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,	)	
Plaintiffs,	)	
vs.	)	No. 12 CV 6403
SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation,	)	Chicago, Illinois
Defendant.	)	March 23, 2017 1:30 p.m.

VOLUME 7-B

TRANSCRIPT OF PROCEEDINGS - Trial

BEFORE THE HONORABLE WILLIAM T. HART, and a Jury

APPEARANCES:

For the Plaintiff:

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
BY: MR. R. BRENT WISNER
12100 Wilshire Boulevard, Suite 950
Los Angeles, California 90025
(310) 207-3233

RAPOPORT LAW OFFICES, P.C.
BY: MR. DAVID E. RAPOPORT
MR. MATTHEW S. SIMS
20 North Clark Street, Suite 3500
Chicago, Illinois 60602
(312) 327-9880

Court reporters:

Judith A. Walsh, CSR, RDR, F/CRR
Charles R. Zandi, CSR, RPR, FCRR
219 South Dearborn Street, Room 2504
Chicago, Illinois 60604
(312) 435-5895
judith_walsh@ilnd.uscourts.gov

APPEARANCES (continued:)

For Defendant GlaxoSmithKline:

KING & SPALDING
BY: MR. TODD P. DAVIS
MR. ANDREW T. BAYMAN
MS. HEATHER HOWARD
1180 Peachtree Street N.E.
Atlanta, Georgia 30309
(404) 572-4600

KING & SPALDING, LLP
BY: MS. URSULA M. HENNINGER
100 North Tryon Street, Suite 3900
Charlotte, North Carolina 28202
(704) 503-2631

SNR DENTON US, LLP
BY: MR. ALAN S. GILBERT
233 South Wacker Drive, Suite 7800
Chicago, Illinois 60606
(312) 876-8000

(Proceedings heard in open court. Jury in.)

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

You may proceed, sir.

MR. BAYMAN: Thank you, your Honor.

DAVID ROSS, PLAINTIFF'S WITNESS, PREVIOUSLY SWORN

CROSS-EXAMINATION (Resumed)

BY MR. BAYMAN:

Q. Dr. Ross, before we broke for lunch, I wrote down that you said that you were critical because "emotional lability" was buried in thousands of pages and not put in any tables, correct?

A. No, sir, that's not what I said.

Q. I think you said it was not the basis for summary tables that typically reviewers rely on?

A. No, sir, that's not what I said.

Q. All right. We'll come back to that in a minute. Turn, if you would, then in that PX 263 which is Tab 22, turn to Page 347149.

A. I'm sorry, sir. Could you repeat the Bates number?

Q. Sure. It's 347149.

MR. WISNER: Your Honor, I object. This is not a document that he's ever testified about or even seen. This is from Dr. Healy's direct.

MR. BAYMAN: It's from the same document I was

questioning him about right before we had lunch, your Honor.

MR. WISNER: You put it up on the screen, but I didn't have a chance to object.

MR. BAYMAN: Can you take it down?

You didn't object to it before lunch.

THE COURT: Well, ask your question. We'll see what...

BY MR. BAYMAN:

Q. All right. Have you found Page 347149?

A. I believe this is the correct page.

Q. And you see there are tables on that page, correct?

A. I do.

MR. BAYMAN: Okay. May I publish that to the jury?

THE COURT: Is this in evidence?

MR. BAYMAN: Yes, sir.

THE COURT: All right.

MR. BAYMAN: PX -- Plaintiff's Exhibit 263.

MR. WISNER: Objection, your Honor. It's not in evidence. It was never admitted into evidence. It was shown to the jury during Dr. Healy's deposition -- during his testimony but it was never admitted into evidence. Showing a different expert a different expert's documents --

MR. BAYMAN: Take it down --

MR. WISNER: -- right up there on the screen --

MR. BAYMAN: Take it down.

MR. WISNER: Just using hearsay, it violates the impeachment rule under 603. You can't impeach with extrinsic evidence that the expert has never seen, so I don't know what this is about.

MR. BAYMAN: Judge, these are --

THE COURT: It's not in evidence?

MR. WISNER: No.

MR. BAYMAN: It's not been admitted into evidence. It is a submission to the FDA with respect to --

THE COURT: You can ask him --

MR. BAYMAN: Sure.

THE COURT: -- if he's ever seen it before.

BY MR. BAYMAN:

Q. Have you ever seen this document before?

A. I don't believe so.

Q. For the record, this is Plaintiff's Exhibit 263. And it's a study No. PAR-2906007001 titled, "A double-blind comparison of paroxetine, amitriptyline, and placebo in patients with major depressive disorder with melancholia."

You've never seen that before?

A. I don't recall seeing it.

Q. Are you sure about that?

A. I don't recall seeing it.

Q. You know, though, that in that document, there are tables which show that emotional lability --

THE COURT: Wait, wait, wait. The document is not in evidence, sir. It's not in evidence.

MR. BAYMAN: You --

THE COURT: He hasn't seen it. It's not in evidence.

BY MR. BAYMAN:

Q. You are aware, are you not, and you've seen documents in which GSK has coded suicides and suicide attempts to the preferred term of emotional lability. We saw some right before lunch, correct?

A. So there's two questions there. Which one -- if you could repeat the one you'd like me to answer first.

Q. You've seen documents that GSK submitted to the FDA where GSK coded suicides and suicide attempts to the preferred term "emotional lability," correct?

A. With the understanding that I'm not aware of any rules that said that was how they should do it, yes.

Q. Okay. And you -- Dr. Ross, you told the jury yesterday morning that you reviewed the most current Paxil label as of January 2007 and that the current label still contains language that you think is misleading such as language on emotional lability, correct?

A. I believe that what I said, and I don't have the verbatim text, is that there is no way for anybody to know that emotional lability -- and for the record, I am not even sure that that is a term that's in the current list of terms used

by FDA, other regulators, or regulated industry. There's no way of knowing that that actually refers to events that involved attempted suicide.

Q. My question was: You said you reviewed the current label which is as of January 2017. You said you reviewed that a couple nights ago, correct?

A. Correct.

Q. Okay. And you said that language -- I mean, that the current label is still -- is false and misleading because you think it contains language that's misleading such as the language on emotional lability, correct?

A. That's one of several reasons --

Q. Okay.

A. -- why it is false and misleading.

Q. And you know from your review of that label because Mr. Wisner asked you in 25 or 30 years and you corrected him, in 25 years, had these warnings been changed, and the label today currently has the same warnings that it had in it in 2010. Do you remember that line of inquiry?

A. I noted that the placement of "emotional lability" had been moved to the first position in the current label, that is, the January 2017, after the word "frequent," I believe.

Q. And you know, though, from your review of that current label that Mr. Wisner asked you about that the warnings with respect to the risk of suicide are the same in that label as

they were in the 2010 label at the time Mr. Dolin was prescribed generic paroxetine, correct?

THE WITNESS: Your Honor, could I ask that that question be read back?

THE COURT: Read it back.

(Record read.)

BY THE WITNESS:

A. So there's a couple of different concepts here, so let me try and answer this as succinctly as possible. The label for both branding Paxil and generic paroxetine, which has to follow the brand name, has not been updated with the Paxil-specific information in any way, shape, or form, so you are correct.

BY MR. BAYMAN:

Q. Thank you. And I'm sure that when you saw the label that you looked at, you know that the holder of the Paxil NDA today --

MR. WISNER: Objection. Move to strike.

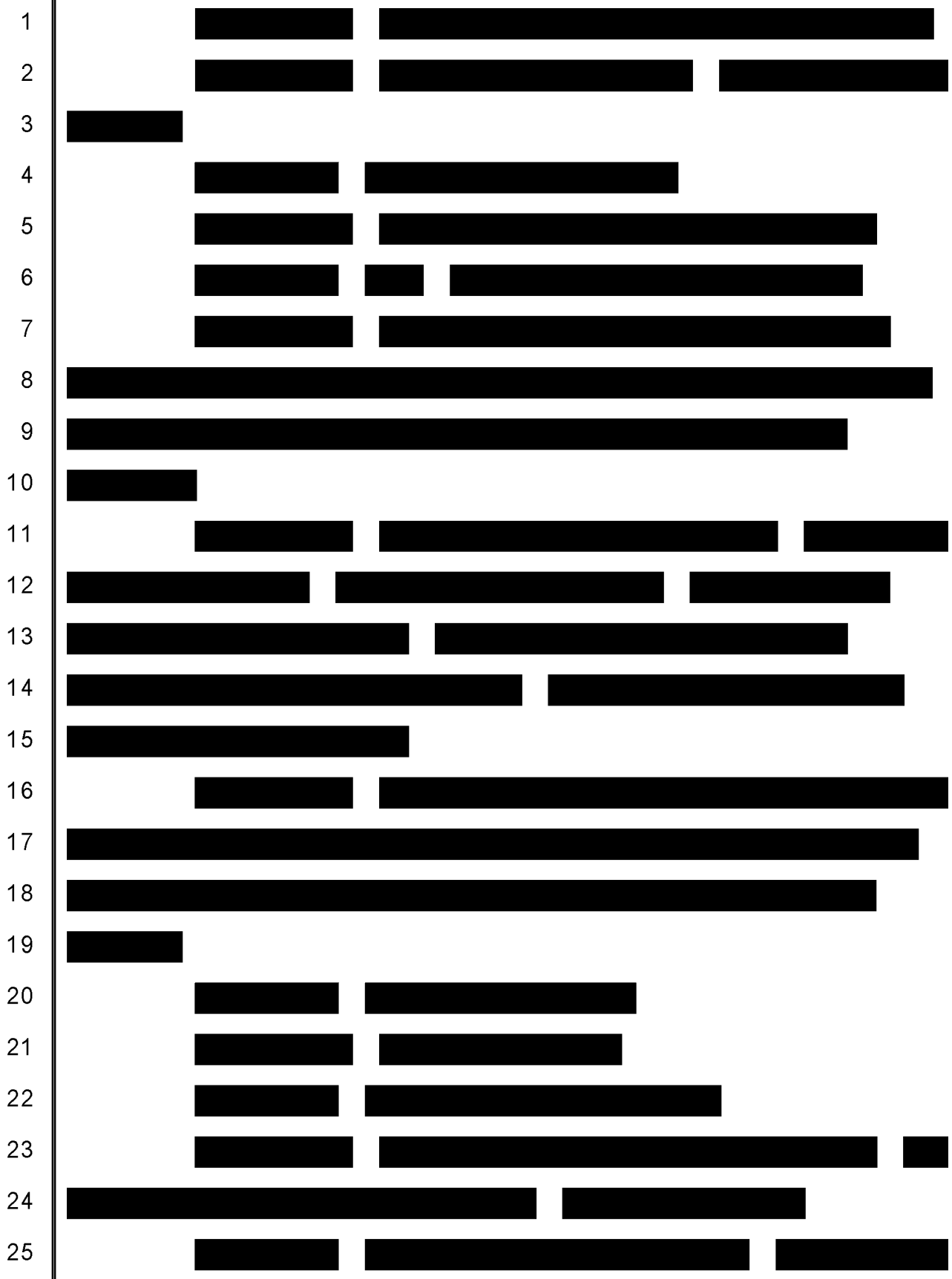
THE COURT: I haven't heard the question yet.

MR. WISNER: The question is prejudicial. May I sidebar, your Honor? You explicitly ruled this out, and they agreed not to do it, and he's about to ask the question.

THE COURT: All right. Let's have a sidebar.

(Proceedings heard at sidebar:)

[redacted]



(Proceedings heard in open court:)
BY MR. BAYMAN:
Q. Doctor, I want to ask you now about GSK's April 2006 label change. You're familiar with that, correct?
A. I am.
Q. And if you would, turn in your notebook to Tab 10, Exhibit 101.
A. Yes.
MR. BAYMAN: And it's Defense Exhibit 101, your Honor, which is in evidence per your March 9, 2017, minute entry.
BY MR. BAYMAN:
Q. Let's take a look at that. You're -- you've reviewed this before, correct?
A. I believe so, yes.
Q. And you said yesterday that there is a lot of back and forth that occurs between a manufacturer and the FDA when a manufacturer attempts to change a label, correct?
A. In some instances, yes.
Q. And that includes sending correspondence back and forth, correct?
A. Among other things, yes.
Q. And that can include having meetings between the drug company and the FDA, correct, to discuss labeling changes?
A. Yes.

Q. That can include having telephone conversations between the FDA and the drug company to discuss labeling changes, correct?
A. Yes.
Q. That can include email back and forth between the FDA and the company about proposed label changes, correct?
A. Yes, with the understanding that any communications, be it email or telephone, do not represent final agency action.
Q. What you're saying is at the end of the process, the agency issues a letter, a formal letter, correct?
A. Correct.
Q. Okay. But that's part of the back and forth that occurs, those kinds of exchanges, correct?
A. Yes.
Q. Okay. So here in this document, if you will look, the second page, the first paragraph, "Conclusions and proposed next steps," do you see that?
A. Yes.
Q. It's -- what's happening is GSK is telling the FDA about its findings for suicide attempts in adult patients with major depression, correct? That's what this correspondence is about?
A. It is informing the FDA of the results and GlaxoSmithKline's interpretation of those results and GSK's regulatory conclusions.
Q. That's -- that's the analysis that we discussed with GSK

and that you discussed with Mr. Wisner on direct with the 7.6 increased risk in major depressive disorders on the secondary end point, correct?

A. So I kind of want to make sure I'm answering your question, understanding it correctly. When you say "2.76," that is the odds ratio --

Q. I'm sorry. I misspoke. I meant 6.7 which was GSK -- the odds ratio GSK found.

A. Okay. They're informing FDA of their finding confirming that there is a sharply increased odds ratio among individuals exposed to Paxil with regard to suicidal attempts.

Q. 6.7 with respect to the secondary analysis of definitive suicidal behavior, correct?

A. Actually, I don't believe it says "the secondary analysis" here.

Q. But you know that that was the secondary analysis?

A. They do not say that here. They do not qualify it in that way as a secondary analysis.

Q. Understood, but you know that from your review, correct, with me? We went over this earlier this morning.

A. I'm just telling you what I'm reading here in plain language. It doesn't say "secondary analysis." It actually does not include those words.

Q. But you know that was a secondary analysis? We talked about this this morning, Doctor.

THE COURT: All right. Go on. Another question.
BY MR. BAYMAN:
Q. The letter goes on to say:
"Based on these most recent findings in the adult patient data set, GSK concludes that some statements in the approved prescribing information will need to be amended to reflect the results from this analysis following completion of the entire analysis."
Did I read that correctly?
A. You did.
Q. Okay. And so basically, what GSK's saying, to try to cut to the chase here, Doctor, is, "We want to amend our label to present this data," correct?
A. The first line says, to make sure that I put this -- my answer in context, "GSK believes that labeling revisions and direct communications with healthcare professionals, HCPs, should be undertaken only after completion of the entire analysis but is willing to discuss earlier labeling changes, communications with HCPs if so desired by the agency."
So they are saying that they believe that it should be undertaken after they finish the entire analysis but are willing to discuss, not commit to revising the label earlier or earlier communications with HCPs.
Q. But you know from your review of the record that GSK actually provided proposed labeling to indicate the data with

respect to the MDD finding, correct?
A. As inadequate as it was, they did submit that in a changes being effected supplement which they could submit 30 -- I'm sorry, implement 30 days after submission to FDA.
Q. You said "as inadequate as it was"?
A. That's correct.
Q. You agree that the May 2006 labeling changes that GSK implemented included the accurate statement that an increased risk in suicidal attempt was observed in MDD patients of all ages, correct?
A. That statement by itself without context is accurate but does not -- I'm not referring -- the word "inadequate" does not refer to that statement alone.
Q. I just asked you if it was an accurate statement.
A. Taken out of context, yes.
Q. Turn to your deposition, Page 279, Doctor.
A. Yes.
Q. "Question: And you agree that the May 2006 labeling change that GSK implemented included -- included the accurate statement that an increase in suicide attempt risk was observed in MDD patients of all ages?"
Your answer was, "Yes, I do agree with that," correct?
A. I just agreed with you a few seconds ago, yes.
MR. BAYMAN: Can we put up Joint Exhibit 5 and blow

it up, please, Roger, and scroll down to -- go to the...
BY MR. BAYMAN:
Q. You would agree with me -- you would agree with me that the warning that GSK issued in May of 2006 that there was an increased risk in patients of all ages that took paroxetine compared to placebo for the possibility of a suicide attempt, correct?
A. That statement was in the CBE supplement that they submitted.
(Pause.)
THE COURT: What are you waiting for, sir?
MR. BAYMAN: I'm just going to have him show it.
BY MR. BAYMAN:
Q. This is what we were talking about, correct? Keep scrolling down. Well, you agree that GSK put that in that label?
A. I do.
Q. Okay. Now, turn in your tab -- turn to Tab 29 in the notebook.
Put that back up. You got it?
Here's what I was trying to pull up earlier. GSK put the data about the MDD finding and then GSK said, "These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of age 24," correct?

A. That is what that text says.
Q. And this is new information that was appropriate to be in the label per a CBE, or changes being effected?
A. If it is accurate and reliable, it would have been.
Q. You don't believe that's accurate and reliable?
A. No.
Q. What's not accurate or reliable about it?
A. Well, if we could highlight the previous sentence, so this states that the majority of these attempts for paroxetine, eight out of 11, were in younger adults aged 18 to 30, but we know from the paper published by GSK employees, Carpenter, et al., that actually eight of 11 were in adults aged 25 and older. There's actually an entry in the table they have that says that.

So when you say the majority were in people older, 18 to 30, that does not state that you could also slice the data so that it was in older adults older than 25. So not having that statement in there, that there are -- you could slice it in more than one way means that the following statement suggests that the higher frequency may extend beyond the age of 24 is at best misleading and at worst false.

Q. Okay. We're going to get to -- Tab 29, Defendant's Exhibit 107.
A. Yes.
Q. Got it? You've seen that before, correct?

A. I believe so.
Q. That is -- that is a record of a conversation between GSK and the FDA, correct?
A. That is GSK's record of the conversation, yes.
Q. And, in fact, Mr. Wisner showed you some FDA conversation records from the 1990s during your direct examination, correct?
A. Can you refresh my memory? When you say "FDA conversations," I'm just trying to make sure I know which ones you mean, if there's an exhibit. I'm not disagreeing with you. I just want to -- I can't recall exactly what you're referring to right now, is what I'm saying.
Q. You recall talking with Mr. Wisner about a record of a conversation that Dr. David Wheadon recorded following his conversation with Dr. Tom Laughren of the FDA about the submitting the reanalysis of the suicide and the suicide attempt data in 2002 and 2003?
THE WITNESS: Your Honor, respectfully, permission to read back the first question here, "You recall there were" -- I believe it was FDA records.
MR. BAYMAN: No, I said conversation records. I'll help you out. Look in your notebook, Plaintiff's Exhibit 124.
THE WITNESS: I'm sorry. I'm responding to the wording of that question so --
THE COURT: Do you want to hear it again?
THE WITNESS: Please, your Honor.

THE COURT: All right. Read it back.

(Record read as follows: "Question: You recall talking with Mr. Wisner about a record of a conversation that Dr. David Wheadon recorded following his conversation with Dr. Tom Laughren of the FDA about the submitting the reanalysis of the suicide and the suicide attempt data in 2002 and 2003?"

THE WITNESS: I apologize. I think the more specific question is where I had gotten -- an earlier question about the general topic of records, conversations in the '90s with FDA. I just want to make sure I'm remembering that correctly, so I think it was a little bit earlier than this specific reference. And again, I'd ask the Court's indulgence.

BY MR. BAYMAN:

Q. Okay. I asked a broader question because he also showed you some from the 1990s, correct?

A. Yes. I just want to understand what exactly it is you said. Let me -- in the interest of time, I thought you might have said, and if I've got this wrong, I really apologize, I thought you might said FDA records of conversations from the '90s.

The only point I wanted to make was the only documentation I've seen of conversations between GSK and FDA staff have been records, documents that were made by GSK. That's all.

Q. Okay. But Plaintiff's Exhibit 124 which is in evidence, do you see that document? Let's put that up.
A. Is this -- I'm sorry, Mr. Bayman. Defendant's Exhibit 107?
Q. No. Plaintiff's Exhibit 124.
A. I'm sorry. Which --
Q. In the other notebook, the notebook Mr. Wisner gave you.
A. Yes.
Q. All right. My only point was, you've seen -- and I can show you others that are in that same notebook -- documents like this reflecting a record of a conversation with GSK and the FDA about labeling or about safety issues.
THE COURT: I don't think -- that's not an issue, is it?
MR. BAYMAN: Well --
THE COURT: Why don't we just go on.
MR. BAYMAN: Okay. Well, I want to show you what's been marked as Defense Exhibit 107, which is a record of a conversation that took place between GSK and the FDA on April 20th, 2006.
THE COURT: Put it on the screen --
MR. BAYMAN: Okay.
THE COURT: -- so he can see it.
MR. BAYMAN: Yes. Sure.
THE COURT: What's your question?
MR. BAYMAN: My question is --

MR. WISNER: Objection, your Honor. I object to this document as hearsay.

THE COURT: Is it in evidence?

MR. WISNER: No.

MR. BAYMAN: Not yet, your Honor. I was getting ready to put it in evidence, and it's the very same kind of conversation records the plaintiff has shown him all day the other day.

THE COURT: That's not necessarily controlling. You have an objection to it?

MR. WISNER: Objection, hearsay.

THE COURT: Okay. May I see the exhibit, please, Mike?

MR. WISNER: May I approach, your Honor?

THE COURT: No, not yet, not until I see the exhibit.

MR. WISNER: Yes. This is the exhibit.

THE COURT: Have you got it there?

MR. WISNER: Yes.

THE COURT: So this is the writer's report of what was said at a conversation, right?

MR. BAYMAN: And he says it's part of the dialogue between the company and --

THE COURT: All right. We've heard that. But as to this particular document, without going into the content, your argument is that it's something that was prepared by someone

who cannot be cross-examined? He said hearsay.

MR. WISNER: Yes, your Honor. And it's -- to the extent that they're arguing an admission, it's not by a party opponent. It's their own party, so they can't use it, whereas --

THE COURT: The objection will be sustained.

BY MR. BAYMAN:

Q. You know that GSK was having discussions back and forth with the FDA about the language of that label?

THE COURT: It's already been covered now, Mr. Bayman. We've been over this several times. The jury doesn't want to hear it over and over again.

BY MR. BAYMAN:

Q. You know that as of -- as of this point in 2006, FDA had not yet completed its review of the data that GSK submitted?

THE COURT: If you know.

BY THE WITNESS:

A. I actually don't know because the only document I have here was prepared by GSK. I don't --

THE COURT: No, sir, just answer --

THE WITNESS: I'm sorry.

THE COURT: Just answer the question.

THE WITNESS: I don't know based on this.

THE COURT: We've got to move along.

THE WITNESS: I'm sorry, sir.

BY MR. BAYMAN:
Q. You know that FDA was considering GSK's changes being effected supplement, correct?
A. So it was that changes being effected supplement was submitted in April of 2006, and FDA completed its review in May of 2007.
Q. Okay. And so FDA still had the time, after GSK submitted it, to come back and disagree with the language in GSK's proposed label, correct?
A. You mean after the submission?
Q. Yes.
A. Certainly.
Q. Okay. I want to take you to Tab 30, Defense Exhibit 114, which is a letter from GSK to the FDA dated April 27, 2006.
A. Excuse me. Yes, sir.
Q. You've seen that before?
A. Yes.
Q. You've seen it as part of your review of the regulatory file in this case, correct?
A. Yes.
Q. And you're familiar with these kinds of letters, correct?
A. Yes.
Q. And so here on April 27th, 2006, this is the letter by which GSK submits to FDA its CBE labeling changes for Paxil, correct?

A. Yes.

MR. BAYMAN: Your Honor, I'd move now for permission to admit Defense Exhibit 114 into evidence.

MR. WISNER: Your Honor, we do not object to its publication, but we would object to its admission because it is hearsay, although under 703, on cross-examination, they can show hearsay documents but they do not get admitted.

THE COURT: Well, you may show it.

MR. BAYMAN: It's a business record, your Honor. It's a letter to the FDA. It's not a hearsay statement. It's --

THE COURT: It doesn't necessarily mean it's a business record, but you may display it.

BY MR. BAYMAN:

Q. Okay. Let's put it up, do this quickly. I'm just trying to put the chronology together for you, Doctor. Will you agree with me, this is the letter transmitting the CBE?

A. This is a -- appears to be. The reason I don't want to say absolutely is because if it were the actual letter, there would be a date and time stamp saying when it was received in the document room.

Q. Well, this is a letter from GSK to the FDA from GSK's files. You don't dispute that, do you?

A. This is a letter. If it is the letter, I'm just saying that there's -- I don't want to say an authentication stamp,

but if you -- for the sake of argument, you're prepared to say that you guarantee that this is exactly the same letter as was actually sent to the FDA, that's okay.

Q. We don't need to --

THE COURT: All right.

MR. BAYMAN: -- trifle over that. Let's turn to Joint Exhibit 4, which is in evidence, the May 2006 Dear Healthcare Provider letter.

THE COURT: What's the question, sir?

BY MR. BAYMAN:

Q. You're familiar with that letter, correct?

A. I am.

Q. Okay. This is where GSK is informing doctors around the United States about the CBE labeling change based on its analysis of Paxil and suicide attempts, correct?

A. Yes.

Q. And attached to the letter was GSK's new labeling for Paxil, correct?

A. I believe so.

MR. BAYMAN: Pull up the first paragraph of the letter, please.

BY MR. BAYMAN:

Q. It's just alerting -- this letter just alerts the doctors that it is changing the clinical worsening and suicide risks subsection of the warnings section for Paxil, correct?

A. I'm going to disagree with that statement, respectfully. And the reason is that there are three --

THE COURT: You don't have to tell him the reason.

THE WITNESS: I'm sorry, your Honor.

THE COURT: Just answer the questions now, and then we'll move along much quicker.

BY MR. BAYMAN:

Q. Is GSK -- is GSK saying, "We would like to advise you of important changes to the clinical worsening and suicide risk subsection of the warnings section in the Paxil and Paxil CR labels"?

A. That -- yes, with the understanding that if it was really a warning HCP letter, it should have said under the regs, "important drug warning information." That's 21 CFR 201.5.

Q. You don't think "important prescribing information" meets that requirement?

A. Actually, what the regulations say is if you are asking -- or I'm sorry, informing providers in a DHCP letter about an important drug warning which is what this is, the envelope that it's sent in, in order to get -- avoid having it just get tossed, has to be in huge type with a red rectangle around it.

"Important prescribing information" would be what would be on the envelope. It does not say anything on the warning. It would not have the same level of prominence. And that is why the FDA has these very specific regulations about

what's drug warning, what's prescribing information, and what is correction of information.

