?
A. Yes.
11:41:15 Q. And when he appointed that out to you, you said, "oh Tom," do you remember that?
A. I don't remember, but that's his first name.
Q. Do you know Dr. Laughren?
A. I do.
11:41:26 Q. How do you know him?
A. Dr. Laughren was the head of the pharaco- -- of the psychopharmacology division at the FDA. And I met him first as a member of the institute of medicine committee on the drug Halcion, a sleeping pill that some of you may remember was the
11:41:50 drug -- the sleeping pill that President George Bush, Sr., took

and threw up all over the Japanese Ambassador. And we re-analyzed all of the data for the drug Halcion for randomized controlled trials and observational data working on concert with the FDA through the National Academy of Sciences. They had commissioned us to do this work and that's where I met Tom originally.

Q. You also met him after he left the FDA, right?

A. Yes, I did.

Q. You guys worked together at an SSRI litigation as experts, correct?

A. I don't think we worked as experts in a litigation, no.

Q. Dr. Laughren testified, as well as yourself, about whether or not SSRI use is associated with birth defects from mothers who were taking them, correct?

MR. DAVIS: Your Honor, I think we are far afield of what's germane.

THE COURT: Sustained.

BY MR. WISNER:

Q. Let's --

MR. DAVIS: Your Honor, could the jury be asked to disregard the question?

THE COURT: Yes, the jury disregard it.

MR. DAVIS: Thank you.

BY MR. WISER:

Q. Let's talk a little bit about the data, Doctor.

You look at data and that's what you do as a statistician, right?
A. Yes, sir.
Q. Now, putting the data aside for one second -- and you're here to talk about whether or not the data shows an association between Paxil use and suicidal behavior, right?
A. Correct.
Q. Putting the data aside, have you ever gone to any of the clinical trials that you looked at and spoke to an actual person who took Paxil?
A. No.
Q. Have you ever talked to someone who took Paxil and attempted suicide, for example?
A. No.
Q. Have you ever gone to someone and said, "what you were experiencing while you are on the drug, is that different somehow from what you were experiencing before the drug"?
A. Well, as a statistician, it would -- it would be -- it would violate internal review boards, it would violate HIPAA and human subject protection for me to have any conversation with a patient in a randomized-controlled trials, so of course I wouldn't do that.
Q. Did you ever ask GSK if you could reach out to a doctor who investigated to see what they have to say?
A. No.

Q. So all of your analysis, really, is not based on any actual speaking to a human being about what they experienced, right?
A. My analyses are based on the reports of individuals of symptoms that they experienced, that they shared with their
11:44:25 doctors, that have been adjudicated by Columbia University, and as well as clinician ratings of the behaviors that they observed, those data have been the focus of -- of all the analyses that I've conducted.
Q. In fact, Doctor, all those clinician ratings scales, all of
11:44:46 the case report forms, all the records that were sent to Columbia, for example, they were collected, prepared, and sent to Columbia by GSK, right?
A. The records, as I understand it, were initially -- for the FDA studies, as an example, were sent initially to the FDA and
11:45:09 then they decided on what they believed were the appropriate things to then send to Columbia for blinded adjudication.
Q. I guess the point of my question, Doctor, I'm sorry it was confusing, all the data that everyone is talking about here comes from them, right (indicating)?
11:45:28 A. The studies that were submitted to the FDA were sponsored by the pharmaceutical company and they collected those data and then shared them with the FDA and shared them with Columbia to do the blind adjudication.
Q. And you've never personally taken the data that was put
11:45:47 together by GSK, compared it with the medical records of what

actually happened in the trials, right?
A. That would not be my area of expertise. I wouldn't be able to -- I don't have the expertise in being able to do that kind of adjudication.
11:46:03 Q. So in that context -- is your testimony that Columbia University got the underlying medical records?
A. They got the narratives.
Q. Yeah, they got the narratives prepared by GSK, right?
MR. DAVIS: Objection; that misstates the evidence,
11:46:17 Your Honor.
MR. WISNER: I asked him a question, he can say yes or no.
THE COURT: Overruled. You may inquire.
BY THE WITNESS:
11:46:23 A. I don't know the exact process. I know that the narratives were shared with FDA and then a decision was made of what to send to Columbia.
I don't know who sent it or what that process was. I wasn't involved with that, of course.
11:46:36 BY MR. WISNER:
Q. I understand, Doctor. You don't know, and that's fine.
But my question, though, is the medical records, the actual -- the doctor charts from these patients who were these clinical trials, not the stuff of the clinical trials but the
11:46:51 actual medical records, that was never sent to the FDA or

