

1 (Change of reporters - Volume 2-C:)

2

3 (Jury enters courtroom.)

4 THE COURT: All right. Thank you very much. Ladies
5 and gentlemen, please be seated. We will resume.

6 You may proceed, sir.

7 BY MR. WISNER:

8 Q. Dr. Healy, in the next part of this diagram, it says,
9 "What This Study Adds." What's the purpose of this portion of
10 your article?

11 A. Again, it's to briefly orient the reader, who isn't going
12 to spend much time reading the entire thing, as to what the
13 key points are.

14 Q. When was this published?

15 A. This was 2005.

16 Q. And the Juurlink article, when was that published?

17 A. That was the same year or 2006, one or the other.

18 Q. Can you please turn your attention to Exhibit 182 in front
19 of you.

20 A. Sorry, this is going to take me just a moment.

21 Right. 182, I have that.

22 Q. All right. What is Exhibit 182?

23 A. This is an article in a journal called *BMC Medicine*, and
24 it's by Ivar Aursnes and colleagues.

25 Q. How do you say her last name?

1 A. It's a he, and he's Ivar. I'm not exactly sure how --
2 now, I've met the man. He's now dead. He was close to death
3 when he wrote this article, but I can't remember how to --
4 actually how to --

5 Q. I'm going to call him Dr. Aursnes. Is that okay?

6 A. Fine.

7 Q. Are you familiar with this article, Doctor?

8 A. Yes, I am.

9 Q. Is it an article that you cite to and rely upon in
10 tendering your testimony for this case?

11 A. Yes, it is.

12 Q. Is this article published in a reliable medical journal?

13 A. Yes, it is.

14 Q. And is the article itself reliable, in your opinion?

15 A. I believe it is, yes.

16 Q. Okay. So, the last article, the one we were talking about
17 a second ago --

18 MR. WISNER: Your Honor, permission to publish
19 portions of this article under Rule 18, 803(18).

20 THE COURT: Yes. You may proceed.

21 BY MR. WISNER:

22 Q. Okay. Doctor, now the previous article we looked at, that
23 was looking at all SSRIs, is that right?

24 A. Correct.

25 Q. Okay. Let's look at this one. What is this one

1 specifically relating to?

2 A. This one is looking at Paxil trials.

3 Q. Let's open it up here, the abstract. It gives the
4 background. It says, "Inclusion of unpublished data on the
5 effects of antidepressants on children has suggested
6 unfavorable risk-benefit profiles for some of the drugs."

7 I'll stop right there. What does that sentence mean?

8 A. Well, it refers to the fact that there is -- I mean, this
9 is the year after -- well, actually, just let me check. This
10 is published what year? This is -- yes, it's also 2005, and
11 this is the year after the question of the use of
12 antidepressant drugs in children and the risk that they might
13 pose in terms of children becoming suicidal and going on to a
14 suicidal act was a hot button issue for FDA and for the wider
15 mental health community.

16 And part of the issue here was that it appeared that
17 there was a great deal of data --

18 MR. BAYMAN: Objection, your Honor. This is the
19 subject of a motion *in limine* again about the pediatric data,
20 and now he's getting into it, as opposed to giving historical
21 context.

22 THE COURT: Yeah. We did say that we weren't going
23 to go into -- generally into the pediatric problems
24 associated --

25 MR. WISNER: Yes, your Honor. This is just the

1 background of this article, which relates to adults. This is
2 not a pediatric article.

3 THE COURT: So, we're not going into the pediatric
4 suicide issue.

5 MR. WINSNER: Fair enough.

6 MR. BAYMAN: And Dr. Healy was getting ready to get
7 into the issue. That was my objection, your Honor.

8 THE COURT: I understand, sir. And that's why I'm
9 cautioning counsel to remind him of our prior ruling.

10 Proceed, sir.

11 BY MR. WISNER:

12 Q. Doctor, let's not get into the drugs causing kids to kill
13 themselves. Okay? Let's focus on adults here.

14 The next sentence here says, "Recent meta-analyses of
15 studies on adults have indicated similar effects. We obtained
16 unpublished data for paroxetine that have so far not been
17 included in these analyses."

18 Do you see that?

19 A. I do, yes.

20 Q. I'll just take a pause for a second. What is paroxetine?

21 A. That's Paxil. That's the generic name for what's -- for a
22 drug that has the trade name over here Paxil, but a lot of
23 different trade names elsewhere in the world.

24 Q. What's paroxetine called in the United Kingdom?

25 A. The trade name's Seroxat.

1 Q. In the clinical trials for paroxetine internally to GSK,
2 do they call it paroxetine or Paxil?

3 A. They -- they can do either. I mean, they can use the UK
4 trade name if the work was done in the UK, the U.S. trade name
5 over here, or they can use the generic name.

6 Q. From a physician's perspective, is there a difference
7 between paroxetine or Paxil?

8 A. No.

9 Q. So, now, it says, "We obtained unpublished data for
10 paroxetine." Do you know what these authors are referring to?

11 A. Well, they've clearly got -- and I didn't know at the time
12 this piece of work was done -- some unpublished data on Paxil.
13 It was clear -- what I was actually trying to say before at
14 the first sentence, one of the things that people had become
15 clear about was there was a lot of unpublished data, whether
16 you're looking at children's trials or adults' trials or
17 whatever. There was a lot of data unpublished.

18 Q. All right. It goes on to read, "The documentation for
19 drug registration contained 16 studies in which paroxetine had
20 been randomized against placebo." Can you please translate
21 that for the jury?

22 A. Yes. These -- they're referring here to the fact that in
23 their searches, that looking at the clinical trial portfolio
24 that GSK, or SmithKline Beecham as they were then, would have
25 submitted to the FDA in the U.S. or MHRA in the UK or EMEA in

1 Europe, given a portfolio of clinical trials that were done on
2 people who were depressed or people with OCD or other anxiety
3 disorders for which the company was seeking indication.

4 Q. Is that what's referred to by registration trial?

5 A. Registration, yes. This is where the company is trying to
6 seek an indication, an approval from FDA to make the claim
7 that our drug could be an antidepressant.

8 Q. It goes on, "We've registered the number of suicides,
9 suicide attempts, and ideation." So, what is that referring
10 to, those three different groups?

11 A. Well, these are completed suicides, suicidal acts, and
12 suicidal ideation. Now, for them to register that, they're
13 not looking at the Hamilton scale that I've mentioned before,
14 just whether the questions were asked about whether a person
15 had ideas or thoughts about harming themselves, but an
16 ideation event is where we've got a crisis. The person has
17 come in and made it clear they're thinking about harming --
18 actually harming themselves.

19 This will often lead to them being removed from the
20 clinical trial.

21 Q. I've seen this phrase in a couple of documents. I want to
22 make sure I understand what it is. What is a fatal suicide
23 attempt?

24 A. That's where you end up dead.

25 Q. Is there anything different between a fatal suicide

1 attempt and a suicide?

2 A. No. I mean, it's -- it is conceivable that you might be
3 able to describe a fatal suicide attempt where the person has
4 made an attempt to kill themselves in possibly all but one
5 case out of 100 would lead to them being dead, being described
6 as a fatal suicide attempt, but usually it means the person is
7 dead.

8 Q. Okay. In the conclusion, it says, "Our findings support
9 the results of recent meta-analyses. Patients and doctors
10 should be warned that the increased suicidal activity observed
11 in children and adolescents taking certain antidepressant
12 drugs may also be present in adults."

13 What is your understanding of this conclusion,
14 Doctor?

15 A. They're saying that there have been concerns about these
16 drugs being given to children. The concerns should not be
17 confined just to children, but other age groups may have the
18 same problem. And, in fact, the first indications there was a
19 problem came from adults, not from children.

20 Q. Why, Doctor, are researchers looking at children as being
21 different than adults for the purposes of suicide? Why does
22 that matter?

23 MR. BAYMAN: Your Honor, once again, we're getting
24 into children and why children are different. This gets right
25 at the heart of the motion *in limine*.

1 THE COURT: But is it going to relate to the
2 testimony here?

3 MR. WISNER: Yes, your Honor. I mean, the black box
4 warning relates to children. It's the first thing on the
5 label, so --

6 THE COURT: You may answer.

7 BY THE WITNESS:

8 A. There is, in my opinion, no difference between adults and
9 children. The problem was outlined first in adults and not
10 children.

11 The risk portfolio looks exactly the same in adults
12 and children. The clinical trial portfolio, the Juurlink
13 articles, and the other, look much worse than anything that
14 has ever been done in children.

15 The one difference in the case of children would be
16 that wherein adult trials, the drugs can be shown to be of
17 benefit, in children, that hasn't been as clear to date.

18 BY MR. WISNER:

19 Q. Now, it refers to -- I'm sorry. Let me call that back
20 out. It refers to in here supporting recent meta-analyses.
21 Do you see that, Doctor?