Q. The letter says, "These labeling changes relate to your adult patient, particularly those who are younger adults." Did I read that correctly?

A. That is what the text states.

Q. And it says, "Please read the full text of the added warnings following this letter. Full copies of the revised package inserts for Paxil and Paxil CR are enclosed."

Did I read that correctly?

A. You did.

Q. And then in the fifth paragraph, GSK tells the doctors in language that it was including in the label, correct?

A. Yes.

Q. And it says:

"Further, in the analysis of adults with MDD, all ages, the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo, 11/3455, .32 percent versus 1/1978, .05 percent. This difference was statistically significant. However, as the absolute number and incidence of events are small, these data should be interpreted with caution. All of the reported events of suicidal behavior in the adult patients with MDD were non-fatal suicide attempts, and the majority of these attempts, 8 out of 11, were in

younger adults aged 18 to 30. These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24."

Did I read that correctly?

A. With the understanding that except for the first sentence, the remainder of the sentences in the paragraph are false and/or misleading, yes, you did.

Q. Your Honor, that wasn't my question.

I just asked, did I read it correctly.

A. Yes.

Q. I know you've said you believe this is false and misleading. You know GSK put these documents on its website for anybody to look at, correct?

A. Yes.

Q. Okay. Then moving chronologically to try to get through this, in December of 2006, FDA convened a public hearing where it discussed the results of its 2006 analysis, correct?

A. I'm -- I'm sorry. I'm not sure which document we're on right now.

Q. We're not looking at a document. I was just asking --

A. I'm sorry.

Q. -- chronologically.

A. I'm sorry.

Q. Chronologically, GSK changed its label in the spring and

then in December, FDA convened a public hearing to release the results of its analysis?

A. I believe that's correct.

MR. BAYMAN: May I approach, your Honor?

THE WITNESS: Thank you, sir.

BY MR. BAYMAN:

Q. Now, Doctor, as part of your work in this case and your regulatory expertise, you are familiar with this document, correct?

A. I believe that I have reviewed it.

Q. This is Dr. Thomas Laughren, his memorandum giving an overview for the meeting of the psychopharmacologic drugs advisory committee, the PDAC. That's the advisory committee, correct?

A. Yes.

Q. And the FDA, when it convenes advisory committees, it frequently, if not always, provides some kind of memo for the committee before the hearings, correct?

A. Yes.

Q. And that memorandum summarizes their official investigation into whatever matter they were studying, correct?

A. Yes.

Q. And this is -- you've seen many kinds of these -- these kinds of memorandum as part of your experience at FDA and as

an expert, correct?
A. Well, most often they have to do with specific products. There certainly are general meetings or hearings regarding class issues, but yes.
Q. This -- yes. This was a class issue, correct?
A. Correct.
MR. BAYMAN: At this time, your Honor, I'd move Exhibit, Defense Exhibit 435 into evidence.
MR. WISNER: Objection, hearsay.
THE COURT: I'll hear you on this later.
MR. BAYMAN: Okay.
THE COURT: Do you need it now?
MR. BAYMAN: I can move on. I can move on -- well, can we publish it without moving it into evidence?
THE COURT: Any objection to that?
MR. WISNER: I don't know if this witness has testified that he relied on it. If he does, then sure.
THE COURT: You can ask him.
BY MR. BAYMAN:
Q. You've reviewed this as part of your work in the case?
A. Yes.
Q. And this is a part of the information in the, what we call the regulatory file that you rely on in giving your opinions in this case?
A. I would say yes.

MR. BAYMAN: Okay. May I publish?
THE COURT: Yes.
MR. WISNER: Your Honor, just to correct the record, I just found out that this is actually already admitted, so we withdraw our objection.
MR. BAYMAN: Okay. I guess it's in evidence.
BY MR. BAYMAN:
Q. Look, if you would -- you had said earlier that what the FDA -- the purpose of what the FDA was doing was to calculate odds ratios with respect to these antidepressants and not to do anything with respect to labeling, correct?
THE WITNESS: I'm sorry, your Honor. I ask that that question be read back.
THE COURT: Read it back, please.
(Record read.)
MR. WISNER: Objection, ambiguous.
THE COURT: You may answer if you can.
BY THE WITNESS:
A. I would say that the -- my previous testimony which I stand by is that that analysis was done to address a specific question but -- as the direct purpose, but as you and I also discussed, I didn't say, well, it had nothing to do with labeling. I think it was -- as I've said previously, there's more things than just randomized controlled trials in making labeling decisions about safety.

BY MR. BAYMAN:
Q. To move along, I just want to call your attention to the last two sentences in this document in the first paragraph. "The purpose" -- the document says:

> "The purpose of the December 13th meeting is to update the committee with our findings from this meta-analysis. We will present our findings and our interpretations of the data, and we will generally discuss our plans for labeling modifications based on these findings."

Did I read that correctly?
A. Yes.
Q. And with respect to this hearing that the FDA convened, people got to come to the hearing and voice their views about what the product labeling should say in light of the FDA's analysis, correct?
A. Could you be a little more specific? When you -- are you referring to the open public hearing portion of the meeting or the members -- or if you could just clarify.
Q. Actually, both. People expressed their views on what the labeling should say, correct?
A. Yes.
Q. And FDA took those views under consideration, correct?
A. I would hope so.
Q. And after the public hearing -- after the public hearing,

then in May of 2007, FDA announced labeling changes concerning adult suicidality for all antidepressants including Paxil, correct?

A. Correct.

Q. Turn, if you would, to Tab 32, Defense Exhibit 122.

A. I'm sorry. Yes.

Q. That's a May 1, 2007, letter from the FDA to GSK, correct?

A. Yes.

MR. BAYMAN: And your Honor, I believe this is in evidence, but I'm sure Mr. Wisner will correct me if I'm wrong.

MR. WISNER: Yes, it is in evidence, your Honor.

BY MR. BAYMAN:

Q. This letter includes and attaches the labeling information that GSK -- that FDA told GSK and other antidepressant manufacturers to include in their labeling, correct?

A. In terms of, just to be clear, they had reviewed this, found it to be approvable, and the language that's used, "We are requesting revisions to your labeling." So I want to just again for the sake of accuracy say they didn't tell them. They requested it.

Q. Look at your deposition, Page 10 -- Page 303, Line 5, please.

A. I'm sorry.

Q. Are you there?

A. I am.

Q. Okay. The question was:

"Do you see that this -- this is a letter from FDA to GSK which includes and attaches the labeling information that FDA has told GSK and other antidepressant manufacturers that it wants in the labeling?"

And your answer was, "Yes."

Did I read that correctly?

A. I'm sorry. You're in -- on Page 103?

Q. On Page 303.

A. 303.

Q. Line 5.

A. Okay. Yes.

Q. Let's -- let's look at this document, Defendant's Exhibit 122.

A. Okay.

Q. Okay. This, the subject of this document is GSK's changes being effected supplement, correct?

A. Yes.

Q. That GSK submitted on April 27, 2006? I mean, it references -- it references GSK's submission, correct?

A. Yes.

Q. Let's look at the second and third paragraphs.

A. Okay.

Q. This is where -- it says:

"These supplements, submitted under changes being

effected, provide for labeling revisions to the warnings and information for patients section regarding suicidality in young adults based on your analysis of the paroxetine and adult suicidality data. We've completed our review of your supplemental applications, and they are approvable. Before these applications may be approved, you will need to make revisions to your labeling as outlined below so as to ensure standardized labeling pertaining to adult suicidality with all of the drugs to treat major depressive disorder, MDD."

Did I read that correctly?

A. You did.

Q. FDA states explicitly in the letter that the changes to the label are to ensure standardized labeling pertaining to adult suicidality with all the drugs to treat major depressive disorder, correct?

A. Correct.

Q. In other words, the FDA's requiring that the warning sections of the labeling for all antidepressants including Paxil say the same thing with respect to adult suicidality, correct?

A. With the understanding that they're not requiring that the -- there not be any product-specific content in there, yes.

Q. There cannot be any product-specific content in this

warning, correct?
A. I want to draw a -- clarify again what I said and repeat it. You're saying the warning, saying they said that, but they didn't say anywhere in here, product-specific information about suicidality cannot go in the labeling. It does not say that here.
Q. This letter, the FDA's letter, it's not limited to the boxed warning, correct?
A. No.
Q. And the FDA saying that before GSK's changes being effected, the supplement we talked about earlier, will be approved, GSK will need to make revisions to the labeling as outlined below, correct?
A. Yes.
Q. And if you look at the last paragraph on that page, it says:

"Based on the recommendations made by the committee, we believe that additional changes are needed in antidepressant labeling and medication guides to alert practitioners, patients, family members, and caregivers about an increased risk of suicidal thinking and behavior, suicidality, in young adults with MDD and other psychiatric disorders who are taking antidepressant medications."

Did I read that correctly?

A. You did.
Q. And the next sentence states:
"Changes are also needed to inform practitioners about an apparent favorable effect of antidepressants on suicidality in older adults and to remind them that the disorders being treated with antidepressants are themselves associated with an increased risk of suicidality."
Did I read that correctly?
A. You absolutely did.
Q. So the FDA is saying that label -- the labels for all of the SSRIs in all of the antidepressants must include this language, correct?
A. Yes.
Q. And if you look at the second page of the document -- keep going, Roger, the warnings -- you see that this is the text of the labeling change?
A. Yes.
Q. And the box warning is above it, correct, on the page?
A. Excuse me. Yes.
Q. Go to the box warning, Roger.
And again, this is FDA's language that it's sending to the drug companies, correct?
A. Correct.
Q. In the box warning, the third sentence required GSK to

say:

"Short-term studies did not show an increase risk -- increase in the risk of suicidality with antidepressants compared with placebo -- compared to placebo in adults beyond age 24. There was a reduction in Orisk with antidepressants compared to placebo in adults aged 65 and older."

Did I read that correctly?

A. You did.

Q. And the FDA's required box warning was -- also states, "Patients of all ages who were started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior," correct?

A. Correct.

Q. And you would agree at this point in time based on what we have seen earlier that the FDA was aware of the sub-group analysis finding for an increased risk for Paxil in suicidal behavior in patients over age 25, correct?

A. I would agree that they were aware that the CBE supplement which was being responded to here said that there's a risk across all ages. However, they also had been told by GSK that there were eight out of 11 of those patients were in the age group of 18 to 30. It is not clear to me from what I've seen if, as part of that submission, GSK told them that if you

slice the data another way, eight out of the 11 were in older adults.

Q. How many patients -- of those 11, how many patients were older than 30?

A. I can't recall off the top of my head. It would be at least, I believe, at least three, possibly four.

Q. Okay. We'll get to that. You did a table with the distribution, correct, on the ages in your report?

A. Actually, it was a graph.

Q. A graph. Sorry. Okay. We'll get to that.

When FDA announced the labeling change in May of 2007, it was certainly aware of the 2.76 odds ratio finding on paroxetine or Paxil, correct?

A. Yes.

Q. And when they -- when FDA announced the labeling change in May of 2007, FDA's language, the language of FDA's labeling did not include a reference to paroxetine's finding of a 2.76 odds ratio being statistically significant for suicidal behavior, correct?

A. Understanding that it's the sponsor's responsibility to put that in the label, not the FDA's, I would say yes.

Q. This is the FDA's language, though, correct?

A. I understand.

Q. And it doesn't -- it doesn't include the 2.76 odds ratio, correct?

A. As I discussed in my testimony earlier, the sponsor has the responsibility to ensure that that is accurate, that if the FDA doesn't do something, that does not relieve the sponsor of its responsibility.
Q. But we've established the FDA knew of the odds ratio, correct?
A. The one that they had calculated, yes.
Q. They knew the GSK odds ratio, correct? It's in the labeling that we -- that I showed you?
THE COURT: We've been over this now. It's been covered several times.
MR. BAYMAN: Okay.
THE COURT: Let's move on.
BY MR. BAYMAN:
Q. Your opinion yesterday was that GSK should have included language stating that paroxetine induces suicides in adults over age 24, correct?
A. Correct.
Q. But the boxed warning right up here says there was no increased risk of suicidality in adults beyond age 24, correct?
A. For all antidepressants taken as a group.
Q. And it's your opinion then that the language in the 2007 FDA label that FDA drafted, prepared, and ultimately approved is false and misleading, correct?
MR. WISNER: Objection, lacks foundation as to who

prepared and approved.

THE COURT: Overruled.

THE WITNESS: I'm sorry, your Honor. Could I --

THE COURT: You may answer the question.

THE WITNESS: If I could just have it read back.

THE COURT: Read it back.

THE WITNESS: I'm sorry.

(Record read.)

BY THE WITNESS:

A. In the context of the Paxil label because of the data from GSK, I would say yes.

BY MR. BAYMAN:

Q. The box warning wasn't the only section in the label in which FDA wanted class labeling, correct?

A. Correct.

Q. In fact, if we go to the second page of DX 122 halfway down the page --

A. Yes.

Q. -- there's a bracketed instruction, correct?

A. Yes.

Q. And it says, "The following changes should be made to the current language under the warnings, clinical worsening and suicide risk section," correct?

A. Yes.

Q. So that warning is class language, correct?

A. Correct.
Q. And every antidepressant manufacturer had to have that very same warning, correct?
A. Correct.
Q. Okay. That warning -- and the jury has seen it. That goes on for about two pages, doesn't it?
A. It does.
Q. Okay. Let's turn to the fourth page of the exhibit about halfway down. There's another bracketed instruction, correct?
A. Yes.
Q. It says, "The following changes should be made in current language under the precautions, information for patients section," right?
A. Yes.
Q. And that that precaution is class labeling also, correct?
A. That's correct.
Q. So -- and everybody, every antidepressant manufacturer had to have it verbatim?
A. Yes.
Q. And then below the precaution, there's another precaution, "clinical worsening and suicide risk." Do you see that?
A. Yes.
Q. That is also class labeling that every antidepressant manufacturer was required to have in its label, correct?
A. Yes.

MR. BAYMAN: May I approach, your Honor?

BY MR. BAYMAN:

Q. I'm handing you what's been marked Defendant's Exhibit 6323. You're familiar with this document, correct?

A. Yes.

Q. It's an email chain between Renmeet Grewal, G-r-e-w-a-l, at FDA and a Mary Martinson from GSK in May of 2007, correct?

A. And just to be clear, the first page has correspondence with Dr. Arning from GSK.

Q. Okay. Okay. And this is some of the material from what we've been calling the regulatory file that you've relied on in forming your opinions in this case, correct?

A. I'd call this a correspondence subfile, but yes.

Q. Okay. And it's part of the back and forth between the FDA and the GSK about labeling, correct?

A. Yes.

Q. And we've established that the FDA communicates with pharmaceutical companies by email in the regular course of business, correct?

A. It does.

MR. BAYMAN: Okay. And your Honor, at this time, I would move for admission of Defense Exhibit 6323 and ask permission to publish to the jury.

MR. WISNER: No objection.

THE COURT: You may proceed.

MR. BAYMAN: Let's take a look at the --
MR. WISNER: I'm sorry. It's 6323?
MR. BAYMAN: Yes.
MR. WISNER: Defendant's?
MR. BAYMAN: Yes.
MR. WISNER: Okay.
THE COURT: It's also marked Defendant's 79.
MR. BAYMAN: It is 6323 in this case, your Honor.
THE COURT: All right.
BY MR. BAYMAN:
Q. Let's -- I want to take you to the -- these are like emails. The earliest one is the farthest one back.
A. Sure.
Q. Page 3. Do you see that?
A. Yes.
Q. And that is dated May 2, 2007, at 9:40 a.m. Do you see that up there?
A. Yes.
Q. And that's from the FDA's Dr. Grewal or Grewal to Ms. Martinson at GSK, right?
A. Yes.
Q. It's about the adult suicidality letter, that's the subject line?
A. Yes.
Q. And it says, "Dear Mary, please refer to the advisory

committee meeting held on December 13, 2006, regarding adult suicidality data in antidepressant drugs." Do you see that?
A. Yes.
Q. It says, "The agency has come to a decision with final language for the prescriber labeling and medication guide," correct?
A. Yes.
Q. And nowhere in this email, this email right here from the FDA, does it says -- say that the final language to which the reference is limited to the warnings or to the black box, rather, this is about the prescribing -- the labeling, prescribing labeling, and the medication guide, correct?
A. Well, the decision is always about the entire label, but with the proviso that this actually refers to sponsors in general, this is part of a general broadcast where they say, "Sponsor, we're requesting the sponsor submit prescriber labeling."

So this email is directed not just to GSK but all sponsors for this concept, I'd agree with you.
Q. Okay. But nowhere in this email does the FDA say that the final language for the label is limited to the warnings or the black box, correct?
A. No.
Q. The email continues, "Attached is a supplement request letter with new language," correct?

A. Yes.
Q. And it's attaching a letter from the FDA to Ms. Martinson at GSK that attaches the FDA's decided labeling for antidepressants including Paxil?
A. So I assume these are other products for which GSK is responsible. And it does treat them identically -- Wellbutrin, Parnate, and Paxil -- as just all members of the class, you're correct on that.
Q. Okay. Those are other antidepressants, correct?
A. I prescribed one of them.
Q. Okay. And attached to that letter is the FDA's decided labeling for antidepressants including Paxil --
A. Correct.
Q. -- correct? Okay.

And then Dr. Grewal at FDA writes, "We are requesting that sponsors submit revised prescriber labeling and medication guide verbatim as outlined in the attached letter within 30 days from today." Did I read that correctly?
A. You did.
Q. Okay. And "verbatim" means exactly as the FDA put it, correct?
A. They are requesting that sponsors submit revised prescriber labeling and medication guides verbatim. That is what they are requesting.
Q. And if we go then, what I would call, up in the email

chain, you see a response from Dr. Barbara Arning at GSK to Dr. Grewal, Monday, May 7, 2007, at 2:33 p.m., re. adult suicidality letter. Do you see that?

A. Yes.

Q. And Dr. Arning at GSK writes:

"Can I please ask for one clarification? Does FDA intend for Paxil and Paxil CR to keep the Paxil-specific paragraph on young adults that we added in April 2006 in the label in addition to the class labeling provided below, or do you ask us to replace the complete warning section on this topic by the new class labeling?"

Did I read that correctly?

A. So just to make sure I'm understanding, so they're asking, do you want us to keep our current warning that's specifical -- the Paxil-specific paragraph, and it states, on young adults, which I guess means the focus -- from their eyes, focuses on young adults, in the label and just replace that language with the class labeling, or just take it out and remove it on block, as we say, and then put in the new class labeling, yes, I would say that's it.

Q. That's not what I asked you. I said, did I read that correctly?

A. You did.

THE WITNESS: I'm sorry, your Honor.

BY MR. BAYMAN:

Q. Then Dr. Arning at GSK pastes into the email chain the entire section that she's talking about, correct?
A. Yes.
Q. And we know because we saw it earlier, that was the language that GSK had proposed in 2006 as part of its CBE, or changes being effected?
A. Right. This is what she refers to as the Paxil-specific paragraph on young adults --
Q. Okay.
A. -- correct.
Q. Now, go up to the last email in the chain at the top of Page 1. FDA responded to GSK's question on the very same day, May 7, 2007, correct?
A. Yes.
Q. And FDA wrote back to GSK in response to this question, "Please replace the previous warning section with the new language we provided to in the class labeling letter signed on May 9, 2007." Did I read that correctly?
A. You did.
Q. And FDA specifically tells GSK to replace the language that GSK had submitted earlier with -- that's in Dr. Arning's email with the language FDA provided, correct?
A. I'm sorry. Just to be very clear, the project manager said that, Dr. -- Lieutenant Commander Grewal.
Q. Of the FDA?

A. Yes.
Q. You're not suggesting she didn't have authority to speak for the FDA, are you?
A. No, that's not what I was suggesting.
Q. Okay. So you agree with me that GSK was told to replace the language that GSK had asked about earlier in the day that Dr. Arning had posted into the email -- pasted in the email with the language the FDA provided, correct?
A. I would agree that Dr. Grewal sent that email and that's what it says.
MR. BAYMAN: May I approach, your Honor?
THE COURT: Yes. From now on, just hand it to me.
MR. BAYMAN: Okay. Sure.
THE WITNESS: Thank you.
MR. BAYMAN: Okay. I'm handing you what's been marked as Defense Exhibit 6364, which is --
THE COURT: 6324?
MR. BAYMAN: 6324. Excuse me, your Honor.
BY MR. BAYMAN:
Q. Which is a May 11, 2007, letter from GSK to Dr. Tom Laughren at the FDA who we've heard about earlier, correct?
A. Yes.
Q. Okay. And you're familiar with this letter?
A. I am.
Q. And you reviewed this letter as part of your review of

what we've been calling the regulatory file in this case, correct?
A. Yes.
Q. And you -- this letter is one of the documents you rely on in support of your opinions in this case, correct?
A. Yes.
MR. BAYMAN: Your Honor, at this point, I would move for admission of Defense Exhibit 6324.
MR. WISNER: Your Honor, this exact duplicate has already been admitted as Defense Exhibit 126. So now he's entering in duplicates into the record. So I would ask that we just use --
MR. BAYMAN: We'll use 126. That's fine.
THE COURT: Use 126.
MR. BAYMAN: Sure.
THE COURT: I've asked many times to avoid these kind of duplications.
MR. BAYMAN: Your Honor, Ms. Hogan has pointed out, this is a different document because the other document does not have the attachments. This is the complete document. So I'd ask for admission of this one.
THE COURT: Very well.
MR. WISNER: Your Honor, I am looking at it right now. I'm looking at Defense Exhibit 6324. They're both four pages long and contain exactly the same content, so I don't

know what he's talking about.

MR. BAYMAN: Can I just use this one so we can move along, your Honor?

THE COURT: Yes.

MR. BAYMAN: Thank you.

BY MR. BAYMAN:

Q. Take a look at this document, and look at the second paragraph. GSK writes:

"We believe that the Paxil-specific paragraph on young adults that was added in May 2006 to the Paxil, Paxil CR, and Paxil oral suspension prescribing information would complement the class labeling by providing product-specific data based on the GSK-sponsored analysis of paroxetine trials."

Do you see that?

A. I do.

Q. So GSK is specifically asking FDA to keep the Paxil labeling that's cited on Page 2 of this letter, correct?

Can you pull up Page 2?

A. What they're specifically saying is we, therefore, propose maintaining the paragraph within the new class labeling. So that's what they're asking.

Q. Where does it say -- it says "complemented." Where does it say, "within the class labeling"?

A. So -- two, three, four, five, six -- on the seventh line

of the second paragraph on Defense Exhibit 6324, is it possible -- my eyes are just -- I need stronger glasses. So -- oh, I can touch this, can't? Yes. I'm sorry.

I don't know if that's visible to you, but that where it says, "We, therefore, propose maintaining the paragraph within the new class labeling."

Q. I misunderstood you. I thought you were suggesting that taking something out of the class labeling.

A. No, no. I'm sorry.

Q. All right. So and the Paxil-specific language that GSK wanted to include, that's set out at Page 2 at the top, correct? It's not a very good copy on the screen.

A. Yes. That's -- I mean, they've made an -- edited the text a little bit but yes, that's the text that they proposed retaining within the class labeling.

Q. They added the text a little bit to try to comport it with the class labeling because on the third line, I know it's hard to read on the screen, it says, "for all psychiatric disorders combined."

A. Yes. No, I agree. I don't believe that that substantively changes the meaning of the --

Q. But they're making edits to their prior submission --

A. Yes.

Q. -- to try to conform to what FDA was requesting, correct?

A. Well, I don't know what their intent was, but I certainly

don't -- I don't see any reason to find fault with it. Let me put it like that.

Q. Okay. Let's go to Tab 35 in your book, which is Defense Exhibit 127.

A. Okay.

Q. That is a May 15th, 2007, email exchange between the FDA and GSK, correct?

A. Yes, I believe so.

Q. And you've seen this email exchange before, correct?

A. Yes.

Q. It's part of the regulatory file that you reviewed in doing your work in this case, correct?

A. Yes.

Q. And it's one of the documents you rely on in -- to support your opinions in the case, correct?

A. Yes.

MR. BAYMAN: That's -- this one is in evidence, your Honor. This is 127, so let's put that up.

BY MR. BAYMAN:

Q. FDA tells GSK in response to the letter we just looked at:

> "Please submit your CBE application with your requests. We will be discussing all the sponsors's proposals during the last week of May. After we discuss everyone's proposal, I will have a response to your question."

Did I read that correctly?
A. You did.
Q. And we know that the question is, can GSK keep the Paxil-specific label -- language in the label, correct?
A. Within the new class labeling, is the request they've made.
Q. All right. Turn, if you would then, to Tab 36.
A. Yes.
Q. Got that?
A. I do.
Q. That's Defense Exhibit 133, a letter from GSK to the FDA dated May 23, '07, correct?
A. Yes.
Q. You've seen this letter before, also, correct?
A. I have.
Q. It's part of what you reviewed as -- in the regulatory file in this case?
A. Yes.
Q. It's one of the documents you rely on in support of your opinion in the case?
A. It is.
MR. BAYMAN: Your Honor, at this point, I'd move for admission of Defense Exhibit 133.
THE COURT: It may be received.
(Defendant's Exhibit 133 received in evidence.)
BY MR. BAYMAN:

Q. This letter constitutes GSK labeling submission in response to the FDA's announced labeling changes, correct?
A. This is a changes being effected supplement, so where they're putting -- so in other words, one that does not -- FDA can speak to but the sponsor could if they want to go ahead and implement. It's not a prior approval supplement.
Q. And GSK specifically attached proposed labeling to its May 23, 2007, CBE submission, correct?
A. They did.
Q. In the cover letter, the third paragraph, "We are herewith submitting" -- GSK writes to the FDA:

> "We are herewith submitting the changes being effected supplemental new drug application for Paxil, Paxil CR, and paroxetine reflecting the new requested class labeling and the medication guide."

Do you see that?
A. Yes.
Q. And then GSK continues in that paragraph, "The paroxetine-specific language is maintained under the warning section as outlined in our letter from May 11, 2007."
Did I read that correctly?
A. You did.
Q. And, in fact, they're just asking, "Can we maintain" -- well, they're saying, "We're maintaining that Paxil-specific language," correct?

A. Within the new class labeling, yes.
Q. This is a formal submission to FDA to ask FDA that GSK be allowed to keep the Paxil-specific information in the labeling that was the subject of the 2006 changes being effected, correct?
A. Within -- with the clarification that it is within this standardized class labeling, yes.
THE COURT: Let's take a recess, ladies and gentlemen. It seems to be time to stretch.
MR. BAYMAN: Thank you, your Honor.
(Recess from 2:55 p.m. to 3:10 p.m.)

