Michael J. Miller (appearance *pro hac vice*)
Curtis G. Hoke (SBN 282465)
THE MILLER FIRM LLC
108 Railroad Avenue
Orange, VA 22960
Tel: (540) 672-4224; Fax: (540) 672-3055
mmiller@millerfirmllc.com;
choke@millerfirmllc.com

Mark E. Burton, Jr.(SBN 178400)
AUDET & PARTNERS, LLP
711 Van Ness Avenue, Suite 500
San Francisco, California 94102-3275
Telephone: 415.568.2555
Facsimile: 415.568.2556
mburton@audetlaw.com

R. Brent Wisner (CA #276023)
Pedram Esfandiary (SBN: 312569)
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
10940 Wilshire Blvd., 17th Floor
Los Angeles, CA 90024
Telephone: (310) 207-3233
Facsimile: (310) 820-7444
rbwisner@baumhedlundlaw.com
pesfandiary@baumhedlundlaw.com

Attorneys for Plaintiff Alva and Alberta Pilliod

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

COORDINATION PROCEEDING SPECIAL TITLE (RULE 3.550)
ROUNDUP PRODUCTS CASES

THIS DOCUMENT RELATES TO:
Pilliod, et al. v. Monsanto Company, et al.
Alameda Superior Court Case No.: RG17862702

JCCP NO. 4953
PLAINTIFF ALVA AND ALBERTA PILLIOD'S TRIAL BRIEF

Hon. Judge Winifred Smith

Dept. 21

Trial Date: March 18, 2019

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Treatises

Regulations

I. INTRODUCTION

Plaintiffs Alva and Alberta Pilliod both developed non-Hodgkin lymphoma ("NHL") due to their extensive use of the pesticide Roundup manufactured by Monsanto Company. Roundup contains the chemical glyphosate together with the chemical surfactant POEA which helps glyphosate adhere to and penetrate cell walls. Roundup also contains other impurities known to cause cancer. For over forty years, Monsanto has known that exposure to Roundup and other glyphosate-based herbicides (GBHs) have been associated with an increased risk of developing cancer. Yet, to this day, Monsanto has failed to warn consumers of the known cancer risk. Instead, Monsanto has actively concealed critical safety information; refused to conduct recommended carcinogenicity studies; refused to test formulated products due its concern of uncovering damaging information; and flooded the literature with ghostwritten articles to bolster the safety profile of GBHs.

As pointedly stated by Judge Chhabria, "...there is strong evidence from which a jury could conclude that Monsanto does not particularly care whether its product is in fact giving people cancer, focusing instead on manipulating public opinion and undermining anyone who raises genuine and legitimate concerns about the issue." *In re Roundup Prod. Liab. Litig.*, No. 16-MD-02741-VC, 2019 WL 1084170, at *3 (N.D. Cal. Mar. 7, 2019). Monsanto's Director of Medical Toxicology, Dr. Daniel Goldstein described Monsanto's efforts to downplay the risk of Roundup as playing "whack-a-mole" stating "Donna Farmer (glyphosate tox) and I have been playing **Whack-a-Mole** for years and calling it just that. We were joking about it yesterday."[1] Trial Ex. 4 (3/3/2010 email "re: another mole needing a whacking...").

In March 2015, The International Agency for Research on Cancer ("IARC") a part of the World Health Organization's ("WHO"), conducted a thorough, transparent, independent review of the peer-reviewed literature on glyphosate and determined that glyphosate and GBHs were probable human carcinogens associated with NHL. Trial Ex. 2047. The Federal Judicial Center's Reference Manual on Scientific Evidence (3rd. Ed.) ("Reference Manual") considers IARC one "of the most well-respected

[1] Dr. Goldstein acknowledged at deposition that whack-a-mole is "something that we use as jargon internally; issues pop up and we're called upon to deal with them." Goldstein Dep. at 72:18-73:3.

and prestigious scientific bodies," whose assessments of carcinogenicity of chemicals "are generally recognized as authoritative..." 20, 565. On July 7, 2017, after an **independent** review of glyphosate, the state of California's Office of Environmental Health Hazard Assessment ("OEHHA") listed glyphosate as a known carcinogen pursuant to Prop 65. Trial Ex. 1093.