22 A. I do, yes.

23 Q. Do you know what she's referring to here?

24 A. Well, these are the kinds of articles like the one you put
25 up earlier, the Ferguson article, and the kinds of work that I

1 and other colleagues have done even before the Ferguson
2 article, where you try and get either a large number of the
3 clinical trials from a source like the FDA, for instance,
4 which will often -- if you go into the FDA documents that are
5 in the public domain, you can find trials that haven't been
6 published.

7 The Ferguson article looked at all the published
8 trials. Some of the other work I've done have done things
9 like go into the FDA documents and look at the trials that are
10 in there, the suicidal acts linked to those that haven't
11 actually been published.

12 Q. In your opinion, Doctor, does this article lend support to
13 your meta-analysis that there's a relationship between SSRI
14 use and adult suicide?

15 A. I believe it does. And one of the interesting things
16 about this article, while in some respects it looks like
17 they're doing just the same kind of thing that I've done and
18 other people have done, and what I've done, I have to stress I
19 think pretty well every person in the jury could have done,
20 this is a little different. They take a completely different
21 statistical approach to the one that anyone else ever took
22 with this issue.

23 It's a thing called a a Bayesian approach, and if you
24 guys don't know what that means, well, I'm not sure I know,
25 either. Because a great deal of work in this area, as I say

1 people in the jury and the court here could have done a lot of
2 what you hear me say. But this is a little different. It
3 took a very unusual approach, and the thing about it was that
4 it found the same answer taking this approach to the one that
5 I and others had found taking the much more straightforward
6 approach that we took.

7 Q. Now, Doctor, are you aware of whether or not GSK actually
8 responded or critiqued this article?

9 A. Well, they did clearly. I think there was a degree of
10 response that was in the public domain. But there was a
11 follow-up article by this group where they said -- it had been
12 clear that there was an interaction between GSK and
13 themselves, that GSK had thought the approach they took
14 wasn't -- well, it was unorthodox and unusual and perhaps not
15 the one that GSK would have taken.

16 But they respond and say why they believe the
17 approach they took was of value, and people should perhaps be
18 taking this type of approach more often. And they stood by
19 their views as to what the findings were.

20 Q. Now, is this a common practice for a drug company to make
21 a critique against an academic publication?

22 A. Well, it's not awfully unusual. I mean, these things can
23 happen. It's a little unusual, I guess, for it to be quite as
24 extensive as this. It's not a response that GSK appeared to
25 have published in an academic forum. The reason we know about

1 it in an academic forum is Dr. Aursnes and his team, they
2 tried to lay out the two points of view, GSK's point of view
3 and their own point of view in a follow-up article.

4 Q. Now, Doctor, if you could turn to Plaintiff's Exhibit 217
5 in your pile there.

6 A. I have to tell you, as I tell you, I've slightly messed
7 these things up so finding anything is -- I don't think you
8 should have ever let me loose on these, frankly, but do you
9 know which one it is? I'm supposed to be looking for a
10 number.

11 Q. It's 217, Doctor.

12 A. No, no, no, but -- roughly --

13 Q. I have a copy right here. I'm going to walk it up to you.

14 A. All right. Thanks a lot.

15 Ah, right, yes. Sorry. Okay. I've just put that on
16 the floor. That's why I wasn't finding it. Okay. Sorry
17 about that.

18 Q. All right, Doctor. I don't want to know what your office
19 looks like.

20 What is Exhibit 217?

21 A. Well, this is the follow-up article that I referred to
22 where Dr. Aursnes laid out his point of view and his team's
23 point of view, the approach they took, and the GSK point of
24 view, as they understood it, at least. And they explained why
25 they held on not just to the approach that they took but to

1 what they thought the data showed.

2 Q. Is this a document that you cited to and relied upon in
3 offering your testimony?

4 A. Yes, it is. This was a group who aren't linked as being
5 anti drug or pro drug or anything. This is an independent
6 safety monitoring group.

7 Q. And is this the same journal that published the original
8 one?

9 A. No. This is -- it's from the same group of journals, but
10 it's not actually out of the same journal.

11 Q. Okay.

12 MR. WISNER: Your Honor, permission to publish this
13 exhibit to the jury?

14 THE COURT: You may proceed.

15 BY MR. WISNER:

16 Q. All right. Then let me just clarify my misunderstanding.
17 What is BMC Psychiatry? What does that refer to?

18 A. Well, BMC is the group of journals. It's Biomed Central.
19 And one of the things that they were big on was the idea --
20 they were mainly trying -- they hoped to produce articles that
21 were open-access and, where possible, where the data came with
22 the article.

23 Q. Now, what does it mean when an article is open-access,
24 Doctor?

25 A. Well, that means that it's not behind a pay wall, that you

1 don't have to subscribe to the journal. You don't have to be
2 a member of the professional body. You don't have to pay to
3 get it, that it's just there and anyone can access it. The
4 jury could access it.

5 Q. Why are some journal articles open-access and others not?

6 A. Journals are a business, and when one's -- when the
7 open-access -- some of them charge the authors to get their
8 publications there, but often that will be built in to the
9 cost of a grant. When the authors try to get a grant, they
10 say, "We do want to publish the results and we want to make it
11 widely available, so we're going to include the cost of the
12 publication in the grant."

13 Q. Now, this abstract right here is for -- well, before we
14 get into it, quickly, this process of drug companies or even
15 other academics raising questions about methodology and trying
16 to discuss the issues, is that part of the scientific method?

17 A. Yes. There should be debate, and, you know, people should
18 challenge these things. You can, of course, challenge too
19 far. You can just try to keep a debate going when maybe it
20 will have resolved earlier.

21 Q. Now, this process of engaging in scientific debate, is
22 that appropriate in the context of such a serious side effect
23 like suicide?

24 A. Well, I think the issue -- yeah, so if the concern is with
25 the safety of patients, often we should act as though the risk

1 is real and warn about it and have the debate afterwards,
2 rather than have a perpetual debate before the issues get
3 resolved and then we warn.

4 Q. All right. The background to this article says,
5 "Following our previous publication, we have received critical
6 comments to our conclusions as well as new data that are
7 strengthening our findings."

8 Do you see that?

9 A. Yes.

10 Q. What does that mean?

11 A. Well, clearly, there was input from GSK, and it will have
12 been reasonably sophisticated input. And they've obviously
13 thought about the whole thing, but maintain that the approach
14 that they took was still a reasonable one to take and have
15 further data which they believe strengthened the case.

16 Q. Do you know if the new data that they were considering was
17 similar data that GSK had developed in 2006?

18 A. Yes, it appears to be the same data.

19 Q. And this is the data that was put and presented to the FDA
20 in what's called a briefing document, is that right?

21 A. Yes.

22 Q. Okay. We're going to get to that later. I just wanted to
23 highlight it here.

24 Now, it says down here in the results, it says, "We
25 found that the comment to our article by GSK representatives

1 contained errors, misunderstanding, and unwillingness to
2 accept Bayesian principles in the analysis of clinical
3 trials."

4 Do you see that?

5 A. Yes, I do.

6 Q. What does that mean?

7 A. Well, they are, as I say, taking a different approach
8 towards the data. It's one that a lot of people think is
9 maybe a better approach to the conventional approach that we
10 take. There's a lot of people who are true Bayesian
11 believers.

12 THE COURT: You better tell us, Doctor, about
13 Bayesian principles, if you can in a few minutes.

14 THE WITNESS: I don't know that I can, your Honor.
15 It's one of these complex things that --

16 THE COURT: Is it a mathematical formula?

17 THE WITNESS: Well, it isn't. It's an entire
18 approach towards statistics, and it's not the one that's the
19 mainstream within the field. Now --

20 THE COURT: But is it math? Are we talking about --

21 THE WITNESS: Oh, yes, it's math.

22 THE COURT: All right. That's enough now. We've got
23 it.

24 THE WITNESS: Okay.

25 THE COURT: I'll leave it to Mr. Bayman.

1 BY MR. WISNER:

2 Q. Do you think it's appropriate to examine data from all
3 forms of statistical approaches?

4 A. Yes. I mean, it's always useful when different
5 statistical approaches converge and give the same outcome. I
6 mean, I think the data was very strong before this group took
7 this approach, but it's always -- I mean, if the data hadn't
8 turned out, rather, if they took this approach and it hadn't
9 shown the risk that people like me taking a much
10 straightforward or the more usual approach have taken, then
11 that would have been food for thought for everyone.

12 Q. And, Doctor, this leads to a sort of general fanatic
13 question I have about looking at risk. Do you ever think it's
14 appropriate to not look at something?

15 A. No. The whole point behind a scientific method, whatever
16 approach you take, and there's a lot of different approaches
17 you take, but at the heart of everything is the fact we should
18 have access to the data, and our efforts are to try and
19 explain the data that's in front of us.

20 One of the biggest problems in all of this is that no
21 one has access to the data. Everyone here, even this group,
22 are working from data that GSK have put in the public domain,
23 but that's not necessarily the full data set.