(Change of reporters, Volume 7-C.)

[redacted]

(Jury enters courtroom.)

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

You may proceed, sir.

MR. BAYMAN: Thank you, your Honor.

BY MR. BAYMAN:

Q. Wrapping up here, Dr. Ross.

A. Okay.

Q. Turn to Tab 37, if you would, which is Defense Exhibit 128.

MR. BAYMAN: Your Honor, I believe this went into evidence when Dr. Healy testified.

THE COURT: All right.

BY THE WITNESS:

A. Okay.

BY MR. BAYMAN:

Q. That's an e-mail from Dr. Grewal again at the FDA to

several individuals at GSK, correct? You've got to look in the upper right, small type.

A. Yes.

Q. You've seen this before, correct?

A. I believe so, yes.

Q. And you've reviewed this as part of the regulatory file in this case, correct?

A. Yes.

Q. And it's one of the items that you rely on for your opinions in this case, correct?

A. Yes.

Q. This letter's dated June 21, 2007, correct?

A. The e-mail, yes.

Q. The subject, it says, "Paxil Parnate Adult Suicidality Class Labeling Changes," correct?

A. Yes.

Q. FDA writes, "Please refer to our letter dated 5-1-07 requesting class labeling revisions for all drugs to treat major depressive disorder."

That's the letter we looked at earlier before the break, correct?

A. Yes.

Q. And the FDA continues, "We have completed our review of all of these responses."

So, what this means, Doctor, is that the FDA

completed the review of responses from various manufacturers about the labeling, correct?

A. Well, yes. This is specifically, if I understand correctly, to GSK employees.

Q. Right. What I meant about responses, it wasn't just GSK that was -- you know from looking at this issue, it wasn't just GSK that was going back and forth with the FDA about this labeling; other manufacturers were also, correct?

A. That's the implication of the last paragraph on the first page.

Q. Okay. Sure. And FDA writes, "We have completed our review of all of these responses, and we believe, based upon these responses, that the labeling needs to be further edited as follows."

Did I read that correctly?

A. Yes.

Q. And then FDA goes on to specifically state what specific changes need to be made, correct?

A. Yes.

Q. Let's go to the second-to-last paragraph on page 1. And, in fact, just as an example, it says that some of the sponsors had inadvertently omitted the class labeling paragraph starting with "Consideration should be given," correct?

A. That -- yeah, that's what it says.

Q. And it says that some sponsors have incorrectly added the

discontinuation language, starting with "If the decision has been made." Is that what it says, correct?
A. Yes.
Q. And it says, "Attached to this e-mail is the correct labeling incorporating the above changes for your products," correct?
A. Yes.
Q. Nowhere in the letter does FDA authorize the addition of any Paxil-specific language that GSK had requested be kept in the labeling, correct?
A. It is silent on that subject.
Q. And, in fact, on the second page, first full paragraph, the FDA says, "Please be reminded that it is critical that the labeling is consistent for all of these products," correct?
A. That is what it says, yes.
Q. Turn if you would, then, to Tab 38, Defense Exhibit 129.
MR. BAYMAN: Which is already admitted into evidence, your Honor.
BY MR. BAYMAN:
Q. Have you got that, Doctor?
A. I do.
Q. Okay. This is another e-mail from Dr. Grewal at FDA to Barbara Arning at GSK dated June 22nd, 2007, correct?
A. Yes.
Q. And you've seen this before?

A. I have.
Q. This is part of the regulatory information you relied on for your opinions in this case, correct?
A. Yes.
Q. And the subject is, "Adult Suicidality E-Mail," correct?
A. The class labeling for adult suicidality, yes.
Q. It just says, "Adult Suicidality," in the e-mail?
A. I'm sorry. I misunderstood. Yes, that is what the subject says.
Q. And in this e-mail, Dr. Grewal writes, "I received your voice mail as well as e-mail earlier this morning. As for your first question, the agency has reviewed your proposed changes, and we do not believe that your product-specific analysis should be included in the class labeling revisions since the labeling is targeted at a class of drugs. If you would like to discuss this matter further, please submit a formal meeting request."

Did I read that correctly?

A. You did.
Q. And so FDA is saying that it was not accepting GSK's proposed labeling change that had been submitted in the CBE supplement in May of 2007, correct?
A. The one where they had proposed keeping the product-specific analysis within the class labeling, that is correct.

Q. And we discussed earlier that CBEs are to provide the FDA with newly acquired information, correct?
A. Well, not their -- not to provide so much the FDA, but to, in this circumstance, add or strengthen a warning on the basis of newly acquired information.
Q. Okay. Fair enough. But you would agree with me that it's ultimately the FDA's decision to decide whether the newly acquired information submitted by the manufacturer will be included in the medication's labeling, when it will be included, and what is said about the risk at issue, correct?
THE WITNESS: Your Honor, could I ask that that question be read back to me. I again apologize.
(Record read.)
BY THE WITNESS:
A. As a general rule, without getting into the question at issue here, which is, you know, where it is, yes.
BY MR. BAYMAN:
Q. Turn to page 107, would you, in your deposition, line 15.
The question was, "And it is ultimately FDA's decision to decide whether the newly acquired information submitted by the manufacturer will be included in the medication's labeling, when it will be included, and what will be said about the risk at issue?"
And your answer was, "Yes," correct?
A. Yes.

Q. There's nothing in this letter from FDA saying that GSK could put the Paxil labeling somewhere other than in the warnings section, that Paxil-specific data that you assert should be in the labeling, correct?
A. It is silent on that issue.
Q. You would agree that -- and you see in there at the end, end of that second paragraph, "If you would like to discuss the matter further, please submit a formal meeting request." Do you see that?
A. Yes.
Q. And you're aware that GSK did not submit a formal meeting request to FDA about this?
A. As far as I know, they didn't.
Q. And you would agree with me that you do not know what FDA would have done if GSK had made a formal meeting request or attended such a meeting, correct?
A. No, I don't.
Q. And you would agree that at this point in time, in the spring and summer of 2007, FDA made the comment about, "If you want to discuss it, submit a formal meeting request," at the time it made that comment, FDA had already reviewed the data about Paxil and suicidality that had been submitted by the company, correct?
A. Correct.
Q. So, there's certainly no new data on Paxil and suicidality

to submit to FDA for such a meeting, correct?

MR. WISNER: Objection. Lacks foundation, speculation.

THE COURT: If he knows, he may answer.

BY THE WITNESS:

A. I don't really know.

BY MR. BAYMAN:

Q. Are you -- are you aware of any new data at this time on Paxil and suicidality?

A. For example, I've talked about the fact that these analyses were placebo-controlled, just restricted to that. Other information that could represent or be -- supplement the existing reasonable evidence for an association would be things such as adverse event reports and the like. So, I just don't know the answer to that.

Q. Turn in your deposition to page 344, line 15. Do you see that?

A. Correct.

Q. "Question: So, there's certainly nothing new to submit when it came to data about suicidality and Paxil at that time, correct?"

Your answer was, "Correct"?

A. I believe the question was -- you were asking me was there any new information. This says, "So, there certainly is nothing new to submit," so --

Q. To submit when it came to data about suicidality and Paxil.

MR. WISNER: Objection. He interrupted the witness. If he could finish his answer.

BY THE WITNESS:

A. So, if I may finish my answer, the --

THE WITNESS: I'm sorry, your Honor, may I? I apologize.

THE COURT: Sure.

BY MR. BAYMAN:

Q. Go ahead.

A. So, just to give that example, the FDA may have information that manufacturers can get from FDA. I'm specifically referring to what are called adverse event reporting system quarterly data files, which represent side effects reports that may come in to the FDA which a sponsor may not be aware of unless they download those files.

So, it certainly is possible that there was new information. Again, I'm drawing -- it may sound like a semantic distinction, but it's not. The question is: Was there any new information in the sponsor's possession at that point? That's what I was answering at the deposition.

Was there new information that fell outside of this answer? Potentially, yes, which GSK would not have necessarily had. That's what I'm getting at.

Q. GSK wouldn't have had the new information, correct?
A. Correct.
Q. And GSK was the applicant who made the CBE, correct?
A. Correct.
Q. Turn, if you would, to Tab 39. That's Defendant's Exhibit 130, a June 25, 2007, e-mail from GSK to the FDA.
MR. BAYMAN: Your Honor, this was admitted during Dr. Healy's testimony.
BY MR. BAYMAN:
Q. And that's -- have you got that? That's an e-mail from Dr. Arning at GSK back to Dr. Grewal dated June 25 --
MR. WISNER: Objection, your Honor. This was not admitted during Dr. Healy's testimony. It was shown to him and he was asked questions about it, but it was never admitted.
BY MR. BAYMAN:
Q. Okay. You're familiar with this document, correct?
A. Yes, I am.
Q. It's part of what you reviewed; it's part of the regulatory file in this case, correct?
A. Correct.
Q. And, in fact, it's one of the things you rely on for your opinions in this case, correct?
A. Correct.
MR. BAYMAN: Your Honor, at this time I would move

for admission of this exhibit into evidence.

MR. WISNER: That was not a proper grounds for admitting it into evidence. We have no objection to showing it to the jury as part of a cross-examination; but when you put it into evidence, it has to overcome certain evidentiary hurdles, which this has not done.

THE COURT: Well, we won't worry about those hurdles. You may show the exhibit.

BY MR. BAYMAN:

Q. Dr. Ross, you just said you relied on this, correct?

A. Yes.

Q. Okay. We'll show it. It's an e-mail from Dr. Arning back to Dr. Grewal back on June 25, 2007. If we go to the last paragraph, it says, "GSK still believes that the paroxetine-specific language that has been in effect for the past year would be useful for prescribers. Nevertheless, we understand FDA's reasons for keeping the language generic to the class and will implement the labeling after receiving your approval letter."

Did I read that correctly?

A. You did.

Q. Okay. Now, I understand from your testimony yesterday that your position is that GSK could have put the Paxil-specific language somewhere else in the label, correct?

A. That is one of the potential actions that GSK could have

taken.
Q. In fact, you spent about 90 minutes going through the label and pointing out other places where information could be put in the label, correct?
A. Just to be clear, 90 minutes were spent by me responding to questions from Mr. Wisner. I did not take 90 minutes to do that.
Q. Fair enough. And so we're clear, the black box section, the warnings section, the precautions section, the information for patients section, those were all class labeling with respect to suicidality, correct?
A. Correct.
Q. Now -- and you went through, and you marked -- Mr. Wisner marked here different places in the label where you said that language could go, correct?
A. Yes.
Q. And in the regulations, there are -- the label has very defined sections, correct, such as warnings, dosage and administration, correct?
A. It does.
Q. There's a structure to that label, correct?
A. Yes.
Q. At your deposition, you couldn't tell us where the Paxil-specific language should go, correct?
A. I recall being asked about that, but I want to just

clarify, I did not say where it should have gone in my report. I just said that it could have gone somewhere without specifying further.

Secondly, I said at that time I was not sure where it could have gone to. I did not say that's an unknowable or something like that. That was the question I was asked, and I, you know, at that time did not know. But that is something that I've thought about since then.

And anticipating your next question, that is -- did not change the opinions that I offered in my report. I simply said that it could go in the label somewhere other than within the class labeling.

Q. And you yesterday went through all the various places where it could go, correct?

A. Correct.

Q. And -- but you were asked at your deposition, "Where would you put the Paxil-specific information about the risk of suicidality if you claim it should have remained in Paxil's label?" You were asked that, correct?

A. Could you -- I'm sorry. This is a 438-page transcript. If you could point out a page.

Q. Sure, page 403, line 9.

A. 403, line 9. Yes. Okay.

Q. You were asked about that, and, in fact, you were asked, "I want you to specifically tell me where you would put it."

And you said, "I would have to think about that."

Do you see that?

MR. WISNER: Objection. The question just before that is part of the answer. He was actually cut off mid-answer.

THE COURT: Are you starting on line 9?

MR. WISNER: Yes.

THE COURT: Okay. Read it all then.

MR. BAYMAN: Yes, sir.

BY MR. BAYMAN:

Q. "Okay. Where would you put the Paxil-specific information about risk of suicidality if you claim it should remain in the Paxil's labeling?

"Answer: I pointed to a couple of examples, and I've looked at where it could be, but again, it was --

"Question: I want you to specifically tell me where you would put it.

"Answer: I would have to think about that.

"Question: You haven't made a determination about whether it would be under precautions or adverse events reactions or anywhere, right?

"Answer: That was not a question I was asked to address."

Did I read that correctly?

A. Yes.

Q. And you said since your deposition you've come up with some places where that language should go?
A. No. I was asked where it should go in this deposition, and your question just now is I've come up with a couple of places where it should go. I listed places where it could go, and there's a big difference.
Q. So, you understood the question, "Where could it go," to mean not, "Where should it go," but, "Where could it go"?
A. Well, again, you know, at line 16, Mr. Davis said, "I want you to specifically tell me where you would put it." He did not ask me, "where you might put it."
Q. Oh, okay.
A. Okay? So, you know, where should it go? Where is the right place? That's, you know, not what you asked me just now, and that's not what Mr. Davis asked me.
Q. It's not the first time you've testified, correct?
A. This is actually the very first time I've testified in open court.
Q. You're aware that there's certain rules that govern reports for experts when you testify in federal court like we are here today?
MR. WISNER: Objection. Improper opinion. He's not a lawyer.
THE COURT: Yeah, sustained.
BY MR. BAYMAN:

Q. When was it after your deposition -- between your deposition and today that you formed opinions about where the language could go?

MR. WISNER: Objection. Lacks foundation.

THE COURT: Overruled.

BY THE WITNESS:

A. As I was preparing for testimony here and rereading the transcript, I thought about where could it go. You know, I would say it was over the last few weeks.

BY MR. BAYMAN:

Q. Last few weeks. And you've not supplemented your expert report to put that information?

A. This is -- this is not a new opinion in my report. It is consistent with something that's already in my report, so -- and there was no request that I supplement it, so I'm -- no.

Q. Because you're making the distinction between "could" and "should," is that right?

A. No, not with regard to my opinions. I'm just differentiating between the question you're asking, which is, "Where should it go," versus, "Where could it go?" One is more definite than the other.

Q. Okay. And you certainly don't know that if GSK had made a CBE supplement proposing that the Paxil-specific information that you say should be in there be someplace other than as you described, that is, the class labeling, that FDA would have

accepted that, do you?
A. I cannot speak to whether they would have accepted or -- it or not.
Q. Okay. And you can't point -- strike that.
You're not aware of any occasion since 2004 where the FDA has approved labeling for an SSRI, an antidepressant, or any psychiatric medicine where the labeling discusses comparisons between drugs concerning the risk of suicidality, are you?
A. I don't know if there have been -- the FDA has to get an application before it can approve it, so I have no idea what applications, if any, might have been submitted.
Q. Can you turn in your deposition to page 393?
A. Okay.
Q. Line 23. Are you with me?
A. I am.
Q. "Are you -- Dr. Ross, are you aware of any occasion since 2004 where FDA has approved labeling for an SSRI, an antidepressant, or any psychiatric medication where the labeling discusses comparisons between drugs concerning the risk of suicidality?"
And your answer was, "No."
Did I read that correctly?
A. Yeah, and that would still be my answer.
Q. And you agree that the FDA's position is that in order for

a manufacturer to make a comparative efficacy or safety claim about the use of a medication, that a manufacturer must base that on well-controlled studies, correct?

A. In the sense that if it wants to claim it's better than another product, that is what they mean by that, for comparative efficacy or safety.

Q. If it wants to claim it's less risky to another product --

A. Correct.

Q. Correct? Okay.

And the studies that were done as part of the FDA's analysis in 2006, those studies were not designed in a way that allowed, say, sertraline or Zoloft to be compared to paroxetine or Paxil or Paxil to be compared to Prozac, correct?

A. For -- it depends on the purpose for which one is comparison-ing them -- I'm sorry, comparing them.

But they were not designed to compare them, or what -- I'm sorry. I'm just trying to understand your question.

Q. The studies that were done as part of the FDA's analysis in '06, those weren't designed to compare -- or designed in a way that would allow you to compare Zoloft to Paxil to Prozac, correct?

A. Are you talking about the underlying studies that were sent to the --

Q. Yeah.
A. I actually don't know what studies were sent in by those manufacturers.
Q. Okay?
A. I --
Q. The FDA's analysis was not for purposes of making comparative claims, correct?
A. You know, as I've said, I think the immediate question was, when we went over it, does it increase or decrease the risk of suicidality? That was the question on the table. So, could that have then been used to make a comparative safety claim if someone said -- wanted to say, "Well, we are less risky than this other drug"? That is not a question that, really, I was asked to address.
Q. Okay. Fair enough. Are you aware of any study since 2004 where Paxil was compared to other medication -- another SSRI medication in a randomized double-blind placebo-controlled trial where the issue -- the object that was being studied was suicidality?
A. You say the outcome was -- you know, I can't recall at the moment.
Q. Okay. Let's look at Tab 40 in your book, which is an August 2, 2007, approval letter from FDA to GSK. You're familiar with that letter, correct?
A. Yes.

Q. That's part of what you reviewed as part of the regulatory file in this case, correct?
A. Yes.
Q. And you rely on that letter in part in forming your opinions in this case, correct?
A. In part, yes.
Q. That's FDA's -- we talked about formal approval letters earlier. That's FDA's formal approval letter for the Paxil labeling that was implemented in August of 2007, correct?
A. Correct.
MR. BAYMAN: Your Honor, at this point, I'd move Exhibit 344 into evidence.
MR. WISNER: No objection.
THE COURT: It may be received.
(Said exhibit admitted in evidence.)
BY MR. BAYMAN:
Q. And you're -- you said you're familiar with this letter. In the second paragraph, the FDA says that -- blow that up, please.
"We acknowledge receipt of your resubmission of the Paxil NDAs." It goes on with the numbers, and it says, "Your July 3, 2007, resubmission constituted a complete response to our action letter dated May 1, 2007."
Did I read that correctly?
A. You did.

Q. This is FDA's way of saying that GSK complied with the labeling language set out in the May 1, 2007, letter and the attached labeling, correct?
A. Well, the final labeling, as we've discussed. There were some more iterations to it, but -- that all sponsors had to comply with; and I think FDA, as we've seen before, had sent out some changes to the class labeling. But essentially, yes, it kind of closed the whole loop on that.
Q. Okay. Turn to page 3 of the exhibit. That's the Paxil labeling that's attached to the letter.
A. Yes.
MR. BAYMAN: Blow that up, Roger.
BY MR. BAYMAN:
Q. It says, "Short-Term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24. There was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older."
Did I read that correctly?
A. You did.
Q. And as part of FDA's labeling change, the labeling for Paxil as well as the other SSRIs were required to state this, correct?
A. You mean the text in the black box?
Q. Yeah.

A. With the exception of the statement that Paxil is not approved for use in pediatric patients, since I believe there are other -- at least one other SSRI is approved for such use, yes.
Q. I asked you about the suicidality language.
A. I understand what you're asking. I thought you were asking about the language in the whole black box.
Q. Okay. How about this particular phrase, "Depression and certain other psychiatric disorders are themselves associated with an increase in the risk of suicide"?
A. That is part of the class labeling.
Q. Right. And, in fact, you don't know any analysis of randomized placebo-controlled trials on Paxil or paroxetine that shows a statistically significant increased risk of completed suicides in adult patients over 30, do you?
A. With the understanding that that is not the standard for adding a warning to the label, no.
Q. You can't -- doctor, you can't cite any specific instance that you're personally aware of where the FDA failed to carefully control the content of the labeling for Paxil as it relates to adult suicidality?
A. Could you -- I'm sorry. I know you're reading from the transcript. Could you, just for my assistance, direct me to the page you're quoting from?
Q. Was just asking you the question.

A. Well, I know it was a question that was asked during my deposition.
Q. Sure. Page 423, line 9.
A. 423. I sort of remember what I said, but I want to -- I remember that question. The word "control" is what gave it away.

Yes. I said at the time, "Not off the top of my head." And in terms of the answer to the question that you asked me just now, what I would say is when you say -- the phrase "personally aware," I actually want to think of it a little bit; but in terms of being aware, I have concerns about that process very much in terms of what happened during the course of this.

But having said that, I can neither confirm or deny an instance, specific instance where it failed to carefully control the content of the label.
Q. And you couldn't come up with one when you were asked at your deposition, an example, correct?
A. Off the top of my head?
Q. That's all right, Doctor.
A. That's what I said.
Q. Turn to the second page of the cover letter, third paragraph, the FDA's cover letter.
A. Go ahead.
Q. It says -- the FDA says, "Failure to make these changes

within the specified period of time could make your product misbranded," and then it cites 21 U.S. Code 321(n) and 352(a), correct?

A. Yes.

Q. So, FDA is saying that, "The labeling changes that we're approving here for Paxil must be used, because otherwise, the product would be misbranded under the Food, Drug and Cosmetic Act," correct?

A. That is what it's saying here.

Q. So, use of this labeling in August 2007 was not optional for GSK, was it, Doctor?

A. At the specific point in time where they received this -- I'm just having trouble with the question because -- I would say it depends. If they had submitted a Changes Being Effected -- this was on what day? Where are we here?

I'm sorry. Whatever the date was of this letter, if they had the following day submitted a Changes Being Effected supplement putting language, Paxil-specific language into the label in a place other than where the FDA had said, "Well, we don't want it here," then as I've said before, until the FDA had reviewed this, this wouldn't have applied.

And I'd go further and say the question about whether the FDA carefully controlled it really is -- you know, in terms of submitting such a supplement, it's up to the sponsor to do that.

Q. My question was a little bit simpler. It was: The use of this particular attached labeling in August of 2007 was not optional for GSK?
A. Well, actually, it's not a matter of it being optional. GSK submitted Changes Being Effected supplements. Actually, one was submitted later on that year, and they were able to implement it; and it wasn't ruled on by the FDA for four years.

So, to say you may never change this, if that's what somebody is interpreting that as meaning, is not correct.
Q. The FDA is saying, "Implement this labeling," correct?
A. As of right now. It does not prevent them from doing something new.
Q. If the FDA approves this specific prescription drug labeling, the labeling is not in violation of the FDA statute, correct?

MR. WISNER: Objection. Violates this motion -- this Court's ruling on motions *in limine*.

THE COURT: Overruled. You may answer it if you can.

THE WITNESS: I'm sorry, your Honor.

THE COURT: You may answer it if you can.

THE WITNESS: I'm sorry. I actually keep forgetting the question. I apologize.

THE COURT: Read it back, please.

(Record read.)

BY THE WITNESS:
A. Once they had implemented it, they were not at that moment -- the caution about misbranding, and then earlier I mentioned misbranding is not something that's like flicking the light switch. They would have complied with the provisions of this specific letter.
BY MR. BAYMAN:
Q. Look at your deposition, page 94, line 14.
A. I'm sorry. Give me one second here.
Q. Sure.
A. Okay.
Q. The question was, "If FDA approves specific prescription drug labeling, FDA has determined the labeling is not in violation of the FDA statute, correct?"
And your answer was, "Yes," correct?
A. Okay.
MR. WISNER: Objection. Improper impeachment. That's not what he asked him.
THE COURT: Let's proceed.
BY MR. BAYMAN:
Q. So, you're not saying -- well, let me make sure I'm clear.
Wouldn't you agree that using this particular attached labeling was not optional for GSK in August of 2007?
MR. WINSER: Objection. Asked and answered about

seven times.

THE COURT: I think we've been over this now. I think your position and his position has been fully explored. Let's move on.

MR. BAYMAN: Okay.

BY MR. BAYMAN:

Q. And I know yesterday that you listed a bunch of places in the label where GSK, you said, could have put something else, correct?

A. I listed a number where it could have and a number where it would not have been appropriate.

Q. You haven't drafted a specific warning that you say GSK should have put in; you haven't drafted specific language, have you?

A. That's not my job, sir. That's the sponsor's.

Q. Okay. I just wanted to make sure you hadn't drafted any.

And you'd agree with me that by approving the final attached labeling that was just up there, the FDA determined the statements in the Paxil label were neither false nor misleading, correct?

A. On the basis of the information provided to it by GSK, yes, it had made that determination.

Q. Turn in your deposition to page 352, line 6.

The question was, "And do you agree that by approving the final attached labeling, FDA has determined that the

statements in Paxil's labeling are neither false nor misleading?"

And your answer was, "Yeah, I'd agree with that."

Did I read that correctly?

A. You did.

MR. BAYMAN: Your Honor, I have no further questions.

THE COURT: All right. Redirect?

MR. WISNER: Yes, your Honor.

REDIRECT EXAMINATION

BY MR. WISNER:

Q. Good afternoon, Doctor. How are you doing?

A. I'm okay. How are you?

Q. I'm doing all right.

A. Okay.

Q. Okay. Let's get started. I want to get you out of here today.

First things first, just before when defense counsel was asking you some questions about class labeling, I want to follow up just quickly on a couple of things here.

He specifically asked you about whether or not a drug would be misbranded. Do you recall that?

A. If you can -- misbranded under what circumstances? I'm sorry. What's the --

Q. Sure. He asked you a question about whether or not if GSK did not put that class labeling into effect, the drug would be

misbranded. Do you recall that?
A. Yes.
Q. All right. In the entire history of the FDA, do you know of a single instance when the FDA rejected or held a drug to be misbranded because it included a stronger warning about a risk?
A. I am unaware of a single one.
Q. Would you agree that it is, in fact, preposterous to think that the FDA would deny a request to strengthen a warning about a known risk?
MR. BAYMAN: Object to the leading, your Honor, and argumentative.
THE COURT: It's somewhat argumentative.
BY MR. WISNER:
Q. How do you feel about that, Doctor?
A. Well, it's not so much how I feel about it. If I may quote Dr. Robert Temple, who is -- was --
MR. BAYMAN: Objection. Hearsay, your Honor.
THE COURT: Proceed.
BY THE WITNESS:
A. Actually, I'm referring to a deposition given by Robert Temple --
MR. BAYMAN: It's not in evidence, your Honor. It's not even been designated in this case, so we object to it.
BY MR. WISNER:

Q. Did you rely upon that testimony?

THE COURT: Well, let's move on.

BY MR. WISNER:

Q. All right. What is your opinion about whether or not the FDA would have said, "No, GSK, you are not allowed to warn about the risk of adult induced suicide in your label"?

A. That's ridiculous.

Q. Okay. He asked you if you could point out a time when the FDA failed to control the label. Do you recall that?

A. Yes.

Q. Okay. Let's step outside of Paxil for a second. Has the FDA always been correct about the content of all prescription drug labels since the beginning of time?