Columbia, right?
A. I don't know the answer to that.
Q. Okay. Now, you do know that there's been published literature that has come out by researchers that shows that
11:47:06 some of the raw data collected by GSK doesn't accurately reflect the data from medical records specifically as it relates to Paxil, right?
MR. DAVIS: Your Honor, that's improper. And we've already discussed this and it's outside the scope of direct
11:47:24 examination.
THE COURT: Overruled.
BY THE WITNESS:
A. I don't know anything about that.
BY MR. WISNER:
11:47:30 Q. You haven't done any Google searching to find out if there's a published peer-reviewed journal article talking about whether or not GSK hides data?
MR. BAYMAN: Objection, Your Honor. That's argumentative.
11:47:42 MR. WISNER: I'm asking if he's Googled it.
MR. DAVIS: Your Honor, there's no foundation has been laid that that information is the type of information that Dr. Gibbons would reasonable rely upon, nor is there any evidence that any of that happened in adult studies.
11:47:57 THE COURT: The foundation is weak for what you're

asking.

MR. WISNER: Fair enough.

BY MR. WISNER:

Q. I'm just asking have you done any research about this issue or not, that's my question.

11:48:05

A. No, I haven't done any independent research on that.

Q. Okay. You didn't -- in your expert report, you critique Dr. Healy, though, right?

A. I critiqued his expert report.

Q. And he cited that study in his report, didn't he?

11:48:16

A. I don't recall, sitting here right now.

Q. There's a whole section in his report devoted to that study, doesn't he?

A. I don't know which study you're referring to.

Q. Study 329, Doctor. Does that right a bell?

11:48:29

A. Yes, that does.

Q. Okay. So Dr. Healy published an article about 7329, didn't he?

A. I know he discussed it in his expert report.

Q. He published a peer-reviewed journal article about it, didn't he?

11:48:39

A. He --

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

MR. WISNER: He said he peer-received his report and critiqued it. Foundation has been laid.

11:48:54

MR. DAVIS: He's not laid the foundation for whether or not --

THE COURT: Overruled. He may inquire.

He may inquire.

11:48:56 BY THE WITNESS:

A. Could you repeat the question?

BY MR. WISNER:

Q. Sure.

THE COURT: Read it back.

11:49:00 (Question.)

MR. DAVIS: Your Honor, I don't believe that is the question.

THE COURT: Put another question, sir.

MR. WISNER: Sure.

11:49:30 BY MR. WISNER:

Q. All right. Dr. Healy has an entire section in his expert report which you critiqued that deals with study 329, right?

A. I'm just checking in my expert report.

(Brief pause).

11:49:50 BY MR. WISNER:

Q. You are checking in your expert report?

A. My expert report has my notes about my critique of Dr. Healy, so it would have discussion of that.

Q. Let me know when your recollection is refreshed, Doctor.

11:50:00 (Brief pause).

BY THE WITNESS:
A. My memory is is that there was some discussion of study 329 and there were -- that Dr. Healy suggested that there were some issues with the data. I don't remember the specific issues.
11:50:26 BY MR. WISNER:
Q. Okay. Now, on direct you recall this Defendant's Exhibit 7305D.
Do you recall this, Doctor?
A. Yes.
11:50:37 Q. The helmet, and the skier and stuff, right?
A. Yes.
Q. And you told this jury that it would be an improper inference of causation to think that wearing a helmet could cause a broken bone, right?
11:50:51 A. Correct.
Q. Now, let us just say that the helmet is defective, and that when sudden movements are done the helmet blinds you and causes skiers, motorcyclists to run into a tree, okay?
A. Okay.
11:51:07 Q. The helmet then would cause the broken bone, right?
A. It might have both a direct effect and an indirect effect.
Q. To answer that question, you need to ask this guy in the motorcycle, this person on the skis, and the snowboarder to find out what actually happened, wouldn't you?
11:51:25 A. No, I would design a randomized controlled study and

randomized defective and nondefective helmets and see whether or not there was an association with broken bone. I wouldn't ask the people. I would assign an appropriate study.