24 Q. Now, in this conclusion, it says, "We were in our previous
25 publication, with preliminary data and a Bayesian approach,

1 able to raise a concern that suicide attempts might be
2 connected with the use of paroxetine. This suspicion has now
3 been confirmed."

4 Do you see that?

5 A. I do.

6 Q. What does that mean, Doctor?

7 A. Well, again, they're saying their views have firmed up.
8 They're claiming to have come to this with an open mind, to
9 have seen a very clear safety signal before. They now have
10 more data, and they think the results are pretty conclusive.

11 Q. The -- when you look at whether or not a -- sorry.

12 When you look at whether or not a piece of medical
13 literature is reliable and something that you consider, do you
14 take into consideration who authored it?

15 A. Yes. At the end of the day, you really want everybody's
16 input, company's input, non-company people's input. You want
17 the doctors' input. You want the patients' input.

18 I think objectivity doesn't come from a mechanical
19 exercise. It comes from everybody with different biases and
20 completely different points of view getting to look at the
21 data and figuring out, well, how do we explain this, until we
22 get to a point where everybody thinks this is the only way to
23 explain it.

24 Now, that gets harder and harder to do if the data is
25 not -- as I keep repeating, while these -- this group here and

1 others are working from more and more data, maybe better and
2 better data, no one's working from the complete data set.

3 And if there's any evidence that any company --
4 there's an old saying --

5 MR. BAYMAN: Your Honor, objection. He's -- again,
6 we're getting into company conduct and allegations of hiding
7 data, which is the subject of a motion *in limine* which you
8 granted.

9 MR. WISNER: Your Honor, he didn't even mention the
10 defendant. He's talking about looking at authorship. I don't
11 see how that's company conduct.

12 THE COURT: You may answer.

13 BY THE WITNESS:

14 A. Let me quickly put it like this. There's an old saying
15 you've all heard, and I'm sure it's changed since it was used
16 first. For all I know, it may have come from here in Chicago.
17 If I owe the bank a million pounds, I've got a problem. If I
18 owe the bank a billion pounds, the bank has a problem.

19 If companies are shown to hide the data --

20 MR. BAYMAN: Your Honor, now he's saying companies
21 and hiding data. This is in violation of a motion *in limine*.

22 MR. WINSNER: We'll move on, your Honor. I think the
23 point's made.

24 THE COURT: All right. Move on.

25 BY MR. WISNER:

1 Q. All right. Doctor, do drug companies, for example, like
2 the defendant, publish journal articles?

3 A. They do.

4 Q. And do they state who they are when they publish them?

5 A. Well, often the list of authors may not be the true
6 authors, and in all cases in the case of these articles,
7 there's no access --

8 MR. BAYMAN: Objection, your Honor. This is also the
9 subject of a motion *in limine* that you've ruled on.

10 MR. WINSNER: I'm not sure which motion --

11 THE COURT: I haven't heard all the question. Have
12 you finished the question?

13 MR. WISNER: I'm just asking him about whether or not
14 drug companies publish literature and whether or not the
15 authors are who they say they are.

16 MR. BAYMAN: And that's the subject of your motion
17 *in limine*, your Honor.

18 MR. WINSNER: I'm not sure what motion he's referring
19 to, your Honor.

20 THE COURT: That's kind of a general question. Be
21 specific. Sustained your objection.

22 BY MR. WISNER:

23 Q. Doctor, putting aside ghost authorship, okay, we're not
24 going to talk about that. Let's talk instead about do drug
25 companies publish literature?

1 A. Yes.

2 Q. And do employees of drug companies put their names on that
3 literature?

4 A. They may be there, or they may have a big involvement and
5 their names not be there.

6 Q. Now, is there some sort of inherent conflict of interest
7 if a person who's employed by GSK is making statements to the
8 medical community about the product they're selling?

9 MR. BAYMAN: Same objection, your Honor.

10 THE COURT: Overruled.

11 BY THE WITNESS:

12 A. There's clearly a conflict of interest, but I'm not
13 against conflict of interest necessarily. I don't mind that
14 GSK have a view or that I have a view. The problem I've got
15 is if we don't have access to the data so that an independent
16 group like the jury can decide whether they think GSK is right
17 or I'm right.

18 You know, it's the lack of access to the data that
19 makes conflict of interest a big problem, rather than just
20 it's a big problem in its own right, if you see what I mean.

21 BY MR. WISNER:

22 Q. So, it's fair to say, then, that notwithstanding the
23 conflict of interest of company authors, you still consider
24 it?

25 MR. BAYMAN: Objection. Leading, your Honor.

1 THE COURT: Overruled.

2 BY THE WITNESS:

3 A. Yes.

4 BY MR. WISNER:

5 Q. Because you consider everything, is that right?

6 A. Yes. Oh, yes, sure. I mean, you know, I wouldn't rule
7 things out of hand just because they come from one of the
8 companies.

9 Q. We went through a couple of journal articles of various
10 meta-analyses that were done. Were any of those people
11 employees of GSK?

12 A. You mean the ones that we've just referred to? No.

13 Q. All right. Doctor, I want to move on to another section
14 here. And we've touched on it a couple of different times
15 throughout your testimony, but I think I want to sort of
16 clarify and crystallize it for the jury.

17 What types of data have you really looked at to
18 examine the risk of Paxil and suicide?

19 A. I think you've got to look at every kind of data and the
20 biological data of what we know about what actually happens in
21 the brain, and what we know are -- know we don't know about
22 what the drugs can do and things like this are things we have
23 to take into account.

24 The clinical reports, maybe from patients, even
25 reports that are just on the Internet when people describe

1 what happened to them; the reports written by doctors or
2 combinations of doctors and patients together; the clinical
3 trial data, whether it's placebo controls or whether they're
4 controlled by other antidepressants; the trials in healthy
5 volunteers; the trials in patients; the trials in patients who
6 are depressed; the trials in patients who are anxious; and
7 other studies like the Juurlink one you've seen which are
8 cohort studies, which are also controlled.

9 There's a wide body of data here; and if anybody's
10 trying to work out what's actually going on, they need to take
11 all of it into account.

12 Q. All right. Doctor, I heard you mention four different
13 types of data, and I want to go over what they are with the
14 jury so that we can understand what they are.

15 If you could turn to Exhibit 35 in your pile there.

16 A. Guess what. I have it.

17 Q. Look at that. What is Exhibit 35, Doctor?

18 A. Well, this looks like a way to explain the different
19 approaches, for instance, that I believe you should take on
20 the issue. You should be looking at data from all the
21 different kind of sources that you can.

22 Q. And these are the types of data that you reference and
23 discuss in your expert report in this case?

24 A. Yes. This leaves out the brain research that I referred
25 to, but it's more the clinical research.

1 Q. All right. And would using this diagram aid you in
2 explaining to the jury the different types of studies and data
3 that you looked at?

4 A. Yes.

5 MR. WISNER: Your Honor, permission to publish
6 Plaintiff's Exhibit 35 for demonstrative purposes only.

7 THE COURT: All right.

8 BY MR. WISNER:

9 Q. All right, Doctor. This chart says four types of data.
10 The first one references clinical observation. What is that?

11 A. That's when I, for instance, would give a drug, in this
12 case Paxil, to -- it could be a person who's anxious, a person
13 who's depressed, or a healthy volunteer. And I get
14 observations from the person who's on the drug, or I may
15 observe things actually myself. For instance, if they become
16 restless, I may observe it, but the person themselves may not
17 be as aware of it.

18 What you're looking here to get is the best possible
19 description of the event you can, because for anything else
20 you're going to do, whether it's clinical trials or genetic
21 studies or whatever, we want the best descriptions we can have
22 in order to make sure when we go on to do a study that we've
23 got -- the people who have been looked at all have the same
24 condition.

25 Most of what we know about a drug comes from clinical

1 observation like this. It doesn't come from control trials.
2 Most of the things that we know that Paxil does come simply
3 from clinical observation like this. When GlaxoSmithKline
4 maybe gave the drug to healthy volunteers, what their own
5 employees said in many instances, "This drug does this to me,
6 it causes genital numbing, it causes nausea, can cause this,
7 that, and the other, it interferes with my sleep," this is
8 where we get most of the information that we have about a
9 drug.

10 Q. Do you think clinical observation is an important thing to
11 consider in assessing whether a drug can cause a suicidal type
12 of reaction?

13 A. Very important. And it was -- it's not just medical
14 observations. A lot of what got doctors thinking this was an
15 issue came from the people put on the drug who came back to
16 people like me and said, "Hey, Doc, this is different. I've
17 been suicidal before. This is different."

18 A lot of what we get, a great deal of what we get,
19 the observations come from the people on the drugs because
20 they're inside their own body and they know what's happening
21 better than anyone else does.

22 Q. Do you think it's appropriate to discount clinical
23 observation?

24 A. You can't. You'd discount most of what we know about a
25 drug if you were to do that. If you were to just go by what

1 we pick up from controlled trials, which are not designed to
2 give you a good view about what this drug is actually doing,
3 you'd know vastly less about what the drug does.