A. No.

Q. Remember we talked about some examples in the past? We talked about thalidomide. Do you remember that?

A. Yes.

Q. Causing birth defects in children?

A. With the caveat that that was not an approved product at that time, the -- I would say the equivalent of the package insert at that time in Western Europe was not correct.

Q. Now, if we look since the '80s onward, can you think of instances when we discovered that there were serious risks associated with drugs that the manufacturer didn't tell and that the FDA missed?

MR. BAYMAN: Objection. Argumentative, your Honor.

THE COURT: Yeah, it's rather argumentative. You've got to be specific, sir.

BY MR. WISNER:

Q. Okay. Vioxx, have you heard of that?

MR. BAYMAN: Your Honor, objection. This is really far afield from this case.

MR. WISNER: He asked if there was a single instance when the FDA failed to control a label. There are hundreds.

MR. BAYMAN: I said Paxil, your Honor. My question was related to Paxil, your Honor, not any other drugs.

THE COURT: Overruled. You can proceed.

BY THE WITNESS:

A. There are many, many instances when the FDA -- and I've said earlier, I have great respect for the people that I worked with there. Many of them are public health heroes. But they can get things wrong.

In addition, there have been situations I have personally been connected -- not personally, but directly involved in them professionally at FDA where companies would not submit information that they had to FDA, and that affected the labeling.

BY MR. WISNER:

Q. Because at the end of the day, Doctor, who is actually responsible for the drug label?

A. The manufacturer.
Q. Who has the ability to change the label to include truthful information at any time?
A. The manufacturer.
Q. And who in this case, specifically with regard to Paxil, had the ability -- strike that.
Who in this case had the obligation to tell doctors that their drug could cause adults -- strike that -- that could induce adult suicidal behavior over the age of 24?
A. There's not a question in my mind it was the manufacturer.
Q. Who is that manufacturer, Doctor?
A. Until it was -- the NDA was --
Q. Doctor --
A. I'm sorry. When you say at what time, I'm sorry.
Q. Doctor, doctor. Before 2010.
A. Oh, I'm sorry. GlaxoSmithKline.
Q. Thank you. All right. We spent about two hours discussing the FDA's interactions with GSK about a 2006 labeling supplement. Do you recall that?
A. Yes.
Q. Let's start off at the beginning. That labeling supplement, the information that they wanted to warn, was that information false and misleading?
A. When you say this information, I just want to be clear you're talking about the 2006?

Q. Yeah, the information they tried to put in the label and they spent --
A. I believe so.
Q. Okay. So, we spent two hours discussing a supplement that, in your opinion, even if it had gotten in the label, was false and misleading, is that right?
A. Yes.
Q. Okay. Well, let's look at that for a second. Let's go to Defendant's Exhibit 103.

All right. Doctor, this is already in evidence.

MR. WISNER: Your Honor, may I publish?

THE COURT: Yes.

BY MR. WISNER:
Q. All right. So, Doctor, this is the analysis that was sent to GSK in 2000- -- sorry, sent to the FDA in 2006, is that right?
A. I believe so, yes.
Q. Okay. I want to call your attention -- this came up on cross-examination. I want to call it out here. It states in this footnote, "Definitive suicidal behavior included events classified as completed suicide, suicide attempts, and preparatory acts toward imminent suicidal behavior. In the results of the current analysis, there were no completed suicides or events classified as preparatory acts."

Do you see that?

A. Yes.
Q. So, to be clear, the analysis that formed the basis of the 2006 submission purported to the FDA that there had been zero suicides on Paxil, is that right?
A. Correct.
MR. BAYMAN: Objection. Mischaracterizes the evidence.
MR. WISNER: Sorry. I didn't catch that.
THE COURT: I didn't, either. Go on.
BY MR. WISNER:
Q. And the analysis that the FDA did in 2007, that also included data contained zero Paxil suicides, right?
A. Correct.
Q. Now, we know, because we've seen the documents, that there were a lot more than zero Paxil suicides on Paxil clinical trials, right?
MR. BAYMAN: Objection. Argumentative, your Honor, and leading.
THE COURT: Overruled.
THE WITNESS: May I answer?
THE COURT: You may answer.
BY THE WITNESS:
A. We do know.
BY MR. WISNER:
Q. But none of those suicides, none of those instances where

people actually killed themselves on this drug were included in any of this data?
A. That is correct.
Q. Do you think that was right?
MR. BAYMAN: Objection. He's asking an ethical opinion now, your Honor.
THE COURT: If he has an opinion, he may say it.
BY THE WITNESS:
A. So, I'm going to -- when you say right, I'm going to interpret that as scientifically or regulatory -- from a regulatory scientific perspective, was that correct? And the answer is no.
BY MR. WISNER:
Q. Now, when we talk about class labeling -- we're going to come back to these suicides in one second, but when we talk about class labeling, Doctor, does class labeling set the ceiling of potential warnings or the floor?
A. Generally the floor.
Q. So, you're saying a manufacturer can look at that floor set by the FDA and say, "You know what, I'm going to do right by these people, and I'm going to do a better one," is that right?
A. I would --
MR. BAYMAN: That's argumentative, your Honor. Objection.

THE COURT: Yeah. Put your questions without including commentary.

MR. WISNER: Yes, your Honor. Sorry. I'm trying to get him out of here today. All right. I will.

BY MR. WISNER:

Q. Doctor, can a manufacturer include better warnings than the class labeling?

A. Well, let me put it like this. If there is reasonable evidence of an association and they have -- they have that evidence, I would say not only can they, they should. And I pointed to some examples in my report of where manufacturers have done that.

In one case -- I'm sorry, both cases involving class labeling, one in which the product-specific language, this was for olanzapine, which is made -- or was made allegedly at the time by one of the -- the manufacturer of the major competitor to Paxil, in which that labeling was publicly available on the Web, they were able to do that.

So, I would say not only can they, they should.

Q. All right, Doctor.

MR. WISNER: Permission to publish Joint Exhibit 4 to the jury? It's already in evidence.

THE COURT: You may proceed.

BY MR. WISNER:

Q. All right, Doctor. We're looking at a GSK letter dated

May 2006. Do you see that?
A. Yes.
Q. And they went over this on cross-examination. Do you recall that?
A. Yes.
Q. This is the letter that went to physicians, is that right?
A. Physicians and other healthcare professionals.
Q. Thank you, sir. So, right here in this paragraph is the paragraph that we talked about a little bit. I want you to go to the middle of the paragraph. It says, "All of the reported events of suicidal behavior in adult patients with MDD were non-fatal suicide attempts." Do you see that?
A. Yes.
Q. Is that true?
A. No.
Q. Would it be fair to characterize that as a downright misrepresentation?
MR. BAYMAN: Argumentative, your Honor.
THE COURT: Yes. Sustained, sir.
MR. WISNER: Sorry, your Honor.
BY MR. WISNER:
Q. Is that a misrepresentation?
A. Given how carefully these -- I would use a somewhat different word. I would say that was a lie.
Q. So, in this letter sent to all physicians in May of 2006

which contains the information that GSK went over for two hours being submitted to the FDA, in your opinion, it contains a lie?

A. Yes.

Q. All right. Let's consider another document.

MR. WISNER: Your Honor, permission to publish Joint Exhibit 5.

THE COURT: Proceed.

BY MR. WISNER:

Q. Doctor, this is the 2006 label. Do you see that?

A. I do.

Q. Okay. Let's look at the clinical -- the warning language that they put in the actual label at that time.

All right. So, in the part right here, this is the paragraph I think we're all interested in. Do you see where it says, "Young adults," Doctor?

A. Yes.

Q. All right. I want to draw your attention to the sentence right here. "In the older age groups, aged 25 through 64 years and greater than 65 years, no such increase was observed."

Do you see that?

A. Yes.

Q. Is that true?

A. No.

Q. How do we know that?
A. From the Carpenter paper.
Q. And is that the one where they showed this specific age group had an infinitely greater risk of suicidal behavior?
A. That is the one.
Q. It goes on to read, "Again, all of the events were suicide attempts."
Do you see that?
A. I do.
Q. Does that indicate that there were no completed suicides in the MDD trials?
A. It doesn't here indicate that.
Q. I'm sorry. Does it say that?
A. Yes.
Q. So, it doesn't say that anybody died, doesn't it?
A. No.
Q. In fact, it suggests that nobody died, doesn't it?
MR. BAYMAN: Objection, your Honor. Leading.
THE COURT: He may answer.
BY THE WITNESS:
A. It says, as was with the Dear Health Care Provider letter, that none of these suicide attempts resulted in people actually killing themselves.
BY MR. WINSER:
Q. Now, you recall -- I want to talk about these suicides,

okay, in the MDD. So, do you recall the defendants bringing up Defendant's Exhibit 25?

A. Yes.

MR. WINSER: Permission to publish, your Honor.

THE COURT: Proceed.

BY MR. BAYMAN:

Q. This is the document that was the final -- I'll get to the front page. This was the final suicide and death report dated December 20th, 1999. Do you see that?

A. Yes.

Q. All right. This was the one that was sent as the final submission after the earlier July submission, is that right?

A. Yes, and this is what -- well, actually, never mind. Yes, it is.

Q. You talked about this on cross?

A. Sorry?

Q. You talked about this on cross, Doctor?

A. Yes.

Q. Okay. Let's get in to the document.

We looked at this for a few minutes at Attachment 1, and we had this table here. Do you see that?

A. I do.

Q. And defense counsel pointed out that the 12 suicides we had seen in July were now down to six. Do you see that?

A. Yes.

Q. All right. But let's look at the next page. This also has a table that includes suicides. Do you see that?
A. Yes.
Q. What are these suicides?
A. I'm sorry. I need to go to the bottom of the previous page.
Q. Sure.
A. These were deaths in depression trials not in their central database. If I remember correctly, these were what are called locally-funded trials.
Q. So, GSK's main corporation, they conduct clinical trials, right?
A. Yes.
Q. And then these various country affiliates, like GSK France, they conduct clinical trials?
A. Yes.
Q. So, these five suicides right here are from GSK's clinical trials, just not funded by the main corporation, is that right?
A. Well, I'll go further and say that the efficacy data from these is used to support approval of the NDA.
Q. All right. Well, if we go in to the attachment, we spent some time here on Attachment 2, and I just want to take a quick minute and look at this for a second.
So, we have here all of these different patients.

Do you see that, Doctor?
A. Yes.
Q. And we have their gender?
A. Yes.
Q. We have their age?
A. Yes.
Q. And we have that they were taking paroxetine?
A. Yes.
Q. And it says up here at the top that all of these patients, all of them, were in double-blind paroxetine or placebo depression trials, is that right?
A. Yes.
Q. Okay. Let's look through here. Here we have a 42-year-old female suicide. Do you see that?
A. Yes.
Q. Just above that, we have a 50-year-old male, committed suicide?
A. Yes.
Q. Below that farther down, we have an 18-year-old female who submitted suicide?
A. Yes.
Q. And below that, we have a 66-year-old male who committed suicide?
A. Yes.
Q. And then I cut it off there. I'll show it again. Do you

see this one, the 67-year-old female, do you see that, from Italy?
A. Yes.
Q. All right. And if you go on the next page, it continues, and we have some more people. We have a suicide by drowning in the female, 63-year-old female. Do you see that?
A. Yes.
Q. We have a 46-year-old female, suicide. Do you see that?
A. I'm sorry. You said 47.
Q. 46-year-old female.
A. Okay. 46.
Q. Do you see that, Doctor?
A. Yes.
Q. 42-year-old female, suicide overdose?
A. Yes.
Q. Go down further, we have a 31-year-old female.
A. Yes.
Q. We have a male who's 46 below that who also committed suicide?
A. Yes.
Q. So, most of these people are over 30, isn't that right?
A. Just looking at that, I'm actually trying to remember if there was anybody who was under 30.
Q. There was an 18-year-old.
A. Okay.

Q. So, to be clear, all of these people who are over the age of 30, who didn't attempt suicide but actually killed themselves while taking Paxil, not a single one of those people was in the 2006 analysis that GSK conducted where they concluded that the risk didn't go over 30, is that right?
A. That is correct.
Q. I want to focus for a minute on these two. It's hard to see, but do you see that the first one is 559? Do you see that, Doctor?
A. I'm sorry. I lost which one you're on here.
Q. Right here, 559.
A. Yes.
Q. And there's another one that says 513 below that?
A. Yes.
Q. Okay. Now I want to take a minute and actually look at those two suicides just for a quick second.
MR. WISNER: Your Honor, may I approach?
May I approach, your Honor?
THE COURT: Yes. My law clerk?
MR. WISNER: May I approach the witness?
THE COURT: Yes.
BY MR. WISNER:
Q. Doctor, I've handed you an exhibit, Plaintiff's Exhibit 236. Do you see that?
A. Yes.

MR. WISNER: Your Honor, at this time, I'd like to read GSK's response to Plaintiff's Interrogatory No. 1.

THE COURT: All right. Page?

MR. BAYMAN: Your Honor, I don't think this is permissible through this witness. There's nothing indicating he relied on this. It's from another lawsuit.

THE COURT: Is it related to his testimony?

MR. WISNER: Absolutely, it's directly related; and it's their admission, so it's their words.

THE COURT: All right. Read it.

MR. BAYMAN: There's no foundation for that, your Honor.

THE COURT: You don't need any more foundation for an interrogatory. Go ahead.

MR. WISNER: All right.

BY MR. WISNER:

Q. So, in response to Interrogatory No. 1, Doctor, we're on page 4. Okay?

A. Yes.

MR. BAYMAN: Your Honor, this is not from this case.

THE COURT: Wait, wait. Oh, it's not from this case?

MR. BAYMAN: No, sir.

MR. WISNER: No, it is not, your Honor, but it's part of the -- I don't want to say it out loud.

THE COURT: Let's go to sidebar.

(Proceedings heard at sidebar:)

[redacted]

[redacted]

(Proceedings heard in open court, jury present:)

BY MR. WISNER:

Q. All right. There we go.

All right. Doctor, we're looking at this exhibit, Defense Exhibit 25. And I don't know --

MR. WINSER: At this time, your Honor, I'd move Defense Exhibit 25 into evidence.

THE COURT: All right. It may be received.

(Said exhibit admitted in evidence.)

BY MR. WISNER:

Q. Now, we have these two patients, 559. Do you see that, 559?

A. I do.

Q. We're going to table that for a second. There's another study there, 513. Do you see that?

A. Yes.
Q. Okay.
THE COURT: What's your question?
MR. WISNER: May I approach, your Honor?
THE COURT: All right.
BY MR. WISNER:
Q. Doctor, I've marked this document as Plaintiff's Exhibit 314. Does this document reflect a suspect adverse reaction report?
A. It does.
MR. BAYMAN: Objection, your Honor. This is an individual adverse event report that you've ruled out, number one. Number two, there's nothing in the witness's report or anywhere else to say that he's ever seen this before, and we would object to it.
MR. WISNER: Your Honor, it's their document. It reflects an adverse event report that happened in their clinical trial. I just want to show it to him --
THE COURT: And you know that adverse events are subject to scrutiny.
MR. WISNER: Your Honor, this is from the clinical trial. It's the one that's reported right here. This isn't a spontaneous one. This is an actual clinical trial adverse -- this is an official report of what happened, the narrative.
THE COURT: Has the doctor studied this?

MR. WISNER: Not until right now.
THE COURT: Then the objection will be sustained.
MR. BAYMAN: Your Honor, this isn't even on their exhibit list.
THE COURT: The objection is sustained.
MR. BAYMAN: Thank you.
THE COURT: Proceed.
BY MR. WISNER:
Q. All right, Doctor. Do you recall a discussion about -- about a patient that was in the trial 83?
A. There's been a couple of different ones, but I -- there's one in particular that I've been focused on.
Q. Talking about in the trial 83, the patient who committed suicide?
A. Yes.
Q. Okay. Let's see if we can find it here on this chart.
If you look on the right, you have 83. We have a -- right there, suicide by hanging. Do you see that, Doctor?
A. Yes.
Q. So, that's the suicide we're talking about?
A. Yes.
Q. And you testified that you believed that it occurred on a placebo-controlled trial.
A. Based on the heading on this spreadsheet, which says, "Double-Blind Paxil or Placebo," yes.

Q. And you'd agree with me that that suicide by hanging was not included in the 2006 or 2007 analysis that we've heard from the defense lawyers?

MR. BAYMAN: Objection to leading, your Honor.

THE COURT: Overruled.

BY THE WITNESS:

A. Given that they said there were no suicides, it had to have been excluded. It had to have been left out.

BY MR. WISNER:

Q. Now, on direct -- are you aware of whether or not GSK claimed that this study was a placebo-controlled trial when it tried to prove that the drug was efficacious?

A. I believe that is correct.

Q. So, to be clear, when it comes to efficacy, it's a placebo-controlled trial; but when it comes to suicide by hanging, it's not?

MR. BAYMAN: Object to the leading and argumentative, your Honor.

THE COURT: Well, at this point, you may answer, if you can.

BY THE WITNESS:

A. I would say this is a patient under the rules of the analysis, the inclusion criteria, if you will, who should have been included. And I don't see any explanatory note, I haven't seen any explanatory note about why this case was

excluded.

Secondly, there's a big difference between having zero and one. Once you get to one, you have what we call proof of concept. You know something can happen.

Finally, I think this is -- and the patient for 559 is an outstanding -- it's a classic example of why just saying, "Well, FDA can ask for information," it has to know what it's looking for. Otherwise, you'd be looking for a needle in a haystack. You'd have to say, "We want all the line listings from 559 or 83."

BY MR. WISNER:

Q. Now, on cross-examination, the defense lawyer asked you a question about newly acquired information. Do you recall that?

A. Yes.

Q. And newly acquired information is a term of art within the regulations?

A. There's actually, I think, some regulatory definition of it, but it's fairly general.

Q. And newly acquired information isn't just brand new information; it also includes reanalysis of old information, is that right?

A. That is absolutely correct.

Q. So, a manufacturer, at any time, could go back and look at all of those suicides they ignored and make a new decision in

labeling?

MR. BAYMAN: Objection, your Honor. Leading, your Honor, and argumentative.

THE COURT: Overruled.

You may answer.

BY THE WITNESS:

A. So, it would be very, very straightforward if you said, "We're submitting a new CBE supplement," and in order to keep it from just getting tossed out because it contains nothing new, it would be extremely straightforward to say, "The reasonable evidence of association between Paxil and adult suicidality contains the following previously submitted information," new information about the suicides, adverse event reports which address the issue not of frequency, but of things that we've discussed before, like challenge, de-challenge, and rechallenge, information on what the mechanisms of action might be, particularly with regard to akathisia, which we said is a serious side effect that can lead to suicide.

So, it would be -- it's not like you're just repackaging something with a new ribbon. It would be -- if you really wanted to do it, that is, that's the thing.

BY MR. WISNER:

Q. Now, Doctor, I'd like to draw your attention to Plaintiff's Exhibit 122.

MR. WINSER: It's in evidence, your Honor.
BY MR. WINSER:
Q. It's on your screen there, Doctor.
A. Okay.
Q. If we go down here, we have this chart. Do you see this chart right here?
A. I do.
Q. And it says that after GSK removed -- how many suicide attempts did they have to remove to get down to five?
A. I'm sorry. Remove to get down to five?
Q. Yeah, yeah. So, in the original NDA application, there was 42, right?
MR. BAYMAN: Objection. Argumentative.
BY THE WITNESS:
A. I believe 42 is right, so they had to remove 37, basically.
BY MR. WISNER:
Q. All right. And, Dr. Ross, by excluding these studies, they get it down to five, is that right?
A. Correct.
Q. Okay. And even if we do that, there's a risk of .5 percent. Do you see that?
A. Yes.
Q. And in the placebo line, there's a risk of .2 percent?
A. Correct.

Q. Doesn't that show a risk?
A. Yes.
Q. How so?
A. Well, the rate in -- or the incidence, I should say, in Paxil is .5 percent and in a placebo is .2 percent. So, it happened two-and-a-half times more often in Paxil-exposed patients than it did in placebo patients.
Q. And the fact that that's not statistically significant, does that make a difference?
A. I have seen labeling supplements where -- I mentioned during my direct testimony of an adverse event being added as a result of three cases of hemolytic anemia. That certainly was not statistically significant. It doesn't have to be. It's a complete -- it's misdirection to say that it has to be or suggest it.

MR. WISNER: Court's indulgence for one second.

Okay. Your Honor, I just want to let the Court know that it looks like we're probably going to have to go past 4:30 today, so I just want to make the Court aware that I'm not going to get him off the stand today.

MR. WISNER: He means he's going to carry him over until Monday.

MR. WISNER: Yeah, I'm going to have to carry him over until Monday. Unfortunately, there's some things I need to do. And I just wanted to let the Court know in case you

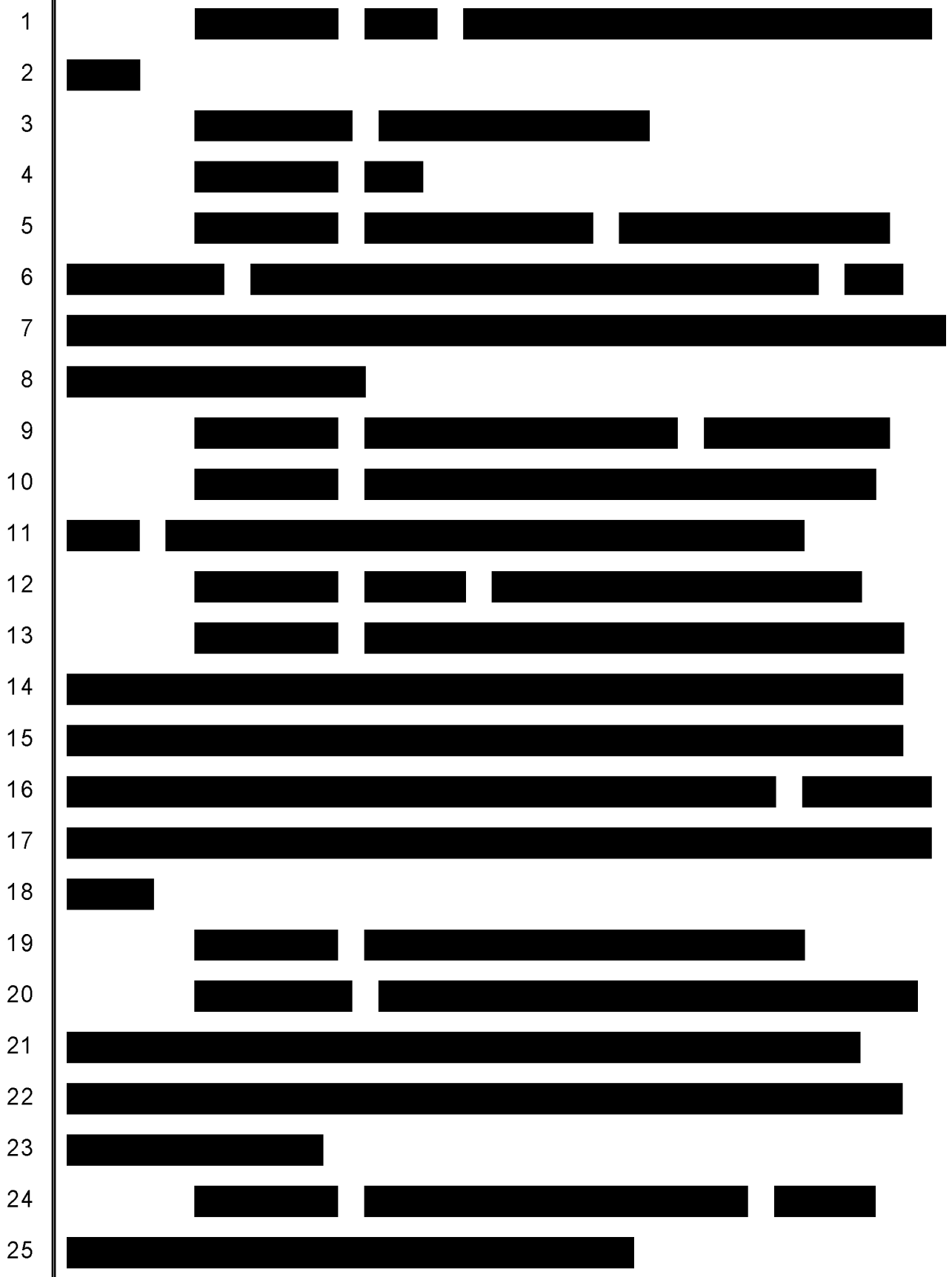
were holding us out here because I said I would get him out.

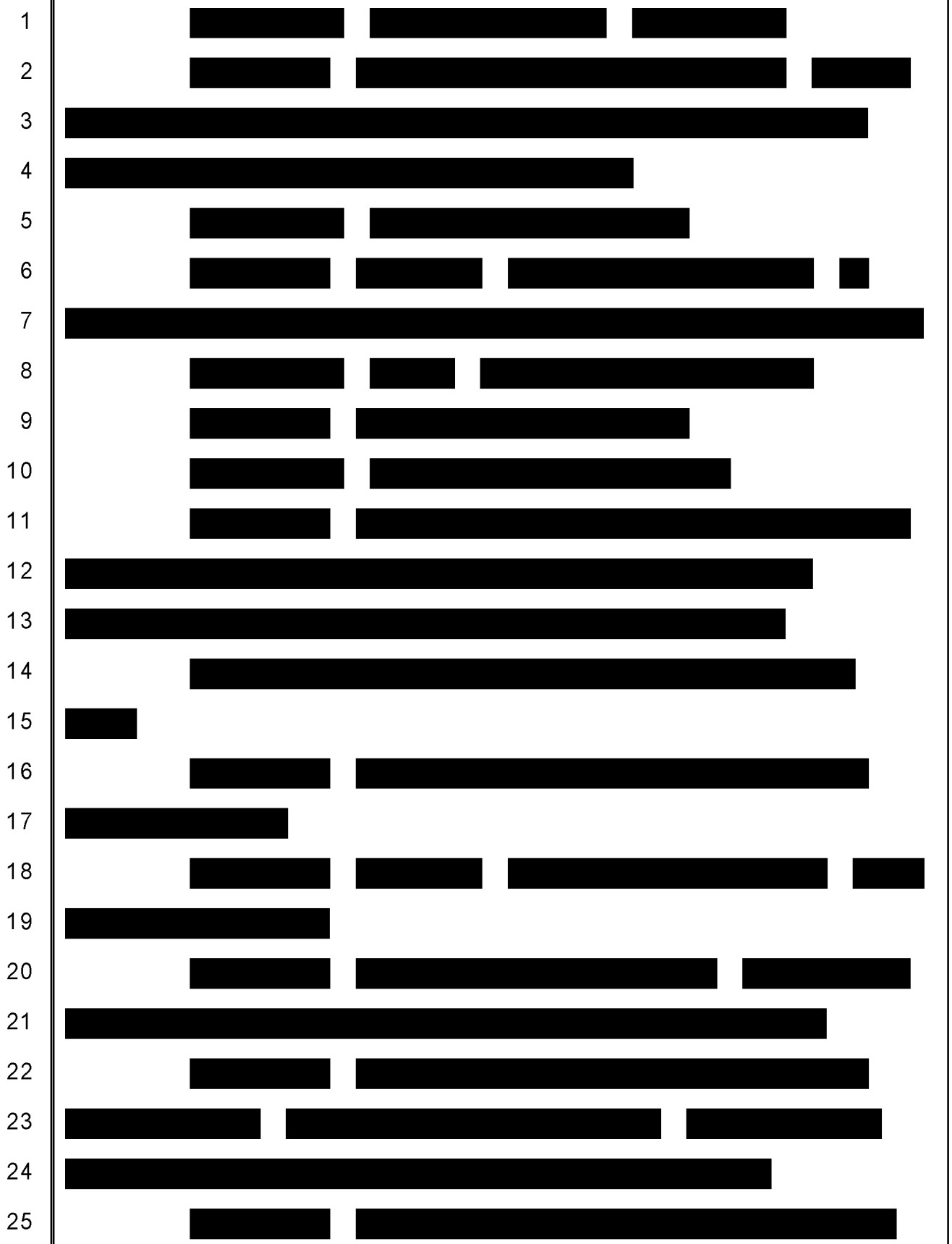
THE COURT: All right. You're going to have to carry him over. Then we'll break, ladies and gentlemen, for the weekend. I know you hate to tear yourselves away from the courtroom like I do, but have a good weekend, and don't forget us. And remember my admonitions to you about this case.

