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MONSANTO COMPANY

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs.

MONSANTO COMPANY,

Defendant.

Case No. CGC-16-550128

DECLARATION OF SANDRA A. EDWARDS IN SUPPORT OF DEFENDANT MONSANTO COMPANY'S TRIAL BRIEF REGARDING OPINIONS DR. BENBROOK MAY NOT OFFER

Honorable Judge Suzanne R. Bolanos

Department: 504
Trial Date: June 18, 2018

I, Sandra A. Edwards, declare as follows:

1. I am an attorney duly admitted to practice before this Court. I am a partner with Farella Braun + Martel LLP, attorneys of record for Defendant Monsanto Company ("Monsanto"). I submit this Declaration in support of Monsanto's Trial Brief Regarding Opinions Dr. Benbrook May Not Offer.

2. Attached hereto as **Exhibit 1** is a true and correct copy of excerpts of the Transcript of Proceedings dated May 10, 2018.

3. Attached hereto as **Exhibit 2** is a true and correct copy of excerpts from the February 9, 2018 deposition of Charles Benbrook.

4. Attached hereto as **Exhibit 3** is a true and correct copy of excerpts from the Expert Report of Charles Benbrook dated December 21, 2017.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on July 23, 2018, at San Francisco, California.

Sandra A. Edwards

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EXHIBIT 1

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY,

Defendant.

_____/

Reporter's Transcript of Proceedings

San Francisco, California

Thursday, May 10, 2018

Reported by:

SHEILA PHAM

CSR NO. 13293

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,
Plaintiff,
vs. Case No. CGC-16-550128
MONSANTO COMPANY,
Defendant.
_____/

Reporter's Transcript of Proceedings, taken at SAN FRANCISCO SUPERIOR COURT, 400 McAllister Street, Department 304, San Francisco, CA 94102, beginning at 9:10 a.m. and ending at 11:00 a.m., on Thursday, May 10, 2018, before Sheila Pham, Certified Shorthand Reporter No. 13293.

APPEARANCES OF COUNSEL

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San Francisco, California, Thursday, May 10, 2018
9:10 a.m. - 11:00 a.m.

THE COURT: I'm required to read the following: The parties and counsel are advised in connection with the June judicial election, a list of contributions is available on the board outside the courtroom door. The list is updated weekly.

Counsel got my written tentative yesterday perhaps.

(Counsel nodding.)

THE COURT: Great.

MR. LASKER: Yes, Your Honor.

MR. MILLER: We have, Your Honor.

THE COURT: My proposal -- and if you've discussed it among yourselves that you'd like to handle this differently, that's fine with me. But my proposal is simply to let perhaps Monsanto go first. They can use whatever time they want. I've told you I'm going to give you each just about an hour, maybe a little bit more than that. You can use it really as you wish. I think you have a better grip as to what needs time and what doesn't need time, and I'm happy to do it that way. I'll turn it over to the plaintiffs and then go back and forth until your time has expired.

Is there any other way you'd like to handle things? Okay.

MR. MILLER: That's agreeable, Your Honor.

MR. LASKER: Thank you, Your Honor. Eric Lasker for Monsanto. And as Your Honor knows, the issues that are before you today, particularly on our Sargon motion and general causation, has been the issue of a seven-day adventure hearing in front of Judge Chhabria and also Judge Petrou, who is the JCCP judge.

And that hearing was continued through until early April when Judge Chhabria, at supplemental adventure hearings specifically on the epidemiology, sort of crystallized the issues and focused the issues similarly to how Your Honor has with the understanding, as Judge Chhabria recognized as well, that the epidemiology really is the key issue here.

And I think the parties, in their briefing, also recognized that fact. That to get to causation in humans and/or Mr. Johnson, general causation, and frankly, given their experts, also specific causation, the epidemiology is really the focus of the inquiry that Your Honor needs to make under Sargon.

And I'd like to focus obviously on the questions Your Honor has raised in the tentative ruling with respect to the epidemiologic issues, how that

variety of different studies?
MR. MILLER: I believe so, yes. Yes, yes. And that's at 88 Regulatory Toxicology and Pharmacology, Pages 45 to 55.
Wasn't that in our brief?
MR. TRAVERS: Yeah.
MR. MILLER: Yes, it was in our brief. Okay.
So that's our Portier argument, and obviously, he's admissible irrespective of pooling. We think pooling has been important and is significant enough.
Now, I'll turn to Dr. Benbrook. I think the Court, in your -- let me -- where is my copy of the Court's tentative? Excuse me one second, Your Honor. I apologize.
THE COURT: Of course.
MR. MILLER: There it is. Thank you, Your Honor.
In your tentative, you cite to the four ways that Dr. Benbrook has been previously allowed to testify. And I understand that by that, you intend to allow him to testify in those areas here. If I misunderstand, I'd better argue the point. And then you do go on to limit some things, but I wasn't sure what all those things meant. I have no intention to have him look at an e-mail and say that proves the corporation is

bad, or that proves the corporation wanted to put profit over people, or anything of that sort.
THE COURT: What would you do with the e-mail, if anything?

[redacted]

MR. MILLER: I'm certainly not.
THE COURT: Do you see my point?
MR. MILLER: But I think when you ask an expert an opinion, I think you're entitled for the jury to hear the basis of it.
THE COURT: Yeah, but you're flipping the issue. The question is whether you're entitled to ask

him the opinion. It's got to be something the jury can't figure out on their own as laypeople, it's got to be an issue that matters to the case, and it has to be that he has a basis -- a factual basis to do it.
I just don't understand what he would do with respect to any e-mails at all. If you think the e-mail shows something dastardly that Monsanto has done and there's, you know, communications there, a smoking gun that you'd really love the jury to read, then wouldn't you just give the jury the e-mails.

[redacted]

So I won't belabor your time, but that's the problem.

[redacted]

[redacted]

MR. MILLER: All right.
THE COURT: Do you think industry standards, for example, and stewardship duty, which in Adams versus U.S. were, apparently, in that case held relevant? Is this a case where industry standards and so-called stewardship duty or ethical obligations -- I'm sorry, industry standards and stewardship obligations are relevant?
MR. MILLER: I think industry standards -- I'm sorry, Your Honor.
THE COURT: That's it.
MR. MILLER: I think industry standards are relevant, and I think there's a standard to warn. When you know about a risk of cancer and you violate that standard, that is an area uniquely requiring expert testimony.
THE COURT: How does that fit into the specific causes of action that are at stake in this case?
MR. MILLER: Because Monsanto certainly knew by 1999 that Roundup was carcinogenic.

