SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Friday, July 13, 2018, Volume 9, Afternoon Session, before the Honorable Suzanne R. Bolanos, at 1:32 p.m.

REPORTED BY:

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INDEX OF PROCEEDINGS

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
CHRISTOPHER JUDE PORTIER		2063		

EXHIBITS ADMITTED

(None.)

Friday, July 13, 2018

1:32 p.m.

Volume 9

Afternoon Session

San Francisco, California

Department 504

Judge Suzanne Ramos Bolanos

PROCEEDINGS

13:30:35

THE COURT: Good afternoon. Welcome back, Ladies and Gentlemen, Counsel, Dr. Portier.

Dr. Portier remains under oath, and Mr. Griffis, you may proceed.

13:32:42

MR. GRIFFIS: Thank you, your Honor.

CROSS-EXAMINATION (Continued)

BY MR. GRIFFIS:

Q. Dr. Portier, at the break we were talking about

13:32:48

the line review article and the attached data tables from the various regulatory studies that have been submitted over the years to various agencies.

Now, the IARC Working Group 112 could have looked at this data if they'd had the time to do so; right?

A. If they'd had -- if they would have had the time, yes.

Q. And when you dug into this data, it was after IARC, right, after Working Group 112?

13:33:17 A. That's correct.

Q. And it took you somewhere around six months to dig into the data the way you wanted to; right?

A. I'm not sure I'm totally finished looking at the data.

13:33:31 Q. Okay.

A. It progresses. It's a lot of data.

Q. More than six months?

A. Yes.

Q. Now, yesterday you identified seven rat studies

13:33:42 that you considered of significant quality -- of sufficient quality to evaluate in a carcinogenicity review, and you showed the jury tumors that you considered to be significant enough to bring to their attention in six of those; right?

13:33:56 A. Those were all tumors that had a statistically significant trend or a pairwise test.

Q. One or other; right?

A. One or the other.

Q. And sometimes those results were achieved by the

13:34:12 application of historical control data and sometimes not;

correct?

A. Correct.

Q. Okay. And there were also five mouse studies that you considered to be of sufficient quality to

13:34:24 evaluate for carcinogenicity purposes; right?

A. That is correct.

Q. And between the two -- and in all five, there were some tumors that you pointed out to the jury?

A. Correct.

13:34:34 Q. And the same things that we just said about the rat studies are true, sometimes it was trend, sometimes pairwise comparisons, and sometimes the results were generated with the use of historical data and sometimes not?

13:34:47 A. Correct. But my conclusions are drawn only on the trend test.

Q. And there were about 30 tumors in all?

A. Give or take. I've never actually sat down and counted them.

Q. All right.

A. Somewhere near 30.

Q. That's many, many more than IARC identified as significant?

A. That's correct.

13:35:06 Q. We're kind of way out beyond IARC here when

talking about the animal carcinogenicity data?

A. Yes. But it's more than was seen by EPA or EFSA either.

Q. You were an invited specialist on Working Group 112?

13:35:21

A. That is correct.

Q. And when you went off to France for Working Group 112, you were a consultant in litigation unrelated to glyphosate for a US law firm; right?

13:35:34

A. No.

Q. You had had conversations and were consulting in cell phone litigation; correct?

A. I -- I don't know what you're asking. I had no contract. I answer questions to people who call me.

13:35:51

Q. There were -- there was a law firm that called you and asked you questions about phone litigation; is that right?

A. There are many law firms that call me, yes.

Q. And you had spoken to them just a few months

13:36:02

before Working Group 112; right?

A. Well, that I don't know. I think it might have -- I can certainly tell you it was two years before Working Group 112, but it was very fragmented contact.

Q. The litigation -- you have a contract with them

13:36:21

now about that; right?

A. Yes, I do.

Q. You have a contract with that law firm about phone litigation; is that right?

A. Yes, I do.

13:36:27 Q. And that litigation is about cell phones allegedly causing cancer?

A. I assume so. I just advise them on the science.

Q. And the science on Plaintiff's side about which you advise them is based partly on Working Group 102,

13:36:44 which you were part of, which was about radio frequency and cell phones?

A. Not really. I mean, it's the same science. Some of it's the same science. There has been new science since then, but they're not asking me about 102.

13:37:00 They're asking me about specific studies and issues like that.

Q. What was the conclusion of 102 about radio frequency?

A. 102 was about radio frequency electric and

13:37:13 magnetic fields.

Q. And do they cause cancer?

A. They -- it was classified as a possible human carcinogen.

Q. And you didn't consider your conversations with

13:37:25 that law firm to be a conflict when you went off to

Working Group 112; Group?

A. Why would it be?

Q. You didn't consider it to be one?

A. Correct. I did not consider it.

13:37:33 Q. Your contract that you have now about glyphosate would have been a conflict had you signed it before; correct?

A. It would have been a conflict in my mind if I'd have even discussed it before.

13:37:43 Q. Yes, sir. You would -- it would have been something you would have felt the need to disclose and something that IARC would have required you to disclose; right?

A. Correct.

13:37:50 Q. And you signed that contract that we've just spoken about with this law firm for cell phone litigation and glyphosate litigation nine days after the Working Group 112 announcement was made; right?

A. I'd have to see the document to get the exact

13:38:08 date.

Q. Do you have -- I've given you a number of binders. Would you please find the one that says that it has deposition transcripts in it?

A. I have it.

13:38:28 Q. Okay. And there are tabs for the dates, and

find your September 5th deposition, please.

A. My tabs are not arranged like that. They're exhibits. This is depositions and expert reports.

MR. WISNER: Exhibit 2212.

13:38:58 Q. BY MR. GRIFFIS: Exhibit 2212. Turn to page 71 and look at line 12, please.

A. Which line 12? There are four line 12s.

Q. Page 71 of the -- there are four pages on a page.

13:39:18 A. Oh, you want page 71.

Q. Seventy-one of the deposition. Yeah. Seventy-one of the deposition. It's not a tree-saving document that we handed you.

A. Yes.

13:39:34 Q. Okay. So do you see that you testified that you signed an engagement letter signing up as an expert consultant with Plaintiff's counsel on glyphosate litigation on March 29, 2015?

A. That's correct.

13:39:57 Q. And that's nine days after the Working Group 112 announcement was made; right?

A. The Working Group 112 announcement was made publicly at the end of the Working Group meeting. You're talking about the *Lancet* oncology publication, is that correct?

Q. Yes.

A. Okay. So --

MR. WISNER: Objection, your Honor. Relevance. This does not pertain to this case.

13:40:19 THE COURT: Overruled.

You may answer.

Q. BY MR. GRIFFIS: Sorry. You were in the middle of an answer there.

A. That -- that -- they are two different things, 13:40:28 but this is after *The Lancet* oncology publication.

Q. Okay. So -- and you're right to orient me about that, sir. There was -- Working Group 112 met for a week, and I don't know -- how many days after that was the announcement made of the results?

13:40:42 A. I believe they make it the same day.

Q. And it's a standard thing with Working Group -- with IARC Working Group's that they publish results in *Lancet*, that's kind of a setup procedure; right?

A. Correct. About two weeks afterwards.

13:40:59 Q. Right. So about two weeks later it went out in *Lancet*, and nine days after that, you signed this; right?

A. That's correct.

Q. And that's for consulting in cell phone and glyphosate litigation?

13:41:09 A. That is correct.

Q. And it wasn't on Mr. Johnson in particular, it was just glyphosate litigation; right?

A. Correct.

Q. And of course, it's a paid contract?

13:41:16 A. That is correct.

Q. When you signed it, you immediately got a $5,000 retainer and are making $450 an hour for your work; right?

A. That was the agreement.

13:41:26 Q. Now, in 2015, you started lobbying agencies in Europe, the agencies that you were talking about earlier today, sir, and in the US, the EPA, in various ways against their conclusions about glyphosate not being a carcinogen; right?

13:41:45 A. That's wrong on two scales.

Q. Tell me what the two scales are.

A. First of all, I don't lobby agencies. That's -- that's a different thing than what I'm doing. I am responding to public comments. I'm responding to

13:41:59 documents that they put forth.

The second point is: I'm not challenging the glyphosate decision. I am challenging the way in which they reached that decision, the science that they used and the way they approached that science.

13:42:13 Q. So you don't mind the decisions you're

challenging the proceedings; is that right?

A. That's pretty much it, yes.

Q. Okay. And you -- so you were communicating with government regulatory -- you don't want to say lobbying. I understand. But you were communicating with government regulatory agencies and trying to change what they were doing; right?

13:42:26

A. Trying to get them to do what their guidelines tell them they should do, yes.

Q. And you thought they weren't doing that, and they should do it a different way? You were trying to influence them?

13:42:40

A. Correct.

Q. Now, for a little bit of context, agencies like EPA and ECHA and EFSA and everything -- and we're just about to explain what all those are -- they don't approve a product like glyphosate one time and then sit on them. They do reregistration reviews; correct?

13:42:50

A. More or less.

Q. Every 10 years, every 15 years. It may vary a little bit, but agencies regularly come back and re-review the science and look at anything new; correct?

13:43:04

A. Correct.

Q. And one of the things that we saw during your examination and in Mr. Wisner's opening statement was a

13:43:18

published version of an open letter from you and from a number of other scientists; correct?

A. That's correct.

Q. That's Plaintiff's Exhibit 293.

13:43:32 MR. GRIFFIS: Would you put up Slide 275, please? It's in evidence.

THE WITNESS: Let me correct that. That is not the published version of the open letter.

Q. BY MR. GRIFFIS: Okay.

13:43:40 A. That's a separate document. It's a different document. It's not the same.

Q. There was an open letter. There was a response to the open letter. And then there was a published -- you initiated a publication. And you were the initiator

13:43:52 of that; right?

A. Correct.

Q. And it was continuing the dialogue?

A. Correct.

Q. It contained some of the contents of the open

13:44:00 letter and some responses to what you'd been told in the response to the open letter; right?

A. Correct.

Q. And we'll get to all that.

MR. GRIFFIS: Could we have Slide 293, please?

13:44:10 MR. WISNER: Your Honor, I don't think I have

any objection to this. I don't know what's going on here. But this is exactly my point: Before stuff just gets thrown up to the jury, I need to see it to make sure I don't have any objections. And he doesn't have to get
13:44:25 permission from you to do it. I just have with every single document, so --

THE COURT: Okay. Is this the document that Mr. Wisner examined Dr. Portier about?

MR. GRIFFIS: Yes. It's Plaintiff's
13:44:35 Exhibit 293, in evidence.

MR. WISNER: I don't think I'll object. I just don't know what he's about to show them. He's just throwing up slides. And so if I can get a copy of it and say, "Yes, we're good," just to make sure.

13:44:49 THE COURT: Okay. All right. Why don't you --

All right. So the clerk is just reminding me it was published earlier, during Mr. Wisner's examination. Can you please refresh Mr. Wisner's recollection?

MR. GRIFFIS: Sure.

13:45:00 MR. WISNER: Your Honor, I don't object to showing the document. That's not what I'm objecting to. I don't even have an objection. These are not the documents. These are created slides.

Sorry. Can I see the Judge?

13:45:09 These are created slides that I -- that I don't

know what they're saying. We just saw deposition testimony --

MR. GRIFFIS: That was a mistake.

MR. WISNER: Okay.

13:45:18 MR. GRIFFIS: This is what we're putting up (indicating).

MR. WISNER: Okay. That's fine. I don't object to that. But before it gets shown, I just need to see it, to make sure it's not misappropriately -- you know,

13:45:26 these aren't the actual documents. They're slides, and there's, like, little cutouts and there's little things, and there's stuff on it that's actually not in evidence. So I just want to make sure -- you know, we're not doing anything fast and loose here.

13:45:37 So I just -- that was my objection. So no objection to this document.

THE COURT: Okay. Very good.

You may proceed.

MR. GRIFFIS: I may have been telling you the

13:45:45 exhibit number instead of the exhibit number. I'm sorry. It's not your fault.

Let me -- Slide 275 is the correct slide.

Q. This is the article that we were shown in opening and shown today during your examination, sir,

13:46:02 called "Differences in the carcinogenic evaluation of

glyphosate between the International Agency For Research on Cancer, IARC, and the European Food Safety Authority, EFSA"; right?

A. That is correct. It's the first page of it in a blown-up dialogue.

Q. Yes, sir. And the -- and you talk about two entities here, the European Food Safety Authority, which you describe as the primary agency of the European Union for risk assessments regarding food safety.

And you say that in October 2015, the European Food Safety Authority, EFSA, reported on their evaluation of the Renewal Assessment Report, RAR, for glyphosate that was prepared by the rapporteur member states during the Federal Institute For Risk Assessment, BfR; right?

A. Can I -- can I look at the document and make sure this is from my document?

Q. Sure.

A. The statement's correct.

Q. Yes.

A. I'm just not going to own the actual -- or I haven't written it unless I see it in my document.

Q. Well --

A. The statement's correct.

Q. -- it's not really important to me whether you wrote those words. What I just read is a factual

description of European reality; right?

A. Correct.

Q. Okay.

A. Yes, it is.

13:47:20 Q. That's the important part.

MR. GRIFFIS: You can take the slide down.

Q. So let's set the stage for this, the open letter and the follow-up publication that you had.

When Working Group 112 issued its report, Europe

13:47:33 was in the middle of one of these reregistration reviews that we just talked about; right?

A. That's what I understand, yes.

Q. Okay. And the European Food Safety Authority is one part of the European Union-wide regulatory authority

13:47:50 that is involved with pesticide and herbicide review. The other part being ECHA; right?

A. Yes.

Q. Okay. And there's an entity over them both. But those are the two primary regulatory bodies; right?

13:48:06 A. The European chemical agency maintains the methods by which people should review chemicals -- any chemical. And they have the authority to label those chemicals and classify them. They give that authority to EFSA for food and pesticides. And so EFSA then does

13:48:27 that.

Q. And they all work together in regulating herbicides and pesticides in Europe; right?

A. They work together to evaluate the data and make recommendations to the European Commission, who then does their thing.

13:48:43

Q. Okay. European Commission -- we're getting awfully -- more technical than strictly necessary for this trial.

A. They classify themselves as science agencies, not regulatory agencies.

13:48:53

Q. Yes.

A. So I'm trying to make that distinction.

Q. Okay. So they're science agencies, and they worth on the European Commission, which follows their advice or not, but makes the actual decision with legal authority; right?

13:49:02

A. Correct.

Q. And then we've heard that the German regulators, the BfR, were the rapporteur for this round of reregistration reviews. Would you please explain what that means?