4 Q. Let's go to the next one here, healthy volunteer studies.
5 What is a healthy volunteer study, Doctor?

6 A. A healthy volunteer is just a normal person who has no
7 condition at all, at least not the condition that you might be
8 thinking of giving the drug for later. Like, they aren't
9 going to be depressed, they won't have any nervous problem if
10 the drug you're looking at is an antidepressant. Normally
11 they won't have anything wrong with them at all.

12 Researchers like me can use healthy volunteer studies
13 to tease out what is it that antidepressants actually do.
14 Companies have to do healthy volunteer studies, and often 30,
15 40, 50, 60 of them or more even before they bring the drug on
16 the market, because they want check and see, "If we give this
17 drug with alcohol, for instance, what happens? If we give
18 this drug when people are driving cars, what happens?" They
19 don't put you out in a car on the road if this drug is
20 untested. They have driving simulators, and they test these
21 things out. They want to see combinations of the drug with
22 other drugs you might be taking.

23 So, this is the reason for doing them. They may be
24 brief and last for just one day. They may last for two or
25 three weeks. They will recruit people who are younger and

1 people who are older. And they'll often follow up with the
2 person afterwards after he's stopped the drugs to see what
3 actually happens during the next few weeks.

4 Q. What value do you get from taking a perfectly healthy,
5 non-depressed person and putting them on Paxil? What do you
6 learn from that?

7 A. Well, you learn a lot about the drug. You see, most
8 people when they hear the word "drug trials" think this is
9 what happens in hospitals when we give drugs to patients who
10 are depressed or have got diabetes or whatever. That's not,
11 strictly speaking, a drug trial.

12 It's not a trial of the drug because you've got a
13 mixture of the condition and the effects of the pill, and it
14 can be very hard to tease out what's being caused by the drug
15 and what's being caused by the pill. But if you give the drug
16 to people who've got nothing wrong with them, this is a trial
17 of the drug, and you see much more clearly what it is the drug
18 has done.

19 Q. Does this -- healthy volunteer studies, are they
20 particularly helpful when the side effect you're looking for
21 is a side effect of the condition you're treating as well?

22 A. Absolutely. This can make it very, very clear. In the
23 case of -- and this applies -- it isn't just the
24 antidepressants, and it isn't just the issue we're looking at
25 today. There's a large number of drugs that can cause exactly

1 the same kind of problem as the condition that we're trying to
2 treat you for. This is -- the diabetes drugs can cause your
3 blood sugar to go the wrong way, you know, for some people.

4 So, these are issues where healthy volunteers can be
5 particularly important. And it's very much the case in the
6 case of the antidepressant group of drugs that these have been
7 very helpful.

8 Q. Have you ever conducted a healthy volunteer study?

9 A. I've actually conducted a few healthy volunteer studies,
10 yes.

11 Q. And what have you -- specifically with SSRIs?

12 A. Yes.

13 Q. What have you learned from them?

14 A. Well --

15 Q. I'm sorry, Doctor. What have you learned from them as it
16 relates to suicide?

17 A. Yeah, in our healthy volunteer trial, we found that two of
18 our healthy volunteers became suicidal on the SSRI that they
19 were given; and this was a blinded trial, so the people didn't
20 know they were getting an SSRI, and we didn't know they were
21 getting an SSRI. There was a different drug in the mix
22 completely. But it was only when these people went on the
23 SSRI and not on the other drug that they became suicidal.

24 This was a very striking finding to me. I've had a
25 chance to review a lot of other healthy volunteer studies.

1 Based on this, my confident conclusion would be if we had a
2 jury of 10 of you, which we do have, let's say we had a jury
3 of 20, then for sure if we were to give every one of the jury
4 an SSRI, at least one of the 20 would become suicidal,
5 possibly a higher number.

6 Q. And this is regardless of these people having a
7 psychiatric condition? These are healthy people?

8 A. Yes. And that's in a sense what makes it easier to see
9 what's going on, because in the case of people who are
10 depressed, you may have people who are suicidal to begin with,
11 where the drug is tremendously helpful and they stop being
12 suicidal. So, you know, it gets a lot more complicated when
13 you're dealing with people who have the same problem that the
14 drug can cause.

15 Q. Did GSK conduct healthy volunteer studies for Paxil?

16 A. They did, yes.

17 Q. Have you reviewed them?

18 A. I have.

19 Q. What have you seen?

20 A. My view is that you see the same problems in the healthy
21 volunteer studies that you see in the clinical populations
22 also. People can become agitated, become nightmarish,
23 apprehensive. And in the GSK healthy volunteer trials, there
24 was one individual who later committed suicide. Whether we
25 can say it was linked to the drug or not is another question.

1 Q. When these healthy volunteers, they're given Paxil and
2 they get this reaction, what happens when these healthy people
3 are taken off of Paxil?

4 A. Well, it -- the reaction can endure, or they can be
5 relatively okay on Paxil and have problems when they stop.
6 And the complaints from people who have took it to begin with,
7 when they stop Paxil having been on it for two weeks can be,
8 "I'm feeling anxious. I'm feeling depressed. I'm feeling
9 tired, fatigued. I'm having bad dreams," so a lot of the
10 kinds of symptoms of people who are depressed.

11 If you were to present these to your doctor, she
12 would say, "You're depressed. I need to give you an SSRI."
13 Well, in natural fact, they can be linked to the treatment as
14 well, either going on the treatment or withdrawing from it.

15 Q. So, if a patient -- a healthy person is given Paxil,
16 becomes agitated, and then that agitation ceases when you stop
17 taking Paxil, what does that tell you as a scientist?

18 A. Well, this moves on to the next -- well, to a specialized
19 form of clinical observation.

20 Q. But I'm talking about in healthy people, Doctor, what does
21 that tell you?

22 A. Well, either in healthy people or people who are -- people
23 who have a clinical problem, this is the most conclusive way
24 to prove cause and effect. If the problem appears from the
25 drug and clears up when you halt the drug, and then maybe

1 reappears if you expose the person to have the drug, this is a
2 more powerful way to illustrate cause and effect than
3 controlled trials or any other method.

4 Q. So, that's for healthy people. Let's look at doing that
5 sort of study in depressed people. The next one here is a
6 challenge, de-challenge, rechallenge study. Before we get
7 into using this diagram to explain it, Doctor, can you tell us
8 what challenge, de-challenge, and rechallenge means?

9 A. Yes, I can. Perhaps the best way to illustrate it was
10 something I learned in Chicago a few years ago. I've been
11 here a few times. The first time I was here was 20 years ago.
12 But about four or five years ago, I was here for a meeting,
13 and somebody else talking about these issues said, "Oh, this
14 is the Christmas tree light bulb test. This is the way to
15 remember it."

16 In the old days -- it doesn't apply as well now, in
17 the old days when you had Christmas tree lights, at least in
18 Ireland and probably here, when they were real bulbs, little
19 bulbs but real, sure as eggs are eggs, when you took the
20 Christmas tree lights down from the attic at Christmas time
21 and put them on the tree and plugged them in, they didn't
22 work.

23 So, what my father used to do, I can recall, was go
24 and unscrew each bulb until he unscrewed one and they came on.
25 And you'd screw it back in again, and they'd go off again.

1 So, you remove the dud bulb. And this is challenge,
2 de-challenge, rechallenge in reverse.

3 Exactly the same thing happens with a drug. If I
4 give you a drug and you turn blue and grow feathers, that's
5 challenge. If we remove the drug and the thing clears up,
6 that is de-challenge. Now, not all conditions will. For
7 instance, you can't do this if people are dead from suicide.
8 You can't do this if the drug causes you to break a leg. Your
9 leg is still going to be broken.

10 But if you become agitated and suicidal on a drug,
11 when you're being given the drug, and you remove it and it
12 clears up, that's de-challenge. And then if you think it's
13 safe, you can do what Carol Locke and Tony Rothschild did and
14 give the person the same drug again and see what happens; and
15 if the thing comes back, that's very like what my colleague,
16 as I said, called the Christmas tree light bulb test.

17 Q. So, let's talk about the challenge step. When you're
18 talking about a challenge, de-challenge, rechallenge study,
19 are you typically referring to depressed patients?

20 A. No. This is the universal approach towards adverse events
21 across the board. Whatever drug you're looking at and
22 whatever condition, whether it's a cardiac condition or an
23 orthopedic condition or a mental health condition. It's
24 embodied in the federal judicial manual as the way to approach
25 cause and effect.

1 Q. Now, specifically when it comes to looking at challenge,
2 de-challenge, rechallenge studies for antidepressants and
3 SSRIs, do you typically start off with a cohort of depressed
4 patients like we have here in this diagram?

5 A. You do and you don't. Let me explain.

6 Q. Okay.

7 A. That's an Irish answer, in case you didn't know.

8 What -- the first article that I wrote was a
9 challenge, de-challenge, rechallenge article, but only on two
10 patients. We gave them the drug. They became suicidal. The
11 problem cleared up when we removed the drug and reappeared
12 when we gave them a different SSRI. That's challenge,
13 de-challenge, rechallenge in just two people. The -- that
14 shows you conclusively the drug caused the problem, but it
15 doesn't give you any idea how often this problem is likely to
16 happen.