THE COURT: I understand that position. But why does it matter that that violates or doesn't violate industry standards? I mean, let's say it turned --

MR. MILLER: I see your point.

[redacted]

Some e-mails -- and I've been handed a note

that I'd better bring it up. Some e-mails are very technical. And I know he's not an expert in reading e-mails, so I'd ask you to punt it to the trial judge for this e-mail or for that e-mail.

Sure, again, a general ruling -- look, we can't just stand up there and gild the case and put e-mails up on the board. I get it. But there will be some e-mails that are technical that involve an understanding of the EPA, and he may need to interpret those. And I'd just ask that you'd punt that to the trial judge for specific instances is all.

THE COURT: And you would tell me that when you disclosed him as an expert, you disclosed him for that purpose as well?

MR. MILLER: Oh, yes, Your Honor. If it's not on our expert report, I certainly won't talk about it to the jury.

THE COURT: I understand.

MR. MILLER: So just moving on to the last issue, which is preemption. We agree with the Court's tentative of -- I mean, it's clear from the Bates case, it's clear from the seven Roundup cases where they tried this and lost that the Court's tentative is right in line with all those, and it's quite correct. And moreover -- and I just want to end with this because we

factored this in as well. The EPA has not said Roundup doesn't cause cancer. Some people at OPP have said that. "OPP" being a division within the EPA. But two of the EPA scientists were on the IARC panel that said Roundup is probably the cause of non-Hodgkin lymphoma. Two of them.

So it's not true that -- it's true that there's some people at OPP that wrote a report that said it doesn't cause cancer, that's true. But it's also true that that report was reviewed by an independent Scientific Advisory Panel, which concluded that OPP, for whatever reason, did not follow their own guidelines.

And we don't know what number because the EPA won't tell us the vote, but a significant number of scientists on the SAP said this could be causing cancer. Some said no, but they didn't tell us the actual vote, so we don't know. But we know that you can buy a book here that has the EPA imprimatur on it, and it's cited in our papers, that tells you product exposure to Roundup studies out there show a risk for non-Hodgkin lymphoma.

We also know if you call the EPA hotline, you'll be put over to an operator who will tell you that there are animal studies and some epidemiological studies that shows an association between Roundup and

non-Hodgkin lymphoma. So to say that blanketly and universally, the EPA has concluded that it doesn't cause non-Hodgkin lymphoma is not squaring with the facts.

But I think we stand on the Court's tentative for preemption. Unless something extraordinary is said in the next couple of minutes, I'm about done.

THE COURT: I appreciate your help.

MR. MILLER: Thank you, Your Honor.

THE COURT: Thank you, sir.

MR. LASKER: Thank you, Your Honor. I just want to revisit a few things that --

THE COURT: Sure.

MR. LASKER: -- Mr. Miller stated in his argument. I'm going to do them largely sequentially.

The first issue that Mr. Miller raised dealt with the Cooper case. And obviously, we have the opinion in the Cooper case. And Dr. Miller -- Mr. Miller noted that there were a couple of studies in that case where the defense experts argue there could be some confounding with smoking, and you didn't adjust for that. And that was the issue that I mentioned in my argument. They were raising a hypothetical situation where you didn't adjust for smoking and we don't know what would have happened if you had.

So the first point, as I mentioned initially,

Off the record.
(Proceedings concluded at 11:00 a.m.)

I, the undersigned, a Certified Shorthand Reporter of the State of California, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were duly sworn; that a record of the proceedings was made by me using machine shorthand which was thereafter transcribed under my direction; that the foregoing transcript is a true record of the testimony given.

Further, that if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript [ ] was [ ] was not requested.

I further certify that I am neither financially interested in the action nor a relative or employee of any attorney or party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: May 14, 2018

Sheila Pham
CSR No. 13293

EXHIBIT 2

THE WITNESS: Much of my report -- there's something over 1,000 paragraphs -- I would say 400 of them simply restate what Monsanto employees or scientists say to each other about some aspect of their understanding of the risks associated with glyphosate-based herbicides. So all of the positions of my own

EXHIBIT 3

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON, Plaintiff, v. MONSANTO COMPANY, Defendants.	Case No. CGC-16-550128

EXPERT REPORT OF CHARLES BENBROOK

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Notes:

1. Several documents are cited by reference to their MONGLY number; others are referenced as a numbered exhibit. In some cases, a reference lists just the first page of a cited source, while in other cases, all pages in the source, or a selected subset of pages, are listed. In all cases where only the first page of a cited source is listed, I may have relied on content throughout the document in forming my opinions.

2. I had in my files many of the documents that appear in the discovery record of this case. At the suggestion of Counsel in such instances, I identify these documents with their MONGLY or exhibit number.

specifically non-Hodgkin Lymphoma ("NHL") for some individuals like Dewayne Johnson, who applied Roundup herbicides in known, high-exposure scenarios.

B. Monsanto's Responsibilities

17. Monsanto was responsible for four things that are central to this case. First, the company was responsible for assuring that the specific herbicide products sold to the school district for which Mr. Johnson worked were as safe as they could be, given existing knowledge and technology.

18. Second, Monsanto was responsible for the content, scope, and effectiveness of the label directions for use, use restrictions, warnings about high-risk scenarios, and worker-safety requirements on the RangerPro and Roundup ProConcentrate labels.

19. While Monsanto had to comply with several generic, EPA requirements regarding what and how such worker safety information appears on an herbicide label, the company bore the primary responsibility to assure that the label directions on its products, as well as any restrictions, warnings, and precautions, were adequate to avoid any "unreasonable adverse effect on man or the environment."

20. Third, Monsanto bore an obligation to draw upon its extensive field testing and scientific resources to progressively improve the utility and safety of its products in two basic ways: (1) through progressively safer formulations, and (2) through label directions and worker-safety provisions that both adequately warn those handling, mixing, and applying Monsanto-brand herbicides about potential high-exposure scenarios, and require adoption and adherence to worker-safety provisions sufficient to prevent significantly elevated exposure episodes.

21. Fourth, Monsanto was and remains obligated to work cooperatively and openly with the EPA to assure that both the company's internal assessments of risk, including worker

risks, and those done by the EPA, are as accurate as possible. This obligation flows from the company's product stewardship pledges, as well as provisions in federal law.

22. Accuracy in worker risk assessments is an essential foundation upon which the company and EPA can then develop effective, commonsense methods to reduce applicator exposures and risk.