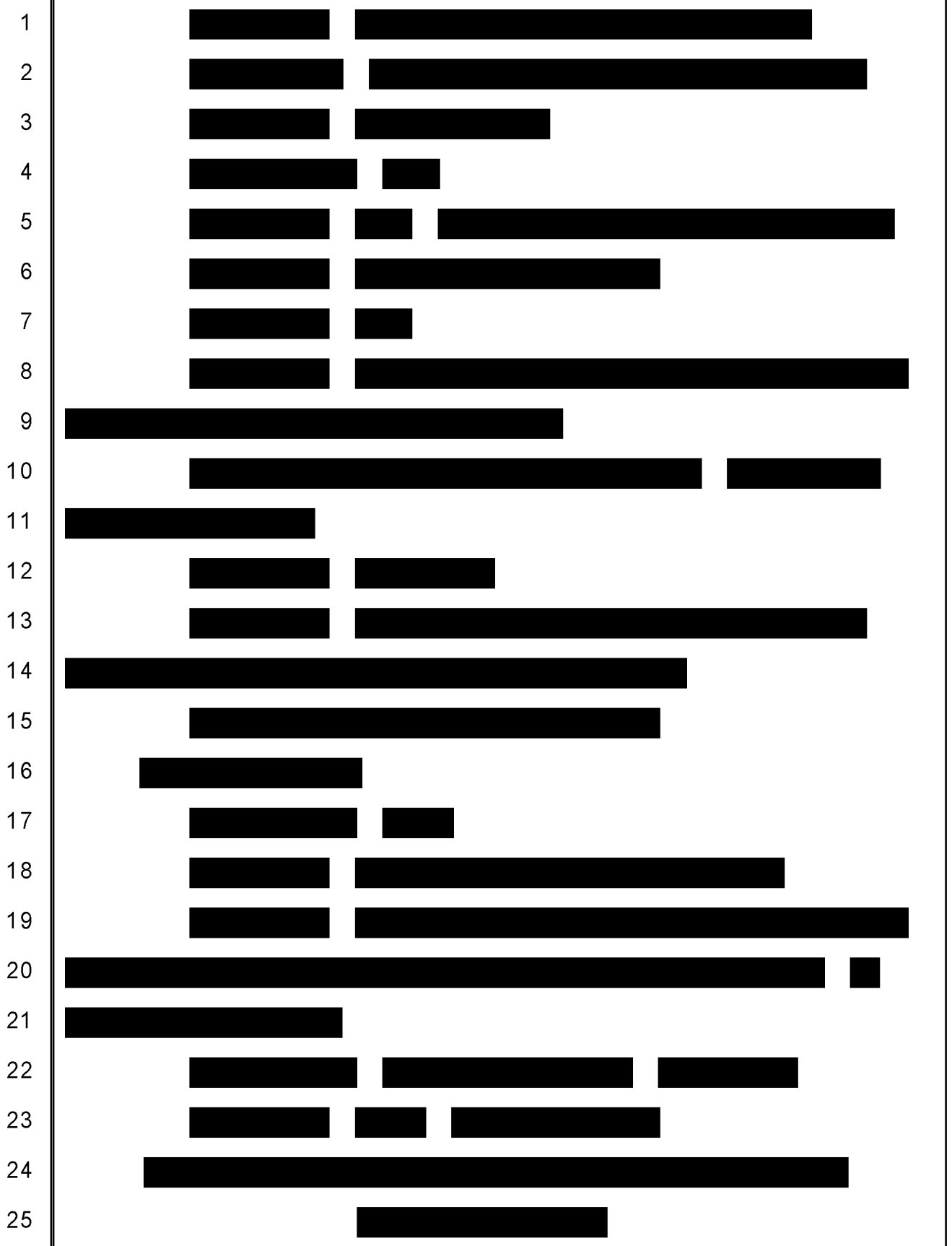
And I thank you again for your service. Thank you.

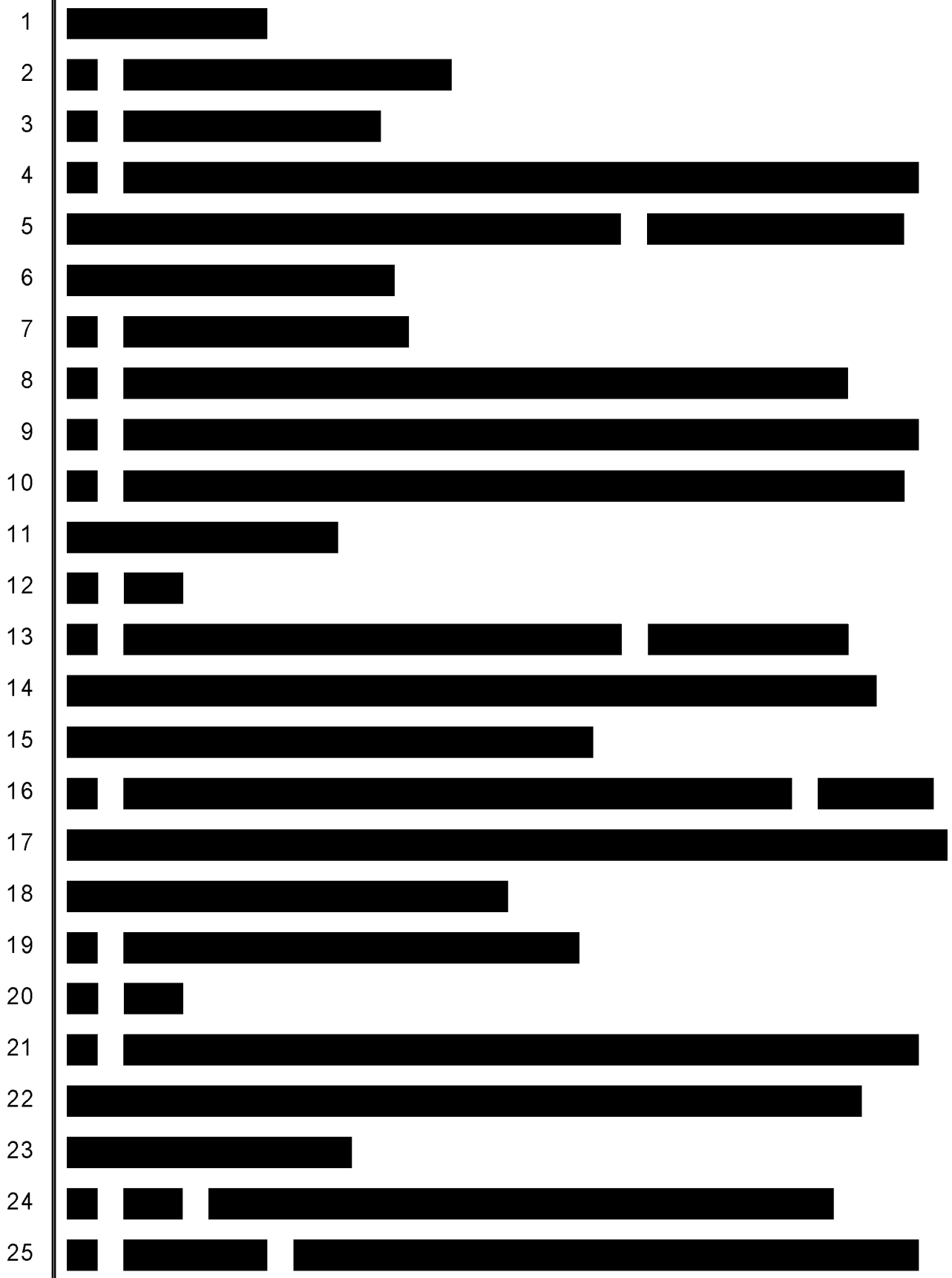
(Jury exits courtroom.)

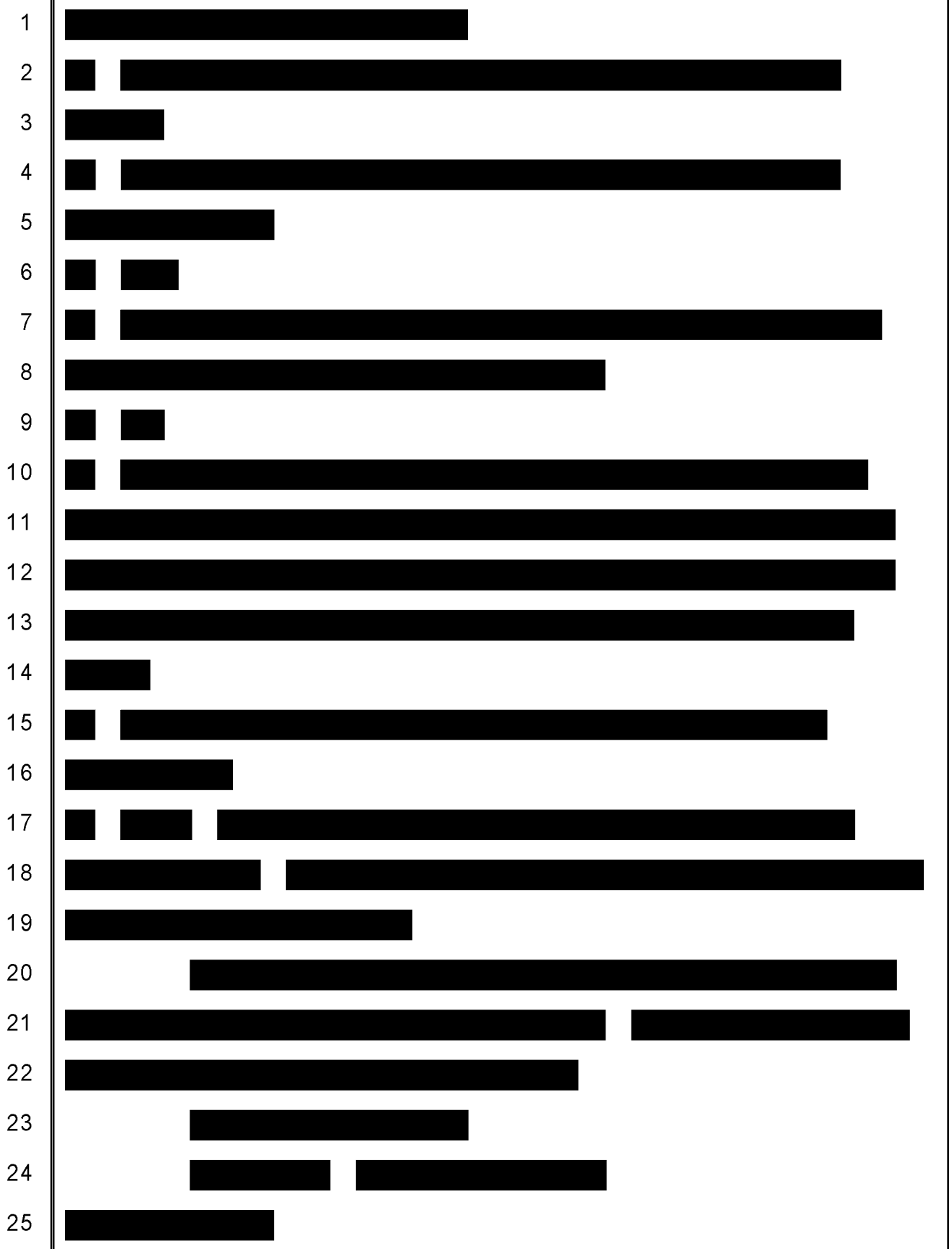
[redacted]