OEHHA allowed Monsanto to submit extensive arguments during its assessment of glyphosate. Upon consideration of Monsanto's arguments and the science underlying IARC's assessment, California denied Monsanto's request to reject IARC's findings stating, for example, that "OEHHA agrees with IARC's determination that these tumor findings are treatment-related and demonstrate statistically significant dose-response relationships;" and that "OEHHA has reviewed the discussion of the mechanistic data for glyphosate provided in the IARC monograph and agrees with IARC's conclusion that 'Overall, the mechanistic data provide strong evidence for genotoxicity and oxidative stress. There is evidence that these effects can operate in humans.'" Trial Ex. 1099, pp. 7, 23[2]

Dr. Luoping Zhang, a biochemical toxicologist from U.C. Berkeley, who served as peer-reviewer for both OEHHA's assessment of glyphosate and the EPA's assessment of glyphosate recently published a paper on February 6, 2019 concluding that there was a "compelling link" between Roundup and NHL based on a review of the epidemiology and toxicological data. Trial Ex. 2332. Dr. Zhang was joined in this paper by two other members of the EPA's Scientific Advisory Panel's review of glyphosate that reached a unanimous conclusion that the EPA failed to follow its own guidelines in evaluating glyphosate. *Id.*

Monsanto still will not warn consumers about the risk of NHL in light of these authoritative assessments by the World Health Organization and the State of California. Plaintiffs Alva and Alberta Pilliod were among those consumers who were not warned by Monsanto of the risk of NHL with GBHs. Alberta and Alva Pilliod have been married for over 48 years. Alberta worked as school teacher and school principal, and Alva, an Army veteran, worked as a sales manager for Goodyear. The Pilliods purchased a home in Livermore, California in 1982 and began regularly spraying Roundup together at their home and at rental properties they managed. On average, the Pilliods sprayed Roundup about fifty

[2] https://oehha.ca.gov/media/downloads/crnr/glyphosatensrlfsor041018.pdf pp. 7, 23.

days per year. In total the Pilliods sprayed Roundup for approximately 1,500 days. The Pilliods had always viewed Roundup as a safe product based on advertisements from Monsanto showing people using Roundup in shorts and t-shirts. Trial Exs. 2968-2977 (videos) Unfortunately, Monsanto's advertisements and representations were false. Roundup causes cancer.

In June 2011, after 30 years of spraying Roundup, Mr. Pilliod was diagnosed with diffuse large B-cell lymphoma (DLBCL), a form of NHL. In March 2015, Mrs. Pilliod was diagnosed with diffuse large B-cell lymphoma of the central nervous system (PCNS). Mrs. Pilliod began aggressive systemic chemotherapy on April 14, 2015. In July 2016, Mrs. Pilliod was diagnosed with relapsed NHL which again required aggressive chemotherapy. The Pilliods had reviewed the label and viewed the instructions on the Roundup bottle. Unfortunately, there was no warning about the carcinogenic risks of Roundup and no warning to take safety measures such as wearing gloves or other safety gear. Had the Pilliods been warned about the risk of cancer then the Pilliods would not have used Roundup®. In fact, after first learning, in January 2017, that Roundup can cause NHL, Mr. Pilliod stopped spraying Roundup and switched to using vinegar as an herbicide. (Mrs. Pilliod had stopped spraying earlier due to physical limitations from her illness).

The Pilliods now brings claims for strict liability and negligence for design defect and failure to warn. The Pilliods are also bringing claims for breach of implied warranty and punitive damages.

II. QUESTIONS FOR THE JURY

Under failure to warn in strict liability, the Pilliods must prove by a preponderance of evidence:

1. That Monsanto manufactured, distributed, or sold Roundup;
2. That Roundup had potential risks or side effects that were known or knowable in light of the knowledge that was generally accepted in the scientific community at the time of the manufacture, distribution, and sale of Roundup;
3. That the potential risks or side effects presented a substantial danger when Roundup is used in an intended or reasonably foreseeable way;
4. That ordinary consumers would not have recognized the potential risks or side effects;
5. That Monsanto failed to adequately warn of the potential risks or side effects;
6. That Mr. and/or Mrs. Pilliod were harmed; and
7. That the lack of sufficient warnings was a substantial factor in causing Mr. and/or Mrs. Pilliods' harm.