This slide shows the dangers that can happen when you use uncontrolled studies, observational studies, uncontrolled studies where there might be an association between -- an indirect association. We might see in an uncontrolled study that there's always a relationship between taking antidepressants and suicide simply because depressed people take antidepressants and depressed people commit suicide, that would be another example of this.

I wouldn't ask the people. I would design the appropriate study. I'd use randomization.

Q. That was my question. You wouldn't talk to the people, you would conduct a randomized controlled trial, right?

A. Yes.

Q. Because you and randomized controlled trials are the gold standard, right?

A. Yes.

Q. It's the best type of data you can imagine when it comes to assessing causal relationships and risk, right?

A. It's the best data that can be imagined in terms of reducing bias from both observed and unobservable sources.

Q. In the entire history of Paxil, there has never been a randomized controlled trial who purpose was an end point of

suicide, correct?
A. I believe there were studies that were conducted in high-risk populations that did look as a primary end point at suicide.
11:53:02 Q. Those were efficacy trials, Doctor, weren't they?
A. I would have to go back and take a look at it, but there were studies that were conducted to look at suicide.
Q. Doctor, you talking about the intermittent brief depression studies, Doctor?
11:53:23 A. I believe so.
Q. Studies 507 and 106 -- 057 and 106?
A. I believe those were the two intermittent brief depression studies.
Q. And they were designed to study whether or not Paxil could
11:53:32 treat the condition known as intermittent brief depression, that's the objective of the study, correct?
A. I believe one of the end points of the study was suicidal thoughts and behavior.
Q. Okay. Fine, Doctor. But an MDD, for example, or -- strike
11:53:42 that.
Is IBD an actual medical condition?
A. It is -- I don't know whether or not it's a DSM-V diagnostic condition, I don't know. I'm not an expert in those diagnostic classifications.
11:54:03 Q. Another thing that you don't know is, you not an expert in

DSM, right?
A. I was one of the reviewers of the field trials of DSM. So have expertise that's related to the conduct, the experiments, I looked at the validity and reliability of DSM. I'm not one
11:54:22 of the clinical experts that would come up with the criteria for why you would have a diagnosis of one of major depressive disorder or IBD.
Q. All right. So my point was, is IBD -- IBD a clinically recognized DSM diagnosis?
11:54:41 A. I don't know the answer to that.
Q. Depression is, right?
A. Yes.
Q. Anxiety is?
A. Well, depression -- the diagnosis in DSM-V is major
11:54:53 depressive disorder.
Q. It's also major depressive episode too, right?
A. You can have that, yes.
Q. So major depression is an actual diagnosis in the DSM, correct?
11:55:03 A. That's correct.
Q. So is general anxiety disorder?
A. Yes.
Q. Social anxiety disorder?
A. Yes.
11:55:08 Q. And there's a bunch of different disorders that are in the

DSM, correct?
A. Correct.
Q. All right. In the MDD trials -- strike that.
In every single clinical trial conducted on Paxil that
11:55:21 has a recognized designation in the DSM, never once was suicide
an end point?
A. Well, if your question is assuming that IBD is not in DSM,
because I don't know the answer to that, that would be the
restricted area where suicide was an end point. The others
11:55:43 were efficacy trials that collected data on adverse events,
including suicide.
THE COURT: All right. State what "IBD" means for the
record.
BY MR. WISNER:
11:55:54 Q. Doctor?
A. Intermittent brief depression. This is usually a form of
depression that is also comorbid with certain personality
disorders. Difficult to treat. And these were studies in
which the patients were at very high risk for suicide because
11:56:13 they had made suicide attempts recently.
Q. You would agree, a study with what kind of condition issue
is not particularly helpful for looking at how these drugs
would affect people with mild depression, right?
A. Oh, I think that those studies are critical. And we've
11:56:31 used the strategy of looking at high risk populations, in

general, for the safety of a variety of different pharmaceuticals.

