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 Thursday, August 2, 2018, Volume 22, Afternoon Session, before the Honorable Suzanne R. Bolanos, at 1:33 p.m.

REPORTED BY:

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Thursday, August 2, 2018

1:33 p.m.

Volume 22

Afternoon Session

San Francisco, California

Department 504

Judge Suzanne Ramos Bolanos

PROCEEDINGS

12:51:11

THE COURT: Welcome back, Ladies and Gentlemen, Dr. Foster remains under oath.

Mr. Griffis, you may proceed.

MR. GRIFFIS: Thank you, your Honor. May Mr. Wisner and I approach?

13:34:04

THE COURT: Yes.

(Sidebar.)

[redacted]

13:34:21

[redacted]

13:34:42

[redacted]

[redacted]

13:35:29 (End sidebar.)

THE COURT: All right. Mr. Griffis, you may proceed. You have ten minutes with this witness.

MR. GRIFFIS: And I need two.

DIRECT EXAMINATION (Continued)

BY MR. GRIFFIS:

Q. So may we have Slide 29, Doctor? And I'd like to just sum up by talking about your conclusions. Can these conclusions that you helped put on the slide be reached to a reasonable degree of scientific certainty?

A. Yes.

Q. Would you describe them to the jury, please?

A. In my view, the plaintiffs' experts have misapplied and over-interpreted the statistical data that -- they've relied primarily, or almost exclusively, on statistical comparisons alone without giving consideration or due consideration to the biological relevance of the changes that are taking place in these animals.

13:36:15 Q. And that's what your -- that's the point you were making when we were talking about the charts and -- particularly this one on the lymphoma --

A. Correct.

Q. -- is that correct? Okay.

13:36:28 Go on, sir.

A. My view is that the data are consistent and that there was no compound-related effects. There was no compound-related carcinogenicity in any of these studies, and routine fulsome assessment of the toxicological data 13:36:49 doesn't support the hypothesis that this is a rodent carcinogen.

Q. We have talked about how there is now much, much more evidence than there was, say in the 1980s, on the issue of animal toxicology; is that right?

13:37:03 A. Correct. So there's been -- since the early

'80s, the first studies that have appeared, there's been numerous studies that have been conducted and none of them have provided any evidence of a consistent change that would lead me to believe that there's compelling
13:37:21 evidence for a compound-related effect.

Q. Yes, sir. And your ultimate conclusion?

A. My ultimate conclusion is that since glyphosate is not a rodent carcinogen, it doesn't support the hypothesis that it could be a human carcinogen.

13:37:41 MR. GRIFFIS: Thank you.

THE COURT: Thank you.

Mr. Wisner.

CROSS-EXAMINATION

BY MR. WISNER:

Q. Good afternoon, Doctor. How are you?

A. I'm fine.

Q. Did you have a good lunch?

A. Reasonably good, yes.

13:37:52 Q. You're not a statistician; right?

A. No, I'm not.

Q. But you would agree that numbers are important?

A. Numbers are always important, especially on my paycheck.

13:38:06 MR. WISNER: Okay. Permission to publish Slide

27.

THE COURT: Very well.

Q. BY MR. WISNER: Mr. Griffis just pointed this out to you, and this is your chart talking about the lymphomas; right?

13:38:23

A. Correct.

Q. And you opined and told this jury that the rate is at 6 out of 50, so that's 12 percent; right?

A. Correct.

13:38:37

MR. GRIFFIS: Okay. Permission to publish Defendant's Exhibit 2552? It was shown to the jury during direct.

THE COURT: Any objection?

MR. GRIFFIS: No objection.

13:38:45

THE COURT: Very well.

Q. MR. WISNER: Now, you arrived at that 12 percent number and you showed the jury this document. Do you recall that?

A. I do.

13:38:53

Q. And this is dated March 2000, and this is about neoplastic lesions in the CD-1 mice; right?

A. Correct.

Q. All right. And if we go into this actual document, it says right here that it involved 51 studies between January 1987 and December 1996; right?

13:39:14

A. Correct.

Q. Now, the Wood study that you're referring to, that was published in 2009; right?

A. Correct.

13:39:24 Q. So this is kind of older data; fair?

A. Yes.

Q. And then I was going through it over lunch, and I found this table. This is Table 3.

Do you see that?

13:39:41 A. Yes, I do.

Q. And this is the neoplasms in males; right?

A. Yes.

Q. And this is tabulating all the data from the charts that are in here; right?

13:39:50 A. Correct.

Q. And if we turn to "Malignant Lymphoma, Whole Body" --

Do you see that?

A. Yes.

13:40:00 Q. -- it says "Percent of Total, 4.09 Percent" --

A. Uh-huh.

Q. -- right?

4.09 percent of 50 would be 2 tumors, not 6?

13:40:11 A. Uh-huh.

Q. Right?

A. Correct.

MR. WISNER: All right. Permission to approach, your Honor?

13:40:19 THE COURT: Yes.

MR. WISNER: I'm handing the witness Plaintiffs' Exhibit 1063.

THE COURT: Thank you.

Q. BY MR. WISNER: Are you familiar with this

13:40:32 document, sir?

A. Yes, I am.

Q. This is an updated version of the same one we're looking at; right?

A. Correct.

13:40:40 MR. WISNER: Permission to publish?

THE COURT: Any objection?

MR. GRIFFIS: No, no objection.

THE COURT: Very well.

Q. BY MR. WISNER: This is the same group of

13:40:48 authors, and they're talking about the same thing, Spontaneous Neoplastic Lesions in CD-1 mice, but this is dated March 2005.

A. Uh-huh.

Q. Sorry, I've got to get a "yes."

13:40:59 And so if we turn the page -- it's been

pre-highlighted for us -- this included some more studies up through 2000; right?

A. Correct.

Q. Okay. And then if we go again to -- let me find this. It would have been Table 3, it's the same table.

13:41:17

See Table 3, "Neoplasms in Males," sir?

A. Yes.

Q. And then we go to "Full Body." That would be on this page, this is page 10.

13:41:36

Do you see that, sir, "whole body"?

And we have the lymphoma?

Do you see that, sir?

A. Yes.

Q. Again, that's a 4.5 percent; right?

13:41:48

A. Correct.

Q. And that would be -- 4.5 percent out 50 would be what? What would that be, 2.25?

A. About that, yes.

Q. We talked about how important numbers are, and this is that chart you created. If, in fact, we were to use the numbers from those publications, this line would actually be a third. It would be down here, wouldn't it?

13:42:02

A. It would be if we accepted those numbers, yes.

Q. And, in fact, if we did that, a lot of these high-dose groups, they're outside of that range; right?

13:42:27

A. They would be outside the range, yes.

Q. There are some other numbers that aren't on here. I just want to verify -- we're going to come back to this study later. You're familiar with the Kumar; study right?

13:42:42

A. I am.

Q. Now, the Kumar study, that wasn't CD-1 mice, was it?

A. No.

13:42:48

Q. That was Swiss albino mice?

A. Correct.

Q. And those types of mice are uniquely prone to lymphoma; right?

A. They are prone, yes.

13:42:56

Q. And the numbers we had from that one though were 10, 15, 16, 19; right?

A. Uh-huh.

Q. And so, again, this would a pretty linear increase in the number of malignant lymphomas; right?

13:43:17

A. Correct.

Q. And you understand that mice are actually the animal that's used to develop lymphoma drugs?

A. Sorry, to develop?

Q. Mice are the animals that are used to develop drugs to treat lymphoma?

13:43:28

A. Yes.

Q. One of the things that you mentioned -- and I wrote this down because I wanted to make sure I heard you right and give you a chance to see if you want to change you opinion on it or not. But you stated that -- you stated that animal models are a poor model for studying cancer. Is that actually your opinion?

A. No. That mischaracterizes what I'm saying.

Q. Okay. What was your opinion?

A. Some animals, depending upon the tumor type that you're looking for, the mouse model could be a poor model to study pathogenesis. Now, if you're using it for screening -- these studies are not designed to study the pathogenesis. They're only screened to study whether or not a tumor appears somewhere in the mouse.

Q. That got me thinking. There's different types of cancers; right?

A. Uh-huh.

Q. Like breast cancer, that's cancer in the breast; right?

A. Yes, it is.

Q. Colon cancer is cancer in the colon; right?

A. Yes.

Q. But lymphoma's a little different, isn't it?

A. Yes.

Q. It kind of starts in the bones, and it can manifest itself in different parts of the body; right?

A. Correct.

Q. So, for example -- I don't know if you know about this case, but our client is suffering from cutaneous T-cell lymphoma. That's on his skin; right?

A. Yes.

Q. But you can get it in your lymph nodes; right?

A. Yes.

Q. You can get it in your gastrointestinal tract; right?

A. I believe so.

Q. When we're trying to look at lymphoma, it would be bizarre to look at a single organ site?

A. It would make sense to look at lymphomas.

Q. You'd look at where they appear anywhere in the body; right?

A. Yes.

Q. A lot of the animals science that we're talking about, they're looking at tumors that appear in different organ sites; right?

A. Because the purpose of the bioassay is to determine whether or not there is any carcinogenic potential of the test substance.

Q. And the theory behind that is if something is

not really a carcinogen and we give animals a bunch of it, there shouldn't be disproportionate numbers of tumors; right?

A. If it's not a carcinogen, then you should -- if it's not a carcinogen, then you would expect that any tumors you would find would be within the background rate.

Q. And you wouldn't expect to see more related to dose; right?

A. You're not expecting to see a dose-response outside of the normal range, no.

Q. One of the things you talked to the jury about was something called a false positive; right?

A. Yes.

Q. And that's when something really doesn't cause cancer, but the data suggests that it does?

A. Correct.

Q. But there's also something called a false negative; right?

A. Correct.

Q. That would be the opposite, that's where something actually does cause cancer, but the data doesn't support that?

A. Correct.

Q. If there truly is no cancer risk, you would

agree with me then that it would make sense that you'd see an equal number of false positive and false negative findings?

A. You would have to ask a statistician on that. That's not something I'm familiar with. In the work that I do, in my discipline, traditionally we're more concerned about a false positive.

Q. Now, the jury has heard from a statistician. They heard from Dr. Portier. You understand he's a biostatistician; right?

A. Yes, I do.

Q. In fact, he's written many of the papers that you yourself rely upon in assessing animal studies; right?

A. I rely on many people. He's one of the people I have cited.

Q. He's actually helped develop the international standards that you rely on; isn't that true?

A. He is one of many, yes.

Q. Let me use the Elmo here. One of the things he explained to us was this idea of a probability, right, because we're trying to estimate something based on data and what's the likelihood that something is true; right? And so if we draw a line and that line is zero effect, okay?

A. Uh-huh.

Q. So nothing is happening. I'll give it zero. In epidemiology it would be like a one; right? We've seen that a lot. If there's truly no elevated rate, you would 13:47:59 expect to see some over here showing a risk and some over here showing not a risk?

A. Correct.

Q. If you did the process enough times, like flipping a coin, you'd have it kind of fall equally on 13:48:12 both sides; right?

A. Correct.

Q. But if you have a situation where they're all just falling on one side of the line, now you're talking about pretty rare probability; isn't that true?

13:48:23 A. That would be unexpected, yes.

Q. That would be like flipping a coin ten times in a row and getting heads; right?

A. Uh-huh.

Q. You can actually calculate the probability of 13:48:33 that, can't you?

A. Right.

Q. Dr. Portier did; right?

A. If you say so.

Q. Well, you read his report, didn't you?

13:48:40 A. Right. I believe there was a section where he

talked about flipping coins, yes.

Q. He said that based on the data we're seeing here, the likelihood of seeing this much going in the same direction, it's like one out of 10,000; isn't that true?

13:48:54

A. Yes.

Q. So one way to avoid this problem would be to -- I can say figuratively or quite literally -- throw some of those findings away; right?

13:49:07

A. I think it would be mischaracterizing what I did in my analysis. I'm not throwing them away. I'm looking at the study and evaluating the quality of the study and what the biological data are telling me. It's not that I'm just looking at it from the point of view of probability. I'm looking at it and saying okay, based on what I'm seeing -- for instance, in the Sugimoto study -- I'm seeing animals in the high-dose group that now have liquid stool, they're losing body weight, their body mass is now 10 percent lower than what it should be.

13:49:25

13:49:44

This is not -- this isn't an issue where they're not gaining weight, they've already achieved their maximum weight. They're losing it now. That tells me there's something going on in these animals that is untoward and not expected.

13:49:58

Q. After you do that, you throw them away?

A. Again, I don't throw them away. I still consider that they're there, but I discount that they're compound-related.

Q. You literally threw them away, didn't you?

13:50:11 A. Yes, we did.

Q. Okay. So another thing that I -- occurred to me, sir, is when -- the earliest mouse study we have on glyphosate is -- what is it? 1981?

A. I thought it was 1983, but I'm not going to

13:50:27 quibble.

Q. Sure. I think 1981 is the Knezevich & Hogan, but maybe it's '83. I don't know. I'll use your testimony.

And we're currently what? 2018; right?

13:50:39 And Roundup was approved in 1974; right?

A. Okay.

Q. So to be clear, the first study that you could rely upon to assess carcinogenicity wasn't until almost ten years after it was approved?

13:50:57 A. Correct. In my review of the data, that's what I had to look at.

Q. All right. Now, I know on one of the slides you said that rodents are not tiny people; right?

A. Correct.

13:51:16 Q. Okay. But you agree that generally when you see

tumors arising in rodents, that's indicative that it might be algogenic in humans; right?

A. If I see an increase that's statistically significant and a biologically relevant increase in the number of tumors, that gives me a reason to look further and -- and evaluate whether or not these are compound-related effects. And if they are, obviously we'd want to regulate on that basis.

Q. Great. I'm going to set up a board here.

So one of the things that Dr. Portier took issue with, okay, was all these people saying something is not biologically relevant. And his problem was no one's told him what the heck that means. So I'm going to ask you: What does that mean to you, sir?

A. What does it mean when something's biologically relevant?

Q. That's right.

A. Do you want to give me an end point to look at or --

Q. Well, what are the issues you're looking for? I mean, what's the things that you're assessing? And I think you've talked about them in your direct; right?

A. Correct.

Q. So what are they?

A. So I'm looking for things that deviate from the

background. So --

Q. Controls?

A. So it deviates from the concurrent control.

Q. Concurrent controls or historical?

13:52:44 A. We'll get there. We'll get there.

Q. Okay.

A. So I want to look at the study and look at concurrent controls. Then I'm also going to look at the historical controls. Ideally that would be something

13:53:03 from the same lab in a relatively reasonable time frame.

Q. Okay.

A. And then I might even go broader and look at historical controls for an outcome that we know -- for instance, we might take the malignant lymphomas. I will

13:53:19 look at the Giknis & Clifford study and say: All right. What do we know about this outcome measure overall over time?

Q. Okay.

A. Because I want to be able to integrate my data

13:53:29 into the broader context of what we already know. So, again -- so it's -- historical controls, too, if you will.

Q. Okay. I'll do a little "2" on there to illustrate that point.

A. Okay.

Q. You also look at replication; right?

A. Yes, I look at replication. I ask questions about how common this tumor is in the mouse or rat that I'm looking at.

13:54:01 Q. That's from looking at historical controls; right?

A. It is, but it's also looking at it from the point of view: If I've got a concurrent control, did my study behave the way I would expect it to?

13:54:13 So, you know, if I'm looking at malignant lymphomas, they're common in mice. And if I'm getting 0, then I'm a little concerned about my concurrent control.

Q. Okay. You look for whether or not -- you look for MTD or the maximum tolerated dose; right?

13:54:28 A. I look to see if they have, indeed -- the study had a high dose that approached or was at the MTD.

Q. And you also mentioned dose limit. Do you remember that?

A. Yes.

13:54:39 Q. Is that the same thing as MTD?