CACI 1205. Monsanto has admitted that it has never warned consumers that Roundup can cause NHL. Therefore, the only real questions are whether Roundup was a substantial contributing cause of Mr. or Mrs. Pilliod's cancer and whether the potential carcinogenic nature of Roundup was known or knowable. Under negligent failure to warn, the jury must also decide whether a reasonable company would have warned users that their product could cause cancer. CACI 1222.

Under design defect in strict liability, the Plaintiff must prove to the jury by a preponderance of evidence that:

1. That Monsanto manufactured, distributed or sold the Roundup®;
2. That the Roundup used by the Pilliods did not perform as safely as an ordinary consumer would have expected it to perform when used or misused in an intended or reasonably foreseeably way;
3. That Mr. and/or Mrs. Pilliod were harmed; and
4. That Roundup's failure to perform safely was a substantial factor in causing Mr. and/or Mrs. Pilliod's harm.

CACI 1203. The only real dispute for the jury to decide under design defect is whether Roundup was a substantial contributing factor in causing the Pilliods' NHL. With respect to causation, Roundup needs only be a contributing cause, it does not need to be the only cause of the Pilliods' cancer. CACI 430, CACI 431; *Cooper v. Takeda Pharm. Am., Inc*., (2015) 239 Cal. App. 4th 555, 597, (CACI 431 appropriate where other causes may also have contributed to the cancer)

To meet its burden "the plaintiff must offer an expert opinion that contains a reasoned explanation illuminating why the facts have convinced the expert, and therefore should convince the jury, that it is more probable than not the negligent act was a cause-in-fact of the plaintiff's injury." *Id.* at 578. Here Plaintiff has admissible evidence from experts, as ruled on by Judge Karnow and therefore causation is a jury question. Furthermore "[u]nder the applicable substantial factor test, it is not necessary for a plaintiff to establish the negligence of the defendant as the proximate cause of injury with absolute certainty so as to exclude every other possible cause of a plaintiff's illness..." *Id.* at 578.

The jury may consider whether Monsanto failed to test Roundup®. "With respect to testing of the product, if failure to conduct reasonable testing would have led to the product causing substantial harm, the manufacture is chargeable with negligence if the defective condition could have been disclosed by reasonable testing." CACI 1221. Monsanto has admitted in discovery that it has never conducted

an epidemiological study on Roundup and NHL; and it has never conducted an animal carcinogenicity test on Roundup or any glyphosate based formulations.

Finally, the jury will be asked to consider whether Plaintiff demonstrated with clear and convincing evidence that Monsanto "engaged in that conduct with malice, oppression, or fraud." CACI 3945. "The law in California is that punitive damages are permitted in product liability actions precisely because '[g]overnmental safety standards and the criminal law have failed to provide adequate consumer protection against the manufacture and distribution of defective products. [Citations.] Punitive damages thus remain as the most effective remedy for consumer protection against defectively designed mass produced articles. *Buell–Wilson v. Ford Motor Co.* (2006) 141 Cal.App.4th 525, 562 vacated on other grounds in *Ford Motor Co. v. Buell–Wilson* (2007) 550 U.S. 931, 127 S.Ct. 2250 (citing *Grimshaw v. Ford Motor Co.* (1981) 119 Cal.App.3d 757, 810). Furthermore, punitive damages are available even where "there was a 'reasonable disagreement' among experts" Id. at 559-560. The jury is "entitled to" reject the claims of Defendant's experts in reaching a verdict on punitive damages. Id.

Under the exemplary damage statute "malice does not require actual intent to harm. [Citation.] conscious disregard for the safety of another may be sufficient where the defendant is aware of the probable dangerous consequences of his or her conduct and he or she willfully fails to avoid such consequences." *Pfeifer v. John Crane, Inc.* (2013) 220 Cal. App. 4th 1270, 1299. Furthermore, Courts have long recognized that when circumstantial evidence supports an inference that a manufacturer puts its own interests ahead of the safety of consumers, punitive damages are warranted. *Grimshaw v. Ford Motor Company* (1981) 119 Cal.App.3d 757, 813,814; *West v. Johnson & Johnson Products, Inc*. (1985) 174 Cal.App.3d 831, 869 supra, (affirming award of punitive damages where evidence showed that adequate testing would have revealed an association between tampon use and toxic shock, that the manufacturer's testing was inadequate, and that the manufacturer decided not to do any further testing even with faced with consumer complaints.)