23. The record of this case shows that Monsanto repeatedly failed in carrying out each of these four, essential tasks and responsibilities. Monsanto failed to warn about the risk of NHL, other forms of cancer, or damage to the liver or kidneys, stemming from the use of Ranger Pro and Roundup Pro.

24. Instead, the company overstated the benign nature of its glyphosate-brand herbicides, calling them biodegradable and safe to use, without any qualification. Monsanto also did little to counter the often-heard claim that "Roundup is safe enough to drink."

25. In dozens of instances, the company generated, or came into possession of, scientific information pointing to higher risks than previously recognized. Instead of sharing the information with the EPA, as often required by law, and acting on the new information to update risk assessments and determine whether new, exposure and risk-reduction measures were warranted, Monsanto took active steps to not disclose the information and keep it from becoming public knowledge.

26. In many instances, the company sought ways to undermine the relevance or legitimacy of results in studies that it had commissioned and paid for. Monsanto's determination to change the results of a Bio/dynamics mouse oncogenicity study is a case in point discussed at length in this report.

27. Furthermore, it is important to emphasize that it is Monsanto's responsibility to

take steps to increase margins of safety for users of its products like Dewayne Johnson, through alteration of formulations and addition of new worker-safety language on labels.

28. Such changes should be made whenever the company recognizes an opportunity to make their products safer. Across the pesticide industry, the majority of proactive steps taken to increase margins of safety in the use of specific pesticides are initiated by companies, not the EPA.

29. The number of label amendments proposed by pesticide registrants, and approved generally without change by the EPA, greatly outnumbers label changes required by the EPA.

1. Product Stewardship Standards for Communicating Warnings

30. A company selling a pesticide to the public is responsible for the testing of its product to ensure it can be used safely. It is not the EPA's responsibility to test the product, nor does the agency have the financial resources required to do so.

31. In addition, a company selling a pesticide product to the public bears responsibility for adequately warning users about any potential risks associated with the use of its product. Companies are also obligated to require on product labels practical and effective steps that users must take, or should take to mitigate (reduce) such risks (referred to throughout this report as worker-safety requirements or provisions).

32. While EPA requires and oversees adherence to generic, worker safety labeling requirements, it is crystal clear in the industry that companies bear the primary responsibility to assure that label directions and restrictions are clear, effective, and comprehensive in addressing possible risks from the use of a given product.

33. The purposes for which Dewayne Johnson applied Ranger Pro and other Roundup herbicides, and the methods he used to apply them, were common and routine, as were the

factors giving rise to potentially unsafe exposures from Johnson's lawful applications.

34. This responsibility to warn and mitigate extends to the full range of foreseeable circumstances and situations in which a pesticide can be applied in accord with the directions on its label (e.g., a leaky hose fitting on a backpack sprayer, or an application on a windy day).

35. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), "a manufacturer seeking to register a pesticide must submit a proposed label to EPA as well as certain supporting data." (7 U.S.C. §§ 136a(c)(1)(C), (F))

36. Manufacturers have a duty to update pesticide product labels when new safety information and insights are discovered, for example from tracking documented poisoning episodes. The routine method for them to do so is by requesting EPA to approve a label amendment that builds into a product's existing label, new language imposing additional safety precautions and worker safety provisions.

37. EPA almost always approves such requests for label amendments, and in most cases, quickly.

38. A pesticide product is considered misbranded under FIFRA if:

> "(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment; [or] (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment..." § 136(q)

39. A pesticide product can be misbranded even if the EPA has registered the pesticide and approved its label, because manufacturers bear the responsibility to assure that labels incorporate new and/or adequate safety information and worker safety restrictions to prevent applications leading to excessive exposures and risks.

52. These new provisions were supposed to be on all labels sanctioning use of glyphosate-based herbicides by June 30, 1988, except for very dilute products marketed to homeowners in ready-to-spray bottles.

53. But Monsanto resisted the new worker safety provisions called for in the 1986 Registration Standard, and the most important of them are *still are not included on most of Monsanto's glyphosate product labels in the U.S.*

54. Cancer is not the only adverse health effect possibly associated with use of glyphosate herbicides that Monsanto should have warned users about via product label amendments.

55. Beginning in 1999 Monsanto could and should have added a warning to their labels, and otherwise informed the public, that exposure to formulated glyphosate products can cause oxidative stress and lead to genotoxic damage. In lay terms, such a warning might state "exposure to this product can damage cells and trigger disease."

56. The company was aware of new genotoxicity studies reporting such impacts. To determine the proper course of action moving forward, Monsanto commissioned an internationally respected expert, Dr. James Parry, to review recent genotoxicity studies and render his opinion whether the findings reported were credible.

57. Dr. Parry concluded that some were, and recommended Monsanto take a number of steps to better understand the nature, magnitude and likely causes of newly discovered genotoxic risks stemming from, especially, exposure to formulated glyphosate herbicides.

58. After receiving Dr. Parry's expert report, a reasonable and prudent pesticide manufacturer would have added a genotoxicity warning to Roundup labels, and conducted the additional, more sophisticated and sensitive testing that Dr. Parry had recommended to resolve

"outstanding issues."

59. Instead, Monsanto ended its association with Dr. Parry and refused to do the testing he recommended.

60. Beginning around 2002, Monsanto could and should have added a warning to their label, and otherwise informed the public and biomedical community, that exposures to Roundup formulations increase the risk of a specific cancer, NHL, after learning about the results of two epidemiological studies showing a statistically significant increase in the risk of NHL among users of glyphosate-based herbicides. (Hardell and Eriksson (1999). A case-control study of non-Hodgkin lymphoma and exposure to pesticides, *Cancer* 85: 1353-1360; McDuffie et al. (2001) Non-Hodgkin's Lymphoma and Specific Pesticide Exposures in Men: Cross-Canada Study of Pesticides and Health, *Cancer Epidemiology, Biomarkers & Prevention* Vol 10: 1155-1163)

61. Had Monsanto amended the label to include a risk of NHL in 2002, the EPA would have approved that amendment.

62. These initial NHL results were reinforced in 2003 and 2008 in studies by DeRoos et al. and Eriksson et al.

63. These human epidemiological findings in peer-reviewed science journals take on added importance in light of the confidential, Monsanto commissioned report by Dr. Parry.