A. No. Maximum tolerated does is the maximum dose that the animal can tolerate without showing untoward effects, whereas the limit dose is the limit dose established by OECD.

13:54:55 Q. Okay. So I guess you looked at limit dose as

well; is that right? This is about the nicest my handwriting has ever looked. I'm kind of proud of myself.

All right. What else? You looked at monotonicity?

A. We looked at the dose response and the shape of the dose response curve across studies.

Q. And that's called monotonicity?

A. Monotonic is just one type of dose response curve --

Q. Okay.

A. -- which was -- has traditionally been looked at in cancer studies.

Q. All right. You also mentioned multiple comparisons; right?

A. Yes.

Q. And that's where you're going to expect to see just random spurious results if you do enough tests?

A. Well, that is one thing, yes.

Q. Okay. All right. Let's talk about some of these things.

Now, one of the things that I found, you spent some time talking about the EPA's report; right?

A. Yes.

Q. Let's turn to --

MR. WISNER: Permission to publish, your Honor?

THE COURT: Is this -- what exhibit?

MR. WISNER: Sorry. It would be Exhibit 2481. Defendant's Exhibit 2481.

13:56:26 MR. GRIFFIS: No objection.

THE COURT: All right. Very well. You may proceed.

Q. BY MR. WISNER: So this is the issue paper that you discussed with the jury; right?

13:56:49 A. Yes.

Q. Now, one of the things that I noticed was it says, "Glyphosate issue paper." Why is it called an issue paper? What is it doing?

A. You'd better ask EPA. I read -- I didn't pay 13:57:04 any attention to the title. I only know it's about glyphosate. I don't know why they called it the issue paper.

Q. It's because it was being submitted to a scientific advisory panel; correct?

13:57:15 A. Yes.

Q. And you, in fact, reviewed the scientific advisory panel's response to this issue paper; correct?

A. Yes, I did.

Q. You've served on a scientific advisory panel; 13:57:26 right?

A. Yes, I have.

Q. And that's when the EPA says, "Okay, here's what our thinking is, but let's bring in some outside independent experts and see what they have to say about what we're doing"?

13:57:36

A. Correct.

Q. And they present issues and say, "Here's our thinking. What is your response to it"; right?

A. That's right.

13:57:42

Q. And this issue; right, was just about glyphosate? It was not about the formulated product?

A. That's my understanding, yes.

Q. Okay. And so they asked this panel to get together and look at some things, and they discussed

13:57:55

their ideas. I'd like to go through the response, actually, to this issue paper.

A. Sure.

Q. But before I do that, you told this jury that you came to your opinions independently of this; right?

13:58:09

A. Yes, I reviewed my own review of the studies for the data that I had. I looked at the Greim paper and the appended tables that went with it.

Q. And you came to your opinion, you got your ideas, and then you looked at this, and went, "Hey, we

13:58:26

kind of agree"; right?

A. Correct.

Q. Now, about the Greim paper. You mentioned that's one of the few things that you relied upon that wasn't source data; right?

13:58:35 A. Yes. Because for many of the studies, I did not have source data.

Q. Yeah. And you understand that the Greim article that you're referring to was actually authored by a Monsanto employee; right?

13:58:46 A. I am not aware of that.

Q. You did look at the authors?

A. I looked at the authors, but I don't recall that one of the authors is a Monsanto employee.

Q. Let's take a look.

13:59:07 MR. WISNER: Your Honor, permission to publish Defendant's Exhibit 2570?

MR. GRIFFIS: No objection.

THE COURT: Very well.

Q. BY MR. WISNER: So that's the Greim paper; right?

13:59:14 A. Yes, it is.

Q. And we can see these different authors. One is Helmut Greim and David Saltmiras; right?

A. Right.

13:59:21 Q. And who does he work for?

A. It says here it's acknowledged that Helmut Greim is the Technical University Munich.

Q. Okay. And for David Saltmiras?

A. Saltmiras is from Monsanto. And if you scroll down -- I don't know what number that -- oh, the glyphosate task force.

Q. And that's the -- that's the group of manufacturers who get together and create data; right?

A. What do you mean create data?

MR. GRIFFIS: Object to that characterization, your Honor, testimony by Counsel.

THE COURT: Well, he may answer the -- well, he has answered the question to the best of his ability.

Perhaps you need to --

Q. BY MR. WISNER: Sure. They created this paper; right?

A. What do you mean by created? Created to me sounds like you're saying they fabricated some -- some data as opposed to they authored this paper, which is different.

Q. I mean, you --

A. I'm not splitting hairs. I mean, it's a different thing.

Q. Sure. Sure. And I understand you don't think they fabricated data. We can talk about that later. But

you'd agree with me that they at least authored this; right?

A. I agree with the author list, yes.

Q. And, in fact, that Kumar issue with the viral infection -- remember that discussion?

14:00:36

A. Yes.

Q. That actually comes from this paper, doesn't it?

A. It was mentioned in the text, yes.

Q. And then the EPA popped it right in their analysis, didn't they?

14:00:47

A. I don't know what the EPA did. I know it appears in their analysis. I don't know what process they went through in order to include it.

Q. Okay. But you agree they basically said there was a viral infection. That's what the EPA said; right?

14:01:02

A. The EPA did say there was a viral infection.

Q. Now, you've also reviewed other regulatory agencies' review of the same data; right?

A. Correct.

Q. You look at EFSA's analysis of it, I'm sure?

14:01:14

A. Yes.

Q. And EFSA said there's absolutely no evidence of any viral infection; isn't that true?

A. I would have to see the EFSA -- I mean, there's a lot of material to read here. I don't recall their

14:01:26

exact wording.

MR. WISNER: All right. Permission to publish 2671, the EFSA analysis?

THE COURT: Any objection?

14:01:38 MR. GRIFFIS: No objection.

I would like a copy, if you have one.

MR. WISNER: I don't. I just have it digitally. Oh, no. I do. I do.

Q. All right. Sir, let's turn to -- is it up? No. 14:01:59 Let me put it up. Here we go. All right.

It's 2071. We're on page 71, sir.

And if we read down here, it states, starting right here: "During a telephonic conference" -- "teleconference on carcinogenicity of glyphosate hold by 14:02:25 EFSA, it was mentioned by a US EPA observer that the Kumar 2001 study had been excluded from the US EPA evaluation due to the occurrence of viral infection that could influence survival, as well as tumor incidences. Especially those of lymphomas. However, in the study 14:02:45 report itself" -- I'm going to stop right there.

You haven't actually seen the study report yourself, have you?

A. No, I have not.

Q. It's not publicly available; right?

14:02:54 A. As far as I know, no.

Q. So we're just relying, basically, on what Greim and Saltmiras have told us in the article; right?

A. We're relying upon what they said there with respect to the virus.

14:03:07 Q. And it goes over -- it says, "However, in the study report itself, there was no evidence of health deterioration due to suspected viral infection. And thus the actual basis of the EPA's decision is not known."

Do you see that?

14:03:19 A. I see that, yes.

Q. You reviewed this; right?

A. Yes.

Q. And you reviewed this before you came to the conclusion that there was likely a viral infection; 14:03:26 right?

A. I -- I reviewed the Greim paper. I also reviewed another report from Weber and -- published in 2017. That reports that they had a worm infection.

Q. Now, Doctor, in your report, you discuss a viral 14:03:43 infection; correct?

A. I mentioned a viral infection, yes, I did.

Q. And you had seen this statement from EFSA before you put that in your report; correct?

A. I had seen this from EFSA, yes.

14:03:53 Q. You saw Dr. Portier's report explaining that

there was absolutely no evidence of any viral infection; correct?

A. I saw Dr. Portier repeating what the EFSA report says.

14:04:07 Q. Right. Because they'd actually seen the study report; correct?

A. I don't know what EFSA has seen or not seen.

Q. It says, "However, in the study report itself." That suggests that they've seen the study report; right?

14:04:19 A. It does suggest that, yes.

Q. Okay.

A. But this is a teleconference. I don't know who's on the teleconference.

Q. That was actually my next question. Do you know

14:04:28 if the person calling from the EPA was a man by the name of Jess Rowland?

A. No. I would not know who was on the teleconference.

Q. All right. So let's go back to the EPA

14:04:38 document. And so what I want to go over is the scientific advisory panel's response. And that should be Exhibit 762.

Do you want a hardcopy, as we go through this, sir?

14:04:51 A. Sure.

Q. All right.

MR. WISNER: Your Honor, would you like a copy?

THE COURT: Yes, please. Thank you.

MR. WISNER: Permission to publish?

14:05:23 THE COURT: Any objection?

MR. GRIFFIS: No objection, your Honor.

THE COURT: Very well.

MR. WISNER: We're going to have to use the Elmo.

14:05:46 Q. So we're looking at Exhibit 762. And this is the front page of it. And as we can see here, it's the transmission of meeting minutes and final report.

Do you see that, sir?

A. Yes, I do.

14:05:59 Q. And it's to the acting director of Office of Pesticide Programs.

Do you see that?

A. Yes.

Q. And it's from Steven Knott, the acting executive

14:06:10 secretary of the scientific advisory panel staff.

A. I see that.

Q. And it says, "Please find the minutes and final report"; right? So this is that document?

A. Correct.

14:06:21 Q. And it's -- it's what? How long is it, without

references? I guess it goes 99 pages; right?

A. 89, at least.

Q. Okay.

A. Without references.

14:06:33 Q. Oh, without references. Okay. Fair enough.

And if we turn the page, we can actually see who was involved here. A few pages. Let's go to the actual listing.

We have all these scientists that are part of

14:06:44 this process; right? We have the chair, James McManaman.

Do you see that?

A. Yes.

Q. And then we have all these different scientists who participated, PhD's, and all these other symbols that

14:07:00 I actually don't know what they are.

Do you see that, sir?

A. Yes, I do.

Q. And then it goes on for a while. And there are quite a few scientists involved in this; right?

14:07:07 A. Correct.

Q. And these are the people who are supposed to be independent scientists; right?

A. That's generally the intent, yes.

Q. Now, when they put out the issue paper, they

14:07:16 actually asked for people to comment on the issue paper;

right?

A. Yes.

Q. And people submitted comments to the SAP saying, "Here's what I think. Here's what I think you should do," et cetera; right?

14:07:26

A. Typically when we respond to the requests for comments like that, we will review the document, and we will provide comments. I don't know that we say, "This is what you should do."

14:07:37

Q. Fair enough.

A. We provide -- we're modest for scientists. We provided our recommendations and let them go from there.

Q. And actually, I think I was misconstruing my question. I'm sorry. I think I misspoke.

14:07:51

What I meant was: In addition to the SAP preparing this report, other people out in the world can send in comments to the SAP to consider; right?

A. Yes.

Q. And Monsanto sent in comments; right?

14:08:01

A. I believe they did, yes.

Q. They had several scientists send in comments; right?

A. I don't know what they had people do. I mean --

Q. Okay. Dr. Portier did as well?

14:08:13

A. Sure.

Q. You've reviewed his comments, in fact?

A. Yeah.

Q. Did you?

A. I don't -- I think I did see his comment to the SAP, but I can't say with 100 percent certainty.

Q. Fair enough. But did you submit any comments?

A. Did I submit any? No.

Q. Okay. Why not?

A. Because I wasn't involved with glyphosate at the time.

Q. Okay. All right. So we go through here, and it has all these different pieces of information. And I kind of want to talk about some of these issues up here on the board.

The first is the concurrent and historical controls; right?

A. Yes.

Q. We talked about that.

And the SAP had some things to say about that, didn't they?

A. Yes, they did.

Q. All right. Let's turn to page 60.

A. 6-0?

Q. Yes. And we see up here at the top, it says, "Please comment on the agency's use and interpretation of

historical control data as a line of evidence to inform the statistical and biological significance of tumor findings for glyphosate"; right?

A. That was the charged question.

14:09:27 Q. Yeah. So the EPA is saying, "Tell us ASAP what you think of what we're doing"?

A. Uh-huh.

Q. And they responded. And just before we start reading this, the way these things read is sometimes it

14:09:38 says "the panel"; right? Like this (indicating). And sometimes it says "some in the panel," or "one in the panel," and that reflects that it's either the group or a portion of it that's expressing that view?

A. Correct. They're -- in these reports, they're

14:09:55 trying to capture the entire flavor of the discussion. So if it's a consensus, they will talk about a panel. If it's something that's one individual, they don't want that loss, they will report that.

Q. Okay. And it says, "The panel recommend that

14:10:10 EPA clearly explain why historical control rates were used in some analysis and not in others. To subjectively choose one historical control incidence data only in situations where concurrent control incidence levels are low is to potentially introduce biases."

14:10:29 Do you see that?

A. Yes.

Q. So then they go on and say --

A. Well, before we leave that, though, let's go back to it. Go back to that comment.

14:10:36 Q. Why is that, sir?

A. Well, your -- the way you characterize it is to say that they've subjectively done that -- concludes that they've subjectively done it. And they don't know that. As a -- as a panel, as a scientist -- and I'm reviewing

14:10:51 the report -- we write things as scientists, and then as a panel that -- that writes the review, we write the report. And sometimes we get everything exactly perfect, which never -- I mean, it rarely happens that you submit a manuscript and you get it back without any comments.

14:11:09 And similarly here, in circumstance like this, maybe they omitted the discussion of why they had -- had used historical control or not used it, because they thought it was obvious, didn't need to be explained or whatever. I don't know. But I can see why that might

14:11:27 happen in a report.

Q. Okay. Is that it, sir?

A. Yes.

Q. Okay. Just so you know, I'm on the clock. So if it's really important, we can do this. But I don't

14:11:36 want to spend my time --

A. But it's also important we get it right.

Q. Sure. I know. But I think your answer was "we don't know"; right?

A. We don't know.

14:11:44 Q. Okay. So then we go down here, and it's talking about the guidelines. You understand the -- you've heard of guidelines. They're talking about the EPA's guidelines; right?

A. Yes.

14:11:54 Q. It says, "The guidelines also state that caution should be exercised in simply looking at the ranges of historical responses, because the range ignores differences in survival of animals among studies and is related to the number of studies in the database."

14:12:09 A. Yes.

Q. It goes on, "There is no evidence in the issue paper that such a careful review was carried out in any of the three studies that utilized historical control information."

14:12:19 Do you see that, sir?

A. Yes.

Q. And then when we go down to the summary, it says, "Summary of evaluation of agreement of EPA analysis with EPA cancer guidelines. Overall, based on the

14:12:39 previous discussion, many panelists concluded that the

use of the historical control information in the issue paper does not adhere to EPA cancer guidelines. There is no evidence that the issue paper authors performed a careful review of any of the historical control data employed as directed by the EPA guidelines, such as discussing the likelihood of genetic drift, differences among animals from different suppliers, differences in laboratory techniques." It goes on for a bunch.

14:12:55

"The timing of studies from which historical control data come is not always clearly stated. Although, it is clear that the 2- or 3-year limit recommended by the EPA guidelines was not met in certain circumstances."

14:13:12

In fact, we were doing that a second ago when we were talking about the rates of lymphoma, weren't we?

14:13:25

A. Yes.

Q. We were talking about data that was almost ten years old?

A. Yes. Now, let's remember, and I'm sorry that you're on the clock, but these are guidelines. They're not tablets from the mount. These are not the 10 commandments. They're guidelines that we're asked to follow. And it's not unreasonable that we deviate from guideline on occasion, as long as we justify why we've done it.

14:13:35

14:13:55

Now, in my reading of this, there is some comment that they may not have provided the evidence of why they've done it. It doesn't mean they didn't do it. It just says they didn't provide the evidence.

14:14:10 Now, this goes back -- feeds back to EPA, so that EPA, when they go forward, it's all part of the transparency issue, so they do things better the next time. It's not saying they got their assessment wrong. They're saying: Who can do it better?