Judge Karnow in denying summary judgment in *Johnson v. Monsanto* held that:

> The internal correspondence noted by Johnson could support a jury finding that Monsanto has long been aware of the risk that its glyphosate-based herbicides are carcinogenic, and more dangerous than glyphosate in isolation, but has continuously sought to influence the scientific

> literature to prevent its internal concerns from reaching the public sphere and to bolster its defenses in products liability actions.

SJ Order at 45. Judge Karnow noted that "intentionally marketing a defective product knowing that it might cause injury and death is highly reprehensible" *Id.* (citing *Boeken v. Philip Morris Inc.* (2005)127 Cal.App.4th 1640, 1690. Judge Bolanos in denying Monsanto's Motion for JNOV in *Johnson v. Monsanto* held that, "the jury could conclude that Monsanto acted with malice by consciously disregarding a probable safety risk of GBHs and continuing to market and sell its product without a warning." 10/22/2019 Order Denying JNOV Motion.

The evidence on punitive damages presented in this case will be substantially similar to the evidence in *Johnson* and will demonstrate that Monsanto was regularly being informed of valid science demonstrating that their GBH produces had the potential to harm, but sought to combat that evidence rather than share that information with its customers.

III. FACTUAL BACKGROUND

Alberta and Alva Pilliod have lived together and have been married for over 48 years. The Pilliods purchased a home in Livermore, California in 1982 and began regularly spraying Roundup at their home and other residences and rental properties until 2017 (35 years) accumulating approximately 1500 days of exposure to GBHs. In June 2011, Mr. Pilliod began experiencing worsening pain in his hip and back. Following a CT-scan and biopsy, he was diagnosed with diffuse large B-cell lymphoma (DLBCL), a form of NHL. In March 2015, Mrs. Pilliod began experiencing vertigo, gait instability and headaches resulting in a fall at her home in Livermore, California. An MRI of her brain on April 6, 2015, revealed changes suggestive of central nervous system (CNS) lymphoma. Id. Mrs. Pilliod began aggressive systemic chemotherapy on April 14, 2015. In July 2016, Mrs. Pilliod was diagnosed with relapsed NHL which again required aggressive chemotherapy.

After performing a differential diagnosis following a review of their history Plaintiffs' experts have concluded, to a reasonable degree of medical certainty that Mr. and Mrs. Pilliod's NHL was caused by their chronic exposure to GBHs. Had the Pilliods known of the association between GBHs and NHL, they would have never purchased or used the products.

A. Authoritative Bodies Consider GBHs a Carcinogen.

Effective July 7, 2017, Glyphosate is now listed as a chemical known to the state of California to cause cancer. Trial Ex. 1093. California relies its own robust analysis of the data and upon the scientific consensus opinions of IARC which concluded in March 2015 that glyphosate was a probable human carcinogen associated with non-Hodgkin lymphoma ("NHL"). Trial Ex. 2047. Even Defendant's expert Dr. Mucci agrees that IARC, "...is one piece of evidence to consider in the evaluation of risk factors for cancer;" and has "never seen that IARC is not a good scientific consensus panel."[3] IARC found that "Case-control studies of occupational exposure in the USA, Canada, and Sweden reported increased risks for non-Hodgkin lymphoma that persisted after adjustment for other pesticides." Trial Ex. 2047. IARC's definition of limited with respect to the epidemiology means that "[a] positive association has been observed between exposure to the agent and cancer for which a **causal interpretation is considered by the Working Group to be credible** but chance, bias or confounding could not be ruled out with reasonable confidence." Trial Ex. 1120, p. 37 (IARC Preamble). Even Defendant's expert Dr. Lorelei Mucci candidly agreed that IARC was correct.[4] The IARC findings on epidemiology were strongly bolstered by sufficient evidence of carcinogenicity in animals and strong evidence of genotoxicity in human cells both in vivo and in vitro. Trial Ex. 1019 (IARC Monoraph) pp. 77-78