Q. You published, Doctor, that randomized controlled trials' biggest limitation is the fact that it often involves patients that you wouldn't see in the regular world, right?

A. I've published that some of the exclusion criteria for randomized controlled trials, which makes you wonder about their generalized ability, is that patients who were suicidal were excluded from those studies.

So having studies that did not exclude such patients, high risk studies, are very important. Our work with antiepileptic drugs, we used bipolar patients who are at the highest risk of suicide in particular to study the effects of antiepileptic drugs on suicide because they were at high risk.

Q. I think that's a "yes," that's what you published, right?

A. I think you mischaracterized what I published. Your statement was about --

Q. We don't have to argue.

A. Okay.

Q. If it's a "NO," Doctor, that's fine.

So this is a diagram. It's Defendant's Exhibit 7035F.

Do you see that, Doctor?

A. Yes.

Q. This is the one you talked about on direct examination?

A. Yes.

Q. Quick question, did you create this diagram?
A. I oversaw the creation of it.
Q. This diagram was used in the defendant's opening statement. Did you help them with their opening statement as well?
11:58:00 A. No.
Q. Now, there's a period called the run-in phase, do you see that?
A. Yes.
Q. And then there is the period that's the controlled phase,
11:58:11 do you see that?
A. Yes.
Q. And then there's an extension phase, right?
A. Right.
Q. Now, you would agree with me that it's inappropriate to
11:58:17 count suicides that occur in the run-in phase as though they occurred during the control phase, right?
A. I would agree that an analysis that's confined to the controlled phase of a randomized placebo-controlled trial should not include run-in phase events.
11:58:39 Q. Let's say you have an analysis that's just looking at things that happened post-baseline. Post-baseline is right here (indicating). Everything this way is post-baseline, right, Doctor?
A. Yes.
11:58:47 Q. And everything before is pre-baseline, right?

A. Yes.
Q. If there was an analysis that was looking at completed suicides post-baseline, it would be inappropriate to include suicides that occurred pre-baseline, right?
11:59:01 A. I would disagree with that.
Q. Okay. Do you recall this document, Doctor, Defendant's Exhibit 7035FF? Do you see that, Doctor?
A. Yes.
Q. And this is a diagram that you -- you prepared this, right?
11:59:18 A. Yes.
Q. And this is meant to illustrate, in your opinion, that the incidents of suicidal attempts in the trials you looked at showed that it was in younger adults, is that right?
A. Yes.
11:59:32 Q. Please turn to Plaintiff's Exhibit 75 in your binder.
(Brief pause).
BY MR. WISNER:
Q. Are you there, Doctor?
A. Yes.
12:00:00 Q. Doctor, if you want me to grab that so it's out of your way.
A. No, that's okay. I'll just put it over here, if that's okay (indicating).
Q. Yes.
12:00:08 You have Plaintiff's Exhibit 75?

A. Yes.
Q. This is integrated summary of safety information from the Paroxetine clinical trials program, right?
A. Yes.
12:00:15 Q. And this is a document you reviewed in preparing your testimony?
A. Yes, I believe so.
Q. Okay. I'm just going to show it to the jury very quickly.
This is the document. And you noticed that it's dated
12:00:27 1989; do you see that?
A. I do.
Q. This was actually the submission made by GSK to the FDA when it initially wanted to get approval for Paxil, right?
A. Yes.
12:00:37 Q. Now, Doctor, I just want to point out something that I'm sort of interested in. It says "Paroxetine" it doesn't say "Paxil," does it?
A. Correct.
Q. Paxil and Paroxetine are the same thing, right?
12:00:49 A. Yes.
Q. Okay. So if we go through this document, I'd like you, Doctor, to turn to -- there's a lot of numbers on this because it's been used a lot and stamped by a lot of people, but the words on the bottom right corner, 281, it looks like this
12:01:08 without the highlights (indicating).

So page 281. Do you see that?

(Brief pause).

BY MR. WISNER:

Q. Let me know when you get there, Doctor.

12:01:29 A. I'm on page 281 that starts with "Belgium open."

Q. You got it. On this page and in the next five pages there are narratives of completed suicides in the original NDA, correct?