14:14:28 Q. Fair enough. It actually, kind of, does, though, because I didn't skip all the details, because I didn't want to spend too much time on it.

But since you raised it, let's look at what the EPA's stat panel said. They go into the specific

14:14:43 studies. They say, "In the case of Lankas, 1981, the issue paper reports only the mean and a range of responses that were provided in the Lankas study report. There is no information on when or where the data studies were performed, from which these historical control

14:15:00 values were calculated. Hence, the relevance of the historical controls is unknown."

And then down here, it talks about the case of Wood. And it basically goes on to say it's not possible that they did it right. "So that the year of completion

14:15:12 of the Wood, et al, study is not mentioned. But it

appeared to the panel that the recommendation that only controls from studies completed within the two or three years of the completion of Wood, et al, could not have been met."

14:15:26 That's saying they don't think they did it right; right?

A. That's what it's saying, yes.

Q. Okay.

A. Now, of course, the SAP does not have all the

14:15:35 information to look at, so --

Q. Okay. All right. There are some other issues on here. We've talked about -- we're going to get to the concurrent controls in a second.

Well, actually, why don't we just start there.

14:15:53 Let's start with the statistical -- the use of statistical significance; right?

And so when you say "concurrent controls," what you're really saying is you have to make sure that what you're seeing in the elevated dose groups is different;

14:16:04 right, than the concurrent control?

A. You're trying to make sure that any change that you're seeing in any of the dose groups is different than your control.

Q. Let's see what the SAP said about that. It

14:16:25 goes, "In summary" -- this is page 52 -- "many panelists

concluded that the issue paper's protocol for assessing the significance of laboratory animal carcinogenicity studies does not appear to have followed agency guidelines. In addition to misinterpret the rule on assessing significance from combined multiple comparison tests in the Cochran Armitage trend test, the issue paper incorporates in the protocol criteria, such as exclusion of dose levels considered above the limit dose without documenting findings that demonstrate that the limit dose was actually exceeded. Requiring a visual confirmation of a monotonic trend and scatter plots of data" --

That means, you know, it goes up; right?

A. Yes.

Q. They said this is not required, but they did require this for some reason. And it goes, "Subjectively incorporating information about historical control levels."

We talked about that already. So here, the SAP is saying the EPA didn't even do what it's supposed to be doing; isn't that true?

A. The -- what I take it to say is that they deviated from the guidelines. They're not saying that the conclusions reached were wrong. They're saying that: You have not documented why and how and what you did when you deviated from the guideline.

Q. Do you know why the EPA was willing to deviate from the guidelines from Monsanto?

A. I have worked with the EPA on different things, and I have not worked with them on glyphosate. But I have seen them deviate from guideline on other occasions.

14:18:04

Again, it comes back to it's a guideline. And typically what we try and do is we always try and provide an explanation of why we could not follow guideline.

Q. All right. Okay. Here's another section I found interesting. I want to get into this multiple comparisons issue; right?

14:18:33

A. Uh-huh.

Q. Now, sir, you would agree with me that from a scientific perspective, looking for multiple comparisons, it wouldn't be appropriate to just look at all the tests to see if there's as many tumors as you would expect; right?

14:18:44

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

Q. Well, you should look at, like, species, you should look at sex, you should look at related tumor sites, to see if there's an elevated rate consistently in those groups; right?

14:18:56

A. Yes. And that is what we do.

Q. Well, let's see what the panel said. This is on page 59.

14:19:14

And interestingly enough, this table that they put in here, it's actually from Dr. Portier, isn't it?

A. Yes.

Q. All right. It said, "Some panel members
14:19:26 suggested that while not discussed in the EPA's cancer guideline as to how it considers the multiple studies for each end point, the most appropriate way to address the scientific question at hand: Is there evidence of carcinogenic in any end point in any species or gender,
14:19:43 is by conducting a pooled analysis for each species, end point and gender combination."

And it talks about a meta-analysis that Dr. Portier submitted to the EPA.

And it says -- this analysis suggests that EPA's
14:19:57 descriptor of, quote, "Suggestive evidence of carcinogenic potential is the appropriate descriptor, given that these pooled analyses show compelling statistical evidence of at least one single positive result in at least one species and gender."

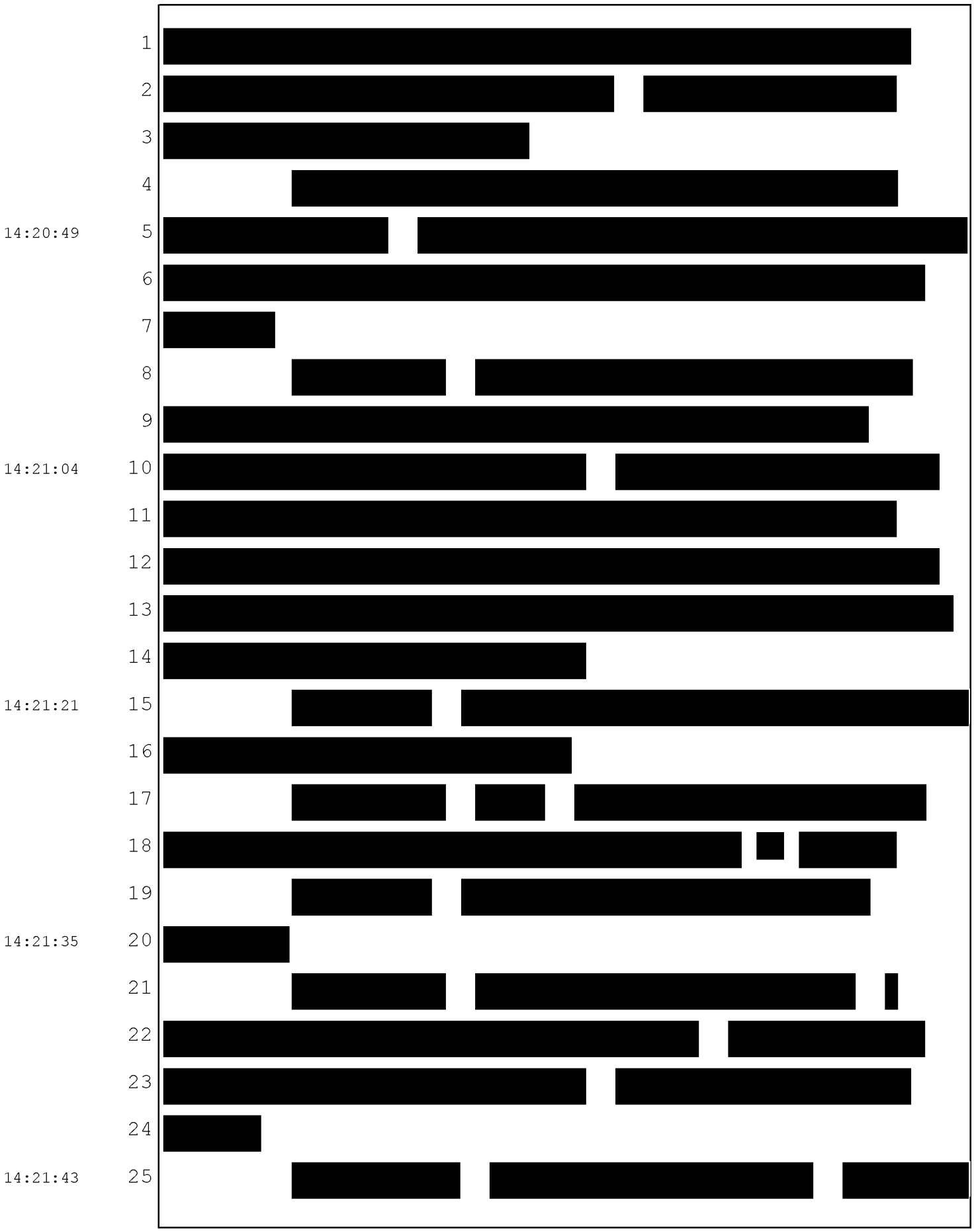
14:20:14 MR. GRIFFIS: May we approach, your Honor?

THE COURT: Yes.

(Sidebar.)

[redacted]

14:20:31 [redacted]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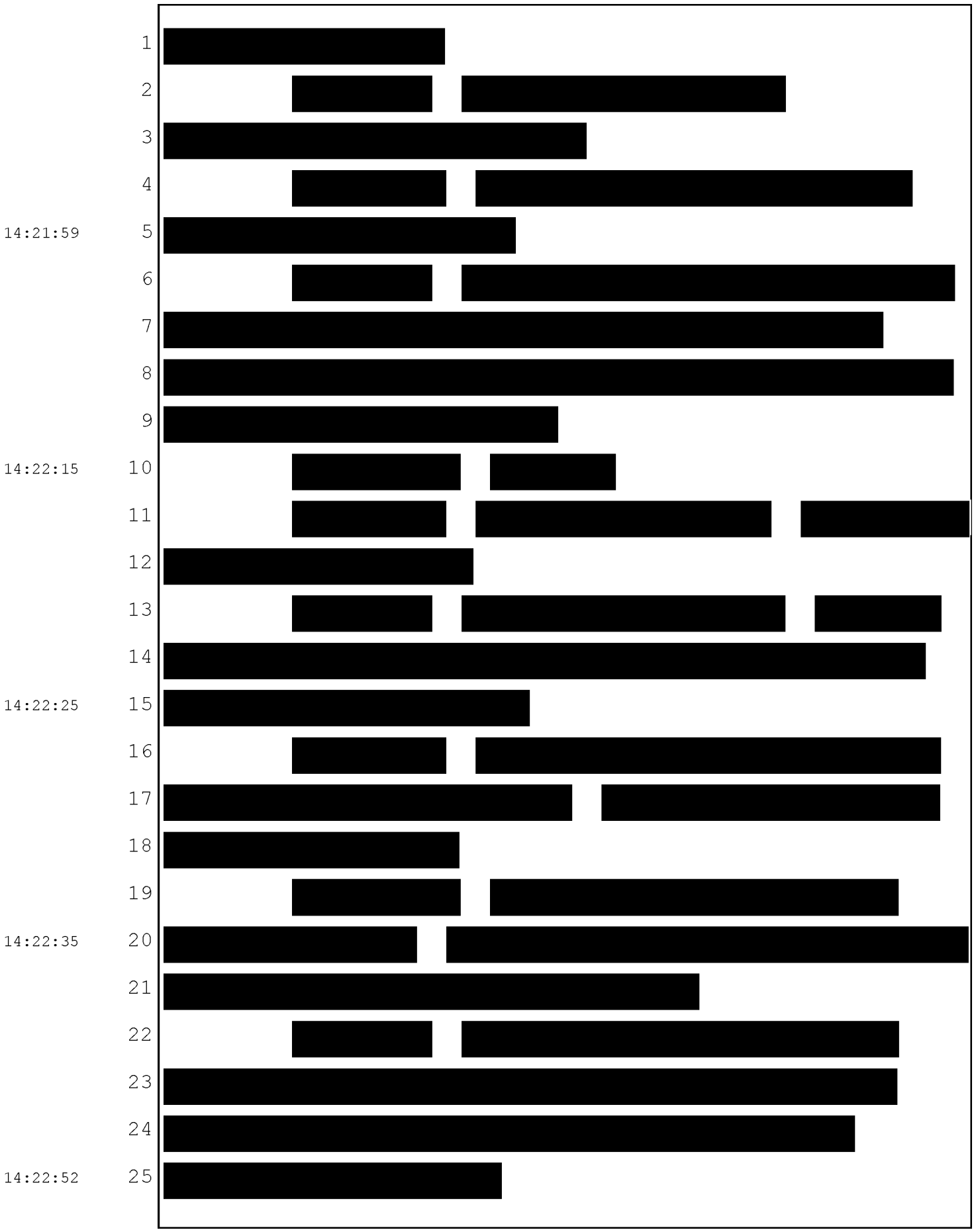
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(End sidebar.)

THE COURT: Okay. Objection is sustained.

You may proceed.

14:23:06 Q. BY MR. WISNER: All right. Let's talk about replication. Let's go to page 72 on this document.

Here the panel says, "Most importantly, before one can conclude that the findings in individual studies are not replicated, one must compare the results across

14:23:37 studies in a rigorous manner. Similar patterns of tumor responses were observed across studies for some tumor categories."

And it lists some tumor types. Do you see that?

A. Yes.

14:23:48 Q. Lung, liver, lymphatic and thyroid tumors.

Do you see that?

A. Yes.

Q. It says, "One panel member was of the opinion that this constitutes reproducible evidence of a

14:24:03 biologically significant carcinogenic effect in rodent liver, lung, thyroid and lymphoid cells."

Do you see that?

A. Yes.

Q. And lymphoid cells, that's the source of most

14:24:14 lymphoma; right?

A. Correct.

Q. All right.

A. But it is one panel member.

Q. This part here is not, sir?

14:24:21 A. Yes.

Q. Okay. All right. Let's talk about this maximum-tolerated dose.

Now, sir, I looked into this. But let's look at what you showed to the jury. If we're doing the Elmo,

14:24:38 let's do it old school.

You showed them an OECD guideline; right?

A. Correct.

MR. WISNER: And permission to publish, your Honor, Defendant's Exhibit 2856?

14:24:51 THE COURT: No objection.

MR. GRIFFIS: That's the OECD guidelines?

MR. WISNER: Yes.

MR. GRIFFIS: No objection.

THE COURT: Very well.

14:24:56 Q. BY MR. WISNER: So this is what you showed the jury; right? This is the OECD guideline, and you mentioned the 453; right?

A. Correct.

Q. There's actually one that's 452; right?

14:25:06 A. There's 451, 452, yes.

Q. Okay. We're going to get to one of those in a second. But this is a guideline for combined chronic toxicity/carcinogenicity studies; right?

A. Right.

14:25:20 Q. And you agree that toxicity is different than carcinogenicity; right?

A. Yes.

Q. Toxicity means it's toxic to the cell, whereas carcinogenicity means it's cancerous; right?

14:25:30 A. Right.

Q. All right. And then you showed the jury Point 23 in here. And you pointed out a limit of 1,000. Do you remember this one? You talked to the jury about this, sir.

14:25:46 A. Yes.

Q. But if you read the beginning of the paragraph, it specifies what this is about. It says, "For the chronic toxicity phase of the study, a full study using three dose levels may not be considered necessary if it

14:25:59 can be anticipated that a test at one dose level equivalent to 1,000 milligrams per kilogram body weight per day is unlikely to produced adverse effects"; right?

A. Right.

Q. So this paragraph is actually talking about the

14:26:14 toxicity phase of a study; right?

A. Correct.

Q. Now, the OECD has actually issued guidelines specifically about carcinogenicity; right?

A. They did, yes.

14:26:26 Q. I want to show you that.

MR. WISNER: Permission to approach, your Honor?

THE COURT: Very well.

MR. WISNER: I'm hanging the witness and the Court Plaintiff's Exhibit 1062.

14:26:52 Q. Sir, I just handed you the OECD 451; right?

A. Yes.

Q. This is the carcinogenicity studies; right?

A. Uh-huh, yes.

MR. WISNER: Permission to publish, your Honor?

14:27:05 THE COURT: No objection?

MR. GRIFFIS: No objection.

THE COURT: Very well.

Q. BY MR. WISNER: All right. So this is the 451. It's pretty recently updated as of June 2018; right?

14:27:17 A. Correct.

Q. And this is the OECD guideline for the testing of chemicals; right?

A. Yes.

Q. Glyphosate's a chemical; right?

14:27:26 A. Yes.

Q. Sorry. I know it's a dumb question, but, you know.

All right. Carcinogenicity studies; right? So this is about carcinogenicity studies?

14:27:33 A. Yes.

Q. All right. Please show the jury or tell me where I'll find the 1,000 milligram dose limit.

A. Well, since this is something that I haven't looked at, it might take me a minute or two, if it's

14:27:48 here.