64. A reasonable and prudent pesticide manufacturer, aware of recently published evidence of genotoxicity, Dr. Parry's evaluation of these studies, and now a series of positive epidemiological studies, would have added a NHL warning to its glyphosate-based herbicide labels, and added long-overdue worker safety requirements, in order to more adequately safeguard the health of applicators and others exposed to elevated levels of glyphosate herbicide.

advisers, and its own internal research that formulated glyphosate-based products are far more toxic than 100% pure glyphosate, a reasonable and prudent pesticide manufacturer would have tested at least the most widely sold, formulated Roundup products to determine if they were genotoxic and/or carcinogenic.

71. A reasonable and prudent manufacturer that repeatedly pledges allegiance to sound science would not engage in a campaign to "orchestrate outcry," "invalidate the relevance," and cut the funding of IARC, one of the most respected and authoritative scientific bodies in the world charged with a serious, difficult task -- determining the causes of cancer in the hope of reducing the burden of disease worldwide.

72. Monsanto's failure on the label of Ranger Pro herbicide to adequately warn users about the risk of NHL, and reduce exposures in high-risk application scenarios via prudent worker safety requirements, increased Mr. Johnson's exposure to glyphosate and therefore increased his risk of NHL.

73. Instead of warning the public about the risk of NHL, Monsanto has devoted enormous resources to try to sow doubt and discredit scientifically valid claims that Roundup and RangerPro formulations increase the risk of NHL, as extensively detailed in this report.

3. Responses to Mr. Johnson's Inquiry

74. Importantly, Dewayne Johnson reports that he called a number listed on the RangerPro packaging and was connected to the Missouri Poison Control Center on March 27th 2015. Mr. Johnson asked whether RangerPro was a cause of his NHL, and whether it was safe for him to keep using RangerPro. The operator at the poison control center stated that his symptoms were not consistent with the symptoms following glyphosate exposure, and as a result Mr. Johnson continued to spray RangerPro. (MONGLY00500667). Mr. Johnson reports that the

86. Monsanto responded to EPA's request by arguing no such study was needed. OPP/EPA responded by stating why it felt such a study was indeed essential.

87. After eight years of back and forth covered in detail in this report, Monsanto had displayed to the OPP that it would always be willing and able to take whatever next step was necessary to raise new scientific issues in need of exploration, prior to a final OPP decision on whether the 1983 Bio/dynamics study was positive or negative for cancer, or needed to be repeated.

88. Monsanto also had demonstrated multiple times both its ability and willingness to direct political pressure on the agency. The company's clout in Congress, and at senior levels in Executive Branch agencies, made it possible for Monsanto to continuously raise the stakes facing OPP/EPA, until OPP brought its evaluation of the Bio/dynamics study into alignment with Monsanto's, and as a result, changed the cancer classification of glyphosate in a way acceptable to the company.

89. In short, Monsanto convinced the OPP that it was not an effective use of the agency's limited resources to continue the fight.

90. In 1991, EPA changed its interpretation of the 1983 mouse oncogenicity study, on account of one seemingly "magic" tumor found by a Monsanto-commissioned pathologist, who had been asked to reread the kidney slides in the study. This one magic tumor in the male mouse control group turned the seemingly positive Bio/dynamics mouse study into a negative one.

91. All of the pathologists that worked for the EPA and viewed the mouse kidney slides from the Bio/dynamics study could not see, and did not agree that the magic tumor existed in the kidney of one male, control mouse.

92. All of the pathologists paid by Monsanto to assess the kidney slides for the male

experts to present oral and/or written comments to regulatory agencies or their advisory groups, make presentations to allied groups, and assist in gaining positive media coverage of glyphosate health issues.

100. While the roles and contributions of dozens of glyphosate-friendly scientists are described in the body of my report, there are far too many instances, and individuals, to provide a comprehensive accounting of this tactic. A list of some members in Monsanto's glyphosate safety third party network appears in IV, section C.

101. After my review of records in this case, I am shocked by the scope, systematic focus, and brazenness of Monsanto's efforts to utilize supposedly independent scientists to: (1) restate and amplify company positions and scientific conclusions, (2) influence and contribute to the literature in peer-reviewed, science journals on glyphosate safety issues, (3) shape and control the information accessible to regulators, and (4) reinforce via repetition key Scientific Outreach and PR messages reaching the farm community, allied organizations, the general public, and political leaders regarding the safety of glyphosate-based herbicides.

102. These actions are inconsistent with applicable industry standards and do not comport with how a reasonable company would act with respect to tapping outside scientific expertise in the hope of elucidating and preventing human health risks.

D. Critical Science Judgements Impacting the Use of Glyphosate

1. Why Glyphosate's Cancer Classification was So Important

103. Various terms are used to refer to the potential of a chemical to cause cancer. The term "carcinogenic risk" used in the Monograph series issued by the International Agency for Research on Cancer (IARC) means that "an agent is capable of causing cancer."

104. In this report, I follow standard practice in EPA and the toxicology community.

The word "oncogen" refers to a chemical thought to cause benign or malignant tumorous growths in animals or humans; the term "carcinogen" refers to a chemical thought to cause malignant tumors in animals or humans.

105. The Toxicology Branch within the EPA's Office of Pesticide Programs (OPP) decided that glyphosate should be classified as a possible human oncogen in 1984. This decision posed a significant economic threat to Monsanto, as stated by Frank Serdy, Monsanto's Manager of Federal and State Regulatory Affairs in his March 13, 1985 letter to the OPP Registration Division Director, Doug Campt.

106. In the 1980s, once glyphosate was classified as a potential oncogen, any significant, future expansion in agricultural use of Roundup herbicides would require the establishment of dozens of Section 409 food-additive tolerances to cover the residues that would be present in certain fractions of grains and oilseed crops.

107. But glyphosate-related Section 409 petitions in the EPA pipeline, and any future Section 409 tolerance petitions, would be blocked by the anti-cancer Delaney Clause under then-current law and policy.

108. The Delaney Clause is a provision in Section 409 of the Food, Drug, and Cosmetic Act that prohibits the use of cancer-causing food additives; when pesticide residues concentrate in certain foods or food ingredients (like wheat bran), they are considered a food additive to which the Delaney Clause applied.

2. Negative Genotoxicity Studies Give Rise to a False Sense of Safety

109. The first round of mutagenicity and genotoxicity studies on glyphosate were commissioned by Monsanto in the 1970s, conducted by IBT, and were found to be invalid and/or fraudulent. The second round was done in the early 1980s, and fulfilled the then-existing OPP

mutagenicity and genotoxicity data requirements.

110. The laboratories conducting these cell-assay studies on nearly 100% pure glyphosate for Monsanto reported no evidence of mutagenic or genotoxic effects, and EPA scientists accepted this determination. So, throughout the 1970s and for the next ~40 years, all EPA documents report that glyphosate, and glyphosate-based herbicides, are not genotoxic.