B. Monsanto Has Known of an Association Between GBHs and Cancer For Decades

The EPA's Office of Pesticide Programs processed the initial petition and registration application for glyphosate in the 1970's. A majority of the initial studies relied upon by Monsanto for the registration of glyphosate were conducted at Industrial Biotest ("IBT"). Trial Ex. 1364. After approving the registration of glyphosate, the EPA learned that IBT generated fraudulent data on behalf of its clients, including Monsanto. *Id*. In 1983, EPA noted that the fraudulent data from IBT "caused serious concerns and uncertainty about the potential hazards of the hundreds of pesticides." *Id.* The EPA, however, was restricted from withdrawing the registration approvals for the pesticides that utilized IBT data for its initial approval. *Id*. Mrs. Pilliod testified at deposition that she and her husband would not have used Roundup if they knew it was approved based on fraudulent carcinogenicity data.

[3] Transcript from Daubert Proceedings in MDL , March 5-9, 2018 at 997:15-19.
[4] Daubert Hrg.995:12-17.

Unable to remove these products from the market, EPA required Monsanto to redo toxicological and carcinogenicity studies on glyphosate. Monsanto submitted a mouse oncogenicity study to the EPA in 1983. Following its review of the study, the EPA concluded that glyphosate "was oncongenic in male mice causing renal tubule adenomas…in a dose-related manner." Trial Ex. 867. Understanding the negative effect of the oncogenicity finding, Monsanto set out "to do all that is possible in order to have the Agency reverse its decision." Trial Ex. 69. Monsanto understood the importance of the EPAs oncongenic finding as it could dramatically alter the outcome of its registration applications. The EPA noted that "a prudent person would reject the Monsanto assumption that glyphosate dosing has no effect on kidney tumor production." Trial Ex. 874. Accordingly, the EPA concluded that glyphosate was a Category C oncogene: a possible human carcinogen. Trial Ex. 1370. Mrs. Pilliod that she and her husband would not have used Roundup if they were warned it was a possible carcinogen in the 1980s.

Monsanto found a pathologist to review the slides "in an effort to persuade the agency that the tumors are not related to glyphosate." Trial Ex. 72. The actual slides were received by the pathologist *after* he had agreed to assist Monsanto in their efforts to change the EPA's decision. Following the review, Monsanto argued to the EPA that there was a kidney tumor in the control group which would destroy any significance of the tumor finding in the mouse study. The EPA convened a Scientific Advisory Panel (SAP) to review the toxicological evidence relating to glyphosate. Trial Ex. 70. Monsanto felt that they had an advantage in that they could line up "a large number of experts" to support its position. *Id.*

Independent experts and the EPA pathologist, however, disagreed with Monsanto's position. Nonetheless, Monsanto's efforts to line up experts was successful. The three EPA scientists at the meeting, who all concluded there was "no tumor" in the control group, were simply outnumbered by Monsanto's fourteen paid "experts." Trial Ex. 888. The SAP nonetheless found that the occurrence of three neoplasms in male mice was "unusual" and recommended that Monsanto repeat both the rat and mouse studies. Trial Ex. 1399. The EPA provided Monsanto with specific recommendations regarding the proper design of the study to return proper results. Trial Ex. 894. Again, Monsanto refused to repeat the mouse oncongenicity study.

Monsanto not only refused to conduct studies recommended by the EPA to determine whether glyphosate and GBHs were oncogenic and/or carcinogenic; they also refused to conduct studies recommended by their own consultants. In the 1990's, several published studies concluded that glyphosate was genotoxic. Monsanto retained Dr. James Parry ("Dr. Parry") a well-respected expert in genotoxicity to review the data and offer his conclusions. Following his review, Dr. Parry provided a report to Monsanto that "glyphosate is a potential clastogenic in vitro" and that "glyphosate mixtures may be capable of inducing oxidative damage in vivo." Trial Ex. 38. In other words, "glyphosate is capable of producing genotoxicity both in vivo and in vitro. . ." Trial Ex. 37. Dr. Parry recommended that Monsanto conduct research to determine the genotoxicity of GBHs; the mechanisms giving rise to genotoxicity; and the relevance of these mechanisms to the safety of GBHs. Trial Ex. 38.