Q. I can direct you, if you'd like, to where I think it would be, but I don't want to speak for you, sir.

A. I would expect to find it under dose groups and

14:28:00 dosage, so from 21 on.

It doesn't appear to talk about the limit dose in this one, which is -- as of June of 2018, they may have dropped it.

Q. I'll represent to you, sir, I went back and

14:28:49 looked since 1981. I couldn't find it.

Now, if you look at paragraph 30, right, it says, "For substances administered via the diet or drinking water, it is important to ensure that the quantities of the test chemical involved do not interfere

14:29:04 with normal nutrition or water balance"; right?

A. Correct.

Q. And what that's getting at is if you have too much stuff in the food, mice might not want to eat it and it could cause other problems.

14:29:18 A. If you get too much stuff in the food, it might interfere with caloric intake. It might have effects upon the central nervous system affecting their senses being full, so there's different reasons it does it.

Q. And the only thing I could find that related to

14:29:31 any, sort of, 1,000 milligrams -- and maybe -- is 1,000 milligrams 1 milliliter?

A. 1,000 milligrams per kilogram is not a milliliter, no.

Q. Okay. The only thing I could find was down in

14:29:45 here paragraph 32, so I don't know if that was the same number talking about gavage, where you shove the food down the mouse's throat, right, that's not what we're talking about here; right?

A. No.

14:29:55 Q. You looked at the EPA guideline?

A. Yes.

Q. And it also doesn't have a dose limit in the EPA guidelines, does it?

A. No, it does not.

14:30:03 Q. So where'd you get this from?

A. I got it from my experience of having worked at OECD.

Q. Now, the maximum tolerated dose -- and Dr. Portier explained this to the jury -- is a dose where it's so high that you start seeing it have toxic effects on the animals; right?

14:30:17

A. Right.

Q. It effects mortality, body weight, things like that?

A. Liver enzymes. You get porphyria. Porphyria is where the red blood cells start breaking down.

14:30:28

Q. And in all the mouse and rat studies, how many of them had evidence of that kind of toxicity?

A. I didn't count the number of studies that had evidence of toxicity like that. I do note that -- in the study of Sugimoto where they had diarrhea to liquid stool, that to me is where you've exceeded the dose -- the tolerated dose.

14:30:45

Q. Okay. So you've got Sugimoto. I think Knezevich & Hogan there was a 10 percent body weight in the highest dose?

14:31:02

A. 11 percent.

Q. 11 percent. Okay.

That's pretty much it; right?

A. In the data that I had available to me, yes.

14:31:09

However, if I was -- I anticipated if I was to look at the biochemistry -- the clinical chemistry of those animals, I would be seeing reasons for that body weight loss and the diarrhea.

14:31:28 Q. But you're guessing because you haven't seen it?

A. I'm guessing based on over 30 years of experience in what I've seen when I see body weight loss.

Q. How many glyphosate studies had you looked at prior to doing this case?

14:31:38 A. I had not looked at any glyphosate studies before doing this case. I looked at a large number of toxicology studies.

Q. And glyphosate appears to be able to have a pretty high NTD, doesn't it?

14:31:52 A. Yes, it does.

Q. And it's appropriate -- so when we're doing animal studies, one of the issues is we only have 50 animals in each gender group; right?

A. Sex group, right.

14:32:04 Q. Sorry. Sex group.

And one of the reasons why we use such high doses is not because they're going to be illustrative of what happens in the real world, but it's so we can, sort of, develop a slope dose, right, a slope of what the dose

14:32:20 curve is?

A. You want to know that your study is working, and so that you're able to detect something if something was really there.

Q. Exactly. And so, for example, lymphoma or non-Hodgkin's lymphoma, it's, like, 1 in, what, 5,000 people get non-Hodgkin's lymphoma?

14:32:33

A. It's rare in people, one -- but it's quite common in mice.

Q. I understand.

14:32:44

But it was 1 in 5 in people, and then if you get, like, very specific, like mycosis fungoides, you're going to get, like, 1 out of 100,000. It gets to really high numbers fast; right?

A. Right.

14:32:57

Q. And, of course, the best thing to do, if you could, would be to get 5,000 mice in each group, give them relative dose amounts relative to their body weight, and then count up the tumors after two years, but that would, obviously, be an impossible study to do.

14:33:14

A. Well, it's completely impractical, and I don't know why one would even suggest such an idea. With 50 animals per group, nose to toes, looking at the all the tissues, if you're seeing a statistically significant increase tumors that are biologically relevant in the absence of frank toxicity, then you've got information

14:33:33

that you would be able to then go back for risk assessment purposes to make a decision about carcinogenicity in a blanket way.

Q. Yeah. And I guess that's the point, is one of your gripes with the animal data here is that the doses are so high, but at the same time, we need those high doses so we can actually see what would happen in the real world; right?

14:33:50

A. No. You're not seeing it in the real world. 1,000, 4,000, 5,000 mgs per K is not real world.

14:34:05

Q. Yeah, but neither is three kidney tumors out of 50 human beings. That's pretty high, too; right?

A. Three kidney tumors out of 50 human beings?

Q. Yeah.

A. Well, I can't answer that, because I don't deal with people.

14:34:23

Q. Okay.

A. I deal with mice. They're rare tumors in mice, and in the two studies that we looked at back to back, you've got 1, 0, 1, 3, which wasn't statistically significant, and the next study over is 2, 2, 0, 0.

14:34:32

Q. Well, let's talk about something that you do know, lymphoma. Malignant lymphoma, we're seeing it, you know, six malignant lymphomas in the high-dose group; right?

14:34:48

A. Correct.

Q. And that's out of 50 mice?

A. Correct.

Q. To see 6 malignant lymphomas in humans, you'd have to have 30,000 people; right?

14:34:55

A. You'd need a large number of people.

Q. Right. And so that's why you have the high dose, so you can actually use the data from the animal studies to think, hey, does this substance actually potentiate cancer; right?

14:35:11

A. Correct.

Q. Okay. Let go back to the SAP panel. I want to talk about the -- what they said about the dose issue in the panel. We're looking here now at page 74.

14:35:41

Do you see that, sir?

MR. GRIFFIS: May I approach on this, your Honor?

THE COURT: Yes.

Which report are you referring to now?

14:35:55

MR. WISNER: Oh, this is the SAP panel. This is Exhibit 762.

(Sidebar.)

[redacted]

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14:36:12

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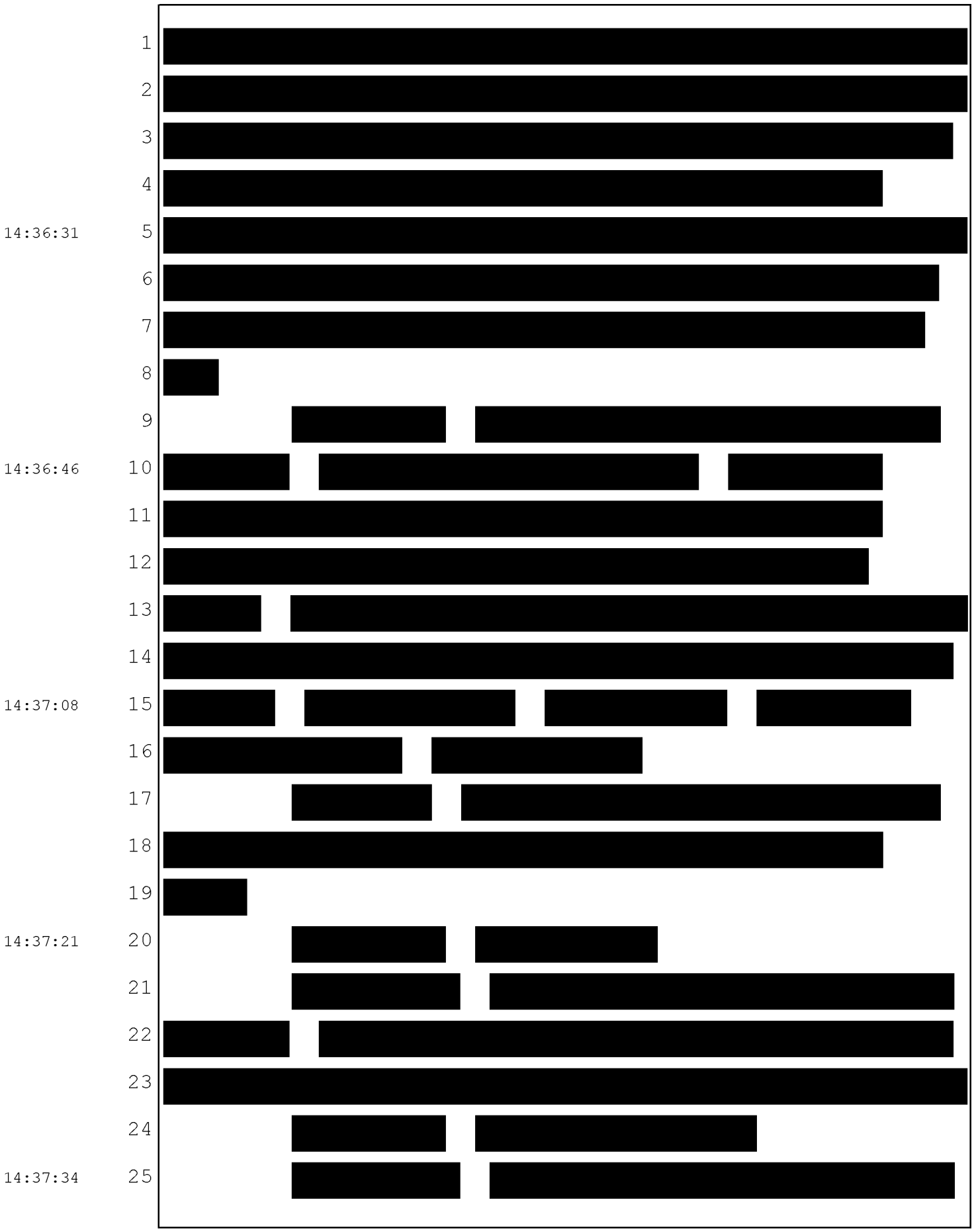
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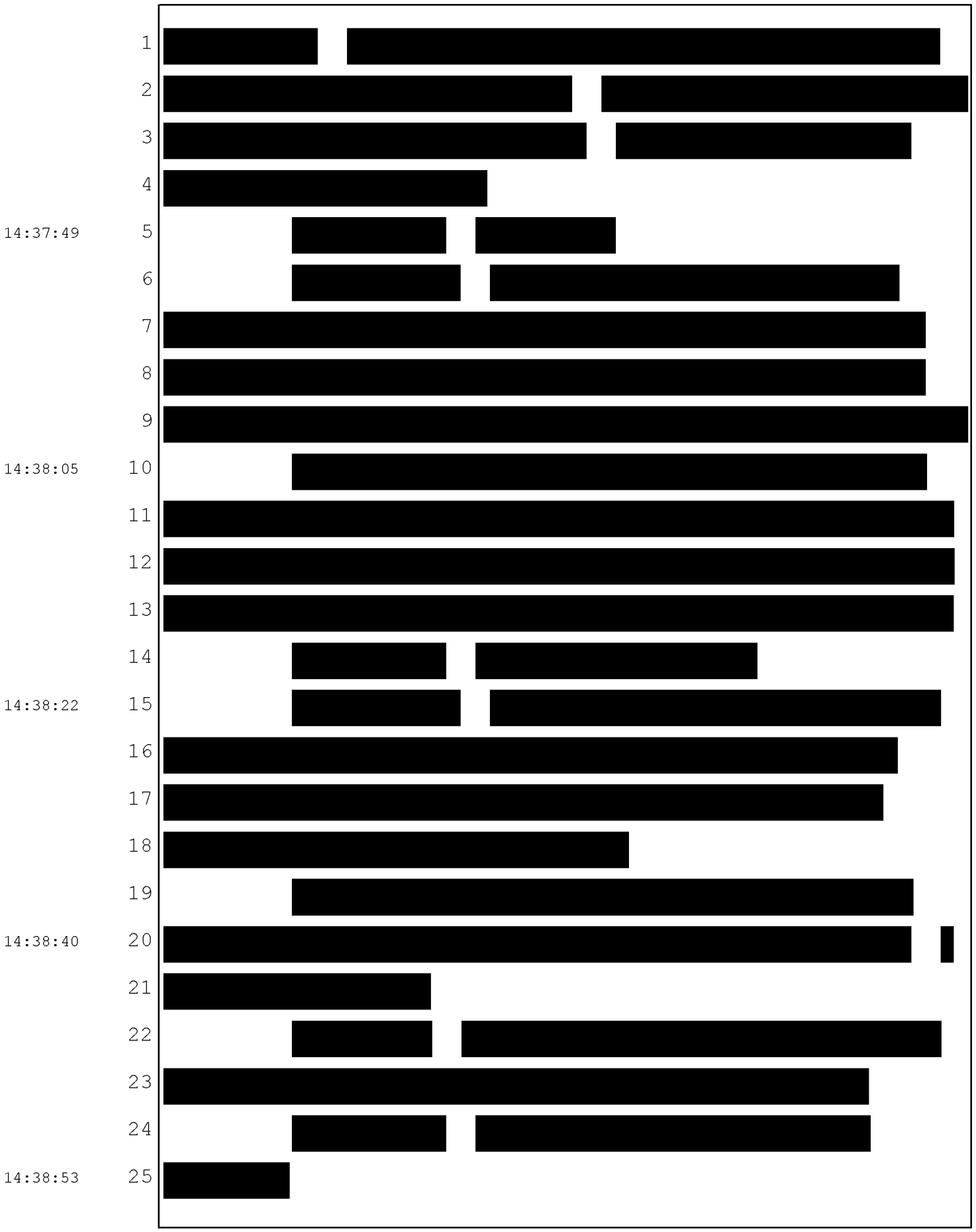
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(End sidebar.)

THE COURT: You may continue, Mr. Wisner, and just keep in mind we need to take an afternoon recess at a convenient point.

MR. WISNER: All right. I'll keep that in mind, your Honor.

Q. We're on page 74; right?

A. Yes.

Q. And it said, "Many on the panel expressed concern that not considering tumor responses at doses exceeding 1,000 milligrams per kilograms per day is not consistent with either EPA 2005 cancer guidelines or standard ways in which bioassay results are typically interpreted. However, the panel also noted that tumors induced at only very high doses are less of a safety concern than those induced at doses within the range of human exposure. Though one panel member noted that it is very likely that workers in manufacturing/formulation and wholesale handling and also persons involved in accidents

and spills may experience these high doses."

Do you see that, sir?

A. I see that speculation, yes.

Q. Down here --

14:40:19 A. But you need to remember that this is -- the SAP report is a report that's prepared when you get people like me together in a room and they say, "No holds barred. Take a look at what we've done, and in this -- the way we've done our assessment. Can we to this

14:40:37 better? Did we go to it right? What would we do next time that might enhance our confidence?"

And so we -- we open the floodgates and we tell them everything that we think. It's not necessarily something that's to be taken as, "Oh, my God. This is

14:40:54 wrong."

Q. Okay. But --

A. I mean, this is all -- it's an iterative process of -- in transparency to try and help EPA make sure they get the best possible conclusion that they can.

14:41:08 Q. I know. But that's kind of the point, though, is these independent experts, they got together and they're pretty critical of the EPA's report, and then we have other independent experts, like IARC who come to a very different conclusion, and this jury's trying to

14:41:26 figure out who's right; right?

MR. GRIFFIS: Counsel's testifying, your Honor.

THE COURT: All right. Do you have a question, Mr. Wisner?

MR. WISNER: Sure.

14:41:33 Q. In trying to figure out who's right, one of the ways of doing it is looking at the quality by which people look at stuff; right?

A. Correct.

Q. And the EPA, they have guidelines that say how

14:41:44 they're supposed to do things; right?