111. EPA's genotoxicity determination played a central role in the successful effort by Monsanto to change OPP's mind on the results of the highly-disputed, 1983 Bio/dynamics mouse oncogenicity study.

112. Despite what EPA regarded as clear evidence of a dose-response increase in renal tubule adenomas in male mice in that mouse study, Monsanto argued, and EPA eventually accepted, that the absence of any evidence of genotoxicity provided strong support for the conclusion that the increase in renal tubule adenomas in male mice was not treatment related.

113. Over and over for decades, the absence of evidence of genotoxicity is cited by Monsanto and the EPA as a reason, if not the major reason, to ignore other evidence of mammalian toxicity following exposure to glyphosate-based herbicides.

114. Unfortunately, glyphosate-based herbicides had always been genotoxic to multiple organisms, and via several mechanisms, but the testing methods available in the 1970s and 1980s had not yet detected such effects.

115. Critically, essentially all of the genotoxicity testing required by the EPA and commissioned by Monsanto was carried out on nearly pure glyphosate, rather than on the formulated glyphosate herbicides people use and are exposed to.

116. The first evidence of genotoxicity of glyphosate-based herbicides appeared in the open, scientific literature in the 1990s (see the genotoxicity study subsection in VI., C.1).

117. By 2003, there was considerable evidence in peer-reviewed scientific journals suggesting that at least certain glyphosate-based herbicides were genotoxic.

118. When the International Agency for Research on Cancer (IARC) reviewed glyphosate in 2015, it found "*strong evidence*" of both genotoxicity and the capacity to induce oxidative stress in cells, two mechanisms that can lead to cancer.

119. In the 1980s, Monsanto was aware of the potential, if not probable genotoxicity of formulated, glyphosate-based herbicides, as opposed to pure glyphosate active ingredient.

120. In response and to this day, the company has worked diligently, and with great success, to avoid having to conduct any further, or more sensitive internal or external genotoxicity studies on formulated Roundup and/or other glyphosate-based herbicides.

121. In my opinion, Monsanto did not want to test their formulated glyphosate-based herbicides because they expected such studies to produce positive evidence of genotoxicity.

122. Any positive genotoxicity assay results would have to be, by law, provided to the EPA. Such data would, in turn, almost certainly lead to new, EPA-mandated restrictions on where and how Roundup herbicides could be used, especially on Roundup labels sanctioning non-agricultural applications with backpack or hand-held sprayers, such as those used by the plaintiff in this case, Dewayne Johnson.

123. Almost inevitably, such new studies would curtail glyphosate FTO, at least to some degree.

124. In 1997 Monsanto reached out to Dr. James Parry, a prestigious, independent academic genotoxicity expert that Monsanto was cultivating as a possible "glyphosate-friendly" spokesperson. To test Parry's scientific beliefs and judgements on glyphosate genotoxicity, Monsanto asked Parry to conduct a preliminary assessment of what he learned from a review of

support will be used to favorably influence current and future possible challenges in the regulatory and public arena." (GLYMON00904774)

1. Cherry Picking Science

144. The record in this case shows that Monsanto does not, in general, use science in the organized pursuit of knowledge and deeper understanding of the potential human and environmental risks associated with use Roundup herbicides, but rather to gain new product registrations, and defend the company's Freedom to Operate, especially when placed in jeopardy by new information regarding potential risks.

145. Monsanto has conducted internal testing to determine what a similar, new study done by another scientist or laboratory is likely to show, prior to committing to pay for the new study by an independent laboratory, the results of which might have to be submitted to the EPA.

146. The reason is clear – Monsanto's priority is to invest testing dollars in gaining new registrations and preserving glyphosate FTO, not to contribute to the science-base needed for refined, more accurate risk assessments and more effective worker-safety label precautions and requirements.

147. Again, in many instances discussed in this report, Monsanto has selectively drawn upon the results of studies, in effect cherry-picking the findings most favorable to its position and desired outcome, while ignoring, or criticizing findings that caste a less favorable light on the safety of glyphosate and Roundup herbicides.

148. In the case of some studies, remarkably, Monsanto does both, highlighting a finding that is aligned with its position, and in general endorsing the quality of the study, only to then elsewhere criticize the study and some negative finding it reports.

149. Monsanto's abuse of science is so systematic and consistent that it seems to track some, perhaps unstated, internal company policy.

200 ppm, from 15 ppm). In addition, Monsanto acknowledged that a Section 409 food additive tolerance in soybean hulls would be required, and proposed that it be set at 100 ppm.

261. As long as EPA considered glyphosate a possible oncogene, approval of the Section 409 tolerance would likely not occur. For example, in an April 18, 1985 memo to the Registration Division and Toxicology Branch from the Residue Chemistry Branch, R.W. Cook reviews a pending tolerance petition that requests increases in glyphosate plus AMPA tolerances in wheat grain and wheat straw. The memo states: "4b. TOX has concluded (W. Dykstra, 3/19/85) that food additive tolerances for glyphosate are not appropriate due to the Delaney rule." (page 4)

262. The soybean grain tolerance was increased from 0.1 ppm to 6.0 ppm in 1985, and to 15.0 ppm in 1990, to cover residues in soybeans harvested from fields sprayed with preharvest glyphosate as a desiccant (i.e., to kill the mother plants). The soybean hay tolerance was raised to 200 ppm, and the soybean straw tolerance was set at 100ppm. The wheat straw tolerance was raised to 40 ppm.

B. Studies on Glyphosate Conducted by IBT Create Massive Hole in Toxicology Dataset

263. Early interactions between OPP and Monsanto were complicated by the IBT pesticide data scandal.

264. IBT was a major contract laboratory doing toxicological studies destined for submission to OPP/EPA for many pesticide manufacturers in the 1970s and 1980s.

265. In 1976, a routine FDA audit of an IBT test facility uncovered problems with the conduct of some studies and lead to a thorough EPA assessment of all studies done by IBT that supported regulatory actions by OPP.

266. Most of the initial toxicological database supporting the early tolerance petitions

and registrations of glyphosate were done by IBT. The "IBT Tracking System Report" released in 1983 notes 30 studies done by IBT on glyphosate, of which 17 were invalid and 2 were pending final judgements (Exhibit B, "Summary of the IBT Review Program," OPP, July 1983).

267. On July 1, 1977, OPP generated a one-page summary of the eight toxicology studies used to support establishment of all existing glyphosate tolerances. All eight studies were submitted between 1972 and 1974, and all eight were done by IBT.