13:49:12

A. I did earlier. They -- the industry submits a document that covers new science and old science, if they want to, related to the chemical they want reviewed. And it's the job of the rapporteur member state to then turn

13:49:29

that information into a report.

In many cases, they write their own report. In this case, they edited and modified the existing report.

Q. Okay. Each time there's a reregistration review, someone is selected -- or it happens in rotation. And this will be Germany, not England anymore, France, Belgium, et cetera. Someone will be selected to do a lot of the legwork and then report to the agencies.

The agencies have a confabulation about the data and just make decisions and make scientific evaluations. And both report up to the European Commission. That's the process; right?

A. That's a lot of process you put onto that one statement.

Q. Yes.

A. The rapporteur's job: Draw the draft, write up the draft that is in -- considered by EFSA. And when you say it's considered by EFSA, it's not the people at EFSA. It's the committee that EFSA brings together from all the member states that considers it. Then goes back and forth until they're happy with it.

Q. So there's not some pan- -- European panel of scientists making decisions for all of Europe. The various regulatory agencies of the countries, which continue to exist, creates this panel. And they -- they

review the data; right?

A. Correct.

Q. Okay.

A. They choose who goes to the meetings.

13:50:58 Q. Right.

Now, this published letter -- the differences letter that we just looked at that was published -- that started out as a couple of emails from you; right?

A. The open letter started out as a couple of

13:51:16 emails.

Q. Okay. The open letter morphed into this published document; right?

A. Getting a response and turning into a published document with less and more detail, depending on what you

13:51:27 look at.

Q. Okay. Anyway, the open letter started out as two emails?

A. I -- I would have to look at the records.

Q. Sure. I'll show them to you in a moment.

13:51:38 A. They started out as a blitz of emails.

Q. You sent an email on November 9th. And you can take a look in your Trial Cross Binder Number 2, Tab 2404, sir.

A. 240 what?

13:52:02 Q. Four.

It's an email from you on November 9th, 2015; right?

A. There are emails before this.

Q. Okay.

13:52:34 A. But, yes, this is my email.

Q. Okay. And I'm just going to read the first paragraph. And read along to make sure I get it right, sir.

"Dear all" -- and this is addressed to a number

13:52:44 of your Working Group colleagues; right?

A. Yes.

Q. Okay. "Dear all, this week the European Food Safety Agency, EFSA, will release their reassessment of glyphosate. In this review, they will conclude that

13:53:02 glyphosate has no carcinogenic potential. This creates two problems, as I see it. The first is that this weakens the strength of the IARC Monograph program to stimulate change in how some of these agents are reviewed and addressed. The second is that it suggests that we

13:53:21 did not do our assessment adequately and that had we seen all of the data they saw, we would have gotten a different answer. I do not intend to let this happen."

That's what you wrote?

A. That's what I wrote.

13:53:34 Q. Okay. Now, sir, you viewed the European

regulators' eminent conclusion that glyphosate has no carcinogenic potential to be a threat to the IARC Monograph program; right?

A. I'm sorry, could you say that again?

13:53:50 Q. Yes, sir.

You viewed the European regulator, EFSA's, eminent conclusion that glyphosate has no carcinogenic potential to be a threat to the Monograph program -- the IARC Monograph program?

13:54:06 A. I viewed their appendix that they did, which compared the IARC review with their review, to be a threat to good science, that IARC was leading on how to evaluate agents for carcinogenicity.

Now, if that's not what it says here, then that

13:54:28 is what I meant for it to say. Because that was the major concern. BfR had written an appendix and gone through and said, "Here's what we did. Here's what they did." And it was simply wrong.

Q. And they did that because your findings made a

13:54:45 splash, and they were pointing out to whoever was paying attention to them how, in their view, their analysis differed from yours and justifying whatever conclusions differed from yours; is that right?

A. Correct. And they were doing that without

13:54:58 having allowed the Working Group to comment on their

document. Hence, the only way for the Working Group to respond was in a public forum since that was the only forum available to them.

Q. You have nominated yourself to be a director of IARC, the director of IARC?

13:55:16

A. For the recent consideration of a new director, yes, I did.

Q. And when will that be decided?

A. It's been decided.

13:55:29

Q. Are you?

A. No.

Q. Okay. The next communication, the next email I'd like to call your attention to, sir, is Defense Exhibit 2403 in that same binder. And that's an email from you to about 500 scientists asking them to join in on your open letter; right?

13:55:58

A. I'm sorry, which one did you say?

Q. 2403.

A. And this is in the same binder?

Q. Apparently not. You sent such a letter, right, sent such an email?

13:56:22

A. I have a 2404, but no 2403.

Q. That's okay, sir. I don't need to put it up.

You can recall sending a letter to about 500 scientists asking them to join in on your open letter;

13:56:38

right?

A. I don't know that it was 500, but it was way more than a hundred.

Q. It was in that ballpark?

13:56:49 A. 500? I don't know, quite honestly.

Q. Okay. Fair enough.

And ultimately 96 people signed on to the open letter; right?

A. That is correct.

13:56:59 Q. And those are the same -- well, including you, although it was actually 94 when it was published, but anyway, we're close.

It's the same people that were ultimately on the publication, with maybe a couple people dropping off?

13:57:13 A. I think the 94 refers to the number of organizations that these people belonged to, but I think it was 96 people.

Q. Okay, 96 people, 94 organizations?

A. Yeah.

13:57:24 Q. All right. And in your email to the scientists, you didn't tell them that you'd been hired by plaintiff's lawyers in litigation; right?

A. That I was consulting with a law firm who was in litigation. No, I did not tell them that in that letter.

13:57:43 Q. In that email?

A. In that email.

Q. Now, you don't consider the open letter or the differences publications that we have seen up on the screen to be a peer review by external scientists of IARC's work; right?

13:58:01

A. That's a -- it's an interesting question. To some degree, it is because it's comparing the IARC Monograph to the -- to the EFSA report, but then some of the authors were part of the writing group for the IARC Monograph. So -- and you don't peer review your own work.

13:58:25

So it's a mixture in that. They're -- they're just documents.

Q. You certainly don't think they went through the IARC review process and looked at all those documents and did the sort of analysis and conversations that you did at Working Group 112?

13:58:37

A. But that's not how peer review works in any situation. If I submit a paper for publication, the peer reviewers don't go and drag up every one of my references and read the reference and compare it against my paper.

13:58:54

Q. The letter -- the email -- I keep saying "letter," I'm sorry.

The email to the approximately 500 scientists was November 11th and the open letter was November 27th?

13:59:08

A. Something along those lines. I thought it was longer than that. It was a tremendous amount of effort.

Q. You don't how much of any evidence the various people who signed on looked at before agreeing to sign on; right?

13:59:25

A. I can certainly vouch for some of them having looked at a lot of the evidence because they kept changing the document. Others didn't make any comments.

Q. A lot of people just signed on and some people were more interested in making edits?

13:59:40

A. I -- it's -- I can't comment on how much each of the individual scientists read on the background documents that were sent.

Q. Now, your open letter describes all of you as independent scientists in the first line, and you're the first signatory and the person to get in touch with if anyone has a question; right?

13:59:53

Look at 2735 in the binder if you need to take a look, sir.

MR. WISNER: Objection. Compound. There's four questions in there.

14:00:07

THE COURT: Can you please break that down, Mr. Griffis, one question at a time.

MR. GRIFFIS: Go to 2735 first, sir.

THE WITNESS: Yes. That is the letter.

14:00:29

Q. BY MR. GRIFFIS: Okay. And the first line says, "We are a group of independent academic and governmental scientists"; right?

A. That's what it says.

14:00:43 Q. And if you turn to the signature page, page 8, signed sincerely, Professor Christopher J. Portier, corresponding author; right?

A. Yes.

Q. And corresponding author is the person you get 14:01:10 in touch with if you have a question?

A. That is correct.

Q. Okay. And that letter doesn't disclose that you, the corresponding author, was a paid consultant in litigation against glyphosate at the time; right?

14:01:22 A. No, it does not. But, of course, it does say the views expressed in this letter are the opinions of the scientists who are listed below and do not imply any endorsement or support for these opinions by any organization to which they are affiliated.

14:01:39 It is clearly describing it as our independent opinions regardless of who pays our salary.

Q. Now, EFSA responded to your open letter with its own open letter; correct?

A. Correct. That was appropriate.

14:01:52 Q. Okay. And this was the -- earlier you said you

were kind of forced into this public forum to engage with them. But forced or not, that's the forum in which you had this scientific exchange about your opinions about how glyphosate should be evaluated; right?

14:02:13 A. And about some of the things that they did, yes. But to be clear, the letter went to Mr. Andriukaitis, who also -- who responded and asked EFSA to respond directly to me.

Q. So you were writing down -- sorry, you were

14:02:25 writing to the European Commission?

A. Correct. Well, to Mr. Andriukaitis --

Q. The President of the European Commission?

A. No. The Commissioner for Health and Food Safety.

14:02:34 Q. The responsible executive at the European Commission who said please respond to Dr. Portier --

A. Correct.

Q. -- and EFSA did so?

So the communications were coming back to you

14:02:45 from EFSA; right?

A. Correct.

Q. Okay. And turn to 2747, please.

A. Okay.

Q. Are you there? 2747 is the letter that was sent

14:03:21 to you from EFSA; correct?

A. Correct.

MR. GRIFFIS: I move the admission of 2747, your Honor.

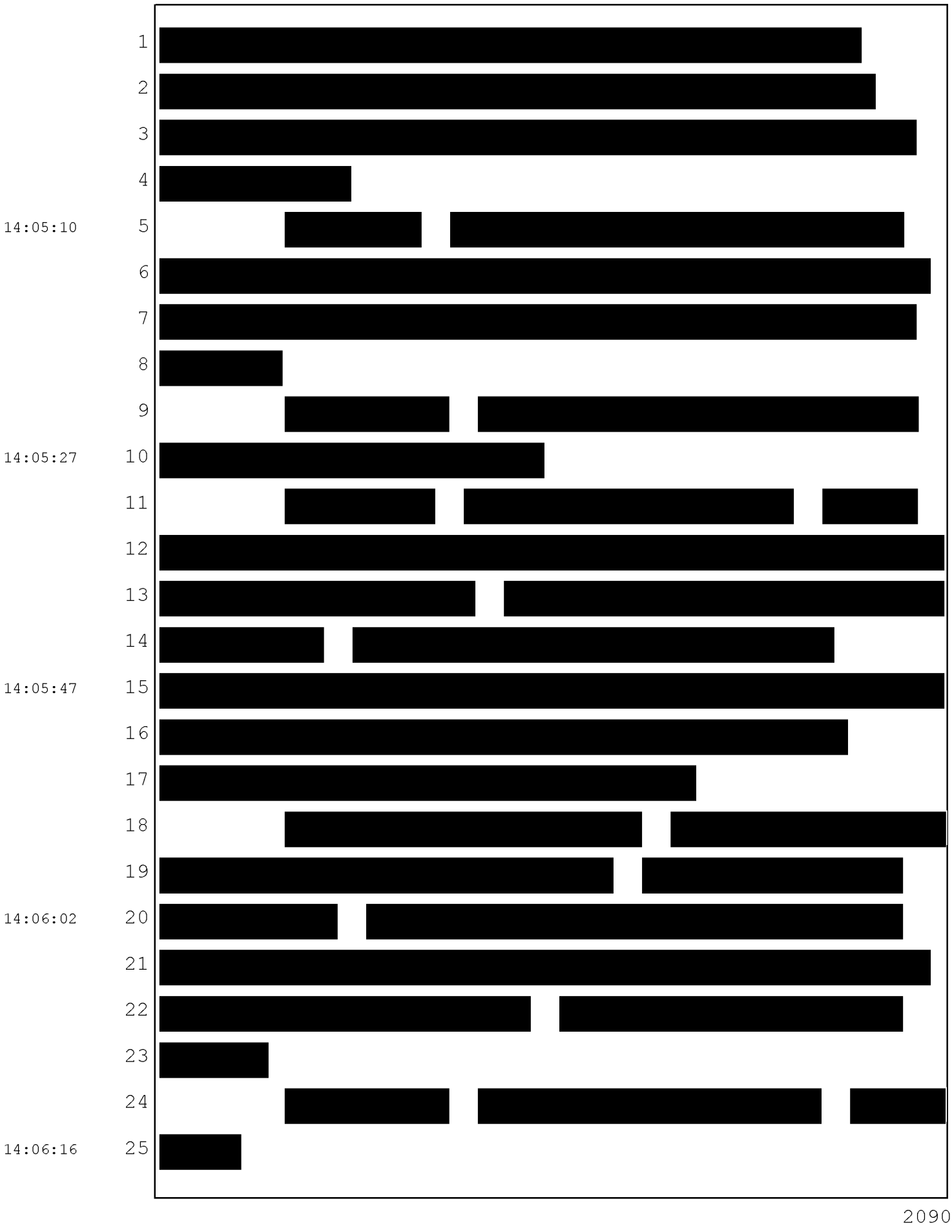
MR. WISNER: Objection.

14:03:28 THE COURT: Any objection?

MR. WISNER: Yeah. Objection, hearsay.

THE COURT: Okay, approach.

(Sidebar.)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[redacted]

(End sidebar.)

THE COURT: You may continue.

Q. BY MR. GRIFFIS: Okay. Sir, we are on 2747, sir, and this is the open -- this is the response to the open letter that you received from EFSA; correct?

A. Correct.

Q. Okay. And take a look at the bottom of the first page, please, where they're talking about the IARC assessment as a possible first step in a full assessment. You were told, sir, by EFSA that in their view, IARC violations can represent a first step in --

MR. WISNER: I don't see where you're reading.

Q. BY MR. GRIFFIS: Okay. I'm sorry. At the bottom of the first page.

A. Sorry, I've got the annex here. Okay. Here.

Q. The bottom of the first page under the header, IARC assessment is a possible first step in a full assessment.

14:08:13 Are you there?

A. I don't see those words exactly.

Q. There's a header that says that.

A. IARC assessment is a possible -- okay, you're looking at the header.

14:08:25 Q. Yes, sir. Now I'm looking at the paragraph under the header.

As the WHO, the World Health Organization states on its website in the preamble to the IARC Monograph. So they're talking about the preamble to the Monograph which

14:08:39 we discussed earlier; right?

A. Yes.

Q. Okay. As the WHO states in the preamble: "IARC evaluations can represent a first step in carcinogen risk assessments to be considered if available by national and

14:08:55 national authorities such as EFSA when carrying out their own assessments. I agree that IARC carries out an important role in the treating assessment of the carcinogenic potential of agents. However, we should not compare this first screening assessment with a more

14:09:12 comprehensive hazard assessment done by authorities such

as EFSA, which are designed to support the regulatory process for pesticides in close cooperation with the member states in the EU."