17 You can expand it up, as one of the other companies
18 in the field did at one point when there was an issue about
19 all this. They said, "We're going to run a randomized control
20 trial. We're going to put into this a bunch of patients who
21 have become suicidal on an antidepressant" --

22 MR. BAYMAN: Your Honor, objection. That's subject
23 to a motion *in limine* on the Beasley protocol that your Honor
24 granted involving Eli Lilly.

25 BY THE WITNESS:

1 A. I can reframe it.

2 MR. WINSNER: Yeah, no problem, your Honor. We're
3 not referring to a Lilly protocol or that they should have
4 used it. This is a completely different line of questioning.

5 THE COURT: Is this the Lilly protocol?

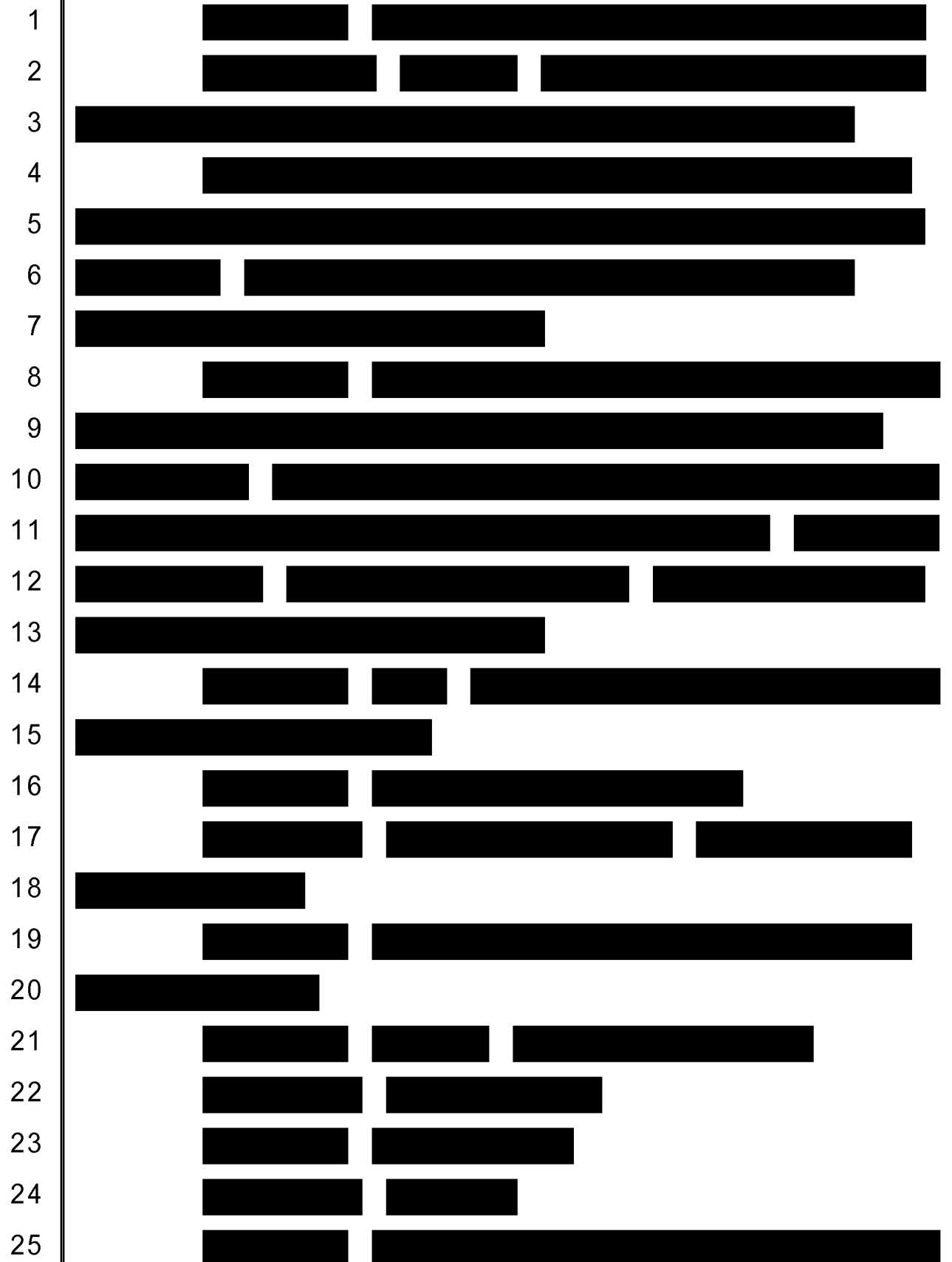
6 MR. BAYMAN: It's the same methodology. That's
7 exactly what he said.

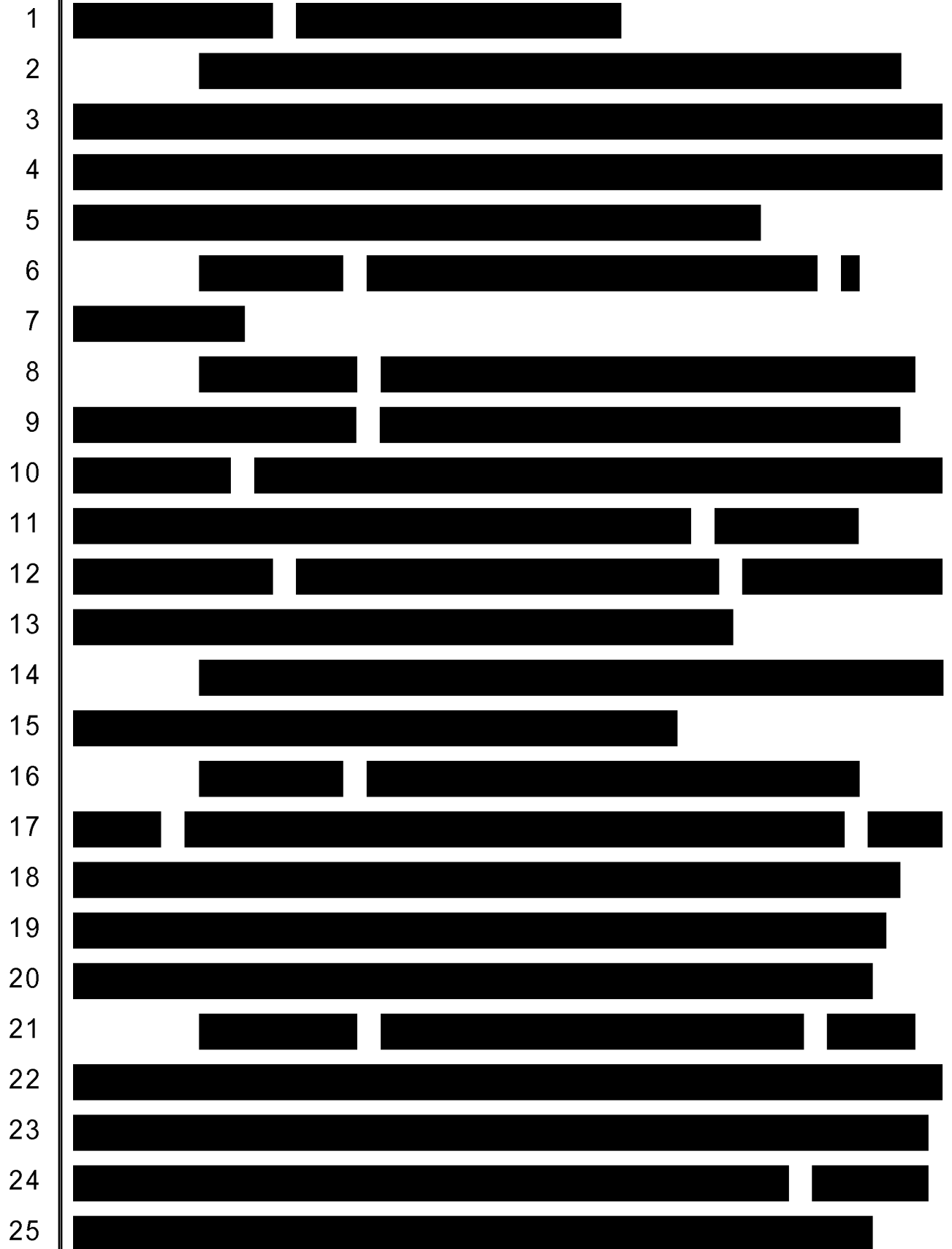
8 MR. WINSNER: Yeah, but he wasn't referring to it.
9 They're the ones who made this an issue, not us. He was just
10 answering a question about how you could do a clinical trial
11 with challenge, de-challenge, rechallenge, nothing to do with
12 Lilly.