268. An August 21, 1978 memo from William Dykstra of the Toxicology Branch to Robert Taylor in the Registration Branch discusses the EPA's assessment of the validity of a key, 2-year chronic oral toxicity study done in Albino rats by IBT. For a variety of reasons, the EPA judged the study to be invalid, yet it served as the basis of the then-current chronic Reference Dose of 0.1 mg/kg/day (called an ADI, or Acceptable Daily Intake in 1978).

269. A July 27, 1982 memo from the Toxicology Division to the Registration Division reported EPA's judgement that the 2-year dog study (No. 651-00565) done by IBT for Monsanto and completed in 1973 was invalid because of missing data, failure to record diet preparation records, and other deficiencies.

270. Accordingly, it took about a decade for EPA to determine that most of the toxicological database submitted to the agency by Monsanto in the mid-1970s, and used by EPA to support all early EUP, tolerance, and registration actions, was invalid.

271. Problems also arose with some of the replacement studies that Monsanto commissioned to replace invalid IBT studies. In July 1979, Monsanto decided to terminate a 2-year mouse study on NNG because of excessive mortality in treated groups of animals (MONGLY04272266).

272. Via an agreement with OPP, Monsanto repeated all of the invalid IBT studies at

different laboratories. In the interim, EPA allowed existing registrations and tolerances to remain in place.

273. The first of the replacement studies were submitted to OPP beginning in the early 1980s. For about a decade, the early registrations and tolerances covering all uses of glyphosate were not supported by a complete set of valid toxicology studies.

C. Contaminants, Adjuvants, and Surfactants

274. The EPA grants two basic types of registrations and labels for pesticides: technical use registrations and labels, and formulated, "end use" product registrations and labels.

275. A first step in the regulatory process typically entails a chemical company applying for and gaining a technical use product label covering a product composed of 100%, or nearly 100% pure active ingredient. Such registrations are granted to basic manufacturers that are involved in pesticide discovery research and development, and own and/or operate chemical plants synthesizing pure, 100% pesticide active ingredients.

276. The EPA labels issued for technical use products generally do not include detailed lists of approved crop or industrial uses, rates of application, or other specific use instructions. They do address proper handling, storage, and transport methods and precautions.

277. Technical use pesticides may be used internally by the basic manufacturer to make its own brand-name formulated product, like Roundup herbicide containing glyphosate as the active ingredient and various adjuvants and surfactants.

278. Technical use products are also sometimes sold to pesticide companies that formulate "end use" products labeled for specific uses. Such "end use" products are ready to be used and applied by farmers, applicators, home owners, land managers, or other people involved in pest management.

503. Dykstra also stated that the study should focus just on unresolved questions from the first study. This concession to Monsanto was presumably predicated on the fact that some of his recommendations would have markedly increased the cost of the study (200 male mice in each group, instead of 50; adding two additional treatment groups).

504. First, the study can include only male mice (cutting the size of the study in half). Second, a "tier approach" was acceptable in the pathology examination phase of the study, focusing first on kidney and liver sections in all groups of male mice. If the "first tier" examination produces no evidence of an oncogenic response, "then additional histopathological examination will not be necessary."

505. Last, the memo states: "The registrant should be requested to submit a proposed protocol for the repeat mouse study to the Agency for comment before the experimental work is initiated."

506. Monsanto continued to resist EPA's call for a new mouse oncogenicity study, and indeed has still not redone the study as requested by EPA.

507. The primary reason is clear – legitimate concern in the company that the results of such a study would affirm the key finding in the original Bio/dynamics study mouse oncogenicity study, and result in EPA classifying glyphosate as a "possible human carcinogen."

B. Monsanto Efforts to Delay and/or Defuse Worker Safety Language on Roundup Labels

508. The 1986 glyphosate Registration Standard (RS) specified new worker safety language that must appear on Roundup product labels in channels of commerce as of June 30, 1988.

509. In a February 9, 1987 letter to the Director of the OPP Registration Division, Monsanto argues that the worker-protection language in the 1986 RS is unjustified, for reasons

> Henry [Abadin] was the one who ended up saying that they [ATSDR] would put glyphosate on hold holding the OPP risk assessment release [he actually meant "pending" rather than "holding" the OPP risk assessment release]
>
> Hope this helps
>
> Breysse, Patrick N…he's the Director of HCEH/ATSDR
> Stephan, James W (aka Jimmy) he's the acting director of the Division of Community Health Investigation
> Henry Abadin…..he's the branch chief
> Hannah Pohl…..is the person doing the work on glyphosate" MONGLY04028722)

627. This Housenger email to Jenkins reads like a status report from a junior staff person to his/her manager. It reflects a desire to be helpful to Monsanto that is fundamentally at odds with Housenger's role as the senior manager of the EPA's Office of Pesticide Programs.

628. On October 13, 2016, Jay Vroom of CropLife America (Monsanto's lobbying organization) called and emailed Jack Housenger to discuss removing epidemiologist Peter Infante from the glyphosate SAP panel and to invite him to a retreat with Monsanto and other Industry executives at a West Virginia casino and resort. EPA-HQ-2017-000442-0000205.

629. On October 14, 2016, the OPP announces that it was postponing the SAP hearing on glyphosate scheduled for October 18, 2016. On October 19, 2016, the OPP announced that Peter Infante would no longer be on the SAP panel evaluating glyphosate.

630. Jack Housenger attended a CropLife retreat at a Casino and Resort with executives of Monsanto and other pesticide companies in November of 2016, one month before a key SAP Panel Hearing on glyphosate. These executives noted that, "[w]e had some quality time with EPA OPP Office Director Jack Housenger to dig into key issues and operational matters at that vital department of EPA." MONGLY07063555.

and/or repeated. (Parry's conclusion number 5 notes one positive study, and three negative or equivocal ones in a category of genotoxicity assays; hence, the split score).

680. Parry then states: "I conclude that glyphosate is a potential clastogenic in vitro." He was unable to draw a conclusion on the clastogenicity of formulated glyphosate-based herbicides because of a lack of studies. And that "glyphosate mixtures may be capable of inducing oxidative damage *in vivo*."

681. It is important to note that Parry's two conclusions, reached in 1999, were basically the same as the primary reasons that the International Agency for Research on Cancer, in its March 2015 monograph on glyphosate, classified the evidence on genotoxicity/Mode of Action as "strong."