Did I get that right?

14:09:25 A. You read it right. I don't agree with it.

Q. On the next page, sir, the second paragraph begins: "EFSA's assessment of glyphosate is an essential part of the EU regulatory system in relation to pesticides, widely regarded as one of the strictest in

14:09:48 the world."

Do you disagree with that?

A. I don't know if it's widely regarded as one of the strictest in the world. I know from my evaluation of what they did for glyphosate, I don't regard them as

14:10:05 strict, and that's certainly true of my 95 other co-authors.

Q. You know what they think. You need that that's what they think?

A. We wrote a letter after we got this response.

14:10:23 Q. Turn to page 6 the appendix, please, or the annex.

And take a look at the headings first to get oriented, sir. This is about evidence from animal carcinogenicity studies and statistical assessments --

14:10:46 A. Uh-huh.

Q. -- of that; right?

A. Uh-huh.

Q. Which was a lot of your testimony with the mouse studies and the rat studies and the tumors; right?

14:10:54 A. Well, other things as well, but that was some of it.

Q. EFSA is of the opinion that the planning of a study before the initiation of the experimentation as established in the respective protocol, which includes

14:11:09 the planned statistical analysis, is a key element in assessing the quality of the study. Therefore, deviations from the statistical analysis used by the study authors should be limited and properly justified; correct?

14:11:23 A. That's what it says.

Q. And they say this is in line with OECD recommendations.

Would you tell the jury in a sentence or two, if you can, what OECD recommendations are.

14:11:35 A. OECD is the Organization of Economic and Cooperative Development. It is an organization that many nations join to try to make things like pesticide review and pesticide evaluation kind of standard.

Q. So they're quoting OECD. The OECD has

14:12:05 recommendations for many, many, many things. That's just

one of them that you just told us; right?

A. Yes.

Q. Okay. And they're quoting OECD recommendations, and I'm going to look at the second sentence there starting "therefore."

14:12:17

"Therefore, the statistical methods most appropriate for the analysis of the data collected should be established at the time of designing the experiment and before the study starts."

14:12:28

Right?

A. That's what it says.

Q. Now the original authors --

A. It goes on to say something else. Can I read a little further?

14:12:37

Q. Yes.

A. Okay. It goes on to say -- where did you stop? I'm sorry.

Q. I stopped with the italics.

A. You didn't take it all the way to the bottom; right?

"Therefore, statistical methods most appropriate for the analysis of the data collected should be established at the time of designing the experiment and before the study starts."

14:13:05

So the problem here is, the word says the -- the

most appropriate method of analysis. So they're assuming that just because they got an analysis and it was the planned analysis, it's the most appropriate analysis.

My argument with them and why they didn't answer it is that the analysis that was done was not the most appropriate analysis.

Q. Yes, sir. You disagree with the OECD guidelines on that.

A. The OECD guidelines that are being quoted here I do not disagree with, but they clearly say the most appropriate must be established at the start of the study. And if they don't use the most appropriate, then that should be questioned, and that's my questioning here.

Q. Okay. It's true that the original authors of each of the seven rat and five mouse studies that you told the jury about did not conclude applying the statistical methods that they had decided on before the study started, that any of those tumors were compound related; correct?

A. I can't say that. I don't have the full study reports. Their conclusions would be in the study reports. All I have is their data and EFSA's reiteration or EPA's reiteration of what they think. But I don't know what the original authors thought.

Q. Okay. Let's go to the last paragraph of that section, sir. We're still on the statistical assessment section.

"As indicated in the open letter and some studies, the same data are statistically significant or not, depending on the selected statistical method."

And you agree with that, sir; right?

A. Yes, I agree with that.

Q. And they say: "It should also be noted that there are no valid studies with statistically significant effects confirmed by both statistical approaches."

Correct?

A. That is not correct.

Q. What is the exception?

A. I'd have to go to my notes, the thing we put up yesterday. There are several that both have a fissure exact test, pairwise wise test being significant and the trend being significant.

Q. Okay. Are those -- you later in this process, in your exchange of communications with the European regulators, told them about eight additional tumors that you believe you'd identified in some of these studies; correct?

A. And in fact, they missed around 15, EFSA. Even after I gave them the eight, I found out I was wrong and

there were more, through someone else's analysis.

Q. And they say that they -- based on these results, the biological relevance of the results, see below, was balanced against the inconsistency observed in the statistical results; correct?

14:15:53

A. Yet their guidelines specifically say that if you see a positive result in a trend or a pairwise comparison positive result, it should be considered positive.

14:16:05

So by arguing that they're inconsistent, they're arguing that they have to have both, and that is in direct violation of their own guidelines.

Q. You testified earlier today that EPA was so amazingly wrong in its evaluation of glyphosate and the conclusions that it came to.

14:16:23

A. The eventual conclusion that there's no -- I forget their category -- no evidence supporting carcinogenicity or something along those lines.

Q. Yes.

14:16:37

A. I find that conclusion astonishing.

Q. Do you also find EFSA's conclusion astonishing and so amazingly wrong?

A. Yes, I do. By their own guideline, they --

Q. Sorry.

14:16:54

A. Let's -- we can take a simple example. Their

guidelines clearly state that if you see two positive animal bioassays, it should be classified as 1B. That's -- that's all that's required for their 1B classification by their own guidelines.

14:17:12 And I've demonstrated over and over again that there are much more than two positive findings in these data. Hence, they have not followed their guidelines, and so I do disagree with them.

Q. They do know what their guidelines are; right?

14:17:25 MR. WISNER: Objection. Speculation.

THE WITNESS: I know what their guidelines are. So do they.

THE COURT: Overruled.

Q. BY MR. GRIFFIS: On page 9, sir. On page 9 --

14:17:40 are you there?

A. Yes, I am.

Q. On page 9 we're in the middle of them addressing various specific tumors that you told them existed in these studies. They talked about renal tumors reported

14:17:52 in mice on page 8, hemangiosarcomas reported in mice on page 9, and then malignant lymphomas reported in mice on page 9. And they go on, and I won't read them all.

That's what's happening on these pages; right?

A. These are not tumors I told them about; these

14:18:14 are tumors they told me about. And I was commenting on

each of their evaluations for each of these tumors.

Q. Okay. Let's go back to the header section.

Additional considerations of the tumors reported in the IARC Monograph, and underneath they say for the assessment of tumors in mice, IARC and EFSA considered two and five studies respectively; right?

A. That is correct.

Q. IARC considered two. Are those the two studies we looked at earlier, the Atkinson study, and they each reported one statistically significant and it wasn't lymphoma; right?

A. That's correct. Neither were malignant lymphoma. But let's make this clear what actually happened. IARC reviewed, and in the IARC review, they used the trend test to find the significance they were talking about. Regardless whether you like the P value or not, that's what they used.

In response, BfR went back, and for some of the tumors they had in mice, including the two observed by IARC, they went and tested all the other studies of the same animal type to see if they saw the same tumors. And when they did that, they found multiple tumors which were part of this discussion.

So they found things after the IARC review because they didn't apply the most appropriate method,

but only to a select number of tumors.

Q. They found additional tumors and concluded, based on their complete review, not just of that issue, that glyphosate was not carcinogenic in humans; correct?

14:20:02 A. That's correct.

Q. Okay. Under "Conclusion," and this is the conclusion of the animal section, sir, on page 10.

Are you with me?

A. Yes, I am.

14:20:27 Q. End of that paragraph, the conclusion paragraph: "In fact, the statistical trend without assessing the biological relevance of the result seems to be the only justification in the IARC Monograph for deviating from the previous evaluation of the same animal studies by the

14:20:46 WHO/FAO JMPR expert group, which concluded that glyphosate does not have carcinogenic potential."

Correct?

A. That's what it says. I still disagree with it. They -- they wave a flag of biological evaluation, and

14:21:07 yet not once in this document or any of their documents do they explain what they mean by a biologically credible finding in anything.

Q. What is the WHO/FAO JMPR expert group, please?

A. That's the World Health Organization, Food and

14:21:30 Agriculture Organization. Both are UN organizations.

This is a committee that sits within WHO but is jointly run by both that reviews pesticide residues in food and makes recommendations for pesticide residue in food, levels that are considered safe and to be used in
14:21:56 commerce really across nations.

Q. The JMPR is a World Health Organization UN agency in the same sort of way that IARC is; right?

A. No. JMPR is a subcommittee. It's just a -- it's a small group of four people who run a committee
14:22:15 that brings people in from the outside to make decisions.

Q. That expert group that operates under the auspices of the World Health Organization disagrees with IARC?

A. No, they do not.

14:22:26 Q. They concluded that glyphosate does not have carcinogenic potential; right?

A. You have to go further. You have to read their entire statement. It goes beyond that. It says in -- from exposures in residues in food. So they're talking
14:22:48 about a very, very specific narrow bit of this.

Q. Okay. I have two questions for you, sir, about that. First of all, they look at the epidemiology evidence and the animal studies and the mechanistic evidence, the three pillars that you talked about today,
14:23:07 right, and yesterday?

A. That is correct.

Q. Okay. And my second question is: Do you agree with them about food?

A. You know, I haven't done a risk calculation for the level of exposure that comes from food. So I can't -- I don't disagree or agree with them. I haven't done the calculation.

Q. Okay. It may well be that they're right that glyphosate does not have carcinogenic potential as far as food exposure risk?

A. I want you to read the exact conclusion they had so that I'm not misstating it and you're not misstating it. Do we have a copy of that?

Q. I'll try to get it for you a little later. I don't have it right in front of me.

A. Then I won't agree or disagree until I hear the exact statement so it's clear.

Q. Yes, sir.

Without seeing that, you don't know whether you agree or disagree, based on the evidence that you've reviewed, that glyphosate has carcinogenic potential for humans through food exposure?

A. I haven't looked at all of the literature on how much glyphosate is in food.

Q. Okay.

A. That was not the focus of what I was doing.

Q. Yes, sir. So you can't say. You would want to do something than you have done so far?

A. I would have to do a lot of work to agree with them. Let's put it that way.

14:24:25

Q. Based on what you've reviewed, you don't disagree with me right now?

A. Again, I want to see the full statement.

Q. Okay. You're not agreeing or disagreeing?

A. Correct.

14:24:38

Q. Okay, let's look at the summary paragraph and then we'll move on from this document, sir. Page 12.

Do you see where I am? Summary. I'm looking at the second paragraph.

A. Okay.

14:24:55

Q. "As reported in the EFSA conclusion, EFSA 2015 A" -- and this is the one that you were upset about in the first place when you wrote your open letter; right?

A. The appendix mostly, but yes.

14:25:07

Q. "As reported in the EFSA conclusion, there is very limited evidence for an association between glyphosate-based formulation and non-Hodgkin's lymphoma and overall evidence is inconclusive for a causal or otherwise convincing associative relationship between

14:25:26

glyphosate and cancer in human studies. There is no evidence of carcinogenicity in either rats or mice due to a lack of statistical significant in pairwise comparison tests. Lack of consistency in multiple animal studies and slightly increased incidences only at dose levels at or above the limit dose/MTD, maximum tolerated dose, lack of pre-neoplastic lesions and/or being within historical control range."

14:25:45

"The statistical significance found in trend analysis in non pairwise comparison per se was balanced against the former considerations. Considering a weight of evidence approach, taking into account the quality and reliability of all available data, it is concluded that glyphosate is unlikely to be genotoxic *in vivo* and does not require a hazard classification regarding mutagenicity according to the CLP regulation."

14:26:05

14:26:22

Did I read that correctly?

A. You read that correctly.

Q. And is that so amazingly wrong?

A. Yes, it is on a number of different scales. Shall I go through it with you?

14:26:37

First of all, there is no such category in the CLP in their guidance document called "very limited evidence in humans." So which is it? Is it limited evidence or is it inadequate evidence?

14:26:54

They've -- they've twisted their guidelines so that they've created a new category that nobody really knows what it means.

And then as far as their five reasons, every single one of them is pretty much not recommended, I mean discouraged in their guidelines, and that's in my expert report. I've walked through all of that.

I'm more than happy to go and look at it and bring it up to you, but this is -- their five or six reasons are exactly the reasons we're concerned about what they're doing scientifically.

Q. You find EPA's assessment of glyphosate to be so amazingly wrong and EFSA and BfR; is that right?

A. Well, there's no difference between EFSA and BfR. It's the same document.

Q. BfR did a renewal assessment report?

A. Correct.

Q. We haven't looked at that yet; right?

A. Well, the comments we made to EFSA were on the renewal assessment report and its addendums.

Q. And you told us earlier that when the rapporteur issues a report like the renewal assessment report, EFSA does its own independent evaluation of that; correct? It doesn't just say, okay, this is our conclusion now and cut and paste it?

A. EFSA characterizes the peer review. I characterize it as an interagency, intergovernmental committee of people appointed to make comments on the document. But that's what they do.

14:28:51 Q. Okay.

A. They're not really independent people because most of them are somehow associated with the governments that they come from, and it's all one general network.

Q. Okay. In May 28th, 2017, you wrote another open

14:29:08 letter to the President of the European Commission, a new president now, President Juncker?

A. Correct.

Q. About the review of carcinogenicity of glyphosate. Now it was about EFSA and BfR and ECHA as

14:29:26 well; right?

A. Do you have the document?

Q. I do. It is tab 3172.

A. Yes.

Q. Yes, you're there, or yes, what I said is

14:29:46 correct?

A. Yes, I am there. And yes, what you said is correct.

Q. And you critiqued their review of glyphosate and told them they were getting it wrong as you had done

14:29:59 about previous reviews in previous letters; right?

A. I briefly summarized the contents from the previous letter because I told the President I didn't want to waste his time. And the purpose of this was really to talk about the tumors that they had missed that
14:30:18 were known then that were not in their risk assessment and yet should have at least been mentioned.

Q. You got a response from BfR and EFSA and ECHA; correct?

A. It was a combined response from all three of
14:30:37 them in one letter.

Q. Yes, sir. One response from all three. That's on 3173.

A. This is not all of it. I got a much more detailed letter than this. Oh, 3178 is the letter I got
14:31:11 from EFSA, which was combined with BfR and ECHA, but the letter itself came from EFSA.

Q. And there's an annex to that?

A. Yes. It's the letter, and then the annex -- the annex gives the details.

14:31:35 Q. The annex gives detail about the scientific analysis about which they're disputing with you?

A. It talks about the tumors I raised concerns about.

Q. And the date here is 05 "lug" 2017, and I've
14:31:51 been informed that that stands for *lugio*, which is

Italian for July. Am I remotely right?