13 MR. BAYMAN: Could we get a sidebar?

14 THE COURT: Yes.

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13 (Proceedings heard in open court, jury present:)

14 THE COURT: Getting close, ladies and gentlemen.

15 All right. Go ahead.

16 MR. WISNER: Thank you, your Honor. Long day.

17 BY MR. WISNER:

18 Q. All right. So, Doctor, I just want to ask you about --
19 I'm not asking about a specific study or anything like that,
20 but how could you design a challenge, de-challenge,
21 rechallenge study as it relates to -- period? How would
22 you do that?

23 A. Sure. You could design the same kind of thing. You could
24 say David Healy and his patient may be -- two patients may be
25 some odd freaks, although a bunch of other people have

1 described the same challenge, de-challenge thing and this
2 problem. You could say, "We really want a much bigger group
3 of people. We want to run a controlled trial where people get
4 exposed to the drug, and if there's a problem, the drug gets
5 stopped, and then they get re-exposed." This could be done.

6 The FDA at one point said this is a good idea, but
7 it's never been done.

8 Q. Now, you did mention that it had been done on a smaller
9 scale, is that right?

10 A. Only in the case --

11 MR. BAYMAN: Your Honor, same objection as before.
12 This is not theoretical.

13 THE COURT: Move on, sir. Let's move on.

14 MR. WISNER: All right.

15 BY MR. WISNER:

16 Q. Have you seen any challenge, de-challenge, rechallenge
17 case reports done before?

18 A. There's a large number of them in the field. The other
19 place where it comes into play is when companies run clinical
20 trials and patients in them go on to a suicidal act or become
21 suicidal or drop out of the trial because they become
22 suicidal, the company monitors or asks to determine, "Did our
23 drug cause the problem or not?"

24 MR. BAYMAN: Your Honor, objection again.

25 THE COURT: Overruled, sir.

1 Go ahead, Doctor.

2 BY THE WITNESS:

3 A. They're asked to decide: Did the drug cause the problem
4 or not? And they take exactly the same approach as I'm taking
5 here -- or as I took with the patients I have. They look at,
6 well, is there any evidence that -- well, first of all, they
7 look and see: Did the problem happen after the patient went
8 on the drug? Was there any hint of the problem there before?
9 After they went on the drug, did it clear up when the drug was
10 stopped? And is there any evidence, then, that the patient
11 got exposed to this drug or a similar drug, and did the
12 problem come back?

13 They also look at issues linked into the dose,
14 whether the problem wasn't there at the start but appeared
15 when the dose got put up.

16 Company personnel -- the only point I'm making is
17 company personnel took exactly the same approach towards
18 trying to decide did the drug cause the problem as I do. The
19 thing is, you see me publish and say, "Look, I think this
20 indicates the drug can cause the problem. It may be very
21 rare, but it can cause it." You don't see company
22 publications like that.

23 BY MR. WISNER:

24 Q. All right. Well, you mentioned several times in this area
25 of challenge, de-challenge, rechallenge Rothschild and Locke.

1 Do you recall that, Doctor?

2 A. I do, yes.

3 Q. Who is Rothschild?

4 A. Anthony Rothschild is a doctor who was working at Harvard
5 shortly after the first reports came out of Harvard of Prozac
6 causing a problem. And this was by a different group of
7 people.

8 Dr. Rothschild was working with a woman called Carol
9 Locke, who I understand to have been the senior author on the
10 paper, but between them they wrote a paper which is referenced
11 in quite a few of the papers you've seen today, Locke and
12 Rothschild. And this was looking at a person who was suicidal
13 on Prozac -- well, three people, where two at least having
14 been given Prozac do things like jump off buildings and are
15 seriously injured; but because there is all sorts of things
16 put in place to keep them safe afterwards, when the problem is
17 cleared up, when the Prozac is out of their system, they take
18 the opportunity to re-expose, with the person's consent, and
19 the people then describe, "The problem comes back when I get
20 re-exposed to this drug."

21 And a further factor which company personnel will
22 take into account when they're trying to work out if this
23 happens in a clinical trial, Dr. Rothschild and Carol Locke
24 introduced an antidote, which you've heard me talk about, a
25 beta blocker called Propranolol; and in two of their cases, at

1 least, this seemed to help a lot.

2 Again, company monitors, if there's any evidence that
3 something has been done to alleviate the problem, if there's
4 any evidence of an antidote, this again goes to the standard
5 approach that everybody takes to determining cause and effect.

6 And company monitors do it with individual cases.
7 Although they're in clinical trials, they still have a duty to
8 do this with individual cases. Or if any of the jury would
9 get in touch with GSK, they would want to do the same thing.
10 They would want to ask exactly the same questions. Were you
11 on anything else? Did it happen after you went on the drug?
12 Did it clear up after the drug was stopped? Did you go back
13 on the drug? What happened?

14 And they have an obligation to follow you up. And
15 based on that, they will often say, "We believe that our drug
16 has caused a problem," even if your own doctor has said, "No,
17 it didn't."

18 Q. All right. Well, do you know if Anthony Rothschild is
19 involved in this case at all?

20 A. I understand he may be involved in this case. I'll have
21 to wait and see.

22 Q. What capacity?

23 A. He's one of the expert witnesses for GSK.

24 Q. I see. Do you know Dr. Rothschild personally?

25 A. We have met many, many years ago. Actually, I met

1 Dr. Rothschild first 20 years ago. I can date it rather
2 precisely.

3 Q. Why is that, Doctor?

4 A. Oh, well, the -- yeah, no, just -- I had -- the issue of
5 Prozac causing people a problem had become a big one.

6 MR. BAYMAN: Your Honor, hearsay.

7 MR. WISNER: Yeah, let's not go there.

8 THE COURT: Let's not go back there. Let's stay with
9 the issues.

10 MR. WISNER: Let's not go there.

11 BY MR. WISNER:

12 Q. Would you recognize a copy of the Rothschild article that
13 we're referring to if you saw it today?

14 A. I thought we put it up earlier. Did we not?

15 Q. No, we haven't.

16 A. Well, yes, I would.

17 Q. Please take a look at Plaintiff's Exhibit 88.

18 THE COURT: The number again, sir?

19 MR. WISNER: 88.

20 BY MR. WISNER:

21 Q. Have you got it, Doctor?

22 A. Well, my filing system has broken down again, I hate to
23 say. I'm a little worried that you may need to help me out
24 again, because it's not coming to hand.

25 Q. One second. I'll get you one.

1 THE COURT: Here you are, Doctor. My system isn't
2 much better than yours, but I don't want to have you sort all
3 of your papers.

4 THE WITNESS: Thank you, your Honor.

5 MR. WISNER: Thank you very much, your Honor.

6 THE WITNESS: Actually, there's two papers here. I'd
7 better give you this one back.

8 BY MR. WISNER:

9 Q. All right. Have you got Exhibit 88 in front of you,
10 Doctor?

11 A. Yes, I do.

12 Q. Great. Plaintiff's Exhibit 88, what is it?

13 A. This is a paper that appeared in a journal called
14 *The Journal of Clinical Psychiatry*. It's called, "Re-exposure
15 to Fluoxetine After Serious Suicide Attempts by Three
16 Patients: The Role of Akathisia," and its authors Anthony J.
17 Rothschild and Carol A. Locke.

18 Q. Is this one of the articles that you cite to and rely upon
19 in your expert report?

20 A. Yes, it is.

21 Q. And is this a reliable article, in your opinion?

22 A. Well, yes, it is. With all of these things, as I
23 indicate, you know, the trick is you want people to look at
24 every article from every point of view. This, I think, is a
25 good article, but you wouldn't hang an entire case on just one

1 article. But it is, well, I thought when I read it first, a
2 very compelling article.

3 MR. WISNER: All right. At this time, your Honor,
4 permission to publish Exhibit 88 to the jury?

5 THE COURT: Yes, you may proceed.

6 BY MR. WISNER:

7 Q. All right. So, let's start with the first page here,
8 Doctor. You mentioned this was written by Rothschild and
9 Locke. Do you see that?

10 A. Yes, I do.

11 Q. Is there any significance about the fact that Rothschild
12 is listed first?

13 A. Not necessarily, no.

14 Q. Okay. Now, if you look at this, it has a section that
15 says, "Case Reports." Do you see that?

16 A. Yes.

17 Q. What are case reports?

18 A. Well, case reports are where a doctor, or these days
19 increasingly a doctor and a patient, say, or a few doctors and
20 a few patients will report on a problem or an issue that
21 they're seeing, or it can be a good outcome, where it's not in
22 the clinical trial literature. You know, drug X may be used
23 to treat condition Y, but, in fact, we're seeing some good
24 outcome or bad outcome maybe when drug X is being used to
25 treat a completely different condition that nobody knew

1 anything about.

2 One way or the other, what you've got is a group of
3 doctors and patients looking at something happening on the
4 drug and trying to take into account everything else that
5 could explain what they're seeing and coming to a conclusion
6 that we think this drug, for instance, has caused that
7 outcome, whether a good or a bad one.