682. In addition to his written report, Dr. Parry provided Monsanto with a detailed list of recommended research activities to clear up lingering questions over the genotoxicity of glyphosate herbicides, the mechanisms giving rise to genotoxicity, and relevance of these mechanisms to the evaluation of glyphosate's other health effects, and especially oncogenicity. (MONGLY01314264)

683. In his final, summary statement in the research recommendations document, Parry writes: "My overall view is that if the reported genotoxicity of glyphosate and glyphosate formulations can be shown to be due to the production of oxidative damage then a case could be made that any genetic damage would be thresholded. Such genetic damage would only be biologically relevant under conditions of compromised antioxidant status."

684. Clearly, in this final paragraph, Parry was delivering to Monsanto a "good news-bad news" message. The "bad news" is glyphosate is likely genotoxic via induction of oxidation damage in cells, and likely other modes of action. The "good news" is that Monsanto might be

able to convince regulators that one or more of these mechanisms might be subject to threshold effects, leading to the possibility that Monsanto could show that the effects are not likely under real-world exposure scenarios.

685. But Parry's added assertion that oxidative damage from exposure to glyphosate herbicides would only be a problem for people "of compromised antioxidant status" is significant.

686. Undoubtedly, Monsanto scientists should have known at the time that most people in developed nations consume a diet seriously deficient in total antioxidant activity, and that most countries and international scientific bodies were recommending about a doubling in the daily servings of fresh or lightly cooked fruits and vegetables in order to increase total antioxidant intake via the diet.

687. Two Monsanto scientists shared their reviews of the Parry report with colleagues. Stephen Wratten wrote an email entitled "Comments on Parry write-up" to Mark Martens and Donna Farmer. It starts by saying: "I was somewhat disappointed…The style and rather casual lack of completeness and preciseness would make it hard to circulate this around to anyone as supporting information."

688. Wratten acknowledges that Parry's conclusion -- glyphosate and formulated glyphosate herbicides are likely genotoxic via an oxidative stress mechanism -- will be hard to disseminate and characterize as "supporting information" for Monsanto's long-held belief, and contention, that glyphosate is not genotoxic.

689. In the next several days in early July 1999, Monsanto officials discuss internally whether to:

- Commission the new genotoxicity research studies Parry recommended;
- Ask someone else to interface with Parry to rough out the edges of his

http://pubs.acs.org/doi/abs/10.1021/tx800218n).

704. On January 5, 2009, Kerstin Kramer, a Monsanto information specialist, sent an email to over a dozen senior Monsanto scientists alerting them to the online release of this study. In her email to Monsanto colleagues, she writes: "As you know RU [Roundup] is under pressure in France particularly and the team needs talking points very quickly. We would need an issue alert and response to the paper." (MONGLY00987424)

705. Two days later, one of the recipients of the Kramer alert, Donna Farmer, replies to several of her colleagues: "As usual, the main objective of Seralini in this type of study is to force us (and the regulators) to set long term studies with formulations and not only the active..."

706. Monsanto failed to provide the Parry Report to the EPA as required under 40 CFR § 159.158. This section of FIFRA spells out the information that must be submitted by registrants:

> (a) General. Information which is reportable under this part must be submitted if the registrant possesses or receives the information, and the information is relevant to the assessment of the risks or benefits of one or more specific pesticide registrations currently or formerly held by the registrant. Information relevant to the assessment of the risks or benefits also includes conclusion(s) or opinion(s) rendered by a person who meets any of the following:
> (1) Who was employed or retained (directly or indirectly) by the registrant, and was likely to receive such information.
> (2) From whom the registrant requested the opinion(s) or conclusion(s) in question.
> (3) Who is a qualified expert as described in § 159.153(b).

D. Monsanto Reliance on Ghost-writing

707. As used in this report, the term "ghost-writing" refers to three types of contributions to a written document by a person not listed as the author, or among the co-authors of a document: (1) producing the first and original draft of a document, or section(s) of a document; (2) revising a document, or its section(s), in a way that adds to or alters the substantive content of the document; and (3) providing information and text, either as original

requested "disclosure of files used in connection with the preparation of the IARC Monograph Volume 112." Prior to responding, she consulted with colleagues on the Working Group and IRAC.

802. She replied that the files belonged to IARC, and the result of their deliberations were explained in detail in the monograph. She then wrote:

> "I found your letter *intimidating* and *noxious* even though transparency is important…It is impolitic to mention possible consequences without identifying the correct background. I find your approach reprehensive and lacking of common courtesy even by today's standards. As a graduate of a British educational system, I consider your letter *pernicious*, because it maliciously seeks to instill some anxiety and apprehension in an independent group of experts…Please avoid contacting me or any of my colleagues in the future regarding this issue." (Emphasis in original; Heydens Exhibit 3-54)

2. Seralini Team

803. On September 19, 2012, a team of French scientists led by Gilles-Eric Seralini published a paper entitled "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" in the journal *Food and Chemical Toxicology* (Vol 50: 4221-4231).

804. The paper reported the results of a two-year rat study. Both formulated Roundup herbicide and GE-corn, fed separately and together, were found to trigger a variety of pathologies including cancer, damage to the pituitary gland, liver, and kidneys, and premature death.

805. The kidney emerged as a particularly vulnerable organ, given that 76% of the impacted parameters were associated with kidney deficiencies.

806. The abstract ends with this statement:

> "These results can be explained by the non-linear endocrine-disrupting effects of Roundup, but also by the overexpression of the transgene in the GMO and its metabolic consequences."

807. The Seralini study was the first, independent two-year rat feeding study designed

to sort out the individual and combined impacts of long-term exposure to a GE corn (NK603) and formulated Roundup herbicide. Previously, Seralini and colleagues had conducted several genotoxicity experiments comparing the toxicity of glyphosate and formulated Roundup in cell assay systems.

808. The paper's findings received extensive media coverage in the U.S. and Europe, and posed a significant threat to Monsanto's commercial interests, as well as a major challenge for regulators who had approved both Roundup and GE corn.

809. The next day, September 20th, David Saltmiras sent an email to Sir Colin Barry and Andrew Cockburn, a consultant working for Monsanto. It marks the beginning of a campaign that would last years, with the goal of discrediting the Seralini paper and team.

810. In the email, Saltmiras calls the paper "junk science," questions what happened with the journal's peer review process, and states: "I also suspect this paper may be in our own best interests – the last rites for Seralini's few remaining shreds of scientific credibility." (MONGLY01096620)

811. Regardless of the merits and faults of the paper, the rapidity and scope of negative commentary, beginning on the day the paper was released, was virtually unprecedented.