A. That's my understanding as well.

Q. Okay. So July 5th, 2017.

In the reply is it says that both ECHA and EFSA
14:32:12 processes were referred to in your letter. I'm in the first paragraph. And in response to a request from the European Commission, this reply has been jointly prepared by the two agencies. And then they say that the German authority, BfR, also has contributed to the response;
14:32:33 right?

A. It says the response was prepared jointly by EFSA and ECHA and that BfR played an important role in the glyphosate evaluation, and it has contributed to this response.

14:32:56 Q. Okay. So it's kind of from all three of them?

A. It's from the two of them, I suspect. They controlled it and they might have taken some of BFR's comments.

Q. On page 1, the third paragraph: "In your letter
14:33:11 you express the view that both EFSA and ECHA, E-C-H-A, failed to identify all statistically significant cancer findings in the chronic rodent carcinogenicity studies with glyphosate. To support this argument you refer to a reanalysis of eight specific tumor incidences reported in
14:33:29 the original study reports from seven animal

carcinogenicity studies."

Am I right so far?

A. That's what it says.

Q. All right.

14:33:36 "Having carefully assessed the reasoning behind the arguments you make, EFSA and ECHA confirm that the original assessments considered all relevant findings. Our detailed technical assessment you will find in the annex to this letter. We consider that none of the

14:33:51 specific findings you bring forward are relevant for the hazard and risk assessment of glyphosate. In our view, the results of any statistical analysis and its related uncertainties have to be weighted for their biological relevance to arrive at a comprehensive toxicological

14:34:09 evaluation of the substance at hand."

Do you disagree with that?

A. That's what they wrote.

Q. Okay.

A. And I don't disagree with it, but they have yet

14:34:17 to show me what they mean by biological relevance that is not there for the tumors that I've been arguing with them about.

Q. You believe that ECHA, along with EFSA and BfR, are completely wrong about this and not following their

14:34:38 own procedures; is that right?

A. Absolutely.

Q. And you've said earlier that you found the EFSA's position to be astonishing or was it EFSA or was it EPA that you said that about?

14:34:53 A. Both of their conclusions that there's no data to support carcinogenicity I find astonishing, especially EFSA, where they say the human evidence is limited. When I've asked in public what very limited means, they said, well, it's limited.

14:35:13 So I find it difficult to understand how when they say the human evidence is limited, meaning there is an association, their definition is in here. Can we read their definition of what "limited" means?

Q. Yes, certainly.

14:35:27 A. That was in that first letter.

Q. When you find it, tell me where to look.

A. It's EFSA's response to my -- the open letter. Does anyone know which tab it is? I think it's here. Tab number 2747.

14:36:21 Yes, here it is. On page 2 at the bottom of page 2. Their definition of limited evidence of carcinogenicity in humans.

"A positive association has been observed between exposure to the agent and cancer for which a

14:36:38 causal interpretation is considered to be credible, but

chance, bias, or confounding could not be ruled out with reasonable confidence."

If that doesn't sound familiar to you, that is the exact wording used by IARC. They are identically the same.

14:36:54

So my concern, on simpler -- simplest grounds, they found there is an association. Causality is reasonable, but it's not quite there, and yet they conclude that there's no evidence of carcinogenicity.

14:37:12

That to me is an astonishing finding. Totally illogical.

Q. Yes, sir. You're telling the jury that they have exactly the same standard, same definition of limited evidence of carcinogenicity and the other criteria as well; right?

14:37:28

A. Correct.

Q. As IARC, and when they looked at the evidence that they reviewed with regard to glyphosate, they reached a very different conclusion?

A. No. They called it very limited, and when asked in public what that means, the answer I've gotten has always been limited evidence.

14:37:38

Q. Let me try again. They have the same standards with regard to -- as IARC to -- sufficient evidence of carcinogenicity in limited evidence of carcinogenicity,

14:37:55

and their overall conclusion about whether glyphosate is a human carcinogen is very different than IARC's?

A. No. But their conclusion about the human epidemiology evidence is very limited. And so when 14:38:16 asked -- because that's not a category -- they call it limited.

So they're saying the epidemiology evidence, there is an association, but in their conclusion, they're saying there is no evidence of carcinogenicity.

14:38:28 Those do not agree because if you have an association, there is evidence. So if nothing else, they should have put it into the inadequate category and not in the no evidence category.

Q. Will you turn to regulatory binder 1. It's a 14:38:47 different binder than the one that's open in front of you now, sir.

A. Certainly. Volume 1.

Q. Yes, sir. Go to 2323, please, and tell us what that is?

14:39:40 A. This is -- I'm sorry, this is EFSA's formal announcement of the conclusion of their peer review for glyphosate. It was published in the EFSA journal in -- well, 2015. January 2015.

Q. And this is what you were upset about in the 14:40:01 open letter. It's what you referenced in the open

letter; correct?

A. No, the open letter was in November. It was --

Q. The first one, I meant.

A. Yeah, the first open letter was before this final conclusion. This final conclusion came out after the open letter, but I got them confused here. This can't possibly be January -- this is not January 2015. This is toward the end of 2015.

It's not this. This carries over a summary of some of the information in the renewal assessment report.

Q. Take a look at 2320. See if that's it.

A. This is the EFSA committee opinion.

Q. Okay. And this is something that you critiqued in the second open letter; right?

A. To some degree, yes, but mostly to the fact that they also missed the same tumors.

Q. And in your correspondence with the European authorities, you've been critiquing 2320, 2323, 2071, and probably a bunch of other regulatory statements and pronouncements that we don't have in this binder; right?

A. I did not critique 2071. That's their classification and labeling guidelines. This is the one for glyphosate specifically.

Q. Yes, sir.

A. Yeah, there are aspects of this that are again

scientifically unsupported.

Q. Okay. Let's take a look at 2320, sir. Would you identify this for the jury?

A. The title is "The Opinion of the Committee For Risk Assessment on a Dossier Proposing Harmonized Classification and Labelling at EU Level," and then the chemical name is glyphosate, iso, semicolon, then other names for glyphosate. Chemicals have multiple names that mean the same thing.

Q. And what is the RAC, the Risk Assessment Committee?

A. It's a committee set up by ECHA. I don't quite understand how it's set up and how the membership is organized. It's multiple people in multiple disciplines who review chemical listings and other things for the European Commission.

They consist of, I think, maybe 25 people, but I can't be certain, with expertise in a variety of different areas. As far as I know, there's only one epidemiologist or two on that committee.

So because they have to have engineers and they have to have agricultural experts and exposure experts and toxicologists and all kinds of people.

Q. Would you take a look at page 26 of Exhibit 2320, sir, which is the European chemicals agency

RAC report you were just describing.

A. Page 26 of 2320. Okay.

Q. Yes, that's right.

And if you flip back for a moment to 25, do you see that this is a section called "Comparison With the IARC Evaluation."

Correct?

A. Correct.

Q. And let's stay there a moment. The first thing that ECHA reports is: "The IARC report is based on publicly available studies and does not consider data from unpublished reports, whereas the CLH report and the RAC opinion are based on both unpublished reports and publicly available studies, resulting in a much broader data set for *in vivo* genotoxicity studies."

"In contrast to the RAC opinion, the IARC report includes studies in non-mammalian animal species."

First of all, did I read that right?

A. You did read that correctly.

Q. Is it correct that the Working Group 112 report is based on publicly available studies and doesn't consider data from unpublished reports?

A. That is kind of correct. The Working Group did work with one of the review papers on the Ames test, which is a genotoxicity -- a mutation test done in

salmonella, which is a microbe, and concluded that it was completely negative based upon all of that. And that summary was from the non-published data. But other than that, no, they didn't do much.

14:46:04 Q. The Ames test -- you just mentioned the Ames test, and would you explain to the jury in less than three minutes --

A. I'm sorry.

Q. -- what that -- no, you've been doing fine.

14:46:20 Just is it possible to explain the Ames test at greater length than that.

A. It's easy to explain.

Q. And why it has been so important historically in cancer risk assessment?

14:46:29 A. I can tell you some of that.

Q. Okay.

A. The Ames test, you take salmonella and put it in a plate. It's a special type of salmonella that doesn't grow because it has a mutation that stops it from growing

14:46:44 out in colonies. Then if you hit it with a chemical, you can -- if the chemical is genotoxic, it can reverse that mutation, take it out.

And so the salmonella then grows into colonies, and you can count the number of colonies that you get,

14:47:01 and that tells you how genotoxic that dose of the

chemical is. So that's the simple aspect.

The test came out in the 19 -- I'm forgetting things -- was long time ago, 1980s, I believe. Early 1980s. And it's a very good test for a quick run of genotoxicity.

14:47:25

In regulatory areas they've used it, and I'm going to say incorrectly, but we have a long scientific debate on that, to decide whether or not a chemical should have a threshold, which means there's a dose beyond which -- below which there's no risk whatsoever versus not having a threshold. It goes all the way down.

14:47:42

Was that fast enough?

Q. Great. Thank you.

And the EPA and other regulators require the submission of certain tests when you want an herbicide or pesticide or a whole lot of other chemicals to be approved for sale. We talked about animal carcinogenicity testing. Ames tests are another category of tests they require; right?

14:47:56

A. I'm not sure that's still true, but certainly in the past, it would have been true that they required Ames.

14:48:12

Q. Including the recent past?

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

Q. Okay. There are a number of other --

14:48:21

A. There's a lot of discussion about getting rid of it because there were better assays.

Q. Okay. But if you want to market a herbicide and you want to go to the EPA with it, you don't just say, I've found some genotoxicity tests and I've decided to test crocodile cells in this petri dish and --

14:48:36

A. To be fair to IARC, that -- those other species were not used in the evaluation. I made that clear.

Q. I didn't mean to impugn anyone's integrity by mentioning crocodiles. I'm just saying you can't just do whatever tests you want. You have to submit a certain battery of tests, and those tests are specified by the regulators; right?

14:48:53

A. Although most regulatory agencies will also negotiate with you. But basically that's true.

14:49:08

Q. I'm basically right. Okay.

So back to page 25, where we're doing the comparison with the IARC evaluation. On page 26, they talk about studies in exposed humans; right? Do you see the bold header?

14:49:25

A. Yes.

Q. You talked today about three studies in exposed humans, Paz-y-Miño 2007, Paz-y-Miño 2011, and Bolognesi 2009, and these three are also discussed here; right?

14:49:46

A. Well, they're -- there is a quick summary note

here, but yes. They're not discussed.

Q. Okay. That's what they're talking about, those three studies. They're named and identified there; right?

14:50:00 A. Correct.

Q. And then the next sentence where they have the little evaluation, they say: "RAC, Risk Assessment Committee, notes that the results from the human genotoxicity studies are equivocal and that their overall

14:50:14 interpretation is challenging due to the time between spraying and blood sampling from two weeks to two months, uncertain exposure estimates, and the combined exposures to glyphosate and co-formulas and other pesticides. RAC concludes that the data available is not sufficient to

14:50:36 conclude glyphosate as the factor likely to explain to association between glyphosate-based" --

"RAC concludes that the data available is not sufficient to conclude that glyphosate is the factor likely to explain the association between

14:50:55 glyphosate-based herbicides and higher incidences of micro nuclei in the studies where this has been observed."

Did I read that right?

A. That's what it says.

14:51:11 Q. Is that something that you vigorously disagree

with as well?

A. Well, they have a mistake. I mean, one of them was five days, not two weeks. And to some degree what they've said is true of some of the studies and not true of others. Some of them are much clearer in terms of what they tell you.

14:51:24

Q. Some of those three?

A. Some of the three. Some parts of those three. Because there's lots of evaluations going on in those three papers.

14:51:36

Q. Okay. Let's look at the overall RAC conclusion and then we'll move on from this paper, sir. It's on page 52. Tell me when you're there.

A. I am there.

14:51:53

Q. Okay. "RAC concludes that based on the epidemiological data as well as the long-term studies in rats and mice, taking a weight of evidence approach, no classification for carcinogenicity is warranted."

A. That's what it says.

14:52:08

Q. Okay. And is that also astonishingly incorrect and so amazingly wrong?

A. It's -- you've asked a simple question for a complicated issue. They're welcome to have their opinion. This is at least an opinion that says -- it doesn't say there's evidence suggesting lack of

14:52:29

carcinogenicity, which is what EFSA said. This at least says we don't see it fitting our criteria for listing.

Now, I disagree with that because I see other things in the science that would put it into a different listing.

So I don't disagree with their conclusion based upon what they did to the data. I disagree with what they did to the data, which should have put it in a different category.

Q. Is what they did to the data astonishing and so amazingly wrong or is it less outrageous --

A. Again, they did the same things EFSA did with the exception of one thing: They didn't throw away positive findings because they were in the range of historical controls. They finally learned that lesson and stopped doing that. But the other errors they continued in the same way as EFSA.

MR. GRIFFIS: Move the admission of 2320, the RAC report, from ECHA.

THE COURT: Any objection?

MR. WISNER: Yes, your Honor. Objection, hearsay.

THE COURT: Okay. Why don't we take this up at a break. And is this actually a good time to take the afternoon recess?

MR. GRIFFIS: Yes, your Honor.

THE COURT: Okay. All right. So Ladies and Gentlemen, we'll be in recess for 15 minutes until ten after 3:00 on the wall clock. Please remember, do not discuss the case.

14:53:53

(Sidebar.)

[redacted]

14:55:27

[redacted]

14:55:52

[redacted]

14:56:12

[redacted]

14:56:25

[redacted]

[redacted]

(End sidebar.)

(Recess.)

THE COURT: Welcome back, Ladies and Gentlemen. Dr. Portier remains under oath. And, Mr. Griffis, you may continue when you're ready.

MR. GRIFFIS: Thank you, your Honor.

Q. BY MR. GRIFFIS: Dr. Portier, I just want to look at one more document. Then we'll move off of the European regulators for a bit. That is Exhibit 3173.

Tell me when you're there.

A. I'm a bit clumsy. I'm sorry.

3173?

Q. 3173, yes.

A. Yes, I'm there.

Q. So this is a document from the BfR, the German regulators, and the title is "Glyphosate: EFSA and ECHA Response to Christopher Portier," and it's a three-page description of their response to you; correct?

15:13:46

A. It's a web page they put up.

Q. And it's summarizing their July 2017 response to one of your open letters; right?

15:14:03

A. Their summary of their response, yes.

Q. They say halfway through the first paragraph, "Christopher Portier, a consultant to a non-governmental organization, wrote an open letter to the commission president in May 2017 in which he said the tumors found

15:14:23

in feeding studies with mice and rats had alledgedly not been taken into consideration in the drafting of the European risk assessment."