A. Correct.

Q. And they didn't follow those guidelines, did they?

A. They followed the intent of the guidelines.

14:41:54 They provided their interpretation. In some cases maybe they could have done a better job of documenting why they deviated from the guidelines, but even with this report, my understanding is that they had still come back with the conclusion that glyphosate is non-carcinogenic. The

14:42:12 same conclusion that's been reached by ECHA, the same conclusion that's been reached by EFSA, also independent bodies or government regulatory bodies.

Q. So the EPA panel was very critical in this part. They said, "The EPA's 2016 practice of disregarding or

14:42:36 giving low weight to results at exposures greater then

10,000 milligrams per kilograms per day seems to be at odds with the EPA 2005 cancer guidelines, which suggest that an exceedingly high does would be 5 percent of the test substance in the feed for dietary studies."

14:42:56 Do you see that?

A. Yes.

Q. That's actually what we looked at a second ago when we were looking at the OECD guidelines; right?

A. Yes.

14:43:03 Q. Then it says, "But 5 percent in feed is considerably greater that 1,000 milligrams per kilograms per day in both rats and mice, and none of the doses utilized in the studies reviewed exceeded 5 percent in feed. Several panel members saw no overriding reason for 14:43:20 disregarding results from exposures greater than 1,000 milligrams per kilograms per day, so long as the dose does not exceed the maximum tolerated dose"; right?

That's the proper scientific approach in a carcinogenicity study; right?

14:43:36 A. The proper approach is to give 1,000 mgs per kilograms per day. You can go higher, yes.

Q. And if you do go higher, like the scientists who did these studies, you'd better look at the results, right?

14:43:51 A. We did look at the results.

Q. But you threw them away?

A. We didn't -- what do you mean by we threw them away?

Q. You literally took them off the board and threw them in the trash, sir.

A. Because I determined that they were not compound-related, based not just on the dose that was given, but also the adverse effects that were seen in the animals, the lack of statistical significance or the lack of a P trend. So there's many reasons, not just one.

Q. Okay.

A. It's on the balance. You know the phrase "weight of evidence"? It's the weight of it all, not just based on one thing.

Q. Yeah, and you're weighting it, after Monsanto's hired you, you weighed it that they all go in the trash bin; right?

A. The way you're characterizing that is that my -- the only reason I did that is because I'm an expert witness for Monsanto, and I take exception with that, because as a scientist, the only thing I have is my objectivity and my lack of bias.

Q. Okay.

A. That's the only thing I've got. At the end of the day, I walk out of here. I go home. The only thing

I can hang on my wall is that I've looked at it in an objective way. And that's what I did. I went and I reviewed the literature to the best of my ability. I searched to make sure that Hollingsworth lawyers, Monsanto's lawyers, didn't give me only the selected things that happened to agree with their view of the world. And I went and searched. I reviewed it, and then only after I had come to my own conclusions, did I then go and look at EPA, EFSA, ECHA, JMPR and look and see what they had concluded.

14:45:13

14:45:31

Q. So then it would be fair to say that you agree with EPA not following their guidelines?

A. I don't have a real comment on whether EPA followed individual or different guidelines. What I'm telling you is I did my independent assessment of the literature, and I came to my own conclusion. It happens to agree with the EPA's conclusion, and they may have got there by a different route, but the conclusion's the same.

14:45:47

Q. One last thing before the break. This last issue, monotonic or monotonicity, here's what the panel said. They said, "The panel noted that the fact that an observed dose response is not monotone typically provides essentially no evidence that the underlying true dose is not monotone."

14:46:00

14:46:22

Do you see that?

A. Yes.

Q. "Checking for monotonicity is not mentioned in the EPA 2005 cancer guideline."

14:46:29 Do you see that?

A. Yes.

Q. So what they're saying is even if it, kind of, goes up and down and back up, that's okay?

A. That's what they're saying, yes.

14:46:42 MR. WISNER: We can take a break, your Honor --

Q. Sorry. Do you want to finish your answer? I didn't mean to interrupt.

A. When you wrote up on the board, you have monotonicity and dose response, in my assessment, I

14:46:53 looked at all the dose responses that were present.

MR. WISNER: We're going to get there after the break.

THE COURT: All right, Ladies and Gentlemen. We're going to take the afternoon recess now. We'll be

14:47:03 in recess until 3:00. Thank you.

(Recess.)

THE COURT: Welcome back, Ladies and Gentlemen. Dr. Foster remains under oath. And, Mr. Wisner, you may continue.

15:03:30 Q. BY MR. WISNER: Doctor, you got water; right?

A. Yes, I do.

Q. So are you familiar with something called a hazard assessment versus a risk assessment?

A. Yes, I am.

15:03:37 Q. And you actually -- you participated in an IARC program; right?

A. Yes, I did.

Q. And you were looking to see if those substances were cancer hazards; right?

15:03:49 A. Correct.

Q. Isn't it true, though, you don't get to a risk assessment until you have first established that it's a hazard?

A. Correct.

15:03:56 Q. And, in fact, the EPA never got to a risk assessment; right?

A. That's correct.

Q. So what the EPA effectively did was a hazard assessment?

15:04:04 A. Correct.

Q. So really if someone were to suggest that the IARC program was doing something different than the EPA, that wouldn't be fair, would it?

A. I think you need to be careful on that in that

15:04:22 they might both do hazard assessments, but they might do

it differently in terms of the data that they look at.

Q. Fair enough. But they're basically doing the same thing. They're trying to decide if something is a hazard; right?

15:04:38 A. I think that's fair.

Q. And the scientific advisory panel stated that, didn't they?

A. Yes.

Q. One of the issues -- permission to publish 762, your Honor?

15:04:53 THE COURT: Any objection?

MR. GRIFFIS: No, your Honor.

THE COURT: Very well.

Q. BY MR. WISNER: On page 82 of the SAP panel, there's a section titled "Scientific Quality of the Agency's Carcinogenic Potential Characterization." And it says, "Quality science is reproducible, free from distortion, credible, built on what is known (sound science), follows logical inferences, and is honest about what is achievable and the limits of available designs and data."

15:05:02 15:05:22 You would agree with that; right?

A. Yes.

Q. "While the issue paper does try to detail the design and data limitations of each study selected, some

15:05:31

of the panel believed that it does not provide sufficient details to support its conclusions." For example -- and it says look at a question. "And this negatively impacts the scientific quality of the report. In addition, many
15:05:47 panel members felt that some of the discussions of study design and data limitations provided in the issue paper introduced and used criteria that were not part of EPA guidelines for these assessments and this further reduces the credibility of the assessment."

15:06:04 Do you agree with that? Not following the guidelines reduces the credibility of the assessment?

A. I think the issue is if they followed the guidelines, did they provide reasons or explanation for why they departed from it. So I think what the -- some
15:06:21 of the panel members are saying, they need to go back and provide better rationale.

Q. Now, ultimately the panel members made a kind of -- they tried to make a conclusion about what they thought; right?

15:06:41 A. Uh-huh. Yes.

Q. And they were split; right? Some of them were split between those members agreeing with the issue paper and conclusions and those members who felt that the characterization of not likely to be carcinogenic to
15:06:56 humans in the issue paper should be replaced by the

hazard descriptor of suggestive evidence of carcinogenic potential.

Do you see that?

A. I see what they recommend.

15:07:07 Q. And that's your understanding, that the scientific advisement panel was not unanimous, they actually had dissenting voices; right?

A. Correct.

Q. And so the ones that supported the EPA's

15:07:19 position, therefore -- they say, "Some panels concluded."

Do you see that?

A. Yes.

Q. And so that's talking about supporting the EPA's

15:07:23 position; right?

And then on the next section, it discusses perspectives supporting the suggestive evidence of carcinogenic potential descriptor.

Do you see that?

15:07:36 A. Yes.

Q. And it says, "Other panel members did not agree with the conclusions. To these members, the weight of the evidence based on the guidelines leads to suggest the evidence of potential carcinogenic effects."

15:07:46 And they go on to explain their reasonings;

right? And they talk about the specific types of tumors that they think are related to dose, and they say, "According to these guidelines, we think that there is convincing evidence" -- okay. Then it goes at the bottom, it says, "According to the 2005 EPA guidelines for carcinogenic risk assessment, the cancer descriptor not likely to be carcinogenic to humans applies if, quote, there is convincing evidence that carcinogenic effects are not likely below a defined dose range. Many panel members" -- it says many, it doesn't say some; right?

A. Uh-huh.

Q. It says, "Many panel members believe that the EPA did not provide convincing evidence of a lack of carcinogenic effects. These panelists agreed that the four findings listed above are adequate to reject the issue paper's conclusion of not likely carcinogenic to humans and support a conclusion of suggestive evidence of carcinogenic potential under these guidelines.

Do you see that?

A. Under the risk assessment guideline, not the hazard.

Q. That's right. It's talking about the guidelines for the EPA's risk -- the EPA's guidelines?

A. Right. But they're doing a hazard, not a risk.

Q. Sure.

All right. Let's change gears a little bit. All right? And let's talk a little bit about some of the data. You had Dr. Portier's charts up here and you had a bunch of tumors listed for the mouse and rats; right?

15:09:19

A. Yes.

Q. And you kind of got rid of all of the tumors in the rats because Mr. Griffis told you that Portier thought the skin ones were the only ones that were relevant; right?

15:09:40

A. That was my understanding of what Dr. Portier's testimony said.

Q. And that's your understanding based on what Mr. Griffis told you; right?

15:09:49

A. Also I had seen the transcript.

Q. Oh, you read his testimony in court?

A. Did I read his testimony in court?

Q. Yeah.

A. I had seen his testimony from court.

15:10:00

Q. Okay. So you saw his deposition.

A. Right.

Q. Did you also see his actual testimony before the jury?

A. Yes.

15:10:07

Q. Okay. You read that?

A. Yes.

Q. Okay. And it's your understanding that he didn't think those other tumors were relevant?

A. That was my understanding.

15:10:22 Q. Okay. You also went through the mouse chart and you got rid of some of them.

Do you remember that?

Let's actually put that up. Permission to publish 1020, your Honor?

15:10:32 THE COURT: Any objection?

MR. GRIFFIS: The mouse chart?

MR. WISNER: Yeah.

Q. So this is -- this should be the mouse chart. It is. And we went through this with Dr. Portier, and

15:10:48 just so you know, he actually marked it up; right?

A. Yes.

Q. So he's not saying that there's trend doses in males and females for each, obviously. He's saying --

A. He marked it up.

15:10:59 Q. He clarified what he's doing. And, you know, one of the things that you mentioned was this like harderian gland adenoma; right?

A. Correct.

Q. You got rid of it; right?

15:11:10 A. I did.

Q. But you never mentioned that tumor in your report, did you?

A. I remember reading about it in the report and I don't remember whether I specifically talked about it in my report primarily because it's a tumor that only appears in mice. There is no equivalent in humans.

Q. But it's a tumor; right?

A. Yes.

Q. And --

A. It's a benign -- it's a benign tumor.

Q. Okay. That was something else you mentioned. You mentioned that certain tumors were benign, like the skin ones in the rats; right?

A. Right.

Q. Isn't it true that benign tumors can turn carcinogenic?

A. Correct, they can. And I saw no evidence in the skin keratoacanthomas that any of them had turned to malignancies. They were benign tumors.

Q. Now, I understand you looked through every single tumor and none of them were carcinogenic or are you saying there was no trend?

A. What I'm saying is in the report that I read and in the tables from Greim, the appended tables, I didn't see any report that indicated that these tumors -- that

there were malignancies in the skin.

Q. Okay. Fair enough.

One of the things that we're interested in knowing about and the reason why we look at adenomas, right, is because we want to know if the substance can induce tumors. It's called oncogenicity; right?

A. Correct.

Q. And that's helpful for identifying carcinogens; right?

A. Correct.

Q. This one you did some stuff. Like, for example, you got rid of the spleen one.

Do you remember?

A. Yes.

Q. And you showed them all these different numbers for multiple comparisons and you're like one of them is bound to be positive; right?

A. Correct.

Q. Now, this one also was never mentioned in your report, was it?

A. No, it was not.

Q. In fact, the first time you learned about it is when you read Dr. Portier's report; right?

A. No, it's not the first time I read it. In my report I focused on what I thought were the most

important things.

Q. So today when you got rid of these two tumors in front of this jury, that was the first time you had done that?

15:13:19 A. I don't know what you mean when you say that's the first time that I had done it. In my review I saw these tumors being mentioned in the reports. I didn't think that they were significant because they only appeared in one study, they weren't relevant in humans,

15:13:36 they didn't show P trends, significant P trend or whatever. And for that reason, I didn't discuss them further. I focused my attention on what I thought were the most relevant things to discuss.

Q. Just to be clear, sir, the harderian gland

15:13:53 adenoma had a significant P trend, didn't it?

A. Okay.

Q. And so did the spleen; correct?

A. Correct.

Q. I mean, the P value for the spleen was .015,

15:14:07 below .05; right?

A. Uh-huh.

Q. And the harderian gland was 0.4, so it's below 0.5; right?

A. Yes.

15:14:16 Q. Okay. All right. So you discussed this -- we

discussed the Kumar, and you actually just kind of got rid of them all because you had this concern about the viral infection; right?

A. I have a concern about the health status in those animals and whether or not I can reliably interpret the data from them.

15:14:33

Q. So you didn't look at any of the tumors in that one carefully?

A. I considered that to be a very low reliability study.

15:14:48

Q. Now, if it was reliable, right, if it was reliable, that would be a different species of mouse; right?

A. It would be, yes.

Q. Showing a statistically significant P trend for malignant lymphoma in males; right?

15:15:01

A. Yes.

Q. So that would be an example of a cross-species, cross-study tumor appearing in the data?

A. It wouldn't be cross species. It would be cross strain. It's another strain of mouse.

15:15:15

Q. Fair enough. Fair enough. You're right.

Okay. I'm going to show the rat one for a second.

Permission to publish, your Honor?

15:15:26

THE COURT: Any objection?

MR. GRIFFIS: No objection.

THE COURT: Very well.

Q. BY MR. WISNER: The rat 1021. And here you got rid of a bunch as well. A lot of these skin keratoacanthomas that are on here you actually didn't discuss in your report, did you?

15:15:34

A. Again, because they wouldn't typically inform a decision of carcinogenicity in my experience.

Q. I thought you said you agreed with Dr. Portier that it was the strongest evidence?

15:15:49

A. From a statistical point of view, yes.

Q. And this Suresh study, you understand that was a limited study; right?

A. Yes.

15:16:04

Q. In fact, what happened is they didn't actually kill and biopsy all of the animals in the middle dose groups?

A. I don't know that that's accurate. What I understand is in Suresh you dose the animals, you collect the tissue and you look at your control and your highest dose, and if you see something going on, then you go back and you analyze the intermediate doses.

15:16:13

So they would have had the tissues. They would have been in vials in formalin or in ethenol at this

15:16:29

point being stored. If the pathologist saw something on the highest dose, he would have prompted -- that would have prompted them to go back and section from the intermediate doses.

15:16:44 Q. Okay. But in the Atkinson study they did the same thing; right?

A. The Atkinson study did the same thing, yes.

Q. And they did find statistically significant tumors in the high doses; right?

15:16:56 A. Yes.

Q. But they didn't go back and sacrifice and -- is it necropsy, necroperise the mice in between; right?

A. Necropsied.

Q. Okay. No one can say it. It's actually not

15:17:10 that hard.

A. Again, the way these studies are done, they're very time-consuming and expensive studies. And so what they would have done is they would have necropsied the intermediate doses and stored the tissue and sectioned if

15:17:25 there was reason to do so. In the Atkinson study, they chose to do some section.

Q. Yeah, but they didn't do all of them?

A. That's my understanding.

Q. That's how things are done today?

15:17:37 A. No.

Q. All right. So back to the mice. And I want to talk to you about one study. Let's talk specifically about the Knezevich & Hogan study from 1983. This is one that was done by Monsanto; right?