812. A week after the paper's release, a Monsanto-funded, retired academic in the U.S., Dr. Bruce Chassy, emailed the journal editor Wallace Hayes calling for the paper to be retracted, in order to save the reputation of the journal. (MONGLY00900629)

813. After Hayes responds and says he will process Chassy's email as a letter to the editor, and give the Seralini team an opportunity to reply in accord with standard journal policy, Chassy quickly replies and writes that his initial email "was a heartfelt expression by a caring colleague who is deeply concerned…My intent was to urge you to roll back the clock, retract the

to Monsanto's comment generation website."

957. The estimated budget for the proposed 3-4 months of activity was $355,000-$400,000.

3. Shaping the Agenda and Supporting Scientific Meetings

958. There are several instances in the record of this case documenting why and how Monsanto played a role in shaping the focus of a scientific meeting to include discussion of glyphosate risk issues, as well as some instances where Monsanto also provided the funding needed for a meeting to occur.

959. In a March 10, 2016 email, Dan Goldstein, Monsanto's "Lead, Medical Sciences and Outreach," contacts a colleague, Allister Vale, a consulting clinical pharmacologists and Director of the National Poisons Information System (Birmingham Unit), in the U.K.

960. Dr. Vale is active in several organizations that convene meetings of medical toxicologists, a group that Monsanto is striving to engage in the ongoing reaction to IARC and debate over glyphosate safety.

961. In his "preliminary inquiry," Goldstein asks Vale if she would work with Sir Colin Berry to "reincarnate" an expert panel, this time composed of European medical toxicologists. (MONGLY0256574-75) He writes that: "Cost (including Honoria) will be picked up by Monsanto via an appropriate granting mechanism which allows for a proper degree of academic independence."

962. Vale and Goldstein meet briefly later in the month at a meeting of the Society of Toxicology (SOT). They discuss the idea raised by Goldstein in the March 10 email, and agree to get back in touch after the meeting.

963. Vale sends Goldstein a March 24, 2016 email apologizing for her limited time

VII. Protecting "Freedom to Operate" and Scientific Deceit Characterize Monsanto's Assessments of and Response to Glyphosate-Related Risks

971. Pesticide companies bear an obligation vested in various laws and regulations, and common corporate decency, to assure that the products they bring to market are safe and will reliably produce the benefits for which they are registered, i.e. control of weeds as in the case of glyphosate.

972. The term "product stewardship" is used within the industry and regulatory agencies to describe and encompass the actions pesticide manufacturers should take on an ongoing basis in the interest of product stewardship, before and after a new use of a pesticide is approved.

973. In the pesticide arena, the sciences supporting both human-health risk assessments and environmental-impact assessments are dynamics and imperfect, and heavily dependent on location- and even application-specific data, which is almost never available. So, in companies and regulatory agencies alike, many assumptions and a considerable degree of judgement is essential in deciding upon the science that must be conducted prior to seeking, and approving a new use of a pesticides.

974. Where to draw the line between presumably safe and possibly risky pesticide uses is also fraught with scientific, social, and political challenges, uncertainty and tension.

975. The same is true after approval, as companies and regulators strive to refine and agree on the nature and magnitude of risks after a pesticide is approved and has been applied for a period of time.

976. But in general, Monsanto claims that they base all their product development, testing, commercialization, and regulatory actions on the best available science. Such science is

which had potential impacts on a number of Monsanto products, including glyphosate.

988. Monsanto established an "FQPA Core Team to engage with EPA as it developed FQPA policies and procedures, and to alert colleagues of possible implications for the labels and tolerances sanctioning use of specific Monsanto pesticide products." (MONGLY03750989)

989. Abby Li [FND/1735] was a member of this FQPA Core Team. She sent a November 20, 1999 email to several Monsanto management team and senior officials regarding the activities of the FQPA Core Team. After listing the six members of the FQPA Core Team, the email stated:

> "This [membership] is a good mix of people that allows us to have external influence as well as ensure that we have practical understanding of the full impact to our products. I'd like to make sure we push hardest on those issues that are threatening our business." (MONGLY03750989)

990. Two days earlier, on November 18, 1999, Abby Li sent an email to 10 Monsanto colleagues regarding a scoping session on the evolving OPP policies governing aggregate risk assessment under the FQPA. (The FQPA directed the EPA to take account of exposures to a given pesticide from water, food, occupational, atmospheric, and any other routes of exposure; such total estimates of exposure from all routes are called "aggregate exposure" in the context of FQPA implementation).

991. The email begins: "Dear people who might be interested in the FQPA,…" The last paragraph addresses the membership of the FQPA Core Team and key areas of expertise that need to be represented. Then, Abby Li writes: "A key goal is to understand how our products are impacted so we know what issues Monsanto should fight the hardest on." (MONGLY03750990)

992. The implication is clear. The number one goal driving Monsanto's assessment of evolving EPA science policies and regulatory procedures is minimizing the impact on FTO and sale of Monsanto products.

suggests the existence of new risks, or higher risks than previously recognized and addressed by the EPA.

1083. The TNO data suggesting that the actual dermal absorption rate for glyphosate in formulated Roundup should be 5% to 10%, instead of 3%, is exactly the type of important, new information that Section 6(a)(2) in FIFRA requires registrants submit to the EPA.

1084. I conclude that the failure to share the results of the preliminary TNO rat skin dermal penetration study was a likely violation of Section 6(a)(2), recognizing that Monsanto may have submitted the data in compliance with Section 6(a)(2).

1085. If Monsanto did make such a disclosure to the EPA of the TNO glyphosate dermal absorption data, the company will surely challenge my opinion and correct the record, by sharing with the court the documents confirming that such a transmission of data was made in accord with Section 6(a)(2) requirements.

4. Nitrosamine Contaminants in Roundup Herbicide

1086. In a July 14, 1977 "Recommendation" in response to a Monsanto request for an extension of an existing Experimental Use Permit (EUP) that would sanction use of 705 gallons of Roundup in 1978, EPA notes that the Toxicology Branch has previously raised concern over the 0.2 to 0.4 ppm of N-nitrosoglyphosate (NNG) in formulated, Roundup herbicide (MONGLY00223253).

1087. The "Recommendation" was to not approve the EUP extension because the petitioner, Monsanto, "…has made no assessment of possible hazards…" to applicators and those handling the herbicide.

1088. Accordingly, since 1977, EPA concerns over the NNG content of Roundup herbicides were among the health and safety issues in play between EPA and Monsanto.