A. If you say so.

12:01:44 Q. Well --

A. I mean I see the first one it says "suicide" and then I see the second one, it says "death."

Q. It says:

> "No adverse events were reported during the first four months of long-term therapy, but during the first week of the fifth month the patient committed suicide by hanging."

Do you see that?

A. I see that.

12:02:07 Q. That is patient narrative of someone committing suicide right?

A. Yes.

Q. All right. So I'm going to take your diagram here, I'm going to put a plaintiff's sticker on it because I'm going to

12:02:17 mark it up. This is going to be Plaintiff's Exhibit 334.

How old was the person who committed suicide by hanging?
A. (No response).
Q. I'll just lead you. That person was 58 years old, correct?
12:02:38 A. It says 58 years old.
Q. Okay. Great. Turn to the next page.
We have another completed suicide on Paxil clinical trials. The patient has taken Paroxetine. He's male, he's 50 years old, right?
12:02:57 A. This person -- it says, "serious adverse event, death," it doesn't say "suicide."
Q. Look at the bottom paragraph:
"On day 144, after three months of long-term therapy, the patient died by hanging."
12:03:08 Right?
A. That sounds like suicide.
Q. Right. Okay. So that's 50 years old?
A. Yes. But these are reports -- the figure that you have in front of you are subjects who are part of placebo-controlled
12:03:21 randomized controlled trials. It's unclear to me what these -- whether these patients were part of those studies or not.
Q. I understand, Doctor. I understand you're focusing on placebo-controlled trials. I'm going to look at other stuff that's not placebo-controlled.
12:03:39 I'll represent to you that none of these were

placebo-controlled trials; okay?
A. Okay.
Q. Turn to the next page:
"...female 56 years old, under clinical interpretation this person suicide by drowning on day 47 of the study period during treatment with medication."
Do you see that?
12:03:50
A. I do.
Q. 56 years old, right?
12:03:56
I'm turning to the next page:
"Female, age 18."
Do you see that?
A. Yes.
Q. And it's on day 44 that the patient committed suicide by overdosage, do you see that?
12:04:11
A. Yes.
Q. All right. The next one is female aged 42, do you see that, Doctor?
A. Yes.
12:04:24
Q. (Reading:)
"Day 10, the patient committed suicide by overdosing with Diazepine, the relationship to that Paroxetine therapy was unknown."
Do you see that?
12:04:33

A. Yes.
Q. All right, so that's 42-year old.
So those are the five completed suicides on Paxil. Now, in preparing for your testimony, we already discussed this, but you relied on the depression of Dr. Kraus, right?
12:04:47
A. Yes.
Q. And during the deposition you were shown a chart that was created that lists out all the suicide attempts from the NDA, correct?
12:04:58
A. I don't recall sitting here now.
MR. DAVIS: Your Honor, I don't think there's a foundation that's been laid to question this witness about Dr. Kraus's chart. Dr. Kraus is going to be here as the next witness.
12:05:13
BY MR. WISNER:
Q. Doctor --
MR. DAVIS: Sometime today.
MR. WISNER: I'll lay a foundation.
BY MR. WISNER:
12:05:19
Q. Doctor, at your deposition you testified that you relied upon the testimony of Dr. Kraus, correct?
A. I reviewed it, yes.
Q. So in his testimony he was shown a chart of attempted suicides. And if you don't recall, that's fine. I'd you to
12:05:37
turn to tab -- to the document Plaintiff's Exhibit 324 of your

binder.

Do you see that Doctor?

A. Yes.

Q. And that was the chart that was shown to Dr. Kraus, right?

12:05:43 You can see on the bottom right it says "Kraus Exhibit 10" and it has the date of May 2015.

A. I see that.

MR. WISNER: Permission to publish, Your Honor.

THE COURT: You may proceed.

12:06:05 (Exhibit published to the jury.)

BY MR. WISNER:

Q. So, Doctor, I have some stars on mine. You can ignore that for now. But if you look down here, it has the age, as well as the patient ID number of all of the attempted suicides in the

12:06:17 original NDA. Do you see that, Doctor?