Is that right?

A. That's what it says.

15:14:35

Q. And --

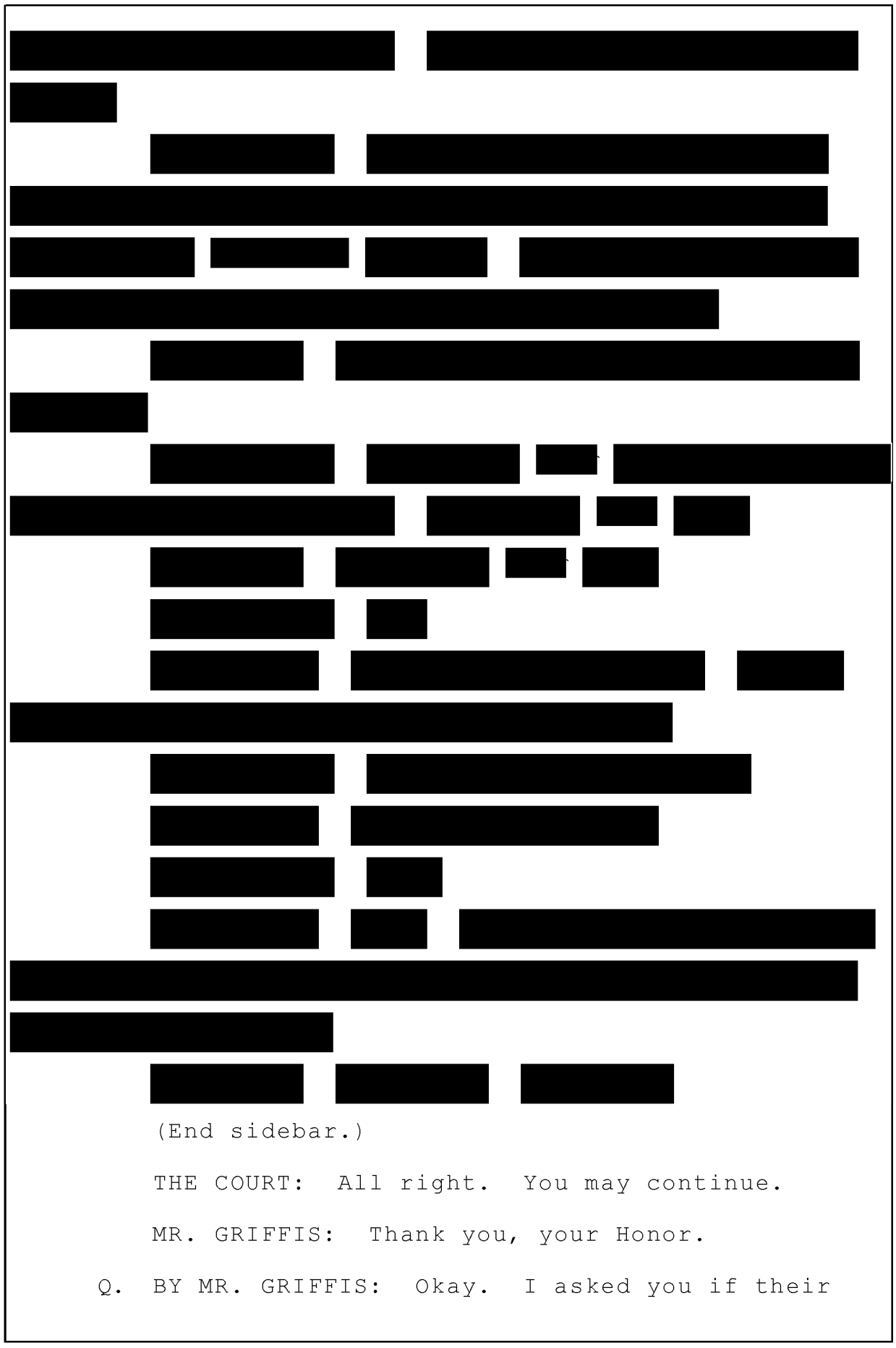
MR. WISNER: Your Honor, could we have a short sidebar. I just have to clarify something with counsel.

THE COURT: Yes.

(Sidebar.)

15:15:02

[redacted]



(End sidebar.)

THE COURT: All right. You may continue.

MR. GRIFFIS: Thank you, your Honor.

Q. BY MR. GRIFFIS: Okay. I asked you if their

characterization of what had happened was correct and I think you answered me, but I don't remember what you said.

A. I didn't answer you.

15:16:23 Q. Okay.

A. I was a government bureaucrat for many years, as well as a scientist, but I was also a government bureaucrat. And I love it when they're very cleaver in their writing. They say all the original studies

15:16:38 mentioned have been taken into account. That is correct. That is not what I was challenging them on. I was challenging them on specific tumors in those studies that they had not mentioned. So this is the case where if you can't say what you got to say, you say something else

15:16:54 that sounds similar.

Q. Okay. I think, though, you jumped a little ahead. Let me read that paragraph you're objecting to first and then we'll talk about it. Okay?

"EFSA and ECHA, EFSA and ECHA, clearly state

15:17:07 that the claim that findings were overlooked is false based on the transparent assessment procedure of European hazard and risk assessment, as well as the available scientific facts. All the original studies mentioned have been taken into account in the evaluations of the

15:17:24 European authorities in accordance with their reliability

and relevance and have been assessed on the basis of agreed scientific principles."

Did I read that right?

A. You did.

15:17:34 Q. And do you believe that that is a false statement?

A. No. That's a correct statement. It just is not a statement regarding what I actually challenged them on.

Q. Okay. Let's go down. There are several

15:17:47 paragraphs that are kind of in a shaded gray text box. Let's move below that to the white text.

"All the original studies on the toxicity of glyphosate cited by Christopher Portier in his letter to the president of the EU commission have been taken into

15:18:04 account in the evaluation of the European authority in accordance with their scientific reliability and relevance and have been assessed on the basis of agreed scientific principles. This means that individual data on the specified tumor types and incidences that have now

15:18:19 been additionally analyze by Christopher Portier using his own method were already known."

And I'm going to pause. They mentioned individual data on the specified tumor types. And they would have had animal level data from those studies that

15:18:35 you didn't in doing their evaluation; is that right, sir?

A. They had -- it was available to them.

Q. Okay. And animal level data means the data on each individual animal, its feeding schedule --

A. I assume. I can't -- I can't say.

15:18:51 Q. That would be normal?

A. That would be normal.

Q. So I'll continue reading.

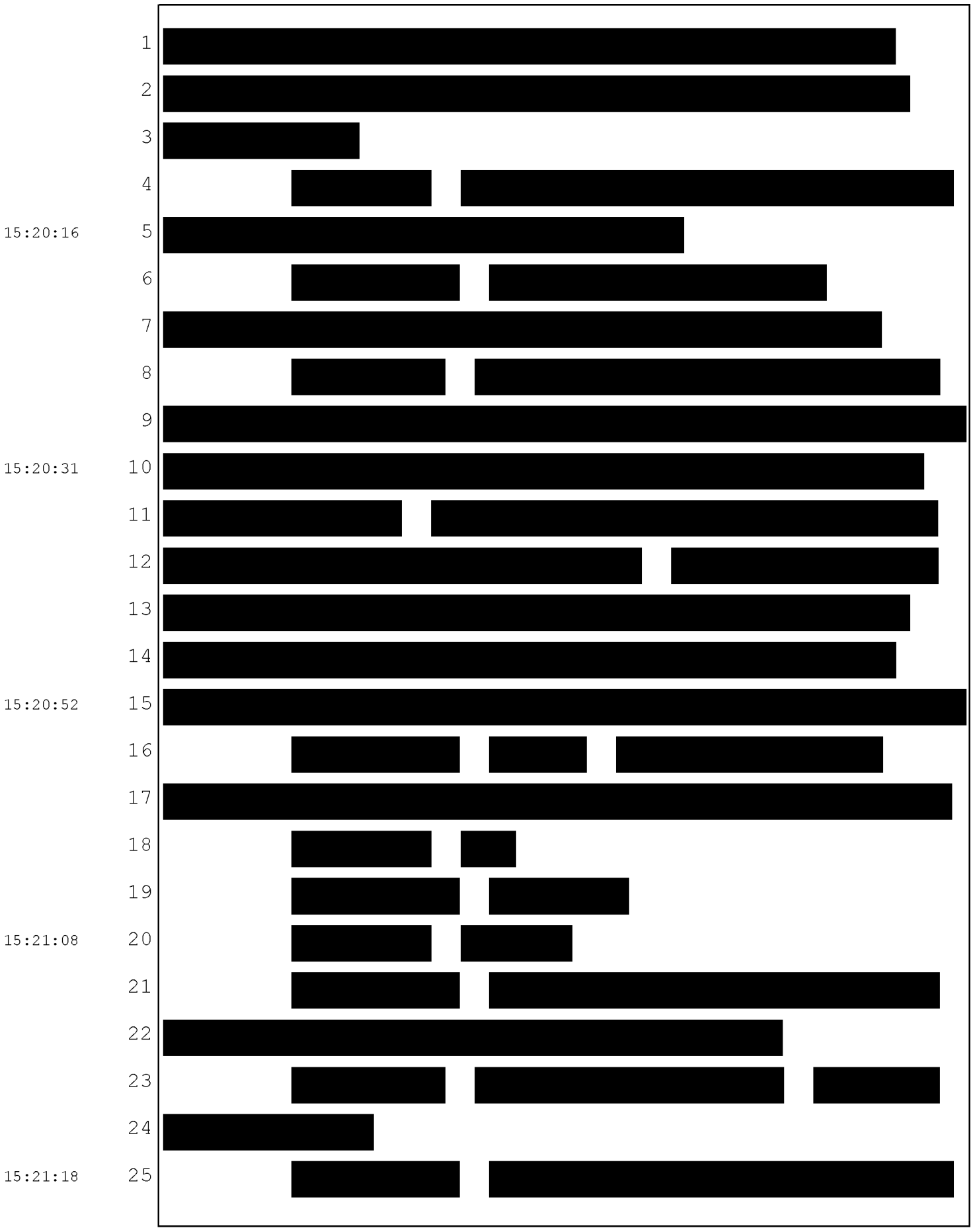
"Following" --

MR. WISNER: Objection. I believe we had a

15:19:01 hearing about this issue and I don't believe the next sentence or the portions thereafter are admissible.

THE COURT: Can you approach, please.

(Sidebar.)


15:20:16
15:20:31
15:20:52
15:21:08
15:21:18

[redacted]

(End sidebar.)

THE COURT: All right. You may proceed.

Q. BY MR. GRIFFIS: On the page 2 of 3, sir, at the top -- are you there?

A. Yes, I am.

Q. Okay. All of the tumor incidences described by Christopher Portier as new -- new in quotes -- can also

be found in the original studies of the manufacturers; right?

A. I don't exactly know what they mean by that statement. That's, of course, where I got the tumor counts from. So of course those tumor counts are in the -- in the appendices of those reports, but I don't have access to those reports themselves. So I don't know if they were in the actual report.

15:22:57

Q. Okay. I'm about to transition here, but let's wrap that up. Yes?

15:23:20

A. I want to say -- so they make a statement here, all of the tumor incidences described by myself as new can also be found in the original studies of the manufacturers. If you look at the report -- the response that BfR sent me, which is 3178, the next tab, I'd like to read just one of their responses to give you an idea of what they mean when they say that.

15:23:47

Q. Okay.

A. So on page 6, his response B, and it has to do with my identifying hemangiomas in females only in Sugimoto FML, which is a CD-1 mice study. I will first note that EPA used this tumor, they evaluated it, discussed it in their risk assessment. So it wasn't new if EFSA had read what EPA did. So here's their response.

15:24:06

15:24:34

"The study author did not report the sum of

hemangiomas total for all tissues, but the incidents in individual tissues."

Now, hemangioma is a tissue of the circulatory system, the lining of blood vessels, effectively. And so it can occur anywhere. Typically when you have those, you combine them from all over the animal and just go, did this animal have a hemangioma or not? That's the usual way of analyzing that type of systemic tumor.

15:24:54

"This benign vascular neoplasm" -- this is going back to them -- "was found in females at different sites. For example, in the spleen, one in the mid dose, in the uterus, one at the mid dose, two at the high dose, et cetera."

15:25:11

They give several others. I'm not going to go through them all.

15:25:27

"No statistical significance was observed for any of these to cite. Even if these findings are summed up, an increased incidence in relation to controls was observed only at the high dose levels of 4,116 milligrams per kilogram body weight per day."

15:25:44

So what that says is we didn't see this tumor, we didn't analyze this. Then they go on:

"As explained in the weight of evidence assessment, an increased incidence of benign tumors observed only at the extremely high dose exceeding 4,000

15:26:02

milligrams per kilogram body weight per day, well above the MTD, is less relevant for classification even if they are not automatically excluded from any consideration."

Now, mind you, if we were to take the time to go back and read EFSA's review of this paper, they would not say the MTD was exceeded. But now in their response they're hinting at maybe the MTD is exceeded.

Finally, in the next sentence: "It is important to note that no progression to malignant hemangiosarcoma was observed."

Now, to my understanding, hemangioma does not progress to a hemangiosarcoma. Hemangiosarcoma is a separate type of tumor arising independently. So now they're using their biological relevance, but they're connecting the wrong tumors. And it goes on and on like this in every one of their responses.

So that is where my frustration lies in the sense that I'm getting a disconnect between what they write in the summary and what they actually write to me.

Q. Do you see, sir, on page 9 under the heading "Were the findings missed in the CLH process?"

A. I do see that.

Q. And we're in Exhibit 3178.

A. Yes, I see it.

Q. Four paragraphs down.

To save a little bit of time, I'm going to start in the middle of the paragraph.

"Although the data referred to by Dr. Portier" -- do you see that?

15:27:49 A. Yes.

Q. Fourth paragraph, halfway: "Although the data referred to by Dr. Portier in Table 1 of this document were not included in the CLH report, hence explained in detail under the heading biological relevance of the

15:28:02 claimed additional tumor studies and significant increases due to glyphosate exposure above, this does not mean that they were not considered by the DS in their assessment. Only the tumor types which the dossier submitter considered to have required further assessment

15:28:26 were included in the CLH report. These comprised the four tumor types in rats and three tumor types in mice listed above."

Did I read that right?

A. You read that right. What it says is that, gee,

15:28:42 we might have seen this tumor increase, but we didn't include it in our report because we didn't think it was important to tell you about it.

And that -- that's an interesting approach to transparency. But more importantly they state, and I'll

15:28:59 repeat it: "Only those tumor types which the dossier

submitter considered to have required further assessment were included in the CLH report."