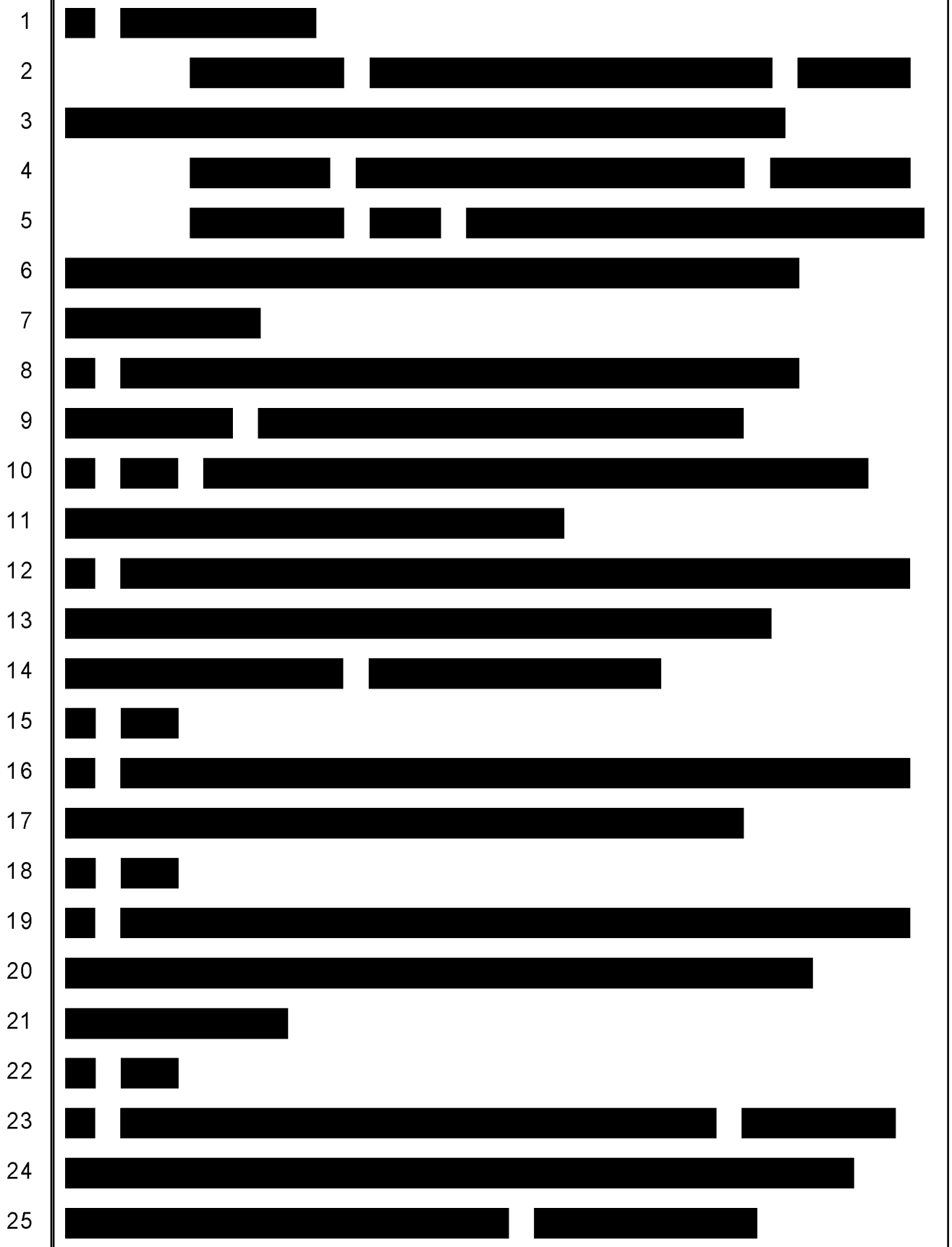


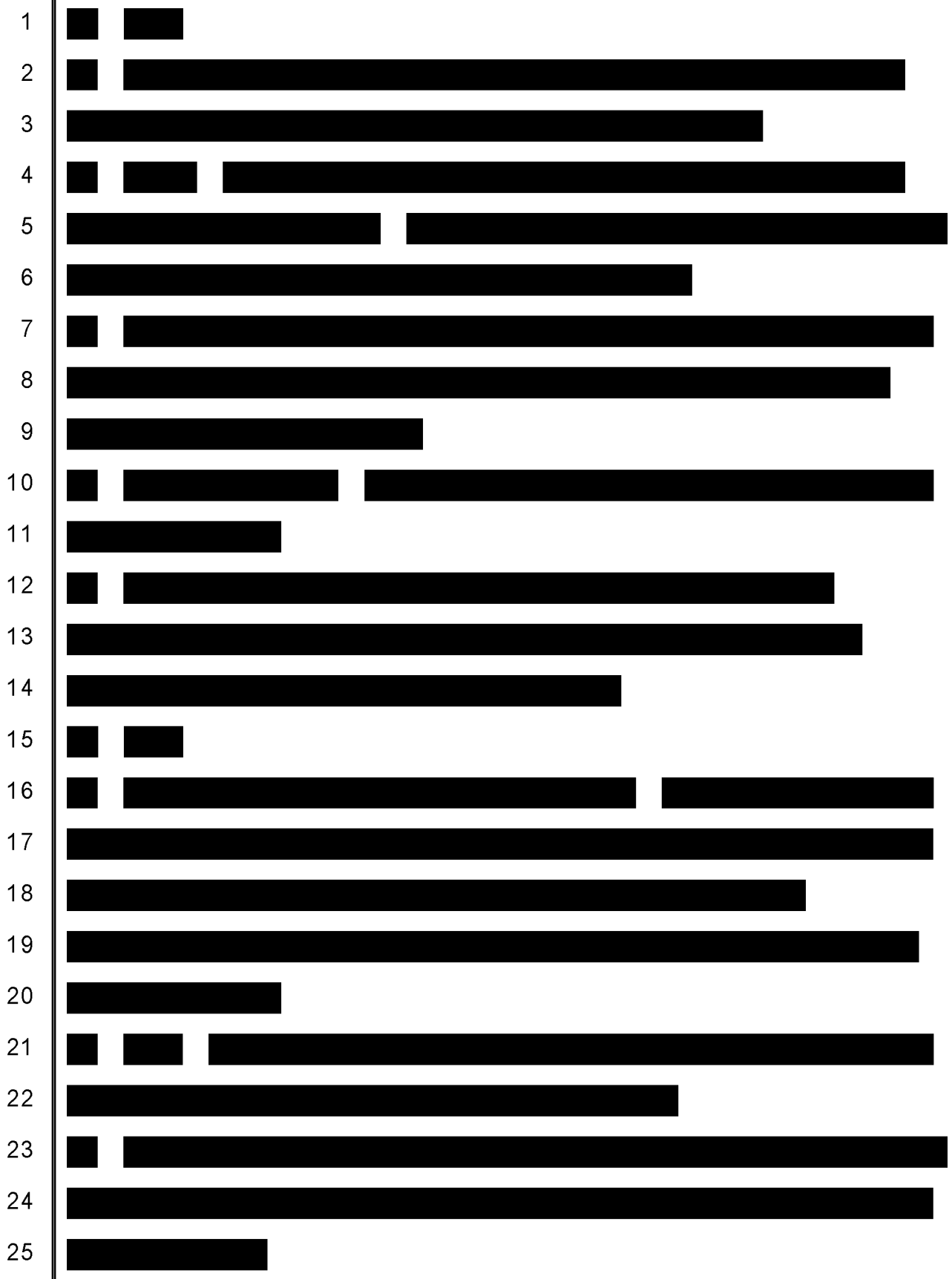


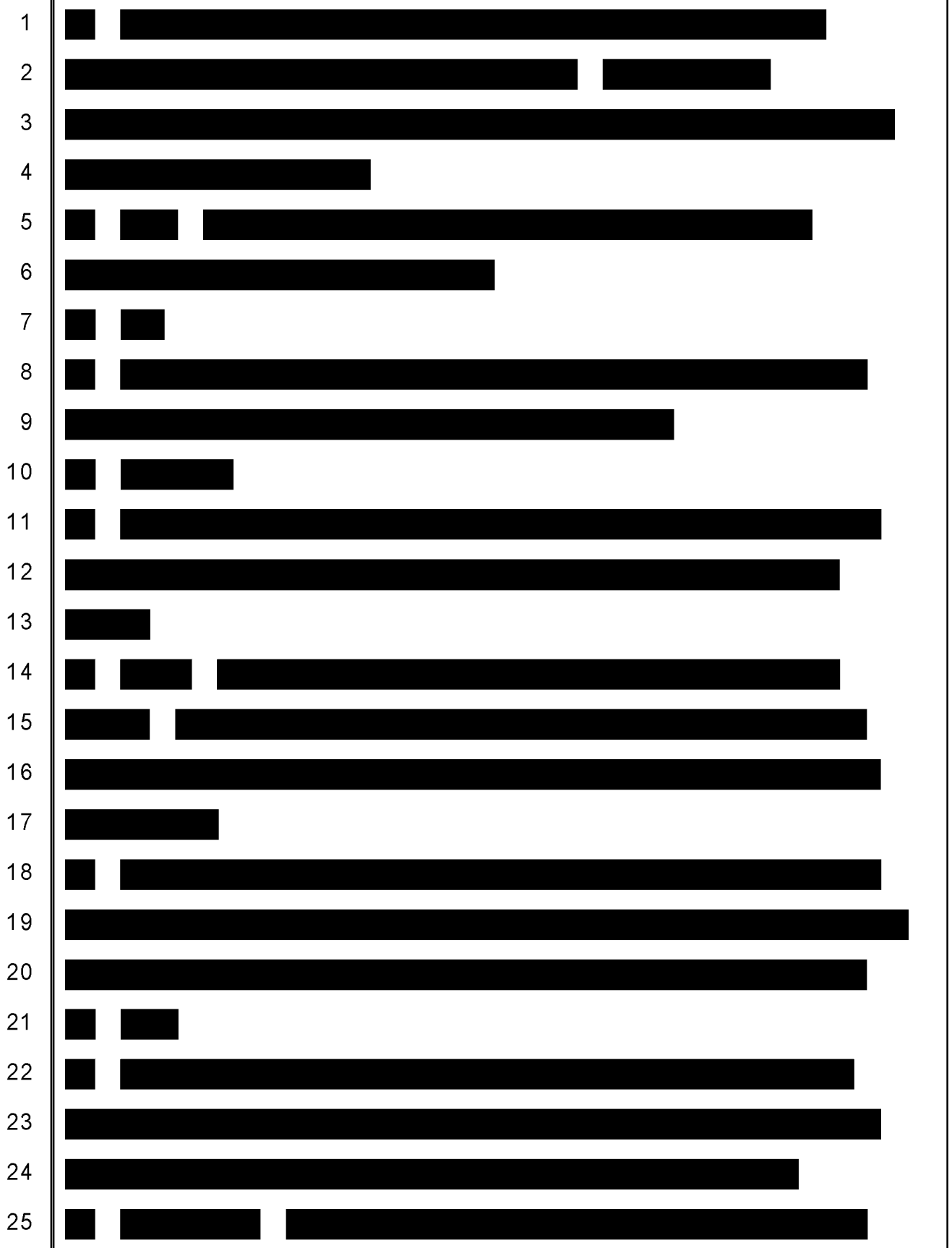


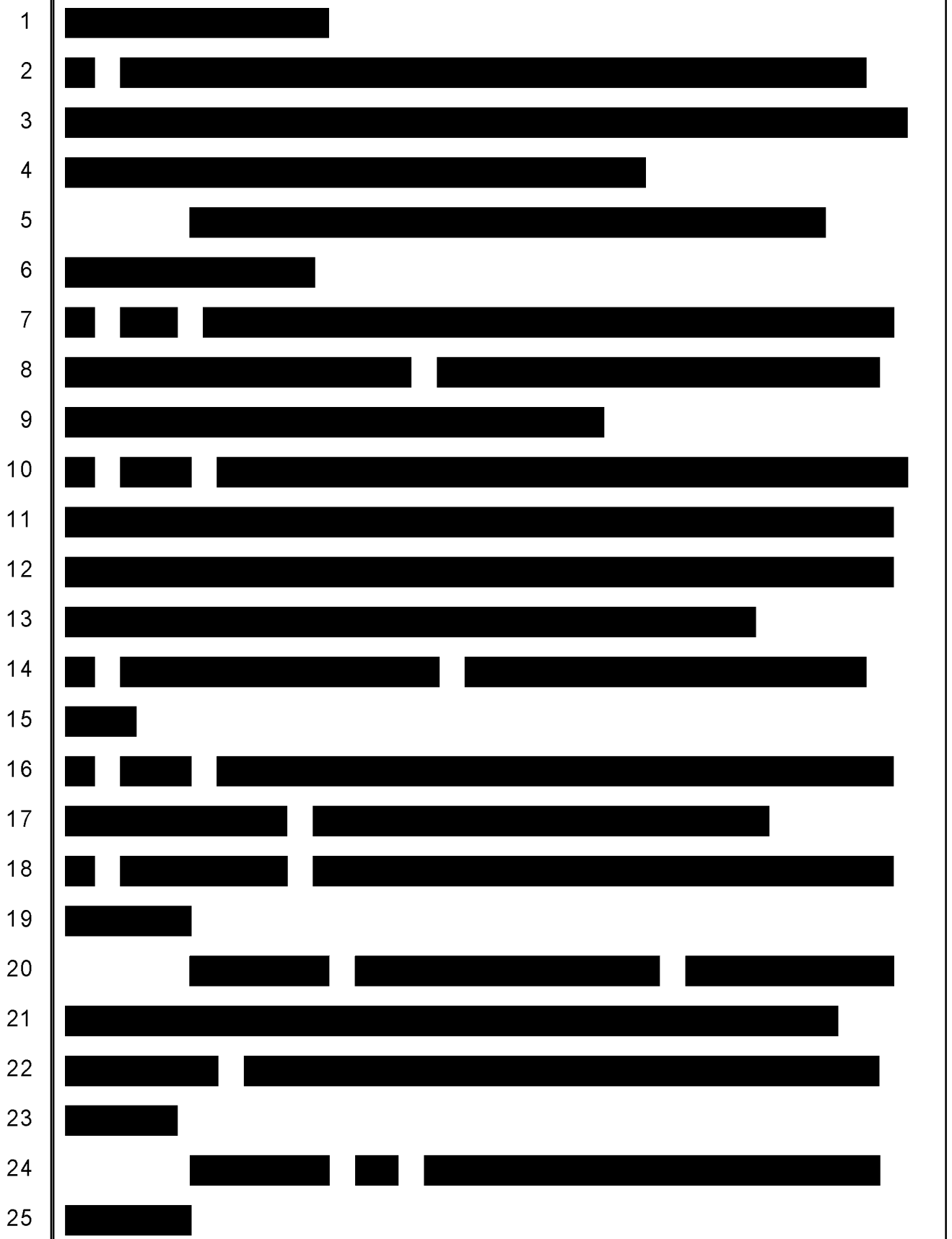


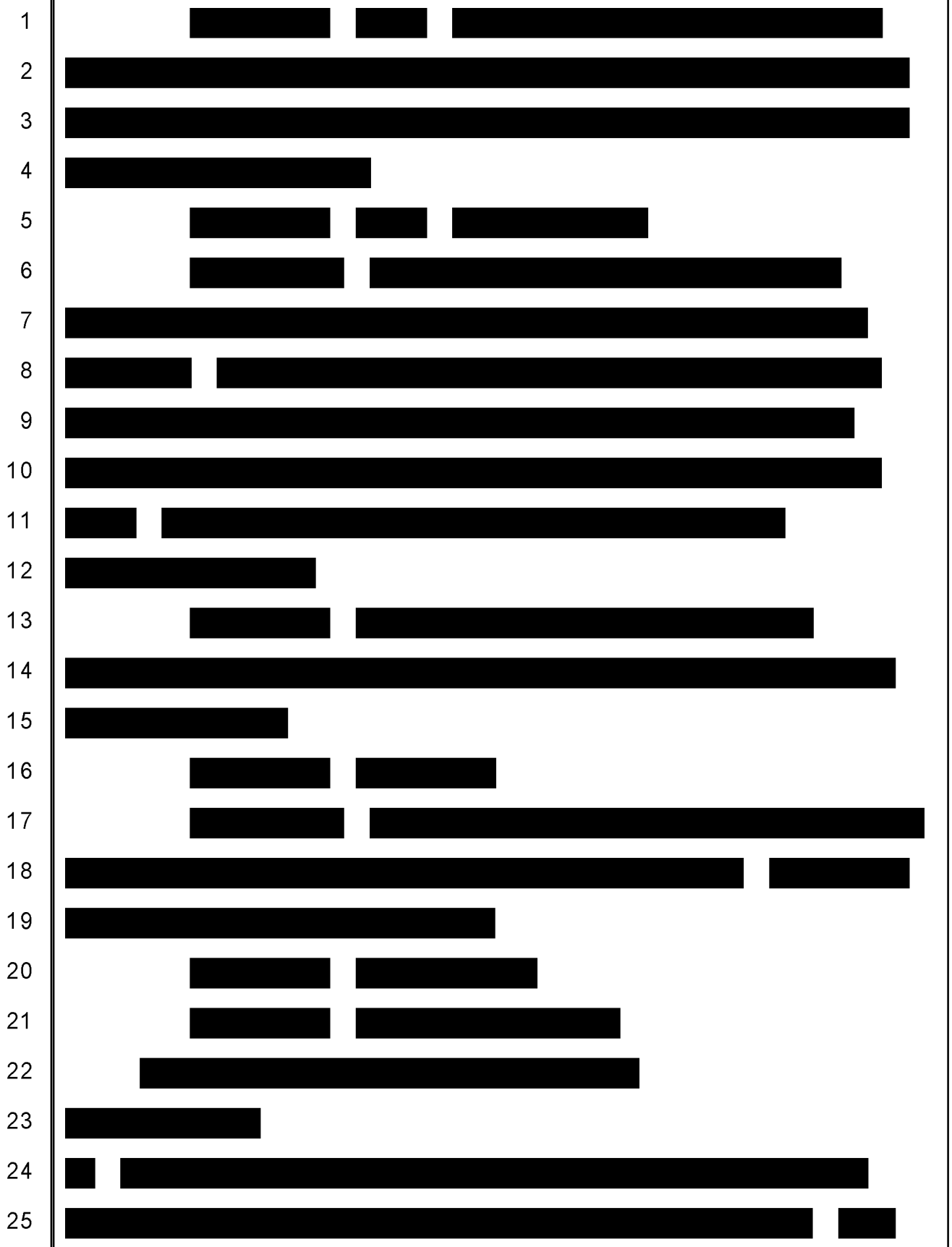


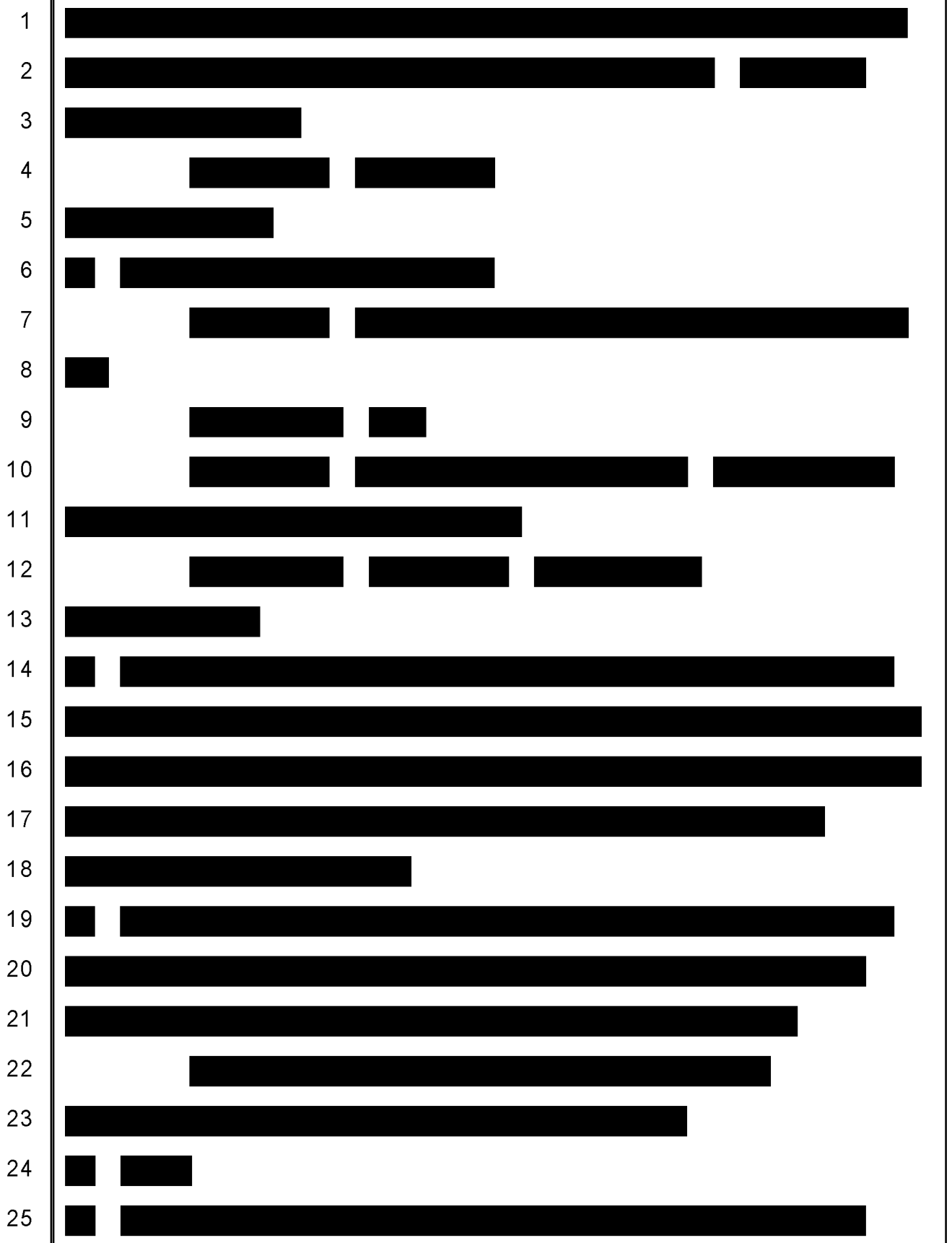


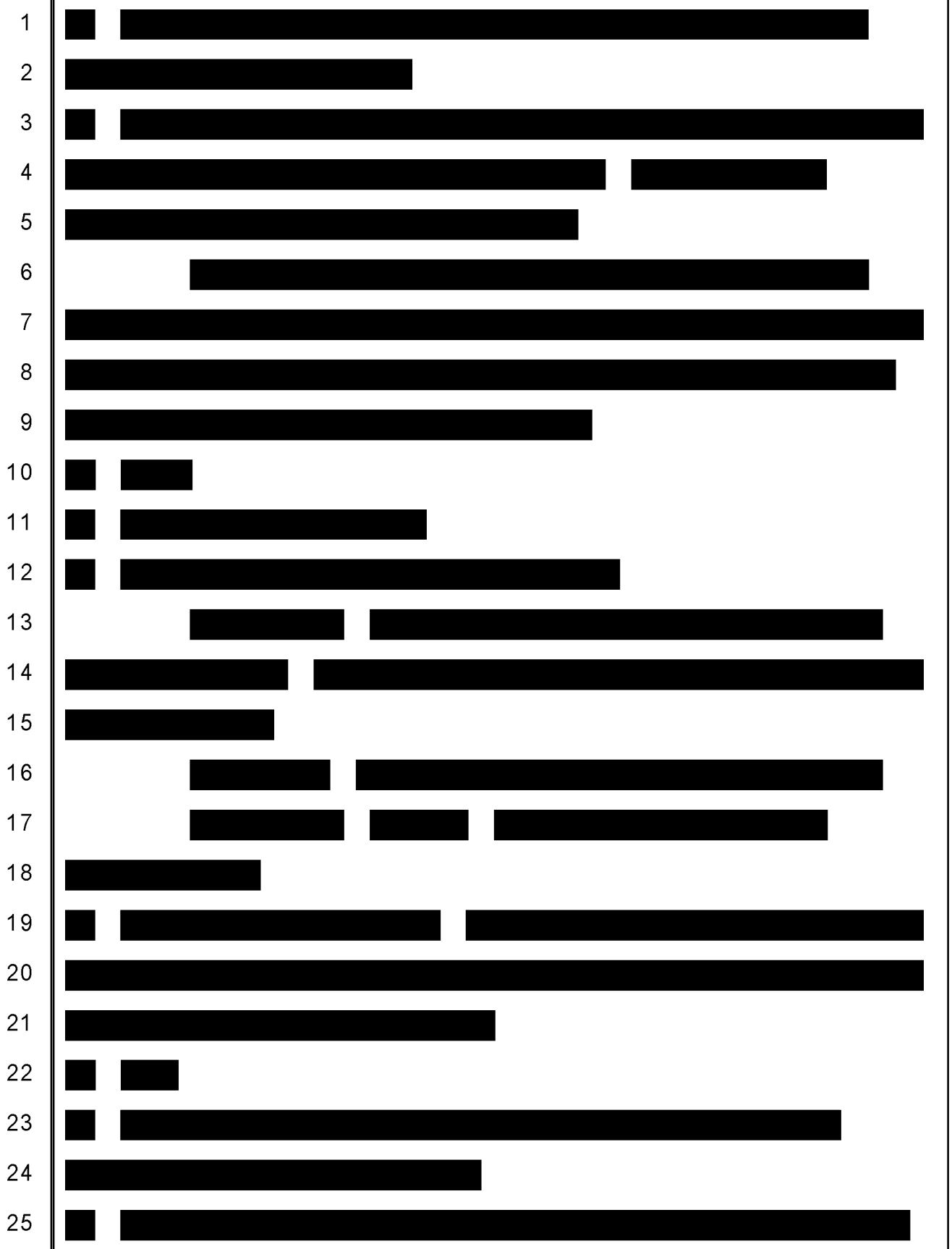


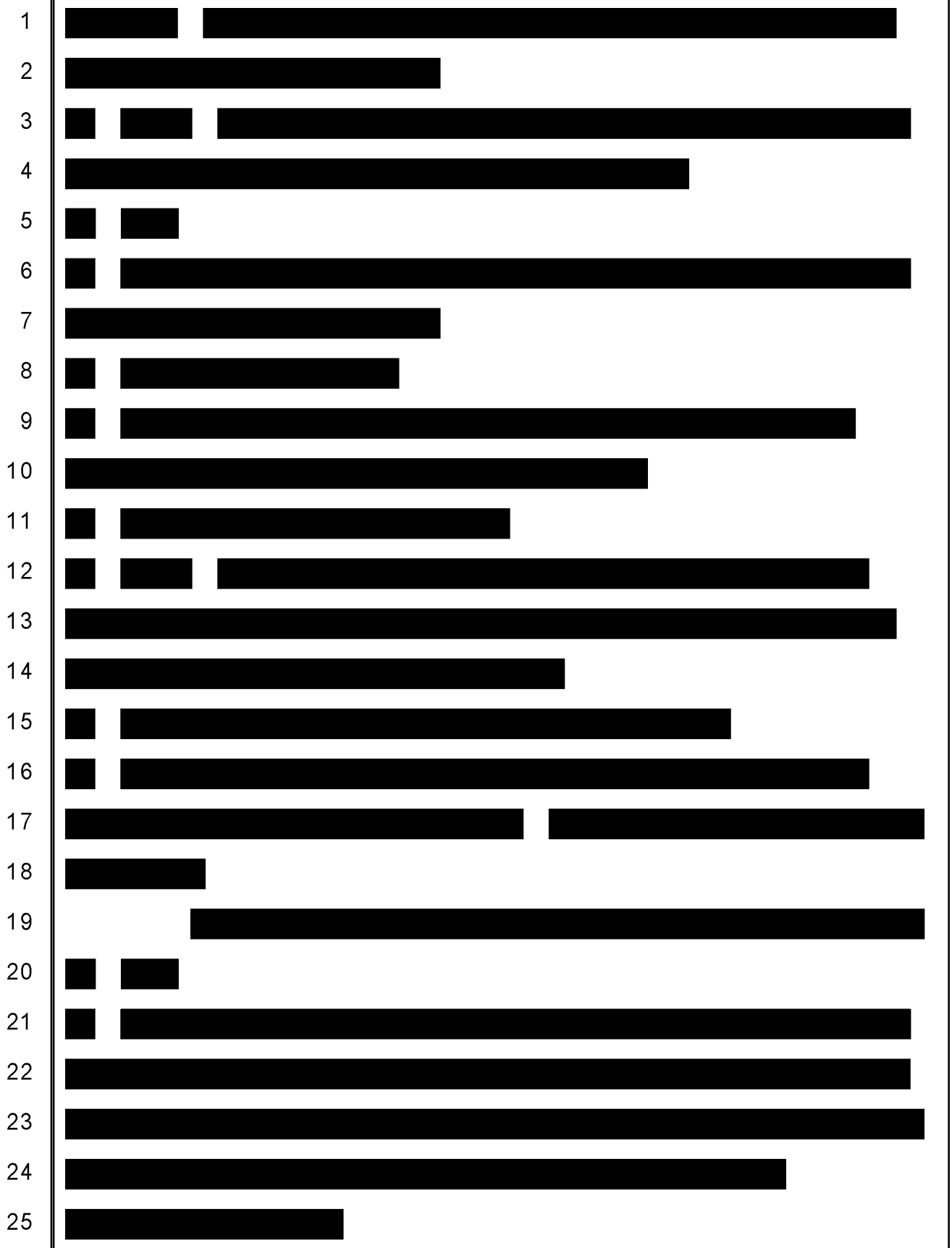


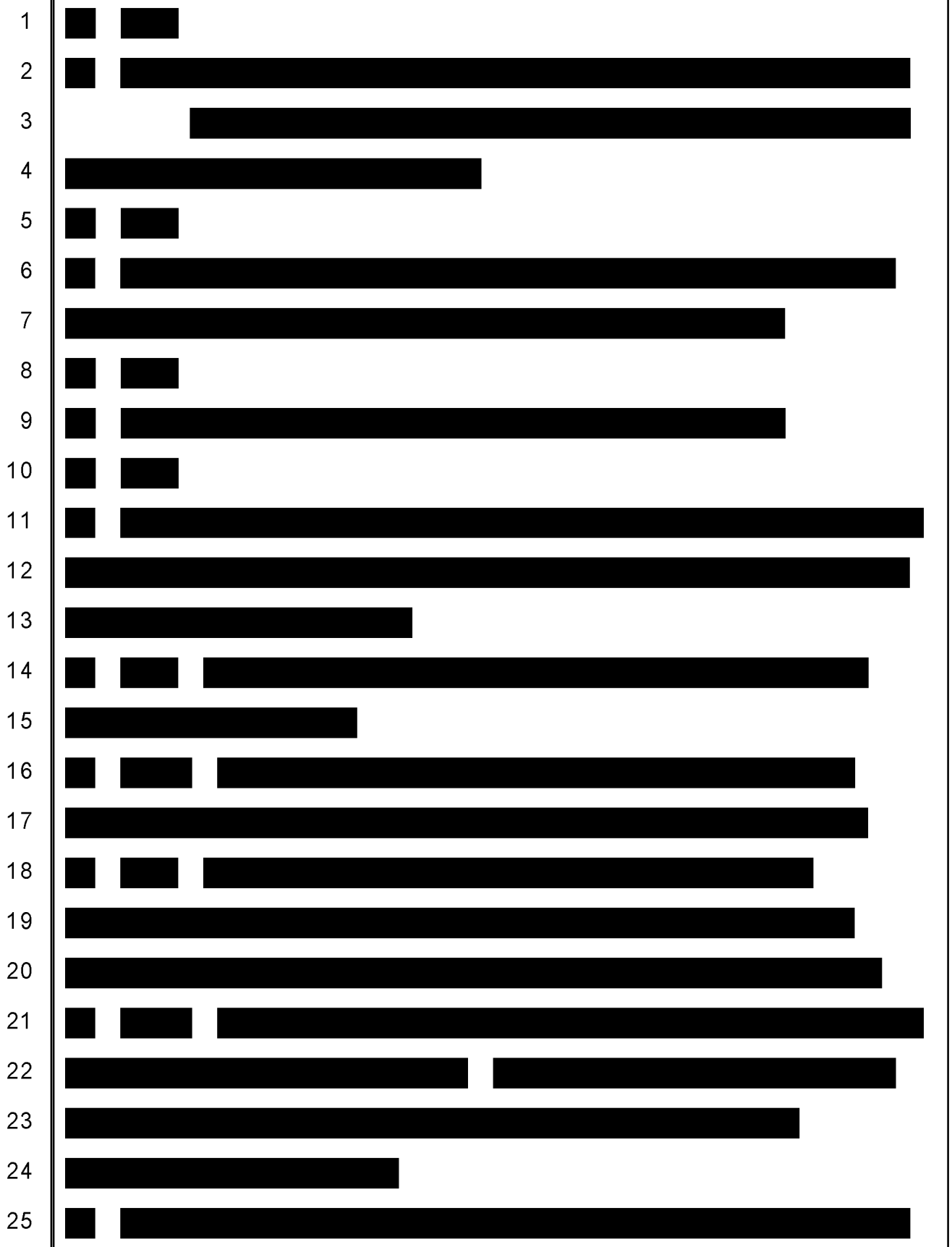


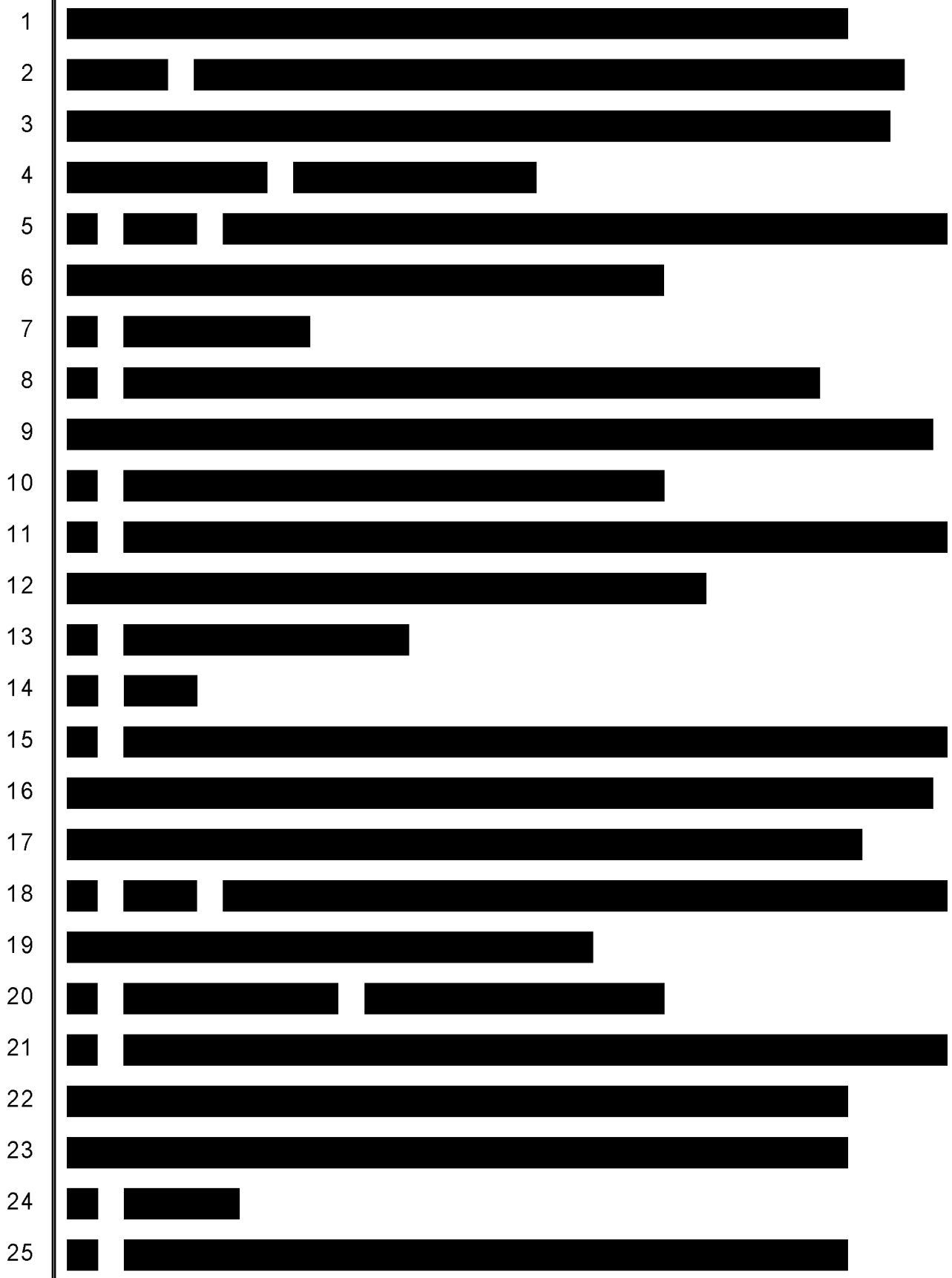


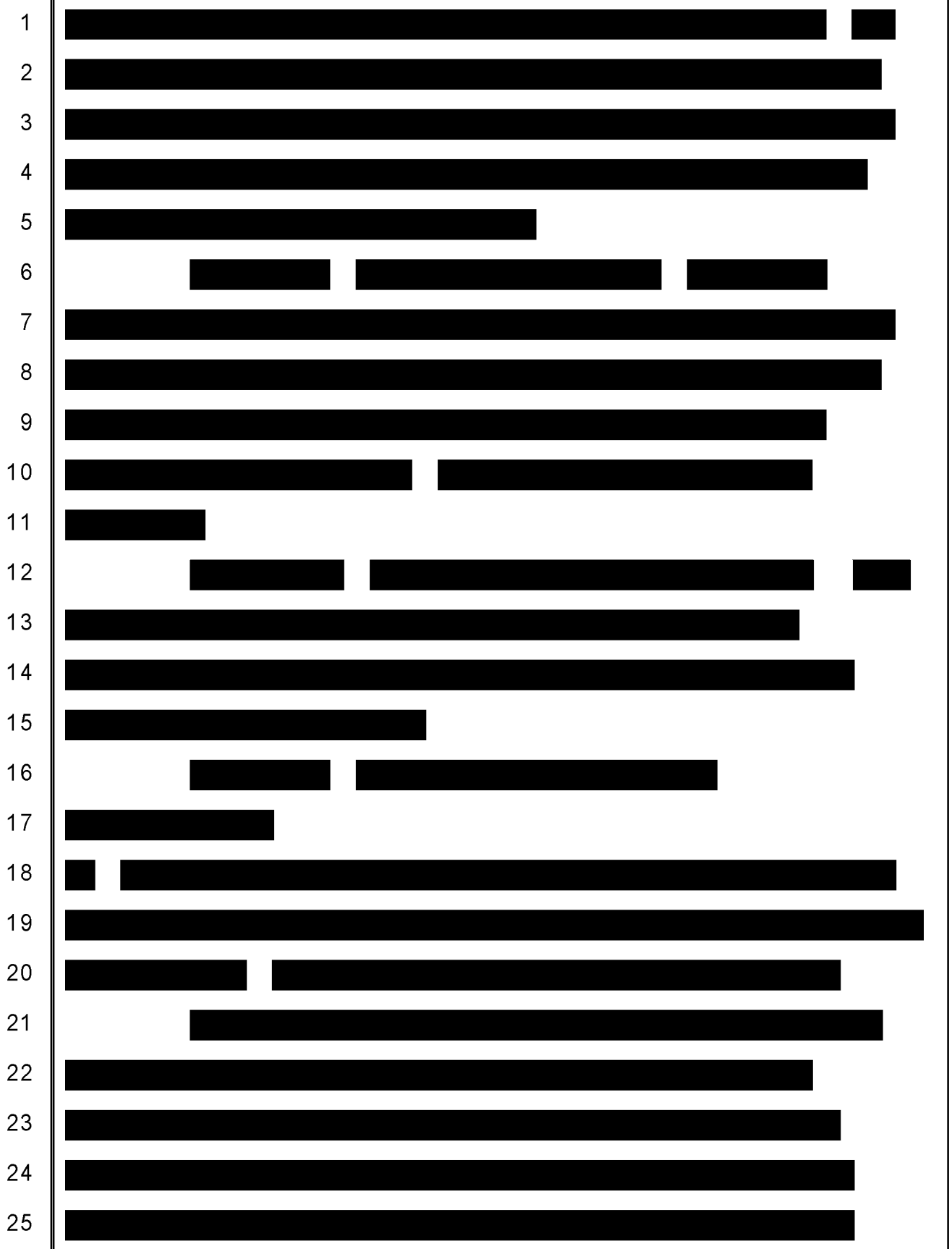