Monsanto, who was accustomed to working with industry-aligned scientists that would work to support their interests, was notably displeased with Dr. Parry's findings. In written communications, Monsanto executives inquired whether Dr. Parry "had ever worked with industry before on this sort of project?" Trial Ex. 38 at 4269. Like EPA's request to repeat the mouse oncogenicity study, Dr. Parry's recommendations were aimed at determining whether GBHs were genotoxic, oncogenic and/or carcinogenic. Again, Monsanto decided that it "simply [was not] going to do the studies Parry suggests." Trial Ex. 35. Monsanto's aim was not to actually determine whether GBHs caused cancer but rather to find an expert that could influence regulators when genotoxicity issues arise. *Id*. Monsanto failed to produce the Parry Report to the EPA as required under 40 CFR ¶ 159.158.

The Parry Report was not the only damaging information withheld from the EPA. Since the registration of glyphosate, Monsanto has worked to convince regulators that the dermal absorption rate for GBHs was extremely low. In response to questions from European regulators, Monsanto retained TNO, a laboratory in Denmark, to conduct rat skin penetration studies using a Roundup formulated product. Trial Ex. 805. The TNO study revealed that 5% to 10% of the glyphosate in the Roundup formulation was dermally absorbed. *Id.* As these results were far higher than the information submitted to the EPA, Monsanto elected to immediately stop any further work with TNO as the results could "blow

Roundup risk evaluations." *Id.* As the TNO data was not sumitted to regulators or the public, Monsanto now asserts that that the estimated dermal penetration rate is less than 1%.

C. Monsanto Refuses To Test Its Formulated Products

Dr. Parry's recommendations for genotoxicity studies and the TNO study results note an important distinction in EPA's review of Monsanto's products. Any review by the EPA is limited to the active ingredient glyphosate and does not consider the carcinogenic effect of formulated products.

Consumers, such as the Pilliods, are never exposed to glyphosate alone; they are always exposed to glyphosate and a mix of inert ingredients. Glyphosate is always used in conjunction with a "surfactant," a chemical which, as further demonstrated by the TNO study, allows glyphosate to adhere to the skin and facilitate the absorption of glyphosate through cell membranes. For this reason, published studies have consistently demonstrated that the risks posed by formulated GBHs are considerably greater than with pure glyphosate alone. Indeed, in 2002, Monsanto executives noted that published studies established that pure glyphosate had no effect on endocrine disruption but the formulated product did. Trial Ex. 43. For this reason, Monsanto was not surprised when their own expert consultants concluded that "[Monsanto is] in pretty good shape with glyphosate but vulnerable with surfactants." *Id*.

For years, the primary surfactant used in Roundup formulations was polyoxyethkene alkylamine (POEA). POEA contains its own toxic impurities and contaminants, including 1, 4-dioxane which has itself been classified as a possible human carcinogen. Trial Ex. 50. Over the last decade European regulators forced Monsanto to phase out the use of POEA surfactants in GBHs, but POEA surfactants are still used in several Roundup products in the United States. Monsanto noted that there were safer POEA-free surfactants available causing one employee to inquire: "Anyway, there are non-hazardous formulations so why sell a hazardous one?" Trial Ex. 471.

The lack of evidence regarding glyphosate's surfactants was not an accident. Since the registration of glyphosate, Monsanto has worked diligently to avoid having to conduct testing on formulated Roundup. In 1999, European regulators informed Monsanto that genotoxicity studies would be required on formulated Roundup to assess risk issues arising from impurities and inert ingredients. Trial Ex. 60. Monsanto affirmed that it would "not support any studies on glyphosate formulations or

other surfactants" and would only do so if "forced to do it." *Id.* In 2015, Monsanto recognized that it had not given any consideration to testing exposures of the formulated products, instead opting to focus only on the carcinogenic potential of glyphosate alone. Trial Ex. 565. Monsanto established this position despite recognition that the surfactant in the formulated products played a role in the tumor promotion skin study. Id.