That basically says since the dossier was submitted by the glyphosate task force, they only considered the tumors that the glyphosate task force considered to be important. That's the way I interpret that sentence.

15:29:17

Q. Would you do this for me, sir. Why don't you list for me, to the best of your memory, all of those regulatory findings after IARC, because you weren't very focused on glyphosate or possibly at all focused on glyphosate before that, after Working Group 112, you read, reviewed and had disagreement with -- we've talked about a number of them, but could you just list them --

15:29:34

A. We -- I'm sorry.

15:29:56

Q. Sorry.

A. Go ahead. I interrupted you.

Q. You said we've discussed everything?

A. We discussed EFSA, BfR, ECHA and EPA. I did look at the California EPA one and that's it.

15:30:12

Q. And in your expert report you listed JMPR as something that you relied on?

A. Yes, I did look at JMPR as well.

Q. I'm going to ask for you to talk about specific documents, but we need to have a sidebar, your Honor.

15:30:30

THE COURT: Yes.

(Sidebar.)

[redacted]

(End sidebar.)

15:31:19 Q. BY MR. GRIFFIS: The JMPR is what?

A. Joint Meeting on Pesticide Residues of the World Health Organization and the Food and Agricultural Organization.

Q. And which findings by the JMPR did you review 15:31:45 and dispute?

A. I did not write to them and dispute any.

Q. Okay. Did you -- which did you review and, in your mind, disagree with?

A. I would have to see the document to remind me.

15:31:58 Q. Okay. Can you tell me for EFSA or BfR or ECHA

or EPA?

A. What parts, like --

Q. Which documents, which -- which findings by those agencies you reviewed and disputed.

15:32:18 A. I reviewed every single finding by the agencies relating to carcinogenesis.

Q. So from March 2015 to now, for EFSA and BfR and ECHA and EPA and JMPR, you reviewed all findings that they've made on the subject of carcinogenesis?

15:32:40 A. Not as much JPR as the others.

Q. So you were somewhat less focused on them?

A. Somewhat less focused on them.

Q. And as to all of those agencies and their findings on cancer, do you find them to be astonishing

15:32:58 and beyond the pale and you can't believe it and those other things that you've been saying today?

A. I find the science by which they reached their decision to be in error, and I would be happy to walk you through each and every one of those if you'd like.

15:33:15 Q. Those in the room would not be so happy, sir.

A. Probably not, but I can list them simply for you and quickly.

Q. Have you not done so yet?

A. It's in the letters.

15:33:28 Q. It's in the letters; right?

A. Yeah, in so many of the letters.

Q. All right. I want to talk about the animal study analyses that you did, sir.

A. Okay.

15:33:40 Q. And first I want to try to, if we can, get some statistical principles straight so that the jury can follow. And so I'm going to try to talk and see if we can reach agreement about this.

First of all, an animal carcinogenicity study 15:34:00 involves dosing a large number of animals, 50 males, 50 females in each dosing group, and we discussed how the doses are set elsewhere in your testimony, and then analyzing them for just about every tumor that can be found in a mouse or rat; right?

15:34:25 A. No. So you have an animal cancer study.

Q. Yes.

A. And they look at, in general, body tissues and they take slices of those body tissues, and they look for tumors in each of those tissues. And some tissues can 15:34:42 have multiple types of tumors. But to analyze, they only analyze things that are either, one, an observation of a tumor, which is very rare, or, two, things that can conceivably be statistically positive. And so that means it has to have at least three tumors occurring in any 15:35:06 groups in the animal study.

Q. Okay. And because I've read your expert reports, I know why you're saying all that. I think you're getting slightly more advanced than I am at the moment.

15:35:18 But to start out with, when you do an animal carcinogenicity study, you're analyzing about 40 tissues for multiple tumors; right?

A. The pathologist is reading 40 tissues for multiple tumors, right.

15:35:34 Q. I don't mean you. One is doing that.

A. As a statistician, I would never analyze that.

Q. I'm sorry. I didn't mean you personally.

So when people are doing these animal studies, there are many dozens of possible kinds of tumors that

15:35:51 could be found, right?

A. Correct.

Q. Okay. And moving away from animal studies to a slightly higher realm of generalization, when you're doing any experiment in which there are multiple tests

15:36:08 and a possibility of finding -- of a particular statistical finding in a particular tumor type is a test; right?

A. Correct.

Q. Okay. So multiple tests -- and that applies to

15:36:20 animal studies as well as other things -- if you have

enough tests, you are going to get a number of positives by chance alone; right?

A. That's not guaranteed.

Q. Okay.

15:36:32 A. You could get some positives by chance alone.

Q. Okay. If you have enough, you're almost guaranteed, but --

A. Correct.

Q. Okay. And the level of the degree to which you

15:36:44 would be guaranteed would approach 100 percent so closely that you wouldn't notice the difference --

A. Correct.

Q. -- at some point? Okay.

And at one point when you were going through

15:37:00 your initial analyses for your expert report, you decided that there were -- how many tests did you decide? 465 tests at issue in these animal studies?

A. No. I used an algorithm put forth by Joe Haseman that led to that calculation.

15:37:20 Q. Okay. So Joe Haseman is a biostatistician as well and was engaged in a conversation with you about these animal studies and these results. Has an algorithm and you decided to apply that. And the purpose of this is to kind of get a denominator of how many different

15:37:40 boxes you could find a statistically significant or

otherwise statistically interesting result in; right?

A. That is correct.

MR. WISNER: Objection. Compound. There were five parts to that question. I want the make sure his answer is to each part.

15:37:53

THE COURT: All right. Please rephrase, Mr. Griffis.

Q. BY MR. GRIFFIS: Okay. You chose a test by Dr. Haseman?

15:38:05

A. Okay. I chose a calculation by Dr. Haseman to give me the number of tests.

Q. Okay. And the reason that you wanted the number of tests is to have a sort of denominator to compare to the number of positives that were found; right?

15:38:22

A. That is why he was doing it. That is correct.

Q. And it's not just something that Dr. Haseman is interested in. Any statistician who is assessing a series of results that involves multiple testing and a whole bunch of possible tests needs to take that into

15:38:41

account; right?

A. They would look at that question and take it into account.

Q. And the reason you look at that is because -- okay, let's back up for a moment and talk about

15:38:53

confidence intervals and p value. A p value of less than

0.5 corresponds to a 95 percent confidence interval corresponds to a 1 in 20 chance, generally speaking; right?

A. Except in the epidemiology confidence intervals are two-sided. In a -- testing in animal studies, they're one-sided. Slight difference, but let's just call it a 1 in 20 chance.

Q. Okay. One in 20 chance. And what that means -- we're still at the level of abstraction, I understand. What that means is that if you are looking for a 95 percent confidence interval in your study, about one out of every 20 times that you do a test, you're going to get a positive just by chance; correct?

A. No. What it means is that if truth is there is absolutely no effect in these -- in these animals of this chemical, then, roughly, because it's -- it gets complicated for small and large backgrounds, roughly speaking, then 1 in 20 times you would actually get a false positive finding.

Q. So if you were testing spring water in mice and rats about, 1 out of every 20 tests you'd get a false positive; right?

A. You might get a false -- you might get a positive in 1 out of 20. It's a statistical probability. It's not a guarantee.

Q. Yes, sir. It's not every 1, 2, 3, 4, 5, 6 and then when you get to 20 you get a positive. There's a chance each time. But on average it works out to about 1 in 20; right?

15:40:37 A. On average.

Q. There are tools that you apply to calculate the number that are expected, and it's not take the number and divide it by 20. It's a little more complicated than that. But these are formulas well-known by

15:40:51 statisticians; right?

A. Correct.

Q. Okay. And the denominator that you started with, the number of tests in these studies, and it's a complicated issue, but you chose Dr. Haseman's

15:41:02 methodology to come up with 465 (inaudible); right?

A. I'd have to look at my expert report to be absolutely certain.

Q. Okay. It's in one of those binders there, sir.

MR. GRIFFIS: 741, perhaps.

15:41:31 THE WITNESS: I have it. 456.5?

Q. BY MR. GRIFFIS: Yes.

A. Correct.

Q. I said 465. I'm sorry. 456.5. So 456 is the denominator for this. And, again, the reason it's

15:41:53 important is because if you're testing spring water or

anything else that doesn't cause cancer 465 times or any other large number of times, you're going to get some false positives almost for sure; right?

A. So first now that I see what you're looking at here, I have to refer to the text a little bit. Because in the text I very clearly state that I put the 456.5, which is all of the animals tested, all of the tests done in all of the animal species into this table for completeness. But that I think the evaluation should be done by strain and by species.

So we can talk about the 456.5, but it would be more interesting to me and more scientifically credible to discuss male Sprague-Dawley rats, female Sprague-Dawley rates, male Wistar rats, et cetera.

Q. First of all, though, sir, you have a column here for combined figures with 465, and you have a row for that. And you have a column for the number of expected positives. And that's expected by chance alone; correct?

A. Correct.

Q. At a 0.05 confidence level; right?

A. There's one for 0.05 and one for 0.01.

Q. And the 0.05 expected is 22.8; right?

A. Correct.

Q. And the observed, i.e., the number that you

actually found, was 18; correct?

A. That is correct.

Q. And so the observed was less than the expected in that column; right?

15:44:02 A. That is correct. That does not imply -- that does not guarantee that the observes don't have true positives. It's simply an evaluation of how far off it is from --

Q. It's almost certain that a number of the mouse 15:44:27 and rat tumors that you told the jury about yesterday are false positives; right?

A. Some of them are probably false positives. There are some of them that I don't believe I would call positive. That's in my document. I summarize all of 15:44:43 them I looked at. We didn't talk about which ones I firmly believe are positive.

Q. I mean, a large number of them, probably the majority, are going to be false positives, given how many -- given the denominators that we're talking about. 15:44:59 Your initial calculation was 22 expected and your actual number of tumors is 30; right?

A. Again, as I state in the document, that's for just completeness of showing all possible things. But if I look at male CD-1 mice, I expect 2.1, and I see 8. So 15:45:26 even though the number down here is 22.8 and 18, I don't

view that as a credible scientific evaluation, because I want to look at the individual sex species, because I don't believe in combining them. They can easily give you different results, and so I evaluate them separately.

15:45:47 Q. Okay. The fact is that when you have a large number of tests, you have a multiple testing problem. That's how it's described; right?

A. That's correct.

Q. And a multiple testing problem is, as we

15:46:04 discussed, the fact that you're going to get a number of false positives and then you need to do further statistical calculations to see if you have more positives -- I suppose they wouldn't necessarily be false positives -- more positives than you would expect by

15:46:21 chance alone; right?

A. Yes. But, again, there -- as EFSA has put it and as I will put it, there are other considerations.

Q. Yes, sir.

A. Okay. As long as we know that -- the minor --

15:46:38 Q. Sorry. I didn't mean to interrupt you.

A. Yes.

Q. There's a statistical side, which is kind of what we're talking about right now, and there's the biological side of that analysis, and you're on the

15:46:49 statistical side of it?

A. But even on the statistical side, you have to worry about, okay, it's not just that I'm seeing this many positive findings in this study, but four of the positive findings are the same tumor in four studies.

15:47:05 Now, you can actually calculate the probability of seeing that under no effect. I have it. But you can do that. So if I really wanted to draw this out, the statistical ins, all kinds of statistical ins, I would of course make those calculations.

15:47:25 Q. Can you tell us which of the tumors you showed us yesterday are false positives?

A. I can tell you -- no. You can never absolutely be certain that you have false positives, false negatives.

15:47:38 Q. Can you tell us how many are false positives?

A. I can tell you which ones I consider so strong that that's what drove my sufficient evidence in animals.

Q. Which ones?

A. The malignant lymphoma in the male mice. The

15:47:52 hemangiosarcomas in the male mice. The skin keratoacanthoma in the rats, both species of rats, both strains of rats. And there's one more, and it's -- I'm losing it. I'm sorry. It's late in the day. I don't remember the last one.

15:48:07 Q. Do you want me to hold up the charts for you?

A. Yeah, that would help.

Never mind. I know which one it is. Hemangioma in female mice showed up in multiple studies even when it wasn't statistically significant by your definition. Many of them were marginally significant. That's what drove my decision. As well as biological reality of those.

Q. So those you listed and not the others; right?

A. No. Those are the ones that predominantly drove my discussion. I'm not going to pick and choose which of the others I'd throw out.

Q. It's statistical, almost a statistical certainty, that if we were able to just know the truth, not have to guess at it statistically, but just know the truth, some of those are false positives?

A. Absolutely. Some I can tell you right now I'd call false positive. If you want to bring it up, I'll try to remember which ones I would toss.

Q. Okay. Let's do that.

A. But there are some in there that I'm just not certain about.

Q. Why don't you come down and show me which ones you'd toss. Start with mice.

A. Okay. Okay. Let's look at the mice. The kidney is something I also -- I think draws my decision

as well. So you've got kidney, malignant lymphoma, hemangiosarcoma. And I didn't use the multiple malignant tumors one to make my decision. That would typically not be done.

15:50:20 Q. Why not?

A. Because there was a long debate on this at the NTD when I was there and running it, and there were a lot of different arguments for and against doing it. Everybody believed it should be reported, but people had
15:50:33 a difficult time believing that you should base a risk assessment on any tumor occurring.

Q. What's your view on that? You wouldn't do it?

A. Mixed. I would have to look very carefully. In this case, I wouldn't do it. But in the case of dioxins,
15:50:57 there's such a strong binding of increased total tumors in humans and rats that I might do it there.

Q. Okay.

MR. WISNER: Excuse me. Can we not use a permanent marker.

BY MR. GRIFFIS:

Q. Which other ones are false positives?

A. Again, I'm not calling them false positives. I'm telling you that they had less weight in my discussion. I didn't feel that the evidence was strong
15:51:23 enough that it would pull me forward. The lung

adenocarcinoma and harderian gland. That's it, because the rest are repeated throughout.

Q. And those could be false positives as well; right?

15:51:44 A. The others, of course.

Q. Yes. And we don't know which are.

A. In any study, any evaluation, you could have more false positives than you could expect. In this case in the male mouse, I made that calculation. If, in fact, 15:52:01 truth is there is nothing going on, then the probability of a false positive with these data is -- for the males -- where did I put that calculation -- it's in the text.

Q. Okay. Let's do the false positives while you're 15:52:26 up.

A. Okay. Anyway, it was less than .01. The rats. So Lankas as a whole got less weight.

Q. Why is that?

A. Because the Lankas study had low exposures, 15:52:41 fairly low exposures. They're the only ones to see the testicular inter cell tumors.