15:17:45 A. I believe that was true, yes.

Q. And this tumor, right here, the kidney carcinomas, would you agree it's probably one of the most debated tumors in the history of mouse studies?

A. Without question.

15:17:59 Q. Okay. Let's go through that story a little bit. All right?

So from my understanding -- actually, let's go through with the documents.

Permission to approach, your Honor?

15:18:10 THE COURT: Yes.

MR. WISNER: I am handing the witness and the Court Plaintiff's Exhibit 467, 591, 537, 469, 453.

Q. BY MR. WISNER: Sir, I've handed you a series of documents. These are various EPA documents related to

15:18:40 the Knezevich & Hogan study; right?

A. Yes, they are.

Q. These are things that you reviewed; right?

A. Yes, they are.

Q. These are things that were actually given to you

15:18:49 by Monsanto's counsel; right?

A. Correct.

MR. WISNER: Permission to publish, your Honor?

THE COURT: Any objection?

MR. GRIFFIS: All of them?

15:18:56 THE COURT: Which one are you publishing at this point?

MR. WISNER: 467 is the first one.

THE COURT: All right. Any objection?

MR. GRIFFIS: Yes, your Honor. May we approach?

15:19:05 THE COURT: Yes.

(Sidebar.)

[redacted]

15:19:30

15:19:50

15:20:10

[redacted]

(End sidebar.)

THE COURT: You may proceed, Mr. Wisner.

Q. BY MR. WISNER: All right, Doctor. All right. So we're on Exhibit 467 and this is dated February 26, 1985.

Do you see that?

15:21:38 A. Yes.

Q. This is specifically about the Knezevich & Hogan tumor that they found, the tumors that they found in the kidney tubules; right?

A. Correct.

15:21:51 Q. And it's from a statistician and it's to the chief of the scientific commissions support staff; right?

A. Yes.

Q. At the EPA. And what they've done is they're going through, kind of looking at this data to find out

15:22:07 if, in fact, it's outside the range of historical controls; right?

A. Yes.

Q. And what's going on here is this tumor, this kidney tumor is actually a pretty rare tumor in mice;

15:22:18 right?

A. Yes, it is.

Q. And so what they found was originally 0 in the control group, 0 in the low-dose group, 1 in the next dose, and then 3 in the high dose; right?

15:22:32 A. That's correct.

Q. And finding three of these tumors in mice in any dose was pretty darn high; right?

A. It was a concern.

Q. And so in response, Monsanto tried to submit information about historical controls trying to suggest or take the position that this falls within that range; right?

A. Is that what Monsanto did? Is that what you're asking me?

Q. Yeah, that's what's reflected in this document.

A. Sure.

Q. And the statistician kind of responds to it in a formal memo and ultimately they disagree with Monsanto; correct?

A. I believe they did, yes.

Q. Go to the last page. This is what I'm interested in. It says -- the second to last paragraph, it says, "Viewpoint is a key issue. Our viewpoint is one of protecting the public health when we see suspicious data. It is not our job to protect registrants from false positives. We sympathize with registrant's problem, but they will have to demonstrate that this positive result is false. Finally, we mentioned that none of the tumors occurred in the control or low-dose groups. Instead there was one at 5,000 PPM and three at

30,000 PPM dose level. This together with the previous comments makes it likely that there is a dose tumor relationship for glyphosate."

Do you see that, sir?

15:23:58 A. Yes, I do.

Q. Now, if these numbers were to have stayed the same, would you have agreed with that conclusion?

A. If these numbers had stayed the same?

Q. Yes.

15:24:08 A. It would have been stat sig, yes.

Q. Statistically significant?

A. Yes. And I would point out that this is the view of the statistician writing to the chief speaking as the statistician, not as EPA.

15:24:23 Q. I understand. That's cool.

All right. Let's turn to the next document. It's 591?

A. Correct.

Q. Now, do you see this is dated March 4, 1985; 15:24:37 right?

A. Yes.

Q. It's about a week after the last document; right?

A. Yep.

15:24:42 Q. And it's the consensus review of glyphosate,

right?

A. Yes.

Q. And there's a bunch of different scientists who signed this document; isn't that true?

15:24:54 A. Yes. I see the names.

Q. Including, I think, the person who wrote the last memo; right? I think it's Herbert Lacayo?

A. Sure. I can't pronounce it either.

Q. I think it's that one. So they go through the

15:25:15 data again and at the very end they come to a conclusion; right? Section E, it's on the second-to-last page, and it says that, "In accordance with EPA-proposed guidelines," and it lists the guideline date, "the panel has classified glyphosate as a Category C oncogen."

15:25:39 Do you see that?

A. I do.

Q. And so that's saying it's a likely human oncogen; right?

A. Yes.

15:25:45 Q. Their opinion is, hey, this actually looks like it is causing tumors?

A. Correct.

Q. All right. So let's go to the next document, 453. And now we jump ahead a little bit. Oh, sorry.

15:25:58 That can't be right.

Now we're at 467, sir.

A. Sorry, we're at who?

Q. 537.

A. 537. Okay.

15:26:22 Q. All right. So now we're in April of 1989. So we're a month later; right?

A. Okay.

Q. And this is from William Dykstra, Ph.D., at the EPA; right?

15:26:34 A. Yes.

Q. To Robert Taylor of the Registration division; right?

A. Yes.

Q. And, again, they explain in the conclusions, 15:26:46 "Glyphosate was oncogenic in male mice, causing renal tubule adenomas, a rare tumor in a dose-related manner"; right?

A. Where are you reading?

Q. Under "Conclusions" on the first page.

15:26:59 A. Okay. Yes.

Q. So, again, by this point, their opinion hasn't changed; right?

A. In that month, no, they had not.

Q. So what happens next, based on your review of 15:27:09 the record, is Monsanto hires a scientist, Marvin

Kuschner; right? Kuschner?

A. Yes.

Q. And he takes a look at the tumor data and he locates what he believes is another tumor in the control group; is that right?

15:27:31

A. That's my understanding.

Q. And it shifts the data from being 0013 to 1013?

A. Correct.

Q. And when you do that, when you add that one to the control group, it actually destroys statistical significance.

15:27:42

A. I don't know that I would go with destroys, but for your narrative, sure, it's now no longer statistically significant.

Q. And so the EPA when they get this, they decide to take a hard look at it?

15:27:55

A. Yes.

Q. They get a pathology Working Group?

A. Yes.

Q. And they do look at it and they go, yeah, there might be a tumor in here?

15:28:03

A. Correct.

Q. And, in fact, a pathologist from the EPA kind of described -- let's turn to Exhibit 469.

A. Okay.

15:28:17

Q. And so this is -- no, don't show it. Don't show it. Sorry.

So this is a document dated December 4, 1985. So we've basically gone a year; right?

15:28:40 A. Yes.

Q. And it's to William Dykstra, the toxicologist reviewer; right?

A. Correct.

Q. And it's from a pathologist at the EPA?

15:28:49 A. Correct.

Q. He reviews it and he says, "Tumors 01013," and he puts the new tumor in parentheses, right, "were found in the kidneys of male mice at different dose levels. There were differences in the pathologists' opinions as

15:29:11 to whether the small localized change in one kidney of the control group represented a tumor or not. In order to provide more information, the agency recommended the preparation of three additional sections from each kidney in the male groups. The lesion was not present in the

15:29:26 recut specimen from the animal in the control group. In the final reevaluation of the questionable control kidney slides, the conclusion was formulated that the pathology staff at Bio/dynamics and I reviewed the lesion and concurred it may be representative of a developing

15:29:45 tumor."

Do you see that?

A. Yes.

Q. Then he says, "I went and looked at it myself under a microscope"; right?

15:29:52 A. Correct.

Q. He goes, "I don't see anything." Well, that's not true. What he says was, "There was no difference, differences in diagnosis between mine and other pathologists' diagnosis with respect to kidney tumors"; right?

15:30:03 A. Yes.

Q. "But with regard to the questionable male control kidney, it is my opinion that the presence of a tumor cannot definitively be established. My interpretation is similar to the conclusion of Bio/dynamics' pathology staff and Dr. McConnell that the lesion," quote, "may be," unquote, "a proliferative change, having the potential to lead to the development of a frank tumor. But that the tissue can be seen under the microscope as a small, well-demarcated focal cell aggregate morphologically different from the healthy looking surrounding kidney tissue, this morphological alteration does not represent a pathophysiologically significant change."

15:30:46 Do you see that?

A. Yes.

Q. So the way I read this is the pathologist says, "I looked at it and I don't really think this is a tumor in the control group"; right?

15:30:56 A. The way he's writing it, he's hedging his bets, he's being careful, and he's saying that it is something that looks like -- it doesn't look like control issue. There are morphological changes here that look like it could be on the way to. So in his mind it's debatable.

15:31:17 Q. Okay. So ultimately what happens is the EPA goes, okay, let's call in a scientific advisory panel; right?

A. Yes.

Q. That's, again, something the EPA does. When

15:31:28 they have questions, they bring in some experts and get their viewpoint on it; correct?

A. Correct.

Q. And the scientific advisory panel comes in and they hear arguments from both sides; right?

15:31:39 A. Yes.

Q. They hear from Monsanto's people and they hear from the EPA; right? Right? Sorry.

A. I don't know who all they heard from. I believe that the key players, the stakeholders, are going to be

15:31:53 there. Yes, there may have been other people as well. I

don't know.

Q. And the EPA is taking the position that, no, this is oncogenic and the detractors are saying, no, it's not because of this tumor; right?

15:32:04 A. I don't know that. I know that Dr. Caza, a pathologist at EPA, has taken a stand. I don't know what EPA overall is saying.

Q. Did Monsanto give you the transcripts of that hearing?

15:32:20 A. I don't recall seeing the transcripts of the hearing.

Q. Okay. Well, ultimately the SAP issues a report; right? And we can show it, but the bottom line of the report is we think it's equivocal, we're not sure, so

15:32:36 let's do it again; right?

A. Yes.

Q. And they actually recommend that Monsanto redo a special sort of kidney study, right, where they would just look at these tumors in the mice; right?

15:32:49 A. Yes.

Q. But Monsanto refuses; isn't that true?

A. I'm not privy to all the back and forth. I don't know if that's true or not. I'm willing to accept your position.

15:33:03 Q. But you agree that EPA wanted it; right?

A. My understanding is EPA wanted it.

Q. And you have never seen that study; right?

A. I have not seen that study.

Q. All right. And so ultimately the EPA does

15:33:21 classify Roundup after a fairly lengthy review; right?

A. That, I don't know. I believe they classified glyphosate --

Q. Sorry. Glyphosate.

A. -- and then by extension, maybe Roundup.

15:33:35 Q. They classified glyphosate in 1991; is that right?

A. Right.

Q. So it took almost ten years to resolve this issue. They finally classified it. And at that point it

15:33:48 gets classified as a Category E; right?

A. Right.

Q. Which means it's not likely carcinogenic to humans?

A. Correct.

15:33:53 Q. All right. The last thing I want to talk to you about is the George study from 2010.

A. Okay.

Q. You talked about briefly on direct?

A. Right.

15:34:02 Q. And the George study is what they call a

promotion and initiator study; right?

A. Yes.

Q. And the idea is -- and like in carcinogenesis, right, is that there's promoters and there's initiators; right?

A. Yes.

Q. And the initiators are things that sort of begin the cancer process?

A. Yes.

Q. And the promoters are things that hurry the process along?

A. No.

Q. Why don't you describe it, because you'll probably do it better.

A. An initiator is a chemical that initiates mutations or changes within the DNA. A tumor promotor is something that facilitates the growth of the tumor.

So, in essence, let's say, you have a mammary tumor that's estrogen dependent. You might have an initiating event and in the presence of estrogen, it promotes the growth of that lesion.

Q. I was talking to a scientist once and here is how he described it. Tell me if you think this is an appropriate way of characterizing it. You have a bunch of schoolchildren in your classroom. Initiators fills

the classroom up with sleeping children. And a promoter is something that wakes up those children so they can start running around and making problems.

Is that a fair way of thinking about it?

15:35:20 A. That is a way of thinking about it. I'm not sure I want to go with sleeping kids.

Q. All right. So they did this study and it looks like they were trying to figure out is this -- is it an initiator or a promoter. That was the purpose of the

15:35:38 study; right?

A. Correct.

Q. Let's take a look at the study. It's Exhibit 765.

Permission to publish?

15:35:44 THE COURT: Any objection?

MR. GRIFFIS: No objection.

THE COURT: Very well.

Q. BY MR. WISNER: All right. So it's up on the screen. Is this the study, sir?

15:35:50 A. Yes, it is.

Q. And it's done by a couple scientists. It looks like these scientists are out of the Indian Institute of Toxicological Research; is that right?

A. That's what it looks like.

15:36:03 Q. Do you know any of these scientists personally?

A. I can't say that I do.

Q. All right. And so they kind of talk about the origins of this study and they say -- it talks about the history of it and it goes, "Glyphosate alone or with its" -- I'll -- "glyphosate alone or with its formulation products, such as surfactants and permeabilizing agents, is usually considered to be harmless under both normal usage and chronic exposure. In 1993, the US EPA categorized this compound into Class E, which means that it's probably not carcinogenic to humans."

Maybe I got the date wrong when I said '91. That's what we were just talking about; right?

A. Correct.

Q. And he goes, "Despite these reports, some case control studies suggested an association between glyphosate exposure and the risk of non-Hodgkin's lymphoma. In another study, both technical grade glyphosate and Roundup were shown to cause a rapid increase in cell division in human breast cancer cells. Glyphosate has also been shown as a skin irritant. Regarding the genotoxic potential, glyphosate exposure to human lymphocytes *in vitro* resulted in increased sister chromatid exchanges, chromosomal aberrations, and indicators of oxidative stress. A recent study from our laboratory also showed the clastogenic effects of

glyphosate in bone marrow cells of Swiss albino mice."

What is a clastogen?

A. A clastogen is causing chromosomal breaks.

Q. "These reports prompted us to investigate its carcinogenic effect in long-term animal bioassay."

15:37:55

Do you see that?

A. Yes.

Q. So it looks like the origins of the study of the scientists were based on their own study which showed the effect in the bone marrows of Swiss albino mice.

15:38:08

Do you see that?

A. It does. And it's interesting because it's hard to pronounce some of the words that they talk about in here, as we've seen throughout the day. And science is very nuanced. And I get that what you're reading and why they're providing the justification for the study. I understand that. But what they're not telling you in any of this is the dose or the concentration that was needed to induce any of the changes that they're talking about and whether or not they're even relevant. And that's very typical in the literature. The story comes later.

15:38:25

15:38:41

Q. Sure. And for what it's worth, I don't think they're trying to give all the data. They have a citation to an article.

A. Right. They're just telling you this was worth

15:38:53

doing in their mind.

Q. Exactly. I'm just trying to get the background of the study.

And so a promoter study -- the promotional aspect of the study kind of works like this. It's kind of complicated, but I think I can break it down. What you do is you apply the substance at issue to the skin of the animal, but before you do that, you put an initiator on it; right?

15:39:03

15:39:17

A. Correct.

Q. And so you give the mouse something that you know initiates cancer; right?

A. Correct.

Q. And then separately you put on a known promoter; right?

15:39:26

A. Or your tests that you think is a promoter.

Q. You do both; right? So you put on a known promotor and you put on glyphosate or Roundup; right? And what you're looking to see is you know the one that has initiated and a known promotor is going to have a lot of skin tumors; right?

15:39:39

A. Well, in this case they're using DNBA, a well-known initiator, and TPA, a well-known promoter.

Q. Exactly.

A. So, yes, these are positive controls.

15:39:51

Q. So they're going to see something. And they want to see what happens when you do this with glyphosate and see that it gets initiated, but how does it promote it, if it all; right?