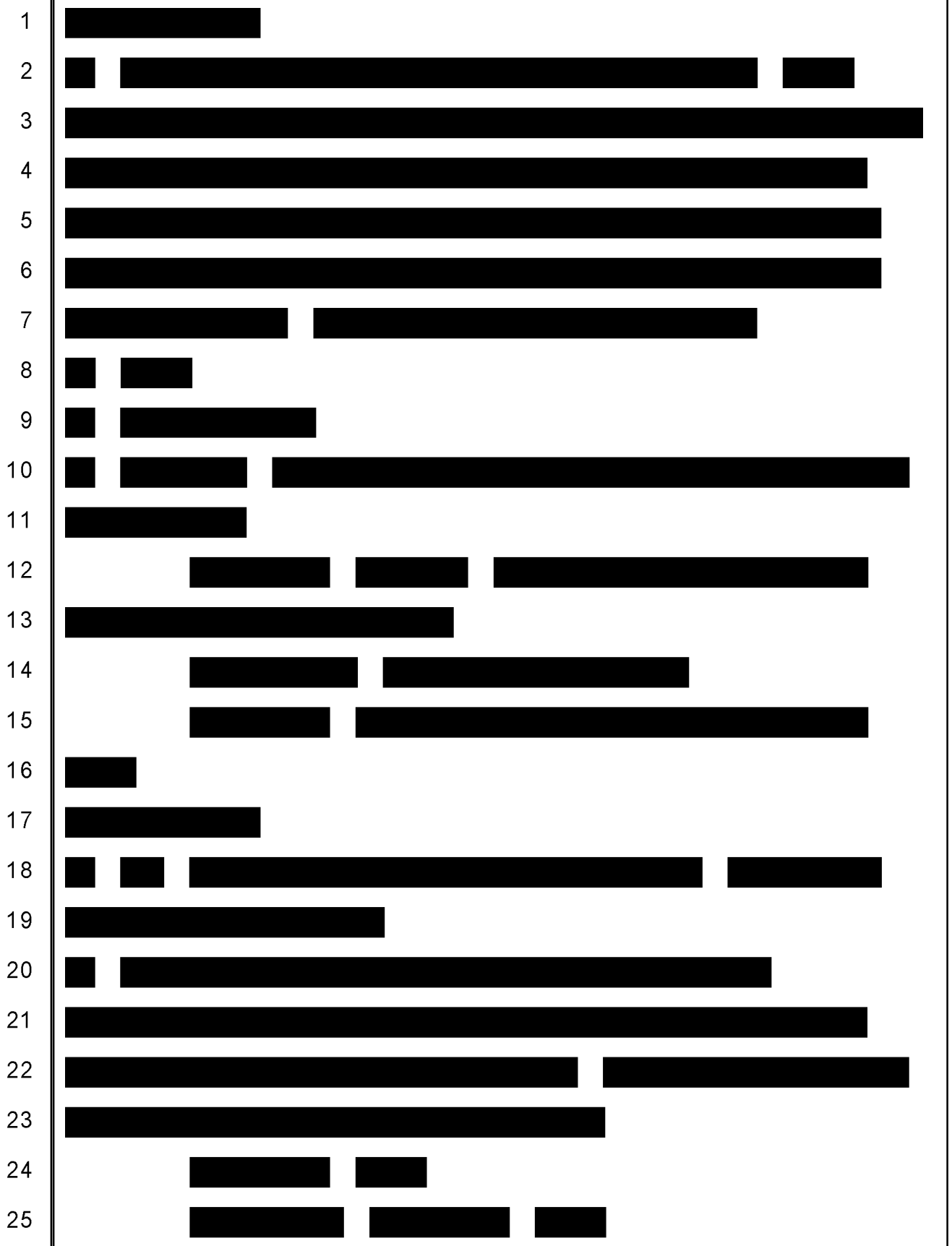


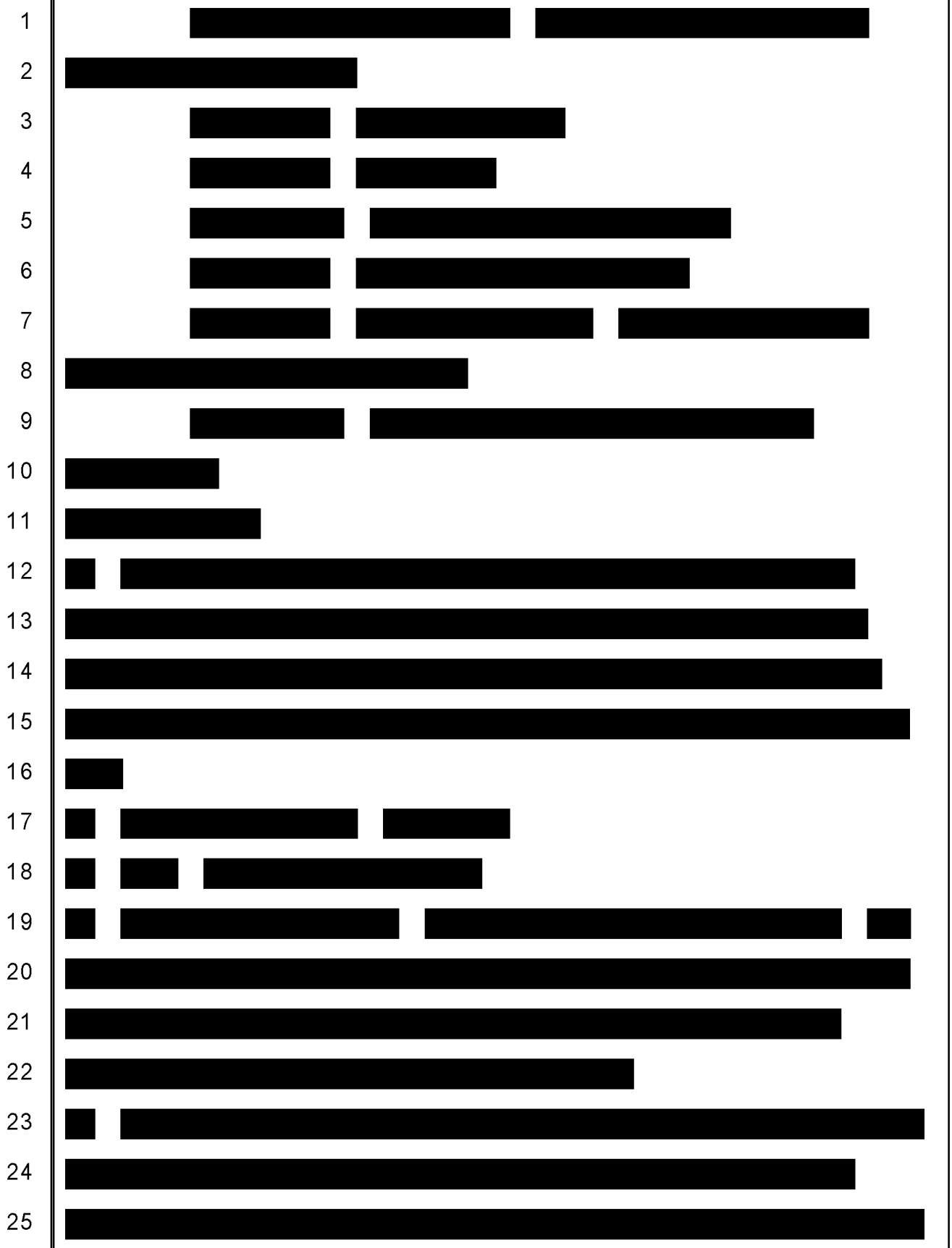


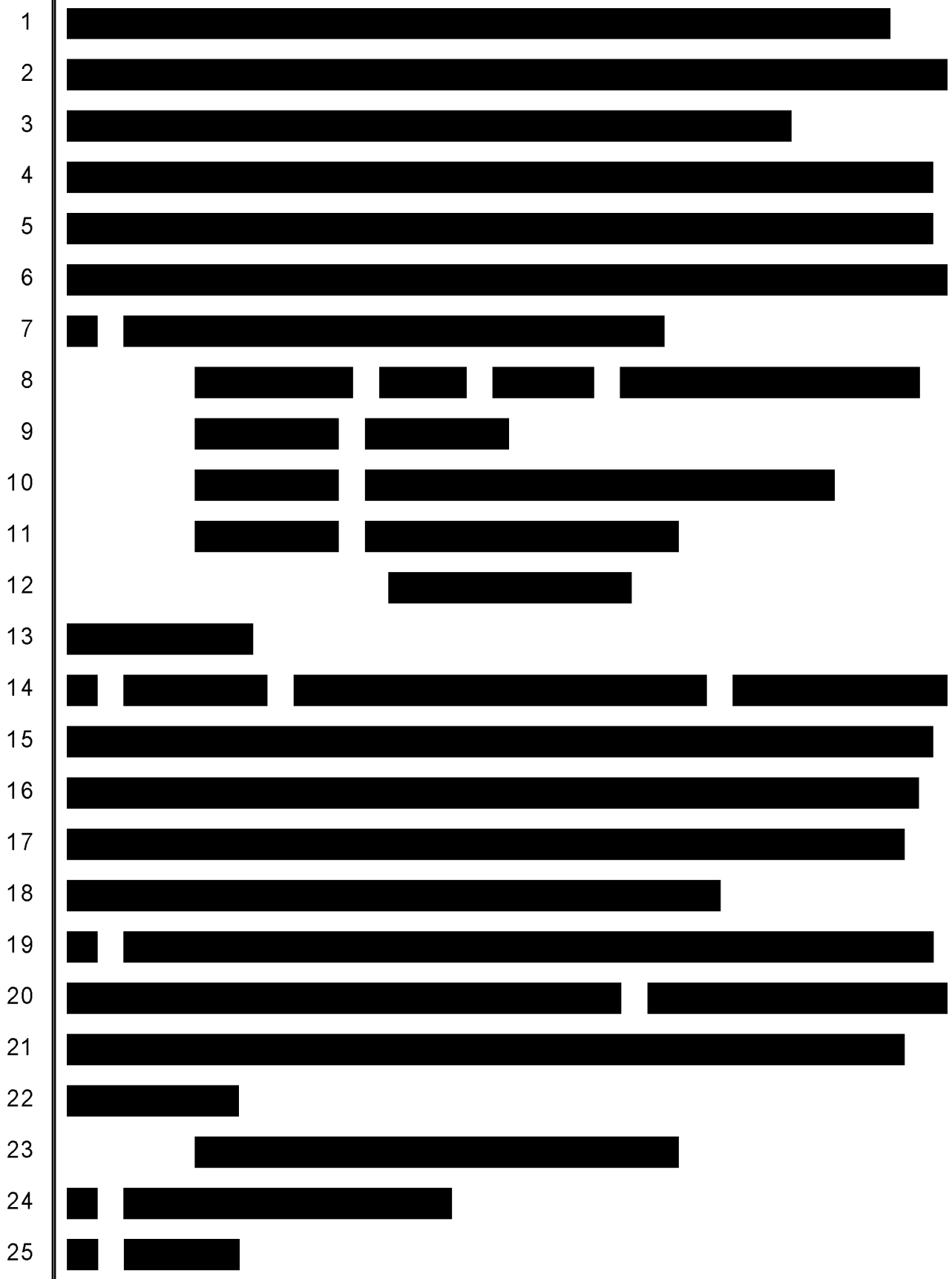


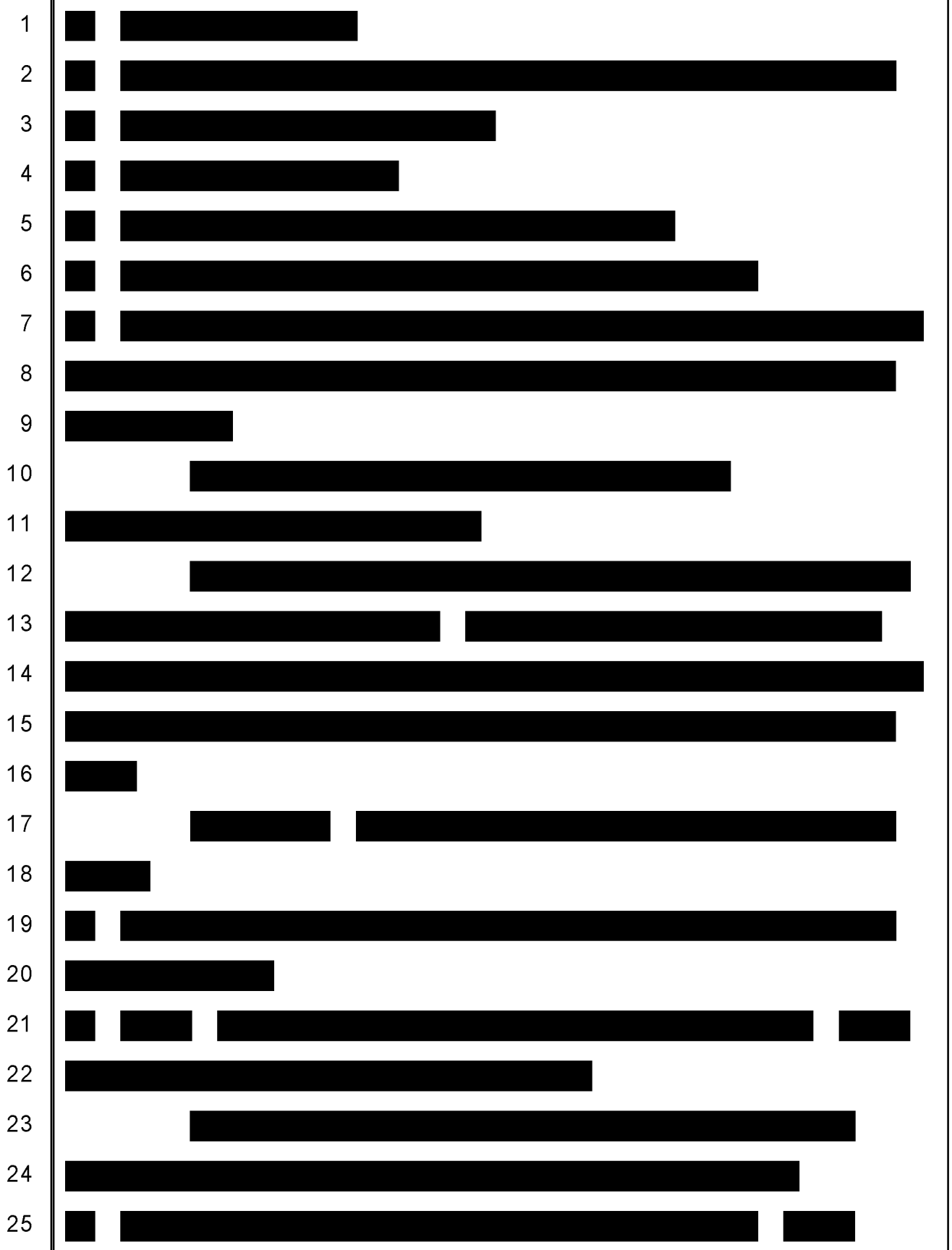


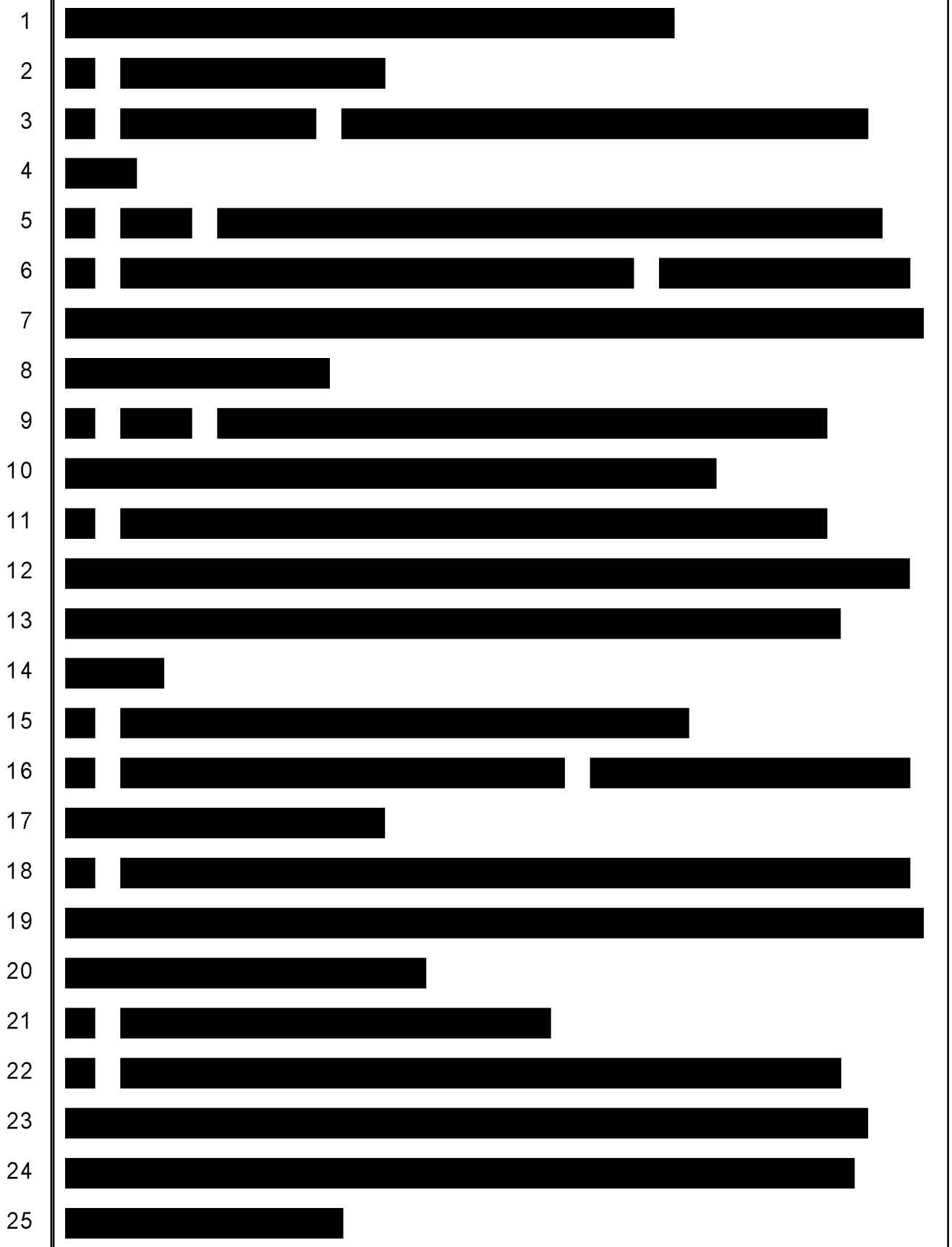


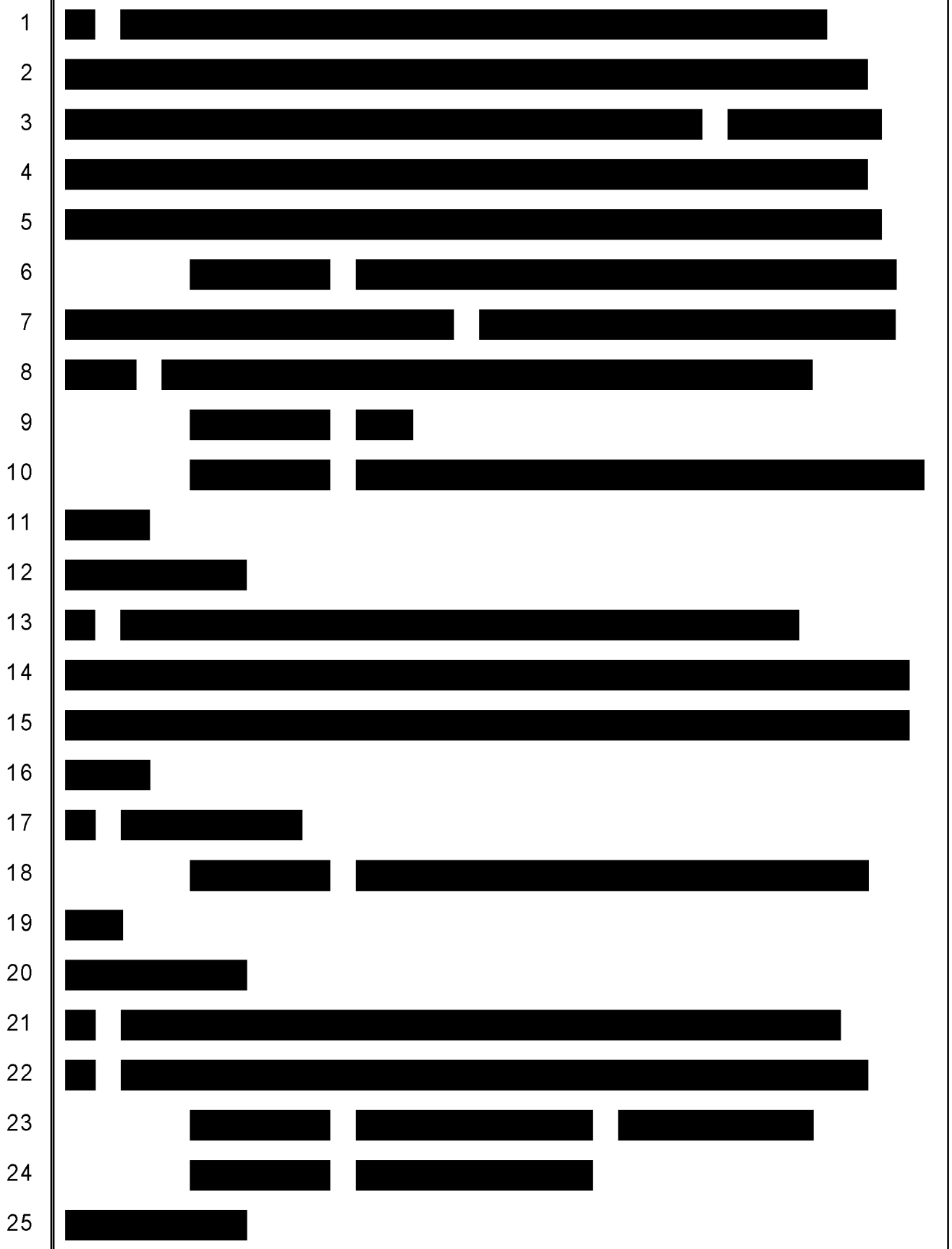


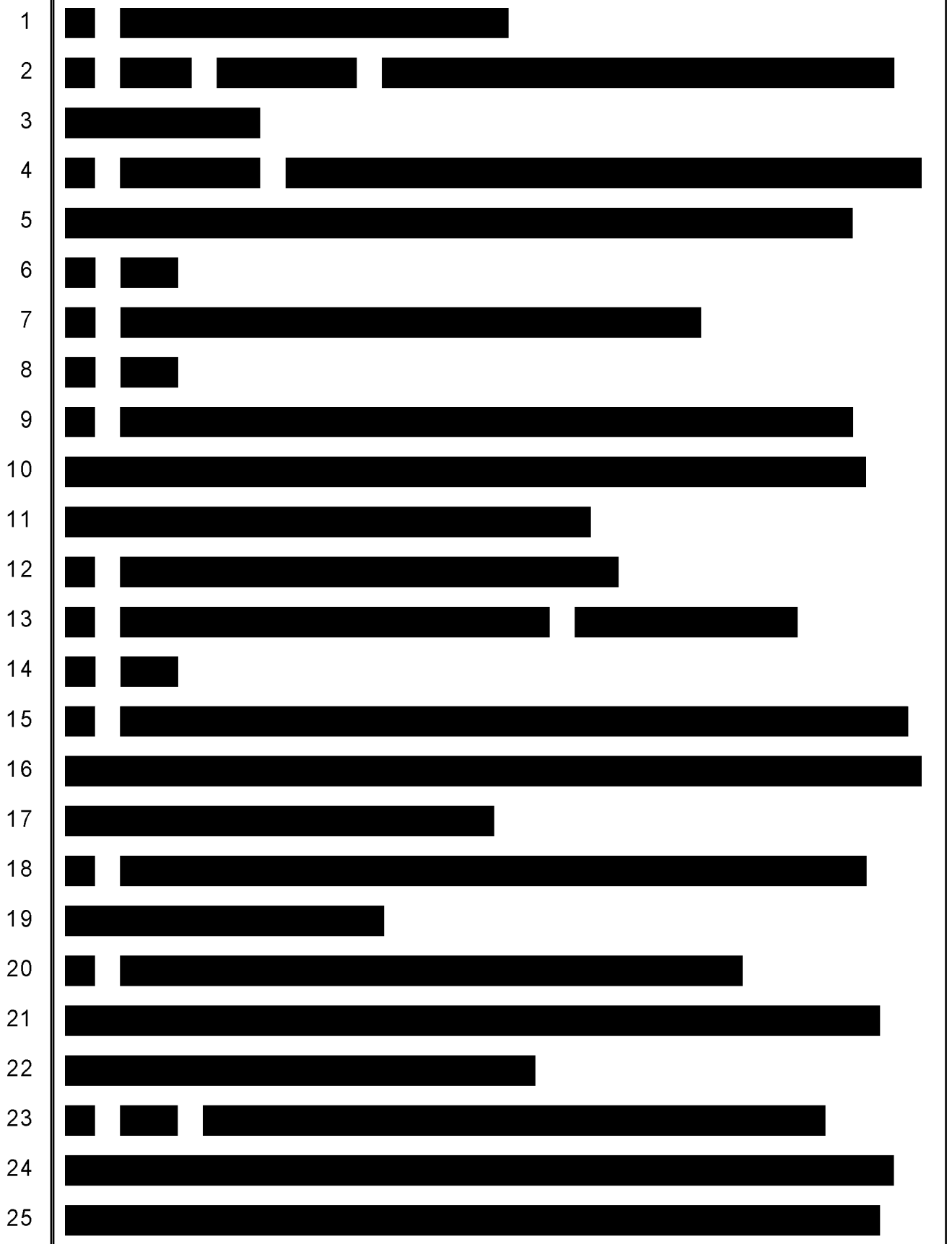


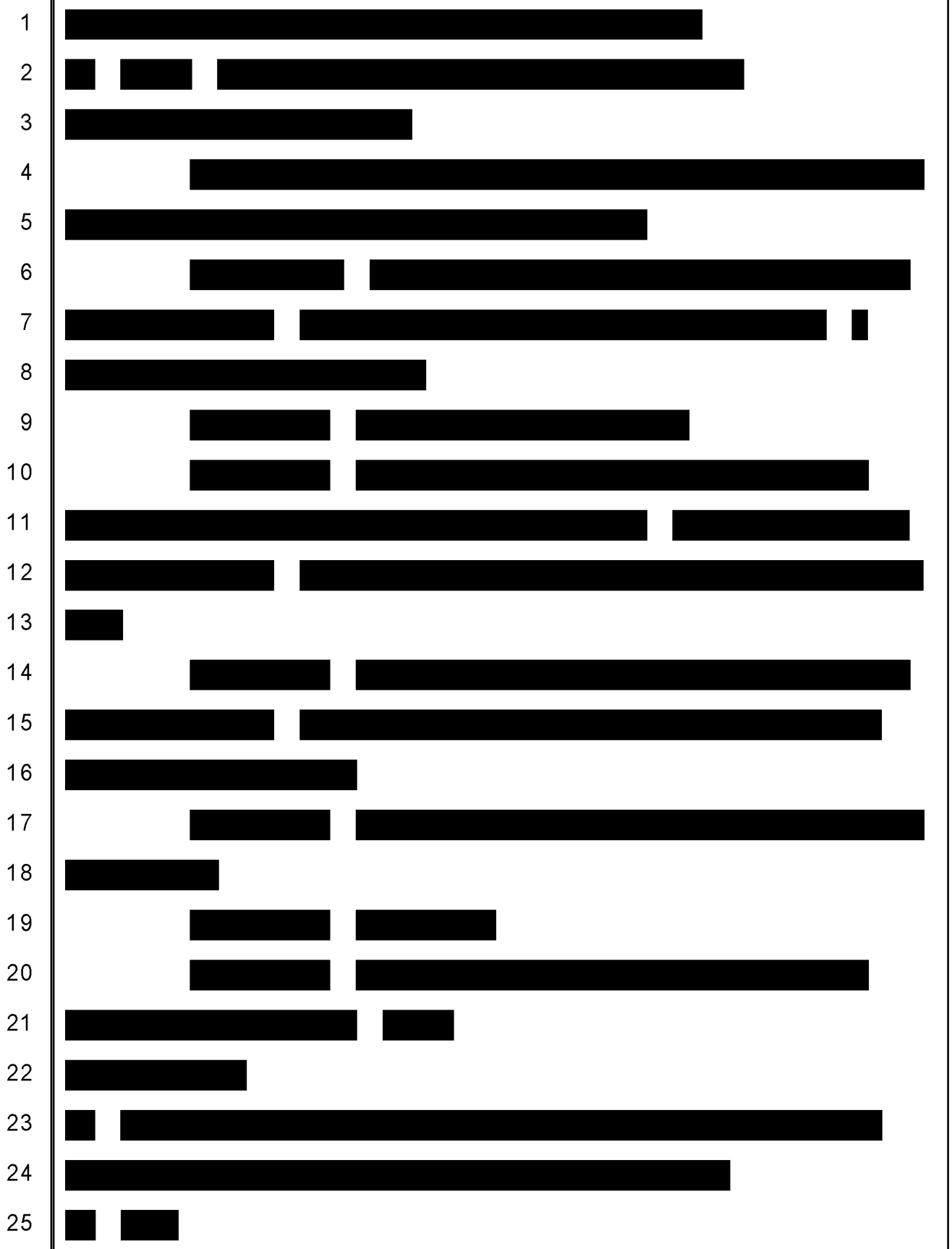


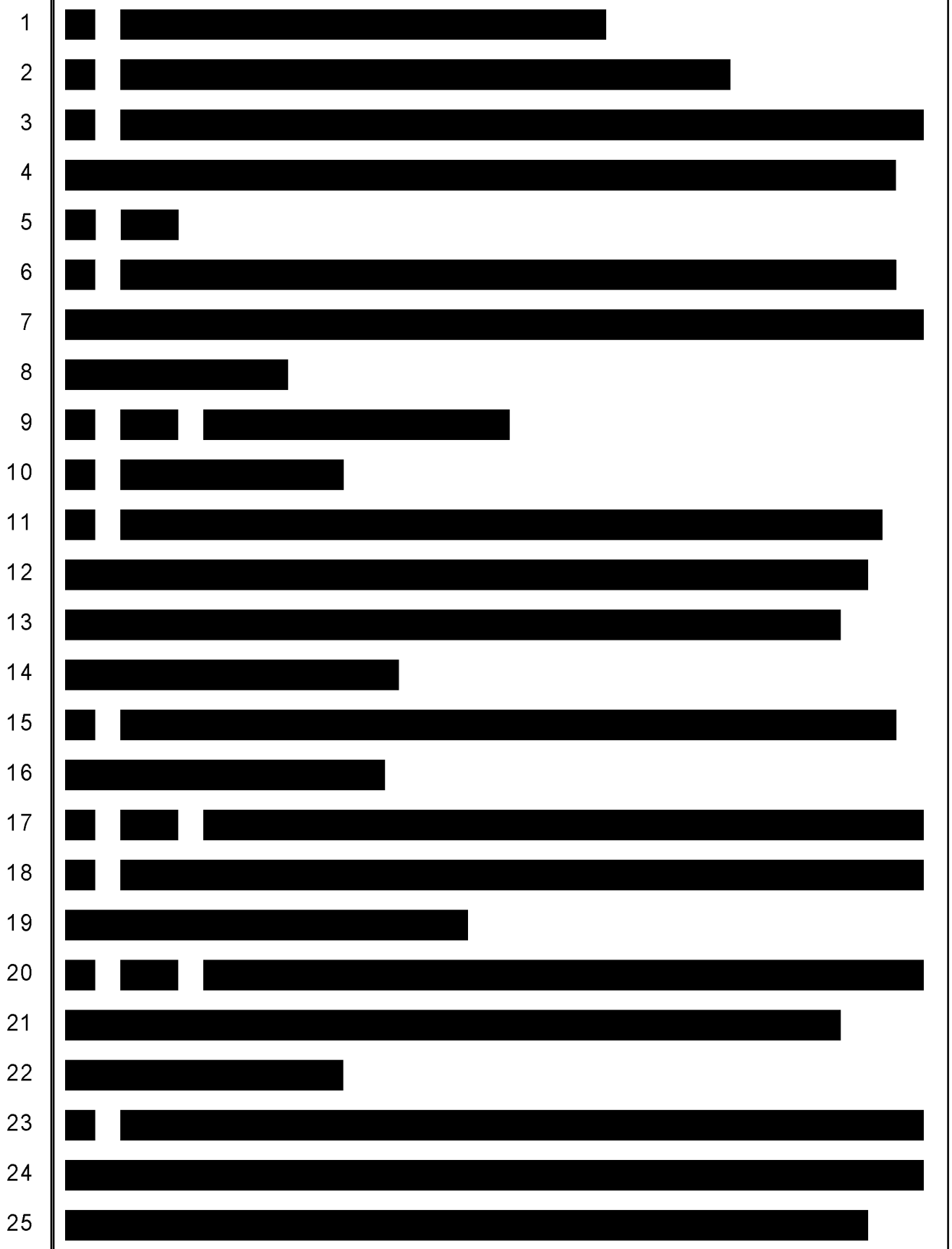


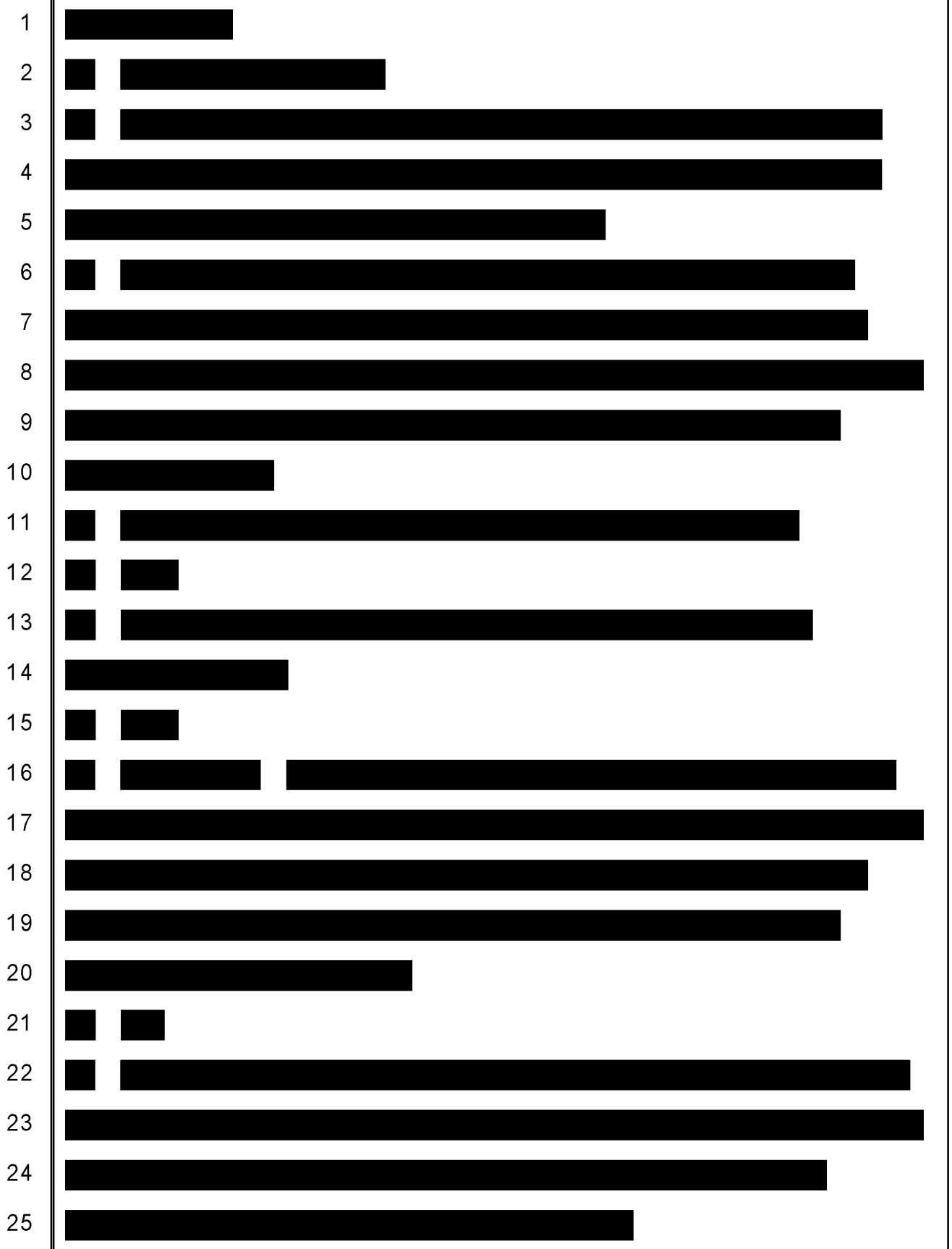


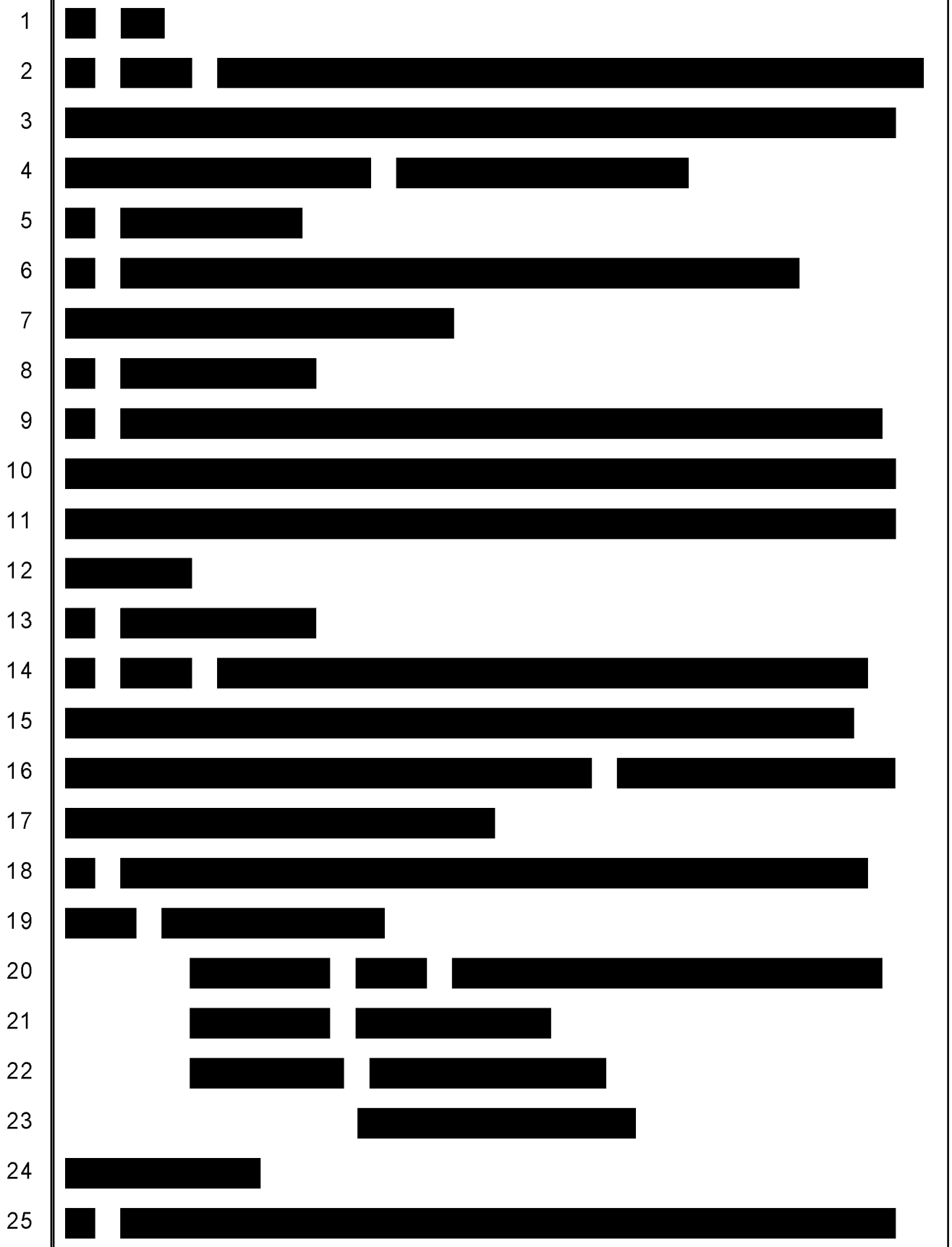


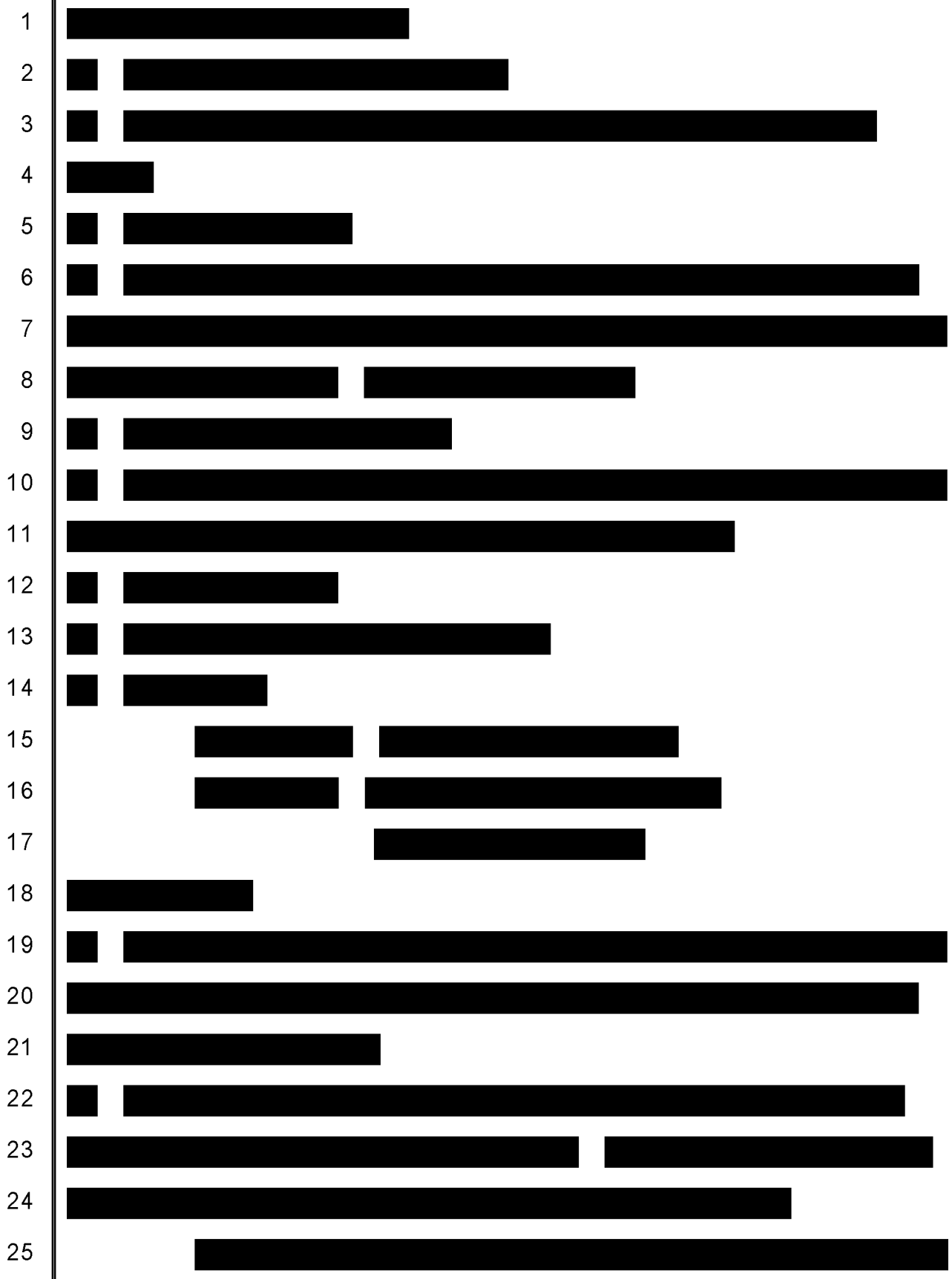