Now, they're a 26-week study. These are all 24-week studies. So I have to be careful when comparing them. Because as the animals get older, they get more 15:52:59 tumors and testicular interstitial cell tumors is one of

those tumors that really increases late in life. And so that might be a true finding, but I certainly can't immediately say it's consistent. There's other things to it. So I'd give that less weight.

15:53:18 The pancreas islet cell tumors, I'd give less weight. In fact, I don't even consider them. Because I said I only use trend to make my decision. And this did not have a positive trend test.

Q. Why don't you cross out the ones you wouldn't

15:53:32 use.

A. I'll put a cross on the side, how's that.

Now, thyroid in this study is more difficult. Because I see thyroid in other places or at least two other places. This is a different thyroid tumor. So in

15:53:48 the rats this is kind of interesting. It could be a false positive. It could be real. I'm certainly not going to throw it out.

Again, here's the pancreas islet cell tumors again. But, again, it's only a pairwise comparison, not

15:54:08 a trend, so I'm not going to consider that very heavily.

Q. Keep going with the Xs in there.

A. But it's weight. It's not yes, no. It all gets less weight. So it's hard for me to just scratch it, but I'll scratch --

15:54:24 Q. You're a statistician and it's hard to say "yes"

or "no" --

A. You bet you.

Q. What's clear is that some of these are wrong. In your view, some are more likely to be wrong than others. And we're asking you to show us the weaker ones at least.

A. Okay.

Q. But any one on there could be wrong; correct?

A. Correct.

Q. And conceivably some of the ones you just put an X on --

A. Could be wrong.

Q. -- could be right?

A. Could be right. Skin keratoacanthoma appear quite a bit. And as I pointed out, in the rat data, that's probably the strongest finding. And the one that would be the strongest one to me saying, yeah, it caused tumors in rats as well. These --

Q. IARC -- sorry to interrupt you, sir.

A. Yes.

Q. IARC found no statistically significant tumors in the rats, as you said yourself right after the IARC meeting. And it was after you'd dived into the Greim data and done a whole bunch of statistical analyses with that data, that you came up with all this stuff,

including the skin keratoacanthoma; right?

A. Correct.

Q. Okay.

A. Mind you, these are benign tumors. They're not malignant tumors.

Q. Yes, sir.

A. And so if you're looking for a carcinogen, then technically these are not carcinogenic findings. These are pre-carcinogenic findings. And IARC would make that classification and so would EFSA and so would EPA.

The basal cell tumors have less weight. The kidney tumors I worry about, even though it isn't consistent in the Sprague-Dawley rats. But I worry about it, because I saw them in the -- in the mice as well.

And so that's not as far down as the basal cell tumors because of that other finding. I mentioned hepatocellular adenomas. The mammary gland finding, while interesting, is not replicated anywhere, so it gets much less weight -- the mammary gland carcinomas are interesting, but as pointed out by the regulatory agencies, lack of adenomas, and it's the only one that has it. I'm not extremely excited about it.

And, finally, the pituitary adenomas, this was in males and females. It was a really strong trend. And even though I don't see it anywhere else, I would be

worried about that. So that gets more weight --

Q. Okay. If you had to guess, how many of those are real?

MR. WISNER: Objection. Speculation.

15:56:59 THE COURT: Sustained.

Q. BY MR. GRIFFIS: If you had to think as a statistician, how many of those are likely to be real? How many of those are likely to be real?

A. -- a statistician wouldn't do it that way. A 15:57:10 statistician would calculate what's the probability of seeing this pattern under null -- under the null hypothesis -- under the hypothesis of no change. They would calculate their probability.

Q. A statistician would agree that there's almost 15:57:26 no chance at all those are real; right?

A. That would be calculated as well.

Q. And they'd agree?

A. I don't know. I could calculate for you what is the probability that all of these are not a false 15:57:39 positive error, that all of them are true findings. Now, I can't calculate that. It doesn't work that way.

Q. Okay.

A. Because your calculation of probability is under the assumption of no effect. To do a calculation under 15:57:55 the assumption of effect, you have to say what that

effect is. And we don't really know what it is. So you do the calculations under 0 effect.

And so I can calculate what's the probability that all of these are false positives, but I can't calculate the probability that all of them are not false positives. I don't think I can calculate that.

Q. Okay. Thank you.

A. You're welcome.

Q. Do you have that first binder that I gave you?

A. Do you know its title?

Q. It is Trial Cross Number 1, the one with Greim in it.

A. Regularly, regulatory, regulatory, cross-examine, depositions and expert reports. I think it's this one. Oh, there's another one.

Okay. What are we looking for?

Q. We are looking at page --

A. Which exhibit?

Q. Oh, I'm sorry. The fat one, the Greim's study.

A. 25 --

Q. 2570. And once you're there, turn to page 22930.

A. 229. Okay.

Q. And do you see how to do that? It's with the numbers at the bottom. So the full number will be

2570_0229.

A. Oh. I was at the wrong place.

Q. It's easy to get lost, because these are all data tables taken from actual studies. But there are numbering. We have master numbering at the bottom.

16:00:32

A. Okay.

Q. Okay. 229 to 30. At the bottom of 229, sir, you see some study results for skin subcutaneous.

MR. GRIFFIS: And can we call that up, please?

16:00:52

Do you have an objection?

MR. WISNER: No. No objection, your Honor.

Q. BY MR. GRIFFIS: 2060, page 0229. It says, "Skin subcutaneous." This is -- so this is a data table from an animal study; right?

16:01:04

A. Correct.

Q. Okay. And what we have here is the -- well, you told us that there were all these different organ systems that are analyzed by the pathologists in the studies; right?

16:01:17

A. That is correct.

Q. And we see a few of them here: Nasal cavities, ovary, pancreas, parathyroid. And I'll stop reading.

And then we have skin subcutaneous at the bottom; right?

16:01:33

A. Correct.

Q. And if you flip the page, skin cutaneous continues. And three down, we have keratoacanthoma; right?

A. Correct.

16:01:55 Q. Okay. These are oral feeding studies; right? And this is a skin tumor?

A. That is correct.

Q. Okay. They aren't dermal exposure studies in any way?

16:02:11 A. They are dermal exposure studies.

Q. These aren't, though.

A. Well, that's what I pointed out earlier. When an animal feeds, it also grooms. And so it gets some of the chemical in the feed onto the skin. That's known -- 16:02:26 calculated for different types of how water loving -- that's the simplest way to put -- the chemical is and how likely it is to penetrate skin and other things. So that's been done. So there is some skin exposure.

Q. Is it scientifically reliable to presume that 16:02:44 the skin exposure is in proportion to the dietary exposure?

A. In proportion. Meaning that the higher -- so if I go from the dietary exposure of 1 to a dietary exposure of 2, that's a doubling. In the skin, the exposure will 16:03:00 also double. That -- that is --

Q. That's a scientifically reliable established thing?

A. I would be willing to say yes, that's scientifically reliable.

16:03:12 Q. Okay. That's a supposition. You haven't seen a study?

A. Oh, no. There are definitively studies on this.

Q. How many different skin tumors are looked at in this particular study result, skin subcutaneous?

16:03:28 A. I count one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen -- fourteen different categories -- fourteen different types. Many of them 0.

Q. Okay. And this is an example of multiple tests, 16:03:45 that we see? Multiple testing problems that we talked about earlier?

A. Not really. Let's see, you would test one, two -- not that one. Not that one. Not that one. Three, four -- no, no, no, no, no. You'd do four.

16:04:15 Q. Okay. I mean -- and maybe I wasn't clear. I didn't mean that there would be 14 false positives out of the skin category. But that -- just looking at one organ system, you've got a whole bunch of tests in which if you ran the experiment over and over again, in any one of 16:04:31 those you might get a false positive; right?

A. No. You -- you -- you don't have 14 tests here. You have 14 pathologies in the various groups.

Q. And if you have three or more positives, you have a test?

16:04:46 A. Correct. And there are only four with three or more positives.

Now, if you want to argue that if we redid the study again, by chance you would have five, then, yes, there will be five tests. But that's a much more

16:05:01 complicated Type 1 error calculation or false positive error rate calculation than the one that's done here.

Q. Yes. Okay.

A. And I can't comment on that one. That's --

Q. So there's not a 1 to 1 correlation between a

16:05:18 conceivable tumor type and a test for doing a statistical analysis. But the more organ systems and possible tumor types you look at, as you do that, your test count is going to go up and your false positive count is going to go up, generally speaking; right?

16:05:34 A. Your possibility of false positives is going to go up. I actually calculated how many studies -- how many number -- how many tumor types with three or more tumors there were in these studies. After I gave up on Dr. Haseman's.

16:05:54 Q. What's the result for squamous cell carcinoma?

A. Three out of 51 in the control; 0 out of 51 in the mid and the low dose; 0 out of 51 in the mid dose; and 1 out of 51 in the high dose.

Q. That's definitely not a significant result; right?

16:06:24

A. I don't have the test in front of me, but I'd be willing to bet that that is not statistically significant.

Q. Doctor, you submitted comment to the EPA in 2016; correct?

16:07:14

A. I believe it was 2016. Yes, I certainly submitted a comment to the EPA.

Q. And in your comments to EPA in October and December 2016, you sent them an analysis arguing that the EPA should classify glyphosate as a carcinogen; right?

16:07:33

A. I don't think I said that. I think I sent them evaluations that showed them where they had made mistakes on their individual tumors, what they had missed and why I didn't believe their conclusions.

Q. And you submitted to them a disclaimer. And the disclaimer said, "This work was done with my own resources and on my own time. I received no reimbursement for any of these comments and no other party has contributed to the drafting of these comments. These comments are solely my opinions and my

16:07:52

16:08:09

responsibility"; correct?

A. You'd have to -- I'd have to see it.

Q. Okay. Take a look at 2929 and 2928 in the large binder.

16:08:31 A. I have a 2928, but there's no 2929 after it.

Q. Okay. Look at 2928.

A. And that's at the beginning of this document.

Q. I'm sorry?

A. That disclaimer is at the beginning of this

16:09:00 document.

Q. This is at the beginning of this document?

A. Correct, this document is my response to comments that Joe Haseman had made to the EPA about my comments and about the EPA assessment.

16:09:23 Q. I'm going to show you, sir, one of the EPA documents that you have said was so amazingly wrong, and I believe you'll find that in regulatory 2.

Let's start with 2437, sir.

Are you there?

16:10:11 A. Yes, I'm here.

Q. Okay. And what is this document?

THE COURT: Counsel, which binder are you in now?

MR. GRIFFIS: I'm sorry. I'm in regulatory

16:10:39 documents binder 2.

THE COURT: Okay.

THE WITNESS: Is this the carcinogenic assessment review committee draft. No. It says, "Final report," but this is a report that went online, came offline, but I think that's this report from EPA.

16:11:01

Q. BY MR. GRIFFIS: Okay. So it's a October 1, 2015, document, Exhibit 2437, entitled "Glyphosate Report of Cancer Assessment Review Committee"; right?

A. That's what it is, yes.

16:11:18

Q. All right. And on page 10, you see the conclusion of the committee. It's that small paragraph after the partial paragraph at the top of the page, "In accordance with the" --

MR. WISNER: Objection. Foundation. I believe

16:11:32

he just testified this was retracted.

THE WITNESS: Yeah, I don't know what became of this document. It was put on EPA's website. Then they took it down and apologized for putting it up out of context. I don't know this -- what happened with this

16:11:49

document.

Q. BY MR. GRIFFIS: Did you read it?

A. Yes, I read it.

Q. And did you read this sentence, the one starting, "In accordance with"?

16:11:55

A. Where?

Q. On page 10, after the first -- after the partial paragraph there is a three-line paragraph.

A. Yes, I'm there.

Q. Okay. Did you read that paragraph when it was online?

A. I don't recall. I don't remember --

Q. Okay.

A. -- honestly.

Q. When this was posted online, did you read and see what the conclusions of the Cancer Assessment Review Committee was?

A. Yes, I did.

Q. And what were those conclusions?

A. I'd have to find them.

Q. Okay. Go ahead.

A. I guess they're on this page, but I was more focused on the epi and animal evidence. I don't remember the *in vivo* work and what they concluded there.

Q. The Cancer Assessment Review Committee's conclusions on the epidemiology in animal studies are something you disagree with; correct?

A. I'd have to read them again.

Q. Okay.

THE COURT: Mr. Griffis, if you can start asking your final questions for today, I do want to leave a

little bit of time for us to discuss the matters outside the jury's presence.

MR. GRIFFIS: Okay.

MR. WISNER: Your Honor, I actually need a sidebar about this document.

16:13:31

THE COURT: Okay. Then perhaps this would be a good time to break, then. Is there anything further that you wanted to ask to conclude for today, Mr. Griffis?

MR. GRIFFIS: We can stop there.

16:13:40

THE COURT: Okay. Then, Ladies and Gentlemen, we're going to adjourn for today. Please remember do not research any of these topics over the weekend. Do not discuss this case, and we'll resume again on Monday at 9:30.

16:13:54

All right. Thank you very much.

THE WITNESS: Your Honor, could I ask you a question?

THE COURT: Yes.