8 Q. That leads me to a question while we're here on the
9 Rothschild article.

10 Do you think it is appropriate, if you're
11 investigating whether or not a drug caused someone's suicide,
12 to start off with the belief that it couldn't possibly have
13 caused the suicide?

14 A. Well, I think in some respects, it would have been very
15 difficult in Boston at that time not to think that these drugs
16 could cause a problem, you know, because some of the first
17 reports had come from Boston. So, I'm sure this was an issue
18 for Dr. Rothschild and Locke. They were alerted to it in a
19 way that a few others weren't.

20 But these reports were coming in, you have to
21 appreciate, from all sorts of places. They came in from both
22 Harvard and Yale; and they don't usually agree on anything,
23 but they were coming from both universities.

24 Q. But methodologically, putting aside the context of the
25 article for a second, but methodologically, do you think it's

1 appropriate, if you're going to look at whether a drug caused
2 someone's suicide, to start off with the belief that it's not
3 possible a drug could cause someone's suicide?

4 A. I don't think you have to do that at all. As I've said,
5 the single greatest way we discover most things about drugs
6 are from people saying, "Hey, this is happening to me." And
7 that doesn't happen if you're intensely skeptical. You have
8 to be open to the possibility that the drug is causing it.

9 It isn't just problems. The single best way to
10 discover new drugs is because patients or doctors recognize
11 something new happening. And the unfortunate thing is, a lot
12 of people say you shouldn't pay heed to case reports. You
13 should only pay heed to controlled trials. And as that
14 culture has grown, we've ended up with less and less new
15 drugs. The supply of new drugs has begun to dry up because
16 we're not paying heed to observations like this.

17 Q. All right. Well, let's look at the discussion here.
18 We're on page -- the second page of it. And I want to
19 actually go through this first paragraph written by
20 Dr. Rothschild. It reads, "Three depressed inpatients, 25
21 through 47 years of age, were re-exposed to fluoxetine."
22 What's fluoxetine, Doctor?

23 A. That's Prozac.

24 Q. Okay. "Were re-exposed to fluoxetine after having
25 previously made a serious suicide attempt while taking the

1 drug. This is the first report, to our knowledge, of patients
2 restarted on fluoxetine after a previous suicide attempt
3 during fluoxetine treatment. We observed that all three
4 patients developed severe akathisia while taking fluoxetine,
5 and they stated that the development of this syndrome in the
6 context of their depressive episode is what precipitated their
7 prior suicide attempts. When re-exposed to fluoxetine, the
8 patients again developed akathisia and suicidal ideation. The
9 suicidal feelings abated when the akathisia was treated by the
10 discontinuation of the fluoxetine or the addition of
11 propranolol."

12 Do you see that? I probably said that wrong.

13 A. Yes.

14 Q. Okay. Walk the jury through what that paragraph is saying
15 by Dr. Rothschild.

16 A. Well, there's been a prior challenge with the drug, and
17 the person has become suicidal. The drug has been removed.
18 When you get to read the case history in detail, when you see
19 the fluoxetine has been removed, the problem clears up. The
20 person still needs treatment. In this case -- well, in these
21 three cases, they've had the opportunity to re-expose the
22 person to fluoxetine in part because other treatment options
23 weren't available to these patients. They were quite unusual
24 patients in that respect, but also because as I said to you
25 earlier, one of them, a woman in particular, was in a

1 wheelchair, so it was rather easy to make sure that she
2 couldn't repeat what she'd just done, which was jump off a
3 building, although what she made clear was, "I'm having
4 exactly the same feelings that led me to do this before."

5 Q. In the next paragraph and a half down, it reads,
6 "Akathisia has been implicated in the development of suicidal
7 ideation, homicidal ideation, and violence." Do you see that?

8 A. Yes, I do.

9 Q. What is homicidal ideation?

10 A. That's where you've got thoughts of violence not just
11 towards yourself, which leads to your own death, but thoughts
12 of violence towards others.

13 Q. Is -- we've talked about violence and suicidality
14 associated with akathisia. What is Dr. Rothschild referring
15 to here?

16 A. Well, the fact is that the state gives rise to people
17 having horrific and unusual impulses. People sometimes end up
18 in a state of fear, but they also end up in a state where
19 they're afraid of the impulses and thoughts that they're
20 having. It's not just that I might take an overdose and end
21 up dead. It's I might kill myself in an awful way, or I might
22 kill others.

23 Q. All right. I want to start -- it crosses over two pages,
24 so it reads down here, it says, "In both cases, sui-," do you
25 see that, Doctor?

1 A. Yes, it's --

2 Q. Okay. "In both cases" -- and then I'll read the rest
3 here. "In both cases, suicidal ideation appeared suddenly,
4 concurrent with the development of akathisia, and disappeared
5 when the akathisia was treated."

6 What does that tell you as a scientist?

7 A. Well, again, the key thing is that it happens after you
8 give the drug. One of the other things is -- but again, we
9 know that these people are very susceptible. These are people
10 who are going through a bad reaction and appeared to have one
11 very quickly.

12 This again ties -- if there's a big delay between
13 giving the drug and the akathisia happening, while that can
14 certainly happen on the drug, it becomes a little harder for
15 an outside observer or the person themselves to make the
16 linkage.

17 In this case, clearly -- I mean, it's just generally
18 when we're trying to work out what happens with these things,
19 if there's a close temporal link between giving the drug and
20 the problem happening, people are more likely to figure out,
21 "Ah, there is a causal link here."

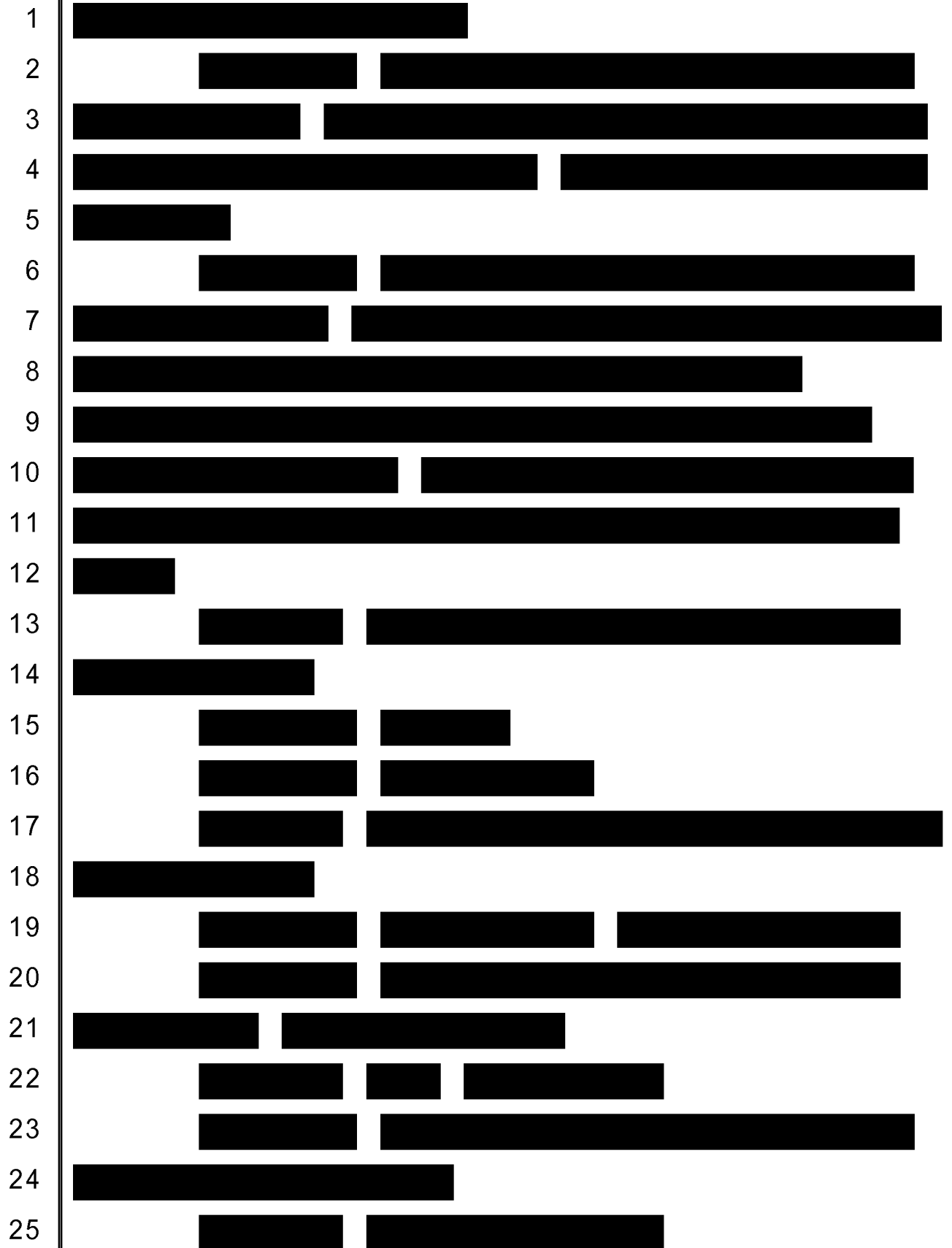
22 Q. If you read down farther, and I'll highlight this part, it
23 says, "Shaw and colleagues reported a case of suicidal and
24 homicidal ideation and akathisia in double-blind neuroleptic
25 crossover study."