A. I do.

Q. And there's also some other dates here about numbers of days after it occurred, start date, and it has timing stuff, but I want to focus on the ages here, okay, Doctor?

12:06:30 A. Sure.

Q. All right. Here's what we're going to do, if you start at the top, it says "age 24," do you see that?

A. Yes.

Q. And it goes all the way down to age 73 for the second to

12:06:41 the last one; do you see that?

A. Yes.
Q. And then there's a placebo one for 67, do you see that?
A. I see it.
Q. Great. What I'd like you to do is I like you to read off
12:06:51 the ages slowly as I mark up this chart; okay?
A. Sure.
Q. So we'll start off with "24."
A. 43. 20. 29. 24. 36. 23. 22. 31. 46. 24. 37. 37.
19. 40. 33. 42. 69. 26. 35. 28. 38. 41. 56. 35. 38.
12:08:07 30. 52. 27. 94. 46. 61. 56. 75. 50. 54. 25. 43. 38.
73. And 67.
Q. All right. "67" and we're done. And then there was -- oh,
that was for placebo, the last one?
A. Yes.
12:08:54 Q. Okay. And actually, Doctor, I actually think they're the
same one on your chart?
A. Could be.
Q. So the placebo made it on here, obviously, but a lot of
these ones didn't make it on your chart. Now, you'd agree with
12:09:10 me, Doctor, that starting at age 30, the vast majority of these
X's are after 30, correct?
A. Well, I would agree with you that the vast majority of the
X's are over 30, but this completely misrepresents what's on
this chart.
12:09:29 Q. So you would agree that the vast majority of the X's are

over 30, correct?
A. If I were to count them up there would be more over 30 than under 30.
Q. 70 percent?
12:09:38 A. If you say.
Q. This is in the original NDA, correct?
A. The original NDA which included lots of uncontrolled studies and studies for which there was no finding of increased risk.
12:09:50 Q. Now, one of the things that was missing from your analysis of the 2006 data was completed suicides, because there was no completed suicides in the MDD placebo-controlled trials, right?
A. That's correct.
Q. And this is just for MDD, right?
12:10:05 A. The -- the -- this chart, before you marked it up, was purely MDD.
Q. The NDA's data was purely MDD as well, correct?
A. It doesn't say that on this -- on this table, but again, these are not randomized controlled trials.
12:10:21 Q. I'm sorry. You reviewed the document, right?
A. I did. I'd have to go back and see if this particular chart is about patients with MDD. I can't tell that just from looking at this one page.
Q. Okay. But looking at the NDA data, you'd agree that the
12:10:37 NDA date that you looked at a second ago, that related to MDD,

right?
A. Well, there are lots of different indications.
Q. Is it your testimony to this jury that the NDA submitted in 1989 had a condition other than MDD in it?
12:10:51 A. I'd have to go back and look at the actual NDA at this point, to look at this document to know that.
Q. So you don't know is your answer, it's not "no"?
A. Oh, no, I don't know.
Q. So one of the things is, you testified that there was no
12:11:04 completed suicide in the MDD clinical trials, right?
MR. BAYMAN: Objection. It mischaracterizes his testify, Your Honor.
MR. WISNER: Well, he can say "no."
THE COURT: He'll tell us.
12:11:13 BY MR. WISNER:
Q. I think he wants you to say I'm mischaracterizing, but what's your answer, Doctor.
A. Could you repeat the question.
THE COURT: Read it back.
12:11:18 BY MR. WISNER:
Q. There --
THE COURT: Read it back.
MR. DAVIS: Your Honor, I would object to Mr. Wisner suggesting that I'm trying to put some answer into the
12:11:28 witness's head.

THE COURT: Sustained.

(Question read.)

BY THE WITNESS:

A. Yes, that's correct. In the placebo-controlled randomized clinical trials.

12:11:46

BY MR. WISNER:

Q. Sure. I'm going to read you an interrogatory question and answer that was given to us by GSK.

MR. WISNER: It's already been admitted into evidence, Your Honor.

12:11:54

MR. DAVIS: Your Honor, it's not been admitted into evidence and there's no foundation to use with this witness.

MR. WISNER: It's an admission by GSK.

THE COURT: Let me see what you want to read.