A. Right.

Q. And what they did is they also compared it to a control group that had nothing on them; right?

A. Correct.

Q. And one of the criticisms you had was there should have been a control that got some alcohol or acetone on them; right?

A. Whatever they were using as the vehicle.

Q. Are those things known to induce tumors?

A. It's not whether they're known to induce tumors, but whether or not they act as a vehicle for anything else that might be on the skin. In order to do these studies, they're not pretty. You shave the mouse and then you treat it with Nair or Veet or whatever in order to get it off, and anybody that's used that knows it's pretty irritating on its own.

Q. Sure. Now, when they did the study, the ones that got the initiator with glyphosate, 40 percent of the mice had tumors in their skin; right?

A. Sorry. I zoned out on that.

Q. Sure. When they did the promotional study, the

ones that got the initiator and then Roundup -- it actually wasn't glyphosate, it was Roundup --

A. Right.

Q. -- they had -- 40 percent of those mice at the end of the study --

A. Had tumors.

Q. -- had tumors in their skin; right?

A. Correct.

Q. And then of the mice that got nothing, they didn't have any tumors in their skin?

A. That's right.

Q. Okay. One of your criticisms was that they didn't get their test product from -- I didn't really understand. What was your concern about the actual product?

A. My concern about the product is I really don't know what it is. They -- they report that it's Roundup that they purchased at the local market. I think we've all seen reports in the news about things that come from some countries that claim to have something in it and on further examination we discover it actually has something else. And in this particular case, I don't know that that was actually Roundup that was sold in that local market. My studies, if we were going to do this, we would purchase it directly from Monsanto with a

certificate of analysis so that we know that it's authentically Roundup.

Q. This is what the study says. Under "Materials," it says, "The commercial formulation of the herbicide glyphosate," and it gives the technical name, "Roundup original, copyright, glyphosate, 41 percent, POEA, 15 percent. Monsanto Company, St. Louis, Missouri."

So it looks like they bought Monsanto-branded Roundup; right?

15:42:22 15:42:38 15:43:01 15:43:11 15:43:23

A. I have no reason to doubt that the scientists legitimately went to the local market and bought a can that -- or a box or whatever it comes in, with this on the label. But we have seen in our experience where we have seen pesticides and other things that have been adulterated and are not actually what the company shipped.

Q. But that's pretty speculative. I mean, that's not what they say happened.

A. If I was a reviewer, that would be a criticism that went back to them. And I can't comment beyond that, you're right, but it is a concern to me.

MR. WISNER: Okay. No further questions, your Honor.

THE COURT: All right. Counsel, can you approach.

(Sidebar.)

[redacted]

(End sidebar.)

THE COURT: Dr. Foster, we have a question from one of the jurors. So please answer this question if you can. The question is, what is the, quote, usual amount of time from when a study is completed and when it is published?

THE WITNESS: Oh my. I don't even know how to begin to answer that. Sitting here, I've got data for ten studies sitting on my desk that I'm not getting.

One of these big type of studies, it could take you two years to run the animal phase of the study and then you've got data analysis and data interpretation. You could be another year to two or three out before you actually get it published. And that would be if you're

publishing it. A company that's submitting the study results for registration, they're not interested in publishing it. They're submitting it for registration purposes. So it's totally different from what I currently do.

15:45:26

THE COURT: All right. Thank you.

So, Mr. Griffis, do you have any further questions?

MR. GRIFFIS: I do, your Honor.

15:45:50

May I proceed?

THE COURT: Yes, please proceed.

REDIRECT EXAMINATION

BY MR. GRIFFIS:

15:45:52

Q. So I have 20 minutes to follow up on that. I feel slightly challenged because there was a lot of EPA stuff and not much in your direct. Let me ask if you know this. The OPP, the Office of Pesticide Programs, from the EPA's report from 2016, we talked about some of

15:46:12

the findings therein and it talked about how you had reached during your independent analysis which preceded you looking at some similar conclusions for some similar reasons based on animal studies; right?

A. Yes.

15:46:26

Q. And we just talked about animal studies, not

their conclusions about epidemiology and mechanisms and so on. Mr. Wisner asked you all sorts of stuff from this SAP report and the SAP is a scientific advisory panel. It's something that the EPA does quite a lot when they have issued a report like this on an analysis of a chemical. They also consult their scientific advisory panel and the general public. Any one of us could have sent in comments. Whether we had anything scientific to say about glyphosate or not, we would be free to do that; right?

15:46:49

15:47:08

A. Correct.

Q. And it's part of EPA's procedures to assess not only the advice of the SAP, but of anyone who writes in. And we heard that Dr. Portier, for example, was one of those people who wrote in with comments and gave some of the same sorts of arguments that he presented to this jury to the EPA; is that right?

15:47:20

A. Correct.

Q. That's your understanding.

So EPA then incorporates and considers this. Did you know, sir, that in December -- December 12th, 2017, they issued a response, the EPA's response to the final report of the SAP in which they addressed the things that the SAP had said? Are you aware of that, sir?

15:47:30

15:47:52

A. Yes.

Q. And they went point by point through the issues raised herein and about which Mr. Wisner pointed out that sometimes there was some consensus and sometimes there was a good deal of disagreement among the various scientists; right?

15:48:08

A. Correct.

Q. And so EPA responded point by point to those, and then, sir, you're aware, issued the 2017 OPP report which incorporated its -- which incorporated its reactions to and responses to the recommendations of the OPP; is that right?

15:48:23

A. That's correct.

MR. WISNER: Okay. We're going to need a sidebar.

15:49:02

(Sidebar.)

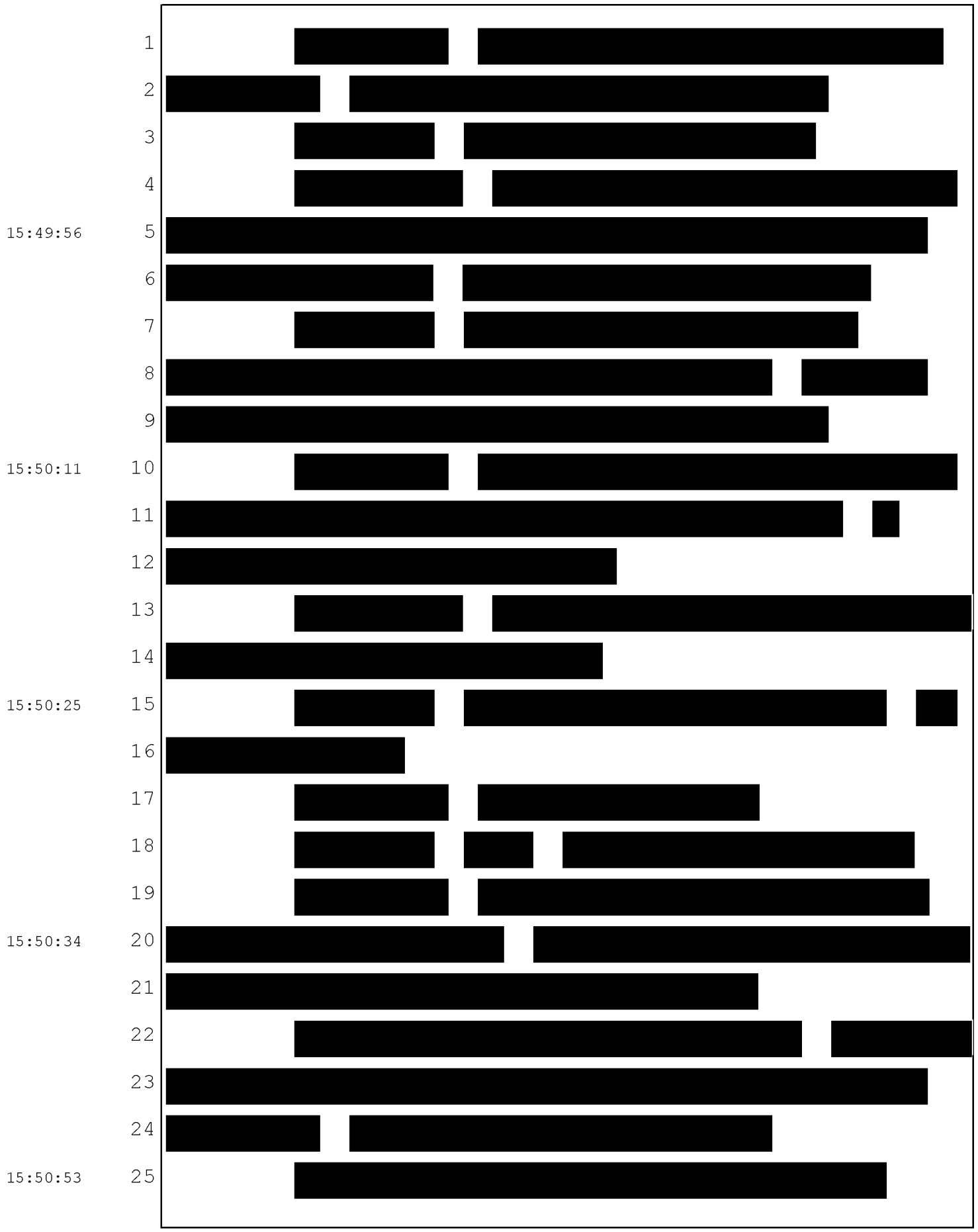
[redacted]

15:49:30

[redacted]

15:49:45

[redacted]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[redacted]

(End sidebar.)

THE COURT: All right. You may proceed, Mr. Griffis.

MR. GRIFFIS: Permission to approach?

THE COURT: Yes.

Q. BY MR. GRIFFIS: I'm handing you the 2017 OPP report, sir. Was that a document you've seen before?

MR. WISNER: Do you have a second copy?

THE WITNESS: Yes.

MR. GRIFFIS: I have a second copy. I don't have a third copy.

MR. WISNER: What is the exhibit number?

MR. GRIFFIS: It is Exhibit 2486.

MR. WISNER: Give me a second to pull it up digitally.

MR. GRIFFIS: Sure.

15:52:01 Q. So do you see at the bottom of page 13, sir -- this is going to be quick. The bottom of page 13 of the 2017 OPP report.

A. I'm on page 13.

Q. Okay. And at the bottom paragraph, the EPA 15:52:22 talks about the fact that the SAP was convened and evaluated the 2016 report and issued a report. And EPA is taking that into account now; correct?

A. Correct.

Q. Okay. And let's turn to page 72. Look at the 15:52:49 bottom. And we're not going to get into all of the bits where there have been changes between the 2016 and 2017 to reflect SAP. But one thing it says at the bottom of page 72 is, "All statistical analyses were re-analyzed for the purpose of this evaluation to ensure that 15:53:10 consistent methods were applied"; correct?

A. I see that, yes.

Q. Okay. And then let's look at the bottom line, sir, on page 97. And this is with regard to -- it assumes the scope of what we asked you to comment on the 15:53:24 animal studies -- this is about animal studies.

Tell me when you're on page 97.

A. I'm there.

Q. Okay. "Based on the weight of evidence evaluation, the agency has concluded that none of the tumors evaluated in individual rat and mouse carcinogenicity studies are treatment related. Due to lack of pairwise statistical significance, lack of a monotonic dose response, the absence of preneoplastic or related non-neoplastic legions, no evidence of tumor progression and/or historical control information when available.

"Tumors seen in individual rat and mouse studies were also not reproduced in other studies. Including those conducted in the same animal species and strain at similar higher doses."

Did I read that right?

A. You did.

Q. And was that the same, sort of, thing you were taking into account -- the same factors that you were taking into account when you did your independent assessment before you looked at any of this?

A. Yes.

Q. Okay. Sir, you were shown a couple of the studies that we talked about when we looked at your chart about the melanoma studies; correct?

A. Correct.

MR. GRIFFIS: And I would like to use the Elmo and publish 3114, the Wood evaluation.

THE COURT: Any objection?

15:55:02 MR. WISNER: 3114? Okay.

MR. GRIFFIS: We showed it before.

MR. WISNER: Okay. Yeah, we showed it before.

Q. BY MR. GRIFFIS: So this is contemporaneous to the Wood study, one of the -- one of the studies that's

15:55:11 up here. Evaluation showing 12 percent of male mice and 12 percent of female mice develop malignant lymphoma; right?

A. That's correct.

Q. So that was not -- and what you have here is not

15:55:24 the average, but the top of a range; correct?

A. Correct.

Q. Okay. And the 12 percent is right at the top of that range?

A. Correct.

15:55:34 Q. So if you did a range around 12, it would actually be like that?

A. Right.

Q. You picked that as the high point, even though it's really an average; right?

15:55:45 And Mr. Wisner asked you about the averages from

Giknis & Clifford. But, again, this was not, sort of, an average, but a range; correct?

A. Sorry. The 6 is a range?

Q. Yes.

15:56:04 A. Six is the average.

Q. Okay. So the 6 is the average? Then you would expect to see as many above as below the average; correct?

A. Correct.

15:56:14 Q. And we don't?

A. Correct.

Q. And when we looked at Giknis, sir -- highlighting doesn't show up, but we can see it here.

The malignant lymphoma, you saw a 1, 1, 7, 2, 1, 15:56:30 1, 1, 4, 2, 2. There's a 7 that's higher than the top figure that we saw in these figures.

A. Correct.

Q. And 13 on the next page, that was higher than the top figure we saw in these figures.

15:56:43 A. Correct.

Q. Correct?

There's the 13. There's the 6. There's a 5 and a 4.

And, finally sir, the document that Mr. Wisner 15:56:55 talked about, and I think he called it an ECHA report --

MR. GRIFFIS: Permission to publish? This is Defendant's 2071.

THE COURT: Any objection?

MR. WISNER: No, your Honor.

15:57:06 MR. GRIFFIS: He gave me a thumbs up.

Q. I think it's actually a BfR document. But we've heard testimony about how the reviews of BfR fed information to EFSA and ECHA that those science agencies then evaluated. So this was a part of that process?

15:57:25 A. Correct.

Q. Let's take a look at what they said about historical controls. This is on page 72.

"However, the mentioned study incidences" -- we're talking about Wood, Sugimoto, et cetera, on the

15:57:46 subject of lymphoma. "The mentioned study incidences ranging from 1 percent up to 32 percent, both sectors combined showed a large variability of malignant lymphoma frequency and would theoretically cover all male and female groups in the studies in CD-1 mice."

15:58:05 Is that an accurate description of the historical controls and what they showed for lymphoma?

A. Yes.

Q. This assumption is supported by further historical control data for CD-1 mice collected from

15:58:16 industry databases, Giknis & Clifford and" -- "or open

literature. According to these data collections, malignant lymphoma is quite common in CD-1 mice. But the reported incidences in different CD-1 strains and among the laboratories were extremely variable. Mostly they were higher in females than in males. But even in males, they reached rates between 10 percent and 20 percent."

Is that right?

A. Correct.

Q. And you picked 6 percent as a reasonable average for your chart; is that right?

A. That's right.

Q. I'd like to talk a little bit about the 35-year-old 1983 mouse study, sir.

And we talked some -- from some documents that you were shown about how things looked to some pathologists and toxicologists in 1985, looking at that study. And that was the one study that they had available to look at in 1985; right?

A. That's right.

Q. Okay. And to a toxicologist, how does the picture look on the subject of renal tubule adenomas now? Today?

A. It looks a lot more clear, given that we've got a much more robust data set to look at. We've got all the rat and all the animal -- all the mouse studies,

sorry, that have been completed. And there's been no replication of the kidney adenomas.

Q. And what does that tell you, as a toxicologist? When you look at a body of data -- you know, we had a
15:59:56 study that was thought to be equivocal. People had disagreements about it. And that study still exists, and that same data still exists. But when you have all this other data, what does that say to a toxicologist, looking at the data set?