1 MR. BAYMAN: Your Honor, we're now getting into drugs
2 that are not even in the class of the medicine that's at issue
3 in this case, so I object.

4 THE COURT: All right. We'll recess now until
5 tomorrow morning, ladies and gentlemen. We'll resume at 9:30.
6 And we will ask you to remember all of the admonitions that I
7 gave you about the case. And don't forget us between now and
8 then, either.

9 (Jury exits courtroom.)

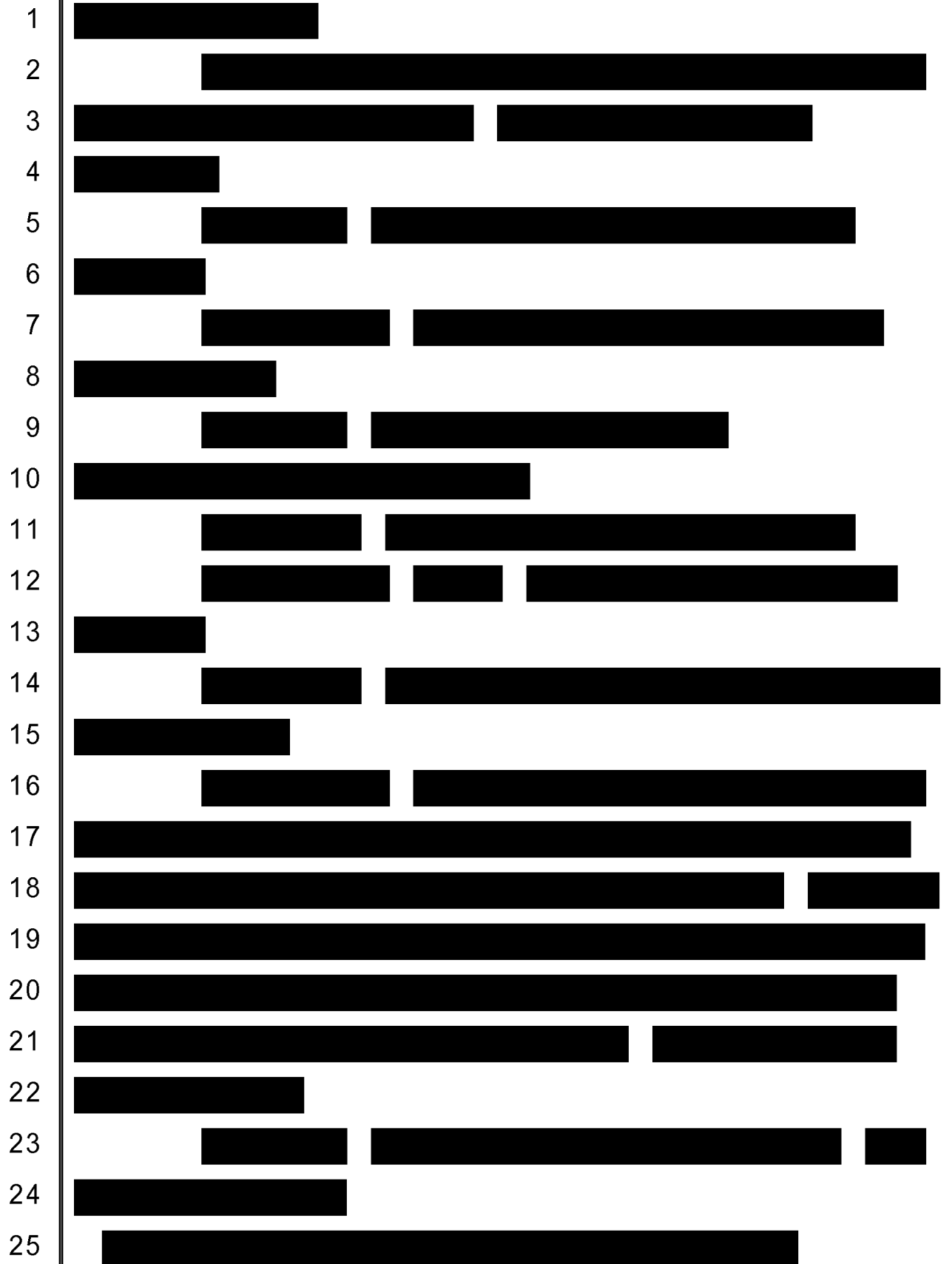
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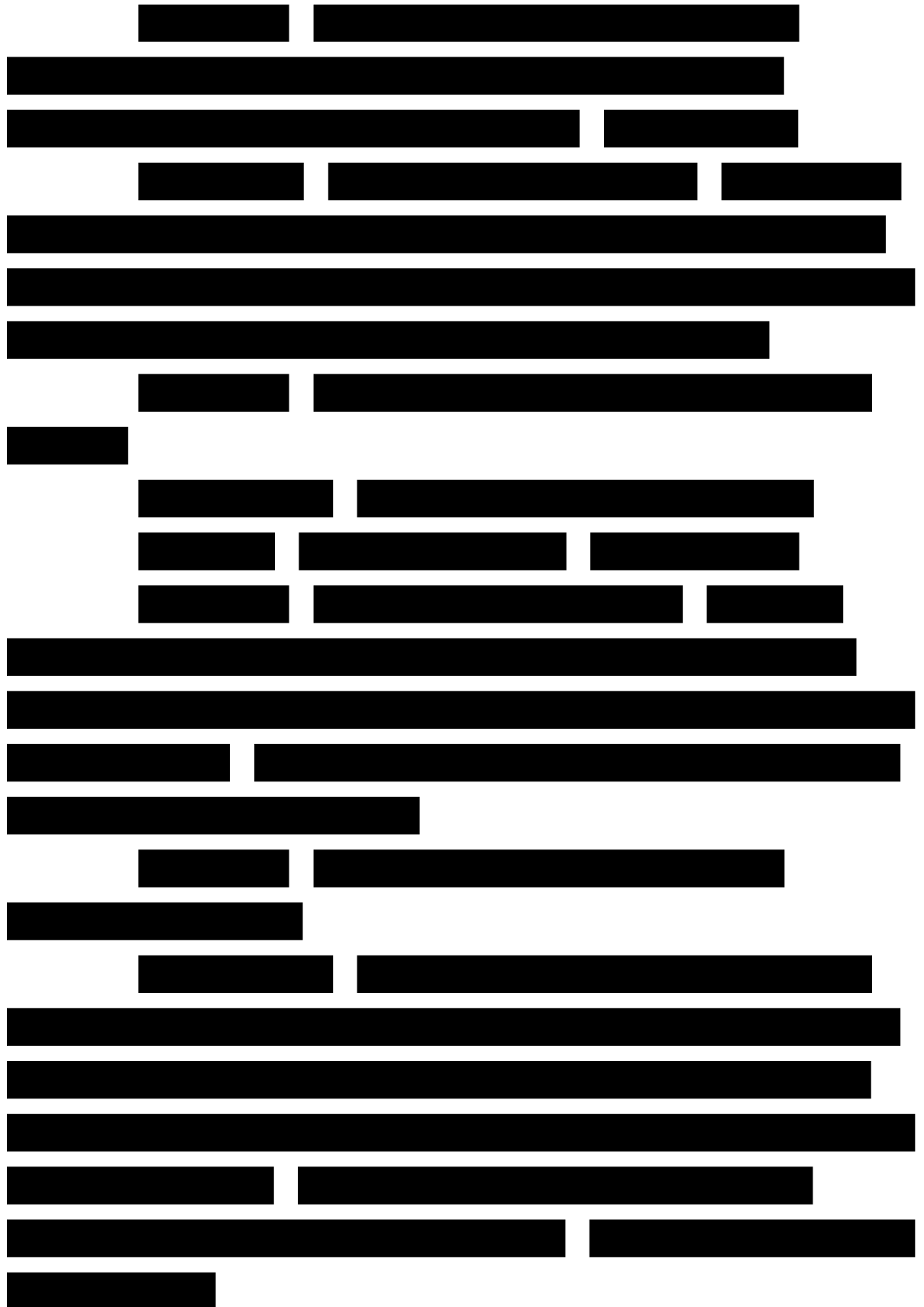


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17 (Court adjourned, to reconvene 3/16/17 at 9:30 a.m.)

18 CERTIFICATE

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

21 */s/Gayle McGuigan*

March 15, 2017

22 Gayle McGuigan
23 Official Court Reporter

Date

24 */s/Charles R. Zandi*

March 15, 2017

25 Charles R. Zandi
Official Court Reporter

Date