12:12:05

MR. WISNER: You've already ruled on it, Your Honor. You said I can use it.

MR. BAYMAN: No, Your Honor. It's not in evidence.

THE COURT: Is this the one I filed on?

MR. WISNER: Yeah.

12:12:13

THE COURT: All right. Then you may read it.

BY MR. WISNER:

Q. (Reading:)

"... interrogatory number 12: According to plaintiff's review of adverse event records/documents and database produced by you

12:12:19

in various Paxil injury and death cases, case ID number 1998030813 committed suicide while taking Paxil during a clinical trial of Paxil. With regard to this specific patient, please state, A, whether this patient did in fact commit suicide while taking Paxil during a clinical trial of Paxil. B, the identification of the clinical trial as listed in the clinical trials that you have made available on the Internet in which this patient committed suicide. And C, whether the clinical trial was placebo-controlled."

"Answer: GSK has conducted a reasonable search for and is providing the responsive information regarding this patient. A, it appears this patient committed suicide during the second week of Paroxetine treatment. B, the clinical trial which this patient participated was study 513. And C, it is believed that study 513 was placebo-controlled."

There is another response, Doctor, interrogatory number 20. Again, I'm not going to read, it's the same question, I'm just going to read you the answer:

"GSK has conducted a reasonable search for and is providing responsive information regarding

this patient. A, this patient committed suicide while taking Paxil during the clinical trial. B, the clinical trial in which this patient participated was local study 559. C, local study 559 was placebo-controlled."

Doctor, I just read to you two completed suicides in MDD placebo-controlled clinical trials that GSK has admitted happened while taking Paxil, neither of those made it into your analysis, right?

A. My analysis is based on the review of the GSK 2006 report and the FDA meta-analysis. And I don't know anything about the details of those studies of whether or not they would have been eligible for submission to the FDA. The FDA reviewed all of the studies. So I don't know any of the details of them.

Q. I just read to you the two admitted completed suicides --

A. But you didn't -- you didn't explain --

MR. DAVIS: Your Honor, again, those are not in evidence.

THE COURT: No, it's before the jury now. Proceed.

BY MR. WISNER:

Q. Doctor, I just read to you two completed suicides in placebo-controlled trials that you are unaware because GSK never told you about them, correct?

A. Not necessarily --

MR. DAVIS: Your Honor, that's argumentative.

THE COURT: Overruled. You may answer.
BY THE WITNESS:
A. Were these studies conducted sponsored by GSK or were these investigator-initiated studies?
12:15:18 BY MR. WISNER:
Q. I asked you a question. I didn't think you could ask me a question. I'll answer your question but if you can please answer my question firs.
MR. WISNER: If you can read it back.
12:15:36 (Question read.)
BY THE WITNESS:
A. I'm not sure whether or not GSK told me about them or not. If the question is, I would have seen these data if they were -- were these studies that were -- that met the criteria for
12:15:50 the FDA analysis or met the criteria for the GSK analysis, I don't know. You're telling me about two patients and you say they were in -- in a -- on a Paxil arm, a Paroxetine arm in a placebo-controlled study. I don't know anything about the details of that study.
12:16:08 So I would -- you know, the fact that I may not have had them in that database may be completely due to the fact that these were studies that were ineligible to be in that meta-analysis.
Q. So, Doctor, let's be clear, you understand that GSK has
12:16:26 locally funded studies and centrally funded studies, correct?

A. I don't know that distinction.
Q. It was in Dr. Kraus's deposition, do you recall reading that?
A. I haven't looked at Dr. Kraus's deposition for a very long time. I can't recall sitting here.
Q. Well, a second ago you asked me a question. What was your question?
A. I asked you whether or not these were studies that were designed and the data were collected and validated through the protocols of GSK or were these investigator-initiated studies.

Investigator-initiated studies would be studies where GSK would have given them the pills but had no -- no role in the design, analysis, validation of those studies. Those studies would not have been eligible for -- for the meta-analysis conducted by the FDA. So they would not have come up in this database.

Q. Doctor, could you please turn to Defendant's Exhibit 25 in your binder.
BY THE WITNESS:
A. I'm there.
BY MR. WISNER:
Q. All right. Doctor, have you seen this document before?
A. I believe so.
Q. What is this document?
A. It's correspondence between the FDA and GSK.