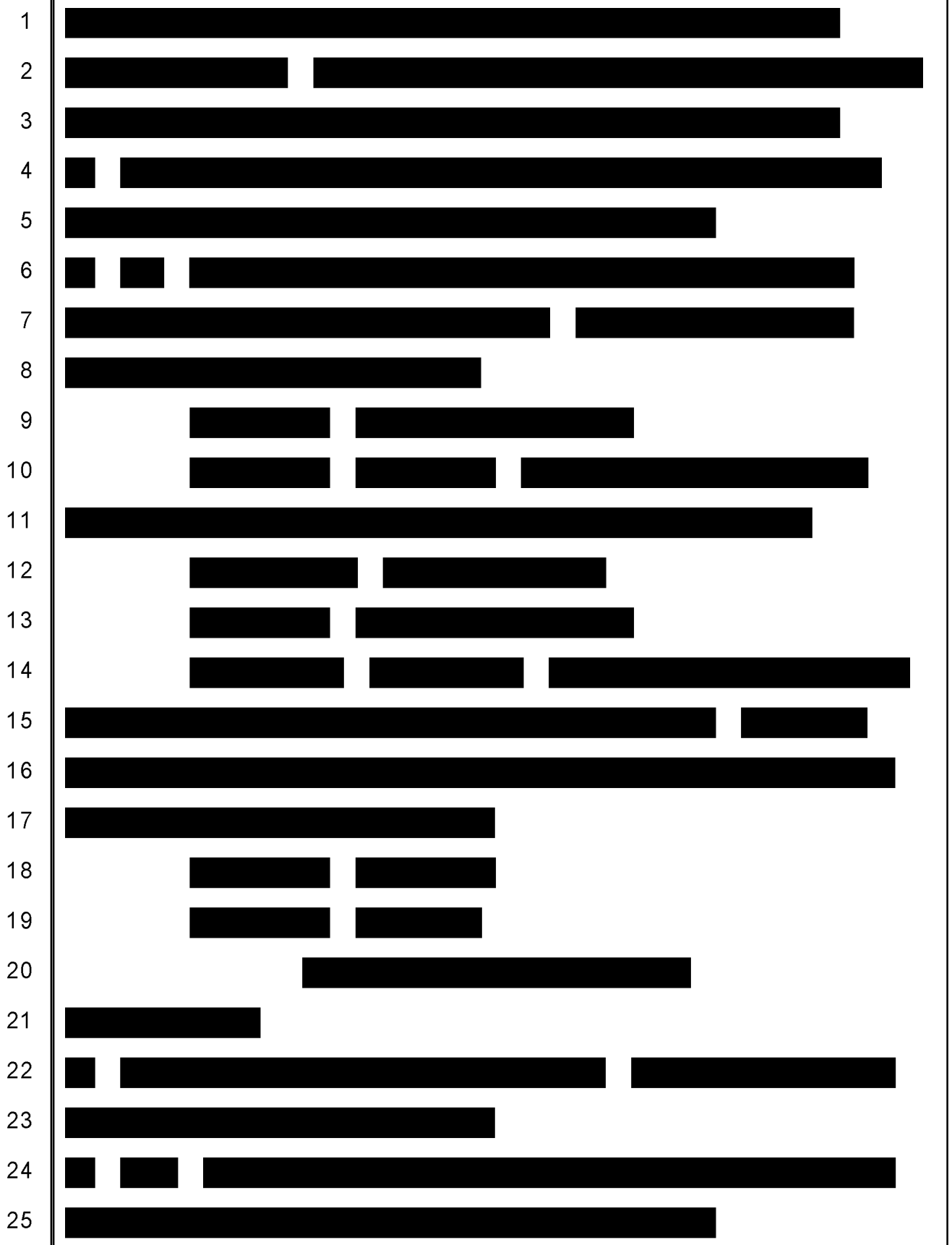


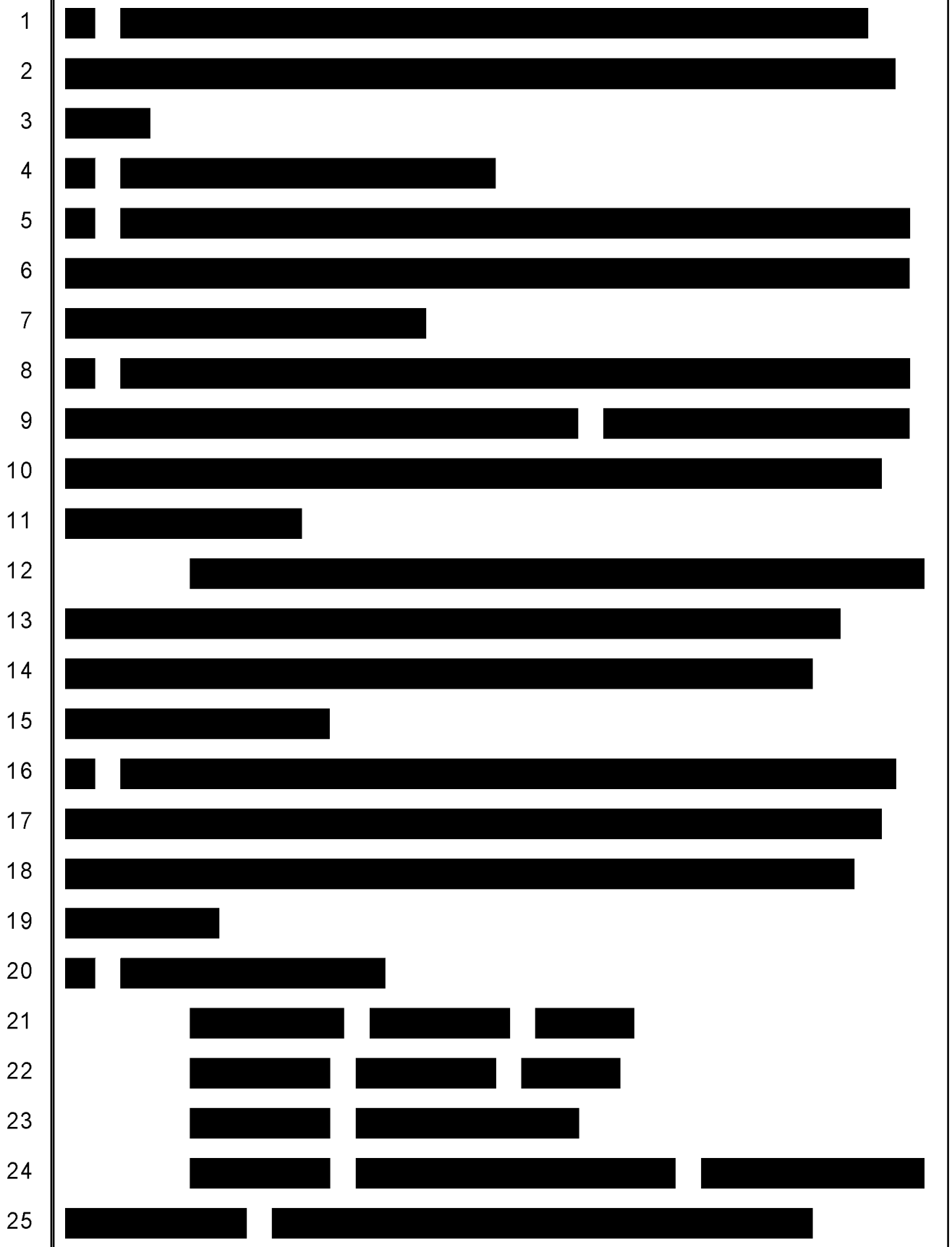



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25









[redacted]

(Court adjourned, to reconvene 3/27/17 at 9:30 a.m.)

CERTIFICATE

We certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/Judith A. Walsh — *March 23, 2017*

Judith A. Walsh
Official Court Reporter — Date

/s/Charles R. Zandi — *March 23, 2017*

Charles R. Zandi
Official Court Reporter — Date