THE WITNESS: I packed my clothes, I'm moving

16:14:02

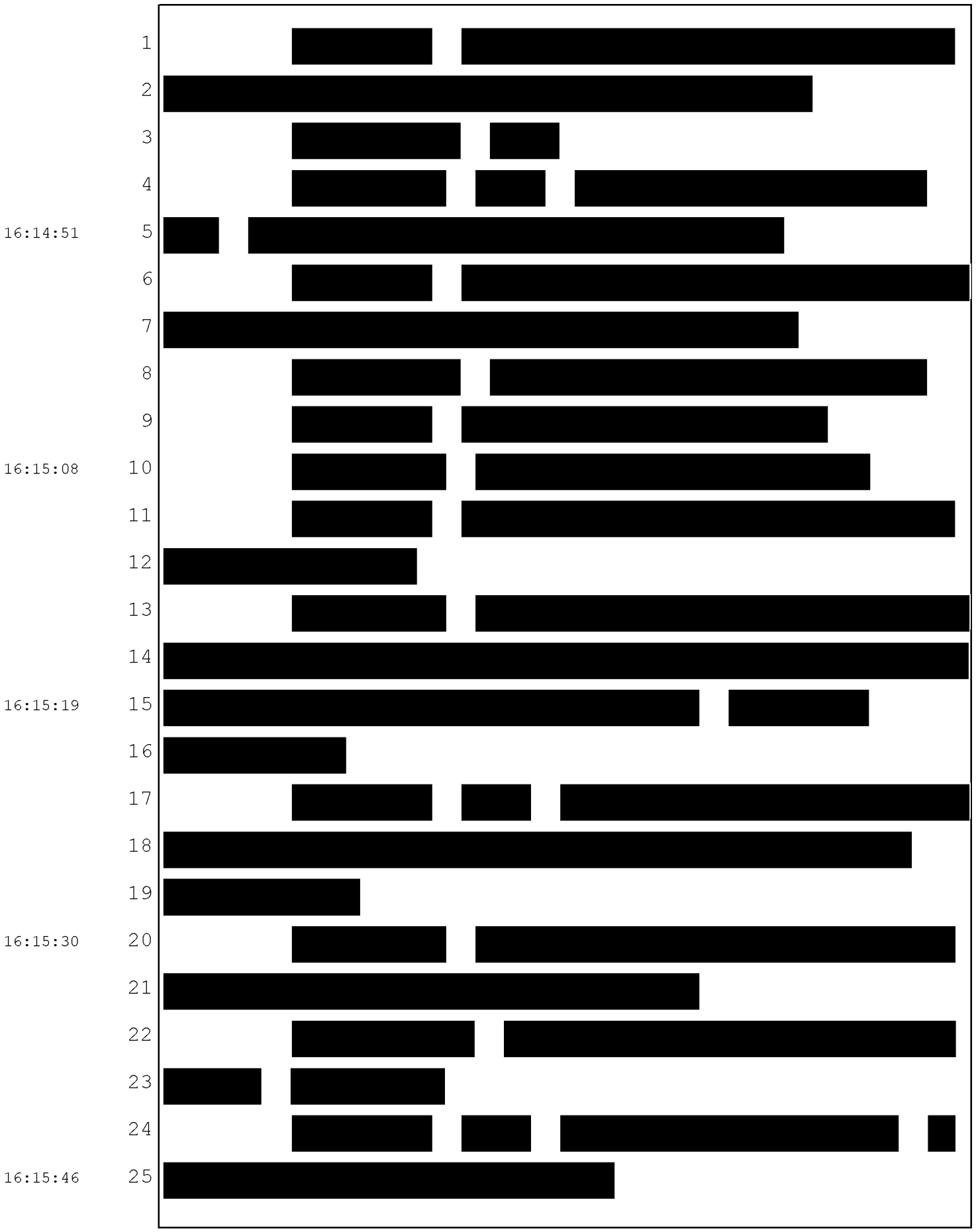
hotels, and I left it in the lawyer's office. Can I go get it?

THE COURT: Why don't we talk about this once the jury has been excused.

THE WITNESS: Okay. Thank you.

16:14:38

(Sidebar.)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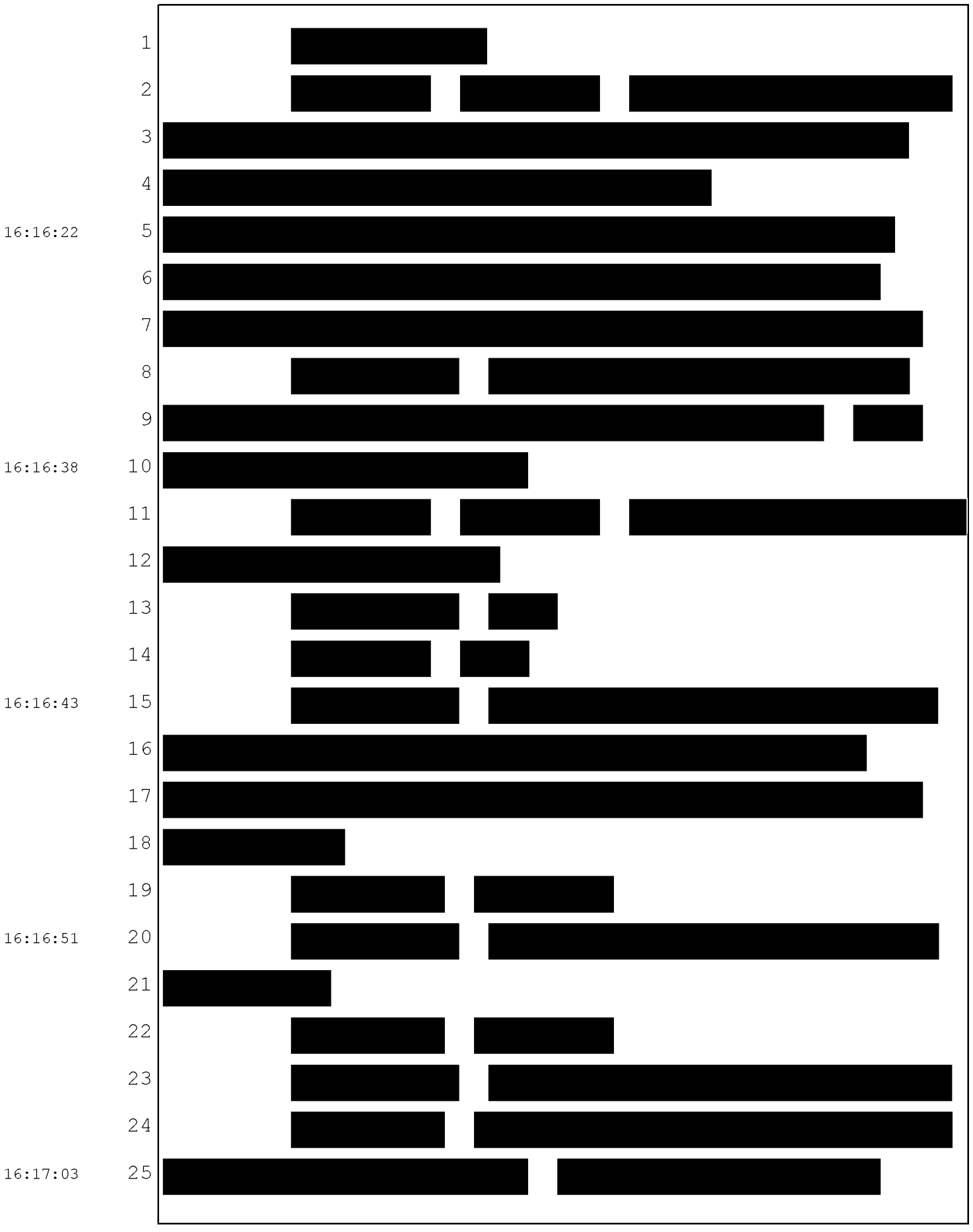
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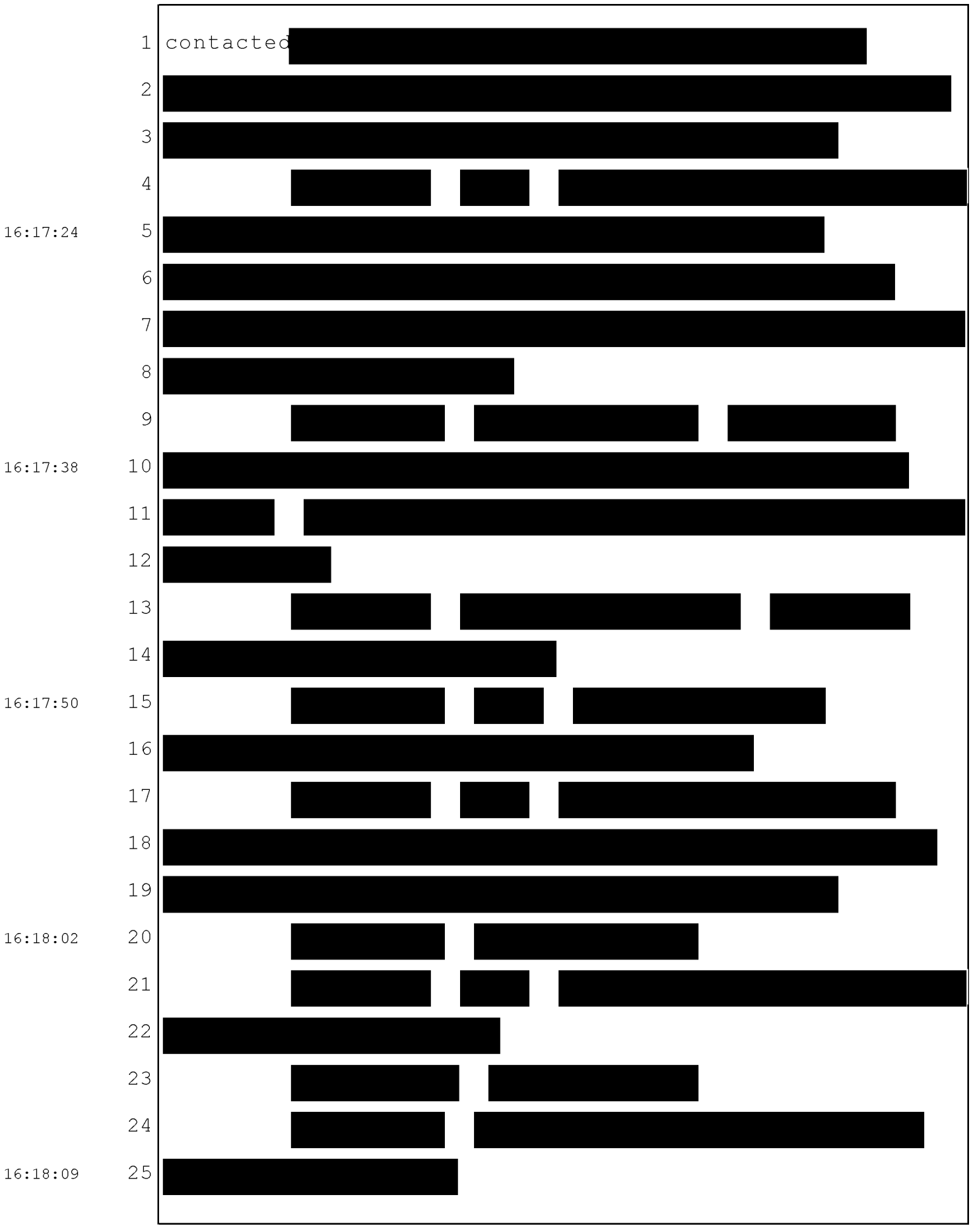
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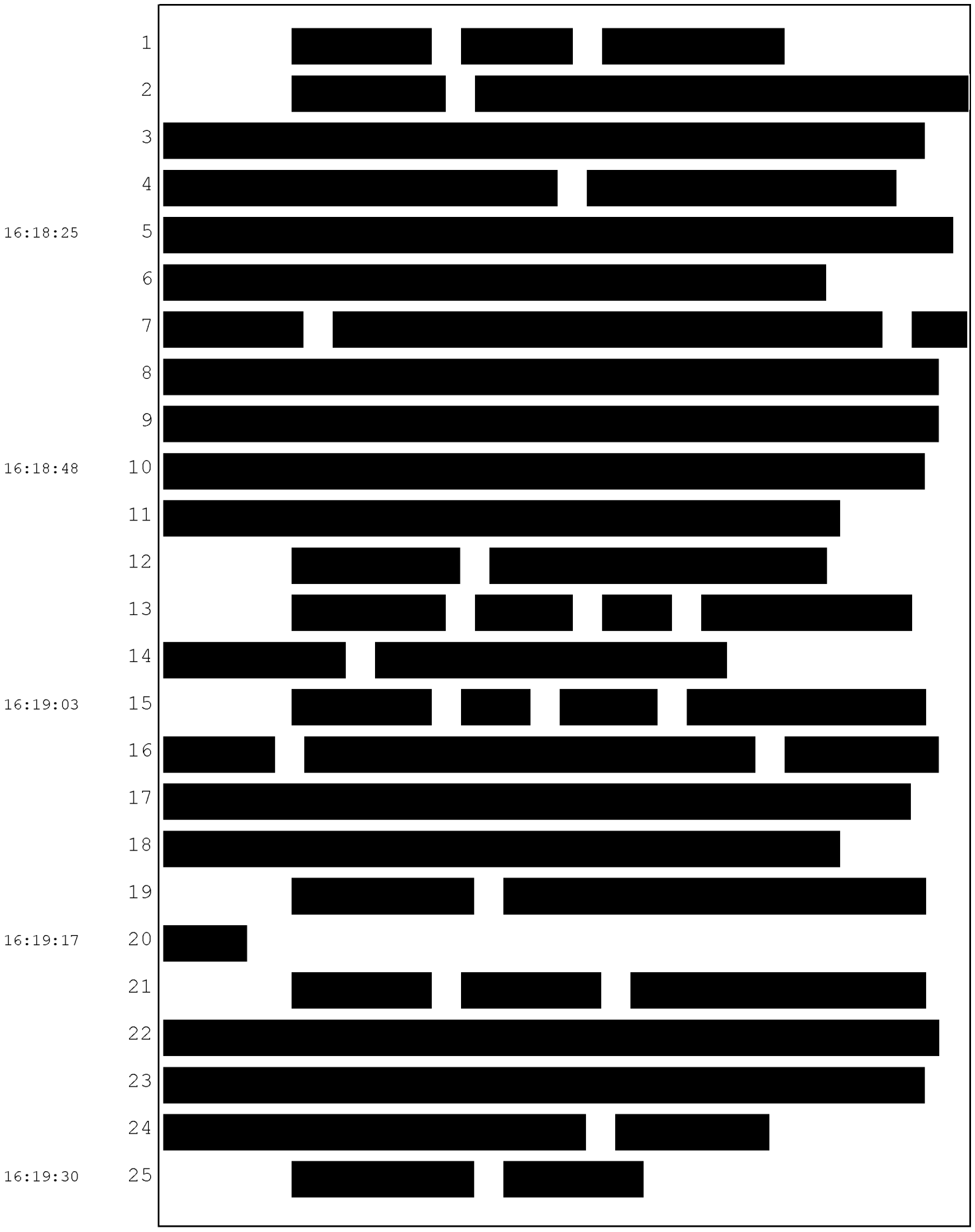
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(Time noted: 4:20 p.m.)

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REPORTER'S CERTIFICATE

I certify that the proceedings in the within-titled cause were taken at the time and place herein named; that the proceedings were reported by me, a duly Certified Shorthand Reporter of the State of California authorized to administer oaths and affirmations, and said proceedings were thereafter transcribed into typewriting.

I further certify that I am not of counsel or Attorney for either or any of the parties to said Proceedings, not in any way interested in the outcome of the cause named in said proceedings.

IN WITNESS WHEREOF, I have hereunto set my hand: July 13th, 2018.

<%signature%>
Leslie Rockwood Rosas
Certified Shorthand Reporter
State of California
Certificate No. 3462