16:00:11 A. The way I would describe this if I was writing my paper would be that there was an initial study that showed a relationship with kidney adenomas, cite the reference, and then I would cite the subsequent studies that had failed to show that there was a similar trend in
16:00:30 similar well-conducted studies, and that the most likely reason for the divergent results could be explained by multiple comparisons. It could also be explained by other things going on in that animal study where, again, it was high dose, and we had some toxicity in the higher
16:00:50 dose.

Q. You know, sir, that the Knezevich and the Atkinson study are the two studies --

MR. GRIFFIS: I'm putting this up from the Monograph, page 33 of the Monograph, with your
16:01:03 permission.

MR. WISNER: Sure. It's Exhibit 166.

MR. GRIFFIS: Thanks.

Q. And over here is the Knezevich study, and we have a conversation with Dr. Portier about the derivation of that figure. He said that he'd actually gotten the calculation wrong, but over here is Atkinson; correct?

A. Yes.

Q. And what was the data from Atkinson about this supposedly rare tumor that you should very rarely see in your whole study for renal tubule adenomas?

A. In the Atkinson study, it was 2, 2, 0, 0.

Q. And the Working Group didn't know about that; right?

A. I'm sorry?

Q. The Working Group didn't know that; right?

A. Correct.

Q. Lastly, I want to talk to you for a moment about the Greim study. We've heard a lot about this. It has 15 pages, maybe, of study, and then there are the appendices. Which part of this was important to you in doing your work?

A. The appendices.

Q. And do you know which section was important to Dr. Portier in doing his review?

A. I have no idea what was the most important to

Portier.

Q. All right. Okay. And let's take a look at --

MR. GRIFFIS: May I publish this?

THE COURT: Any objection?

16:02:21 MR. WISNER: What is it?

MR. GRIFFIS: The Greim study.

MR. WISNER: Yeah, sure.

Q. BY MR. GRIFFIS: It's not a study, is it?

A. No.

16:02:30 Q. It's an article.

A. It's a review.

Q. Here's David Saltmiras from Monsanto Company?

A. Correct.

Q. You didn't notice it was Monsanto Company, but

16:02:38 if you'd been interested in that subject, how hard would it have been to tell, sir?

A. I mean, it's obvious that he is. It wasn't something that I -- in the fullness of time, that I recall paying any attention to, because, again, my focus

16:02:54 was on the data tables.

Q. Okay. You didn't care who had assembled the data for you. Let's look at the end. If you wanted to know about Monsanto's involvement, how obvious would it have been, sir?

16:03:06 A. It's very obvious.

MR. GRIFFIS: Thank you. No further questions.

THE COURT: All right.

MR. WISNER: Very briefly.

THE COURT: Mr. Wisner.

16:03:13 MR. WISNER: Your Honor, permission to publish 2552. It's the --

MR. GRIFFIS: Yes.

THE COURT: Very well.

RECROSS-EXAMINATION

BY MR. WISNER:

Q. Doctor, I'm just going to show you the document again. We just showed it to the jury. This is the Charles River March 2000 document.

Do you see that one?

A. Yes.

Q. And I am not good at math. I'll be honest with you. Okay? But when I look at these numbers, you know, to 2, 2, 1, 4, 1, 3, 1 -- it goes on, and even when I

16:03:47 throw in that 13 on the next page, how does that average to 6?

A. Yeah, it's late, and I'm looking at it. And -- yeah. When I did my assessment of the data, I used range.

16:04:07 Q. Sure.

A. And I misspoke.

MR. WISNER: Okay. No further questions, your Honor.

THE COURT: All right. Thank you. Then, Dr. Foster, you may be excused. Thank you.

(Interruption in proceedings.)

THE COURT: All right. Dr. Foster, if you don't mind, would you mind sitting down for just a moment?

And, Counsel, can I see you at sidebar?

(Sidebar.)

[redacted]

[redacted]

(End sidebar.)

THE COURT: All right. Dr. Foster, we have another question, and I'll read it to you exactly as it's written: "In skin paint study, are they lacking the vehicle for the initiator, or are you referring to vehicle for promotor or both?"

THE WITNESS: I'm referring to both, because I believe the vehicle was the same in both.

THE COURT: All right. Very good. Thank you.

Any further questions from the jurors?

All right. Then you may be excused. Thank you.

THE COURT: All right. Ladies and Gentlemen, we're going to adjourn now for today. Tomorrow we'll resume again at 9:30. Please do not do any research on the case or discuss the case, and we'll see you tomorrow, then. Thank you.

16:07:11

And, Counsel, can you please remain?

(Jury leaves courtroom.)

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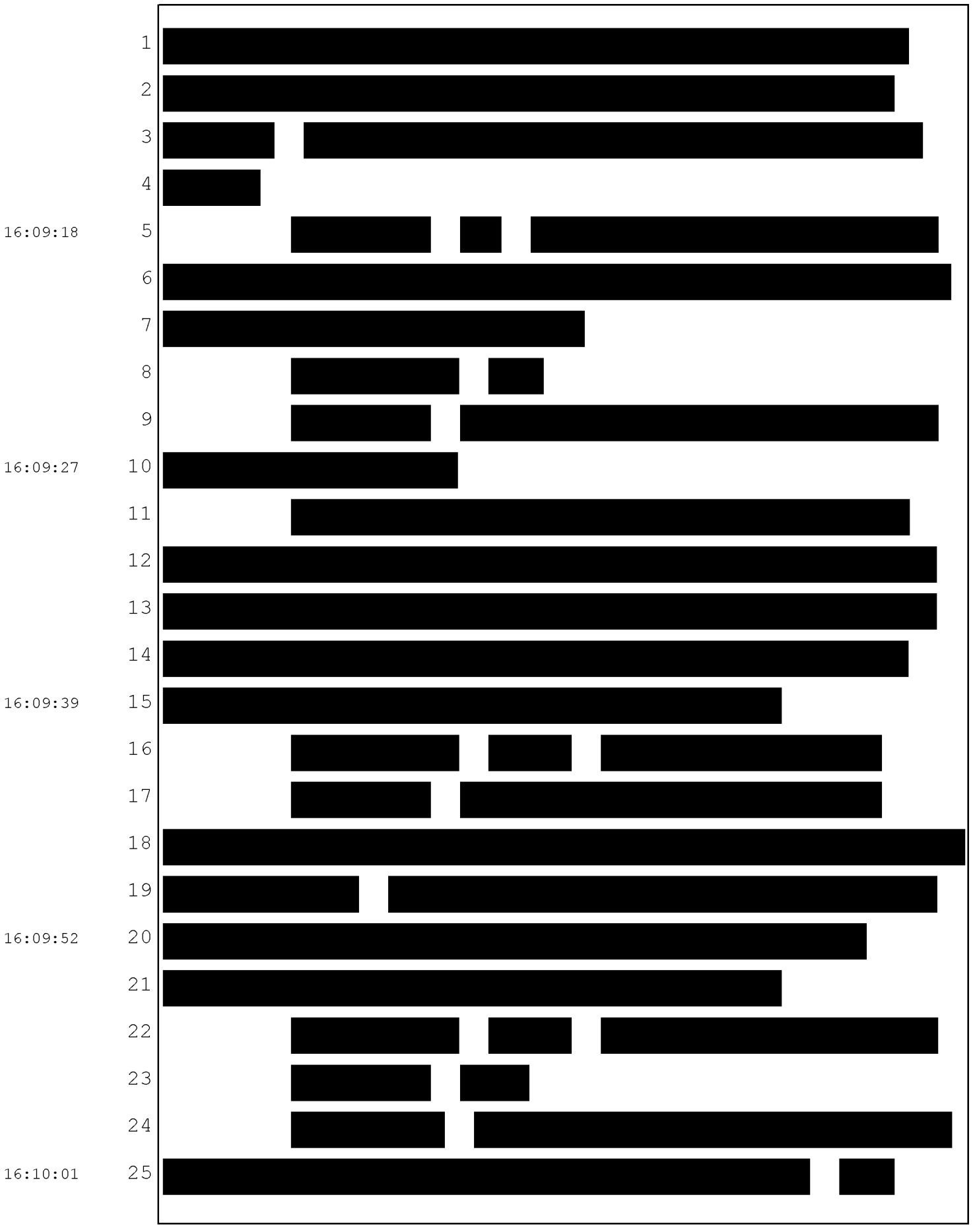
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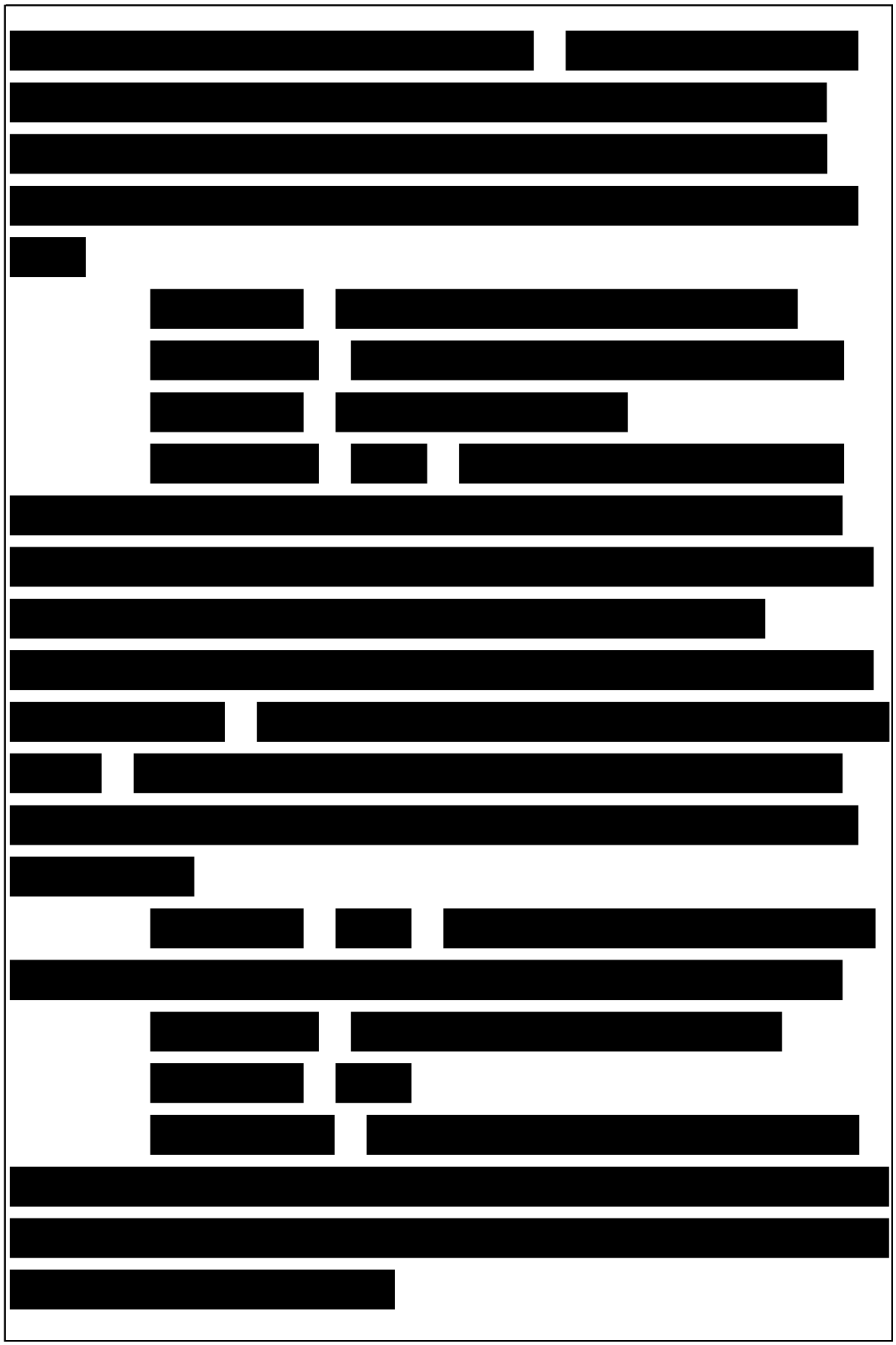

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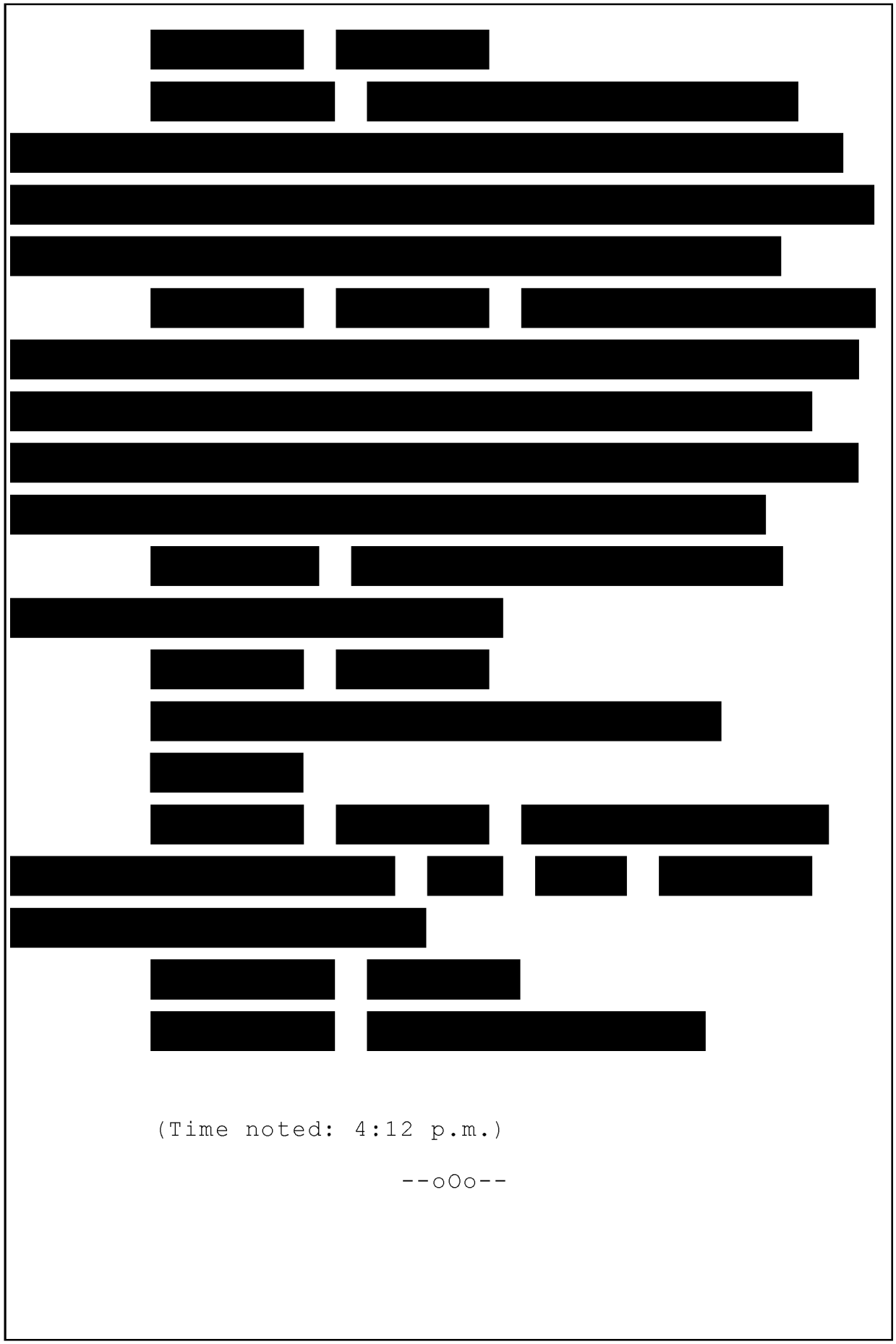

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REPORTER'S CERTIFICATE

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: August 2nd, 2018.

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