Q. Okay.

MR. WISNER: Permission to publish, Your Honor. It's already in evidence.

THE COURT: All right.

12:18:13 (Exhibit published to the jury.)

BY MR. WISNER:

Q. All right. Doctor, it should be on the screen now.

It's on the screen. Do you see that, Doctor?

A. Yes.

12:18:26 Q. Okay. This was a report sent to the FDA, specifically to Dr. Russell Katz of the FDA by GSK, correct?

A. Yes.

Q. And this was sent, it appears, December 16th, 1999; do you see that?

12:18:45 A. I do.

Q. So this is before the 2000 period, right?

A. Yes.

Q. Okay. All right. Now, if we go into here, the official submission, and then there's attachment 1; do you see that,

12:19:00 Doctor?

A. Yes.

Q. And you have reviewed this attachment before, you said that a second ago.

A. At sometime, but I would have to re-review it. I don't

12:19:09 remember it.

Q. Okay. It states here:

"To establish the enumerator of death incidence, the worldwide AEGIS series adverse event database was used to identify deaths reported in all randomized controlled trials. RCTs evaluating whether the immediate release or controlled release formulation evaluating either the immediate release or controlled release formulation for Paroxetine."

12:19:35 Do you see that, Doctor?

A. Yes.

Q. So GSK is combining all the data it can find from all of its controlled randomized controlled studies, right?

A. This is a series of studies, some of which would be placebo-controlled, some of which wouldn't. I don't know if these are just the controlled periods, but, you know, it's a correspondence.

Q. Okay. Great.

It says:

12:20:03 "To establish the denominator --"

This would help clarify, Doctor:

".. of the death incidence, i.e., the total number of patients exposed to double-blind treatment in Paroxetine RCTs in depression, the

12:20:17 central database containing centrally funded

Paroxetine IR trials was used."

Do you see that?

A. Yes.

Q. So the number that they're coming to here is based on the number of patients exposed to double-blind treatment in Paroxetine randomized controlled trials, right?

A. Some of these might be placebo-controlled and some of these might be active comparator studies.

Q. Fair enough. But in either whether it's active controlled or placebo-controlled, there considered well controlled studies, right?

A. There randomized studies and they're double blind. I'm assuming, you know, based on this statement, I haven't reviewed what those studies are.

Q. Okay. But you have reviewed this, right?

A. At some point.

Q. And it came up with a number here of Paroxetine IR 5981, do you see that?

A. Yes.

Q. And just to be clear, Doctor, this specifically referenced and specified that these were depression trials, right?

A. Yes, I see that.

Q. Now, you know in the intermittent brief depression trials that we discussed a minute ago, there were actually no completed suicides, right?

A. That's my recollection.
Q. Good. So let's go down here into the first chart, table 1. It has a Paroxetine group IR. Do you see that, Doctor?
12:21:38 A. I see that.
Q. And a placebo group?
A. Yes.
Q. And it has all the non-suicide deaths, do you see that?
A. I see that.
12:21:48 Q. There was 11 in the Paroxetine arm and only one in the placebo arm?
MR. DAVIS: Your Honor, for purposes of completion I would ask that the additional paragraph be published.
THE COURT: You can do that, sir.
12:22:03 MR. DAVIS: Thank you.
MR. WISNER: We'll get to it, Your Honor, don't worry.
BY MR. WISNER:
Q. So it says non-suicides, do you see that?
A. I see it.
12:22:09 Q. And then it has suicides, do you see that, Doctor?
A. Yes.
Q. It says that there were 6 completed suicides in the Paroxetine IR group, right?
A. I see where it says in table 1.
12:22:25 Q. 6 completed suicides in well controlled RCT's, correct?

A. You know, you're asking me a lot of questions about a document that I haven't seen in a very long time. If you really want me to give you answers about this, you'll have to let me read it -- re-read it.

12:22:41 THE COURT: All right. Let's take the luncheon recess.

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

[redacted]

(Luncheon recess taken from 12:30 o'clock p.m. to 1:30 o'clock p.m.)

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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 5, 2017