The significance of Monsanto's failure to test the formulated glyphosate products was summed up by Donna Farmer, Monsanto's Manager of Toxicology Programs in September 21, 2009 when she confirmed that Monsanto **"cannot say that Roundup does not cause cancer. . . we have not done carcinogenicity studies with "Roundup."** Trial Ex. 2.

D. Monsanto Floods The Scientific Literature With Ghostwritten Articles To Bolster The Safety Profile of GBHs

Monsanto's knowledge of an association between GBHs and NHL was not limited to toxicological and genotoxicity studies. As more and more studies began to establish an association between GBHs and NHL, Monsanto developed a strategy to level the playing field by ghostwriting[5] scientific literature that would help establish the safety of GBHs. Rather than submit the Parry Report to the EPA and conduct the recommended studies, Monsanto elected instead to ghostwrite an article concluding that "Roundup herbicide does not pose a health risk to humans." Trial Ex. 1542 (Williams, et al., Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans. Regulatory Toxicology and Pharmacology, 31, 117-165 (2000)). Although no Monsanto employee is listed as an author, William Heydens, a Monsanto employee, admits that he ghostwrote the manuscript and provided final edits to the paper. Trial Exs. 6, 435. His extensive work in preparing the report caused Heydens to note that he "sprouted several new gray hairs during the writing

[5] The World Association of Medical Editors has put forth the following statement regarding ghostwriting:

> The integrity of the published record of scientific research depends not only on the validity of the science but also on honesty in authorship ...The scientific record is distorted if the primary purpose of an article is to persuade readers in favor of a special interest, rather than to inform and educate, and this purpose is concealed. Ghost authorship exists when someone has made substantial contributions to writing a manuscript and this role is not mentioned in the manuscript itself. WAME considers ghost authorship dishonest and unacceptable.

http://www.wame.org/policy-statements.

of this thing." Trial Ex. 437. EPA has consistently relied on the ghostwritten Williams paper when considering the safety of GBHs.\

Defendant acknowledges that Williams (2000) was important for its business. In a 2010 PowerPoint describing Williams (2000) as an "invaluable asset", Monsanto notes that they are facing "regulatory reviews" with an increased "focus on claims in the peer-reviewed literature." Trial Ex. 479 at 17. Monsanto notes that "Williams has served us well in toxicology over the last decade," but they need a "stronger arsenal of robust papers scientific papers." Id. Because of the need for a stronger arsenal, Monsanto proceeded to ghostwrite parts of at least three more articles relating to genotoxicity and carcinogenicity of GBHs. Trial Exs. 477, 488, 551.

In 2013, Monsanto ghostwrote another article titled "Review of genotoxicity studies of glyphosate and glyphosate-based formulations." The noted "authors" of the study are Drs. Kier and Kirkland, however, internal documents reveal that David Saltmiras of Monsanto was the original author of the paper. Trial Ex. 501. In requesting funding for the manuscript, Saltmiras states that it "will be a valuable resource in future product defense against claims that glyphosate is mutagenic or genotoxic." Trial Ex. 483. However, after the initial draft Monsanto felt that "the manuscript turned into such a large mess of studies reporting genetoxic effects, that the story as written stretched the limits of credibility among less sophisticated audiences." Trial Ex. 488. Therefore, it was decided that a way to "help enhance credibility is to have an additional author on the papers who is a renowned specialist in the area of genotoxicity. Monsanto identified Dr. David Kirkland as the best candidate." *Id.* Again, the EPA has consistently relied on this ghostwritten article in deciding the safety of GBHs.

Monsanto has even ghostwritten articles for the specific purpose of supporting their position in litigation involving NHL and to support its position during the EPA's re-registration decision for glyphosate. Immediately after IARC deemed glyphosate a carcinogen, Monsanto devised a response plan due to the "[s]evere stigma attached to Group 2A Classification." Trial Ex. 717. Part of their plan was to convene an expert panel to "[p]ublish comprehensive evaluation of carcinogenic potential by credible scientists." *Id*. Monsanto noted that the "Genetox / MOA" section would be important for "future litigation support." With respect to the expert panel it was noted that from a legal perspective such a panel

would be "[a]ppealing; best if use big names; better if sponsored by some group." *Id.* Monsanto proceeded with arranging the expert panel and worked with Intertek, an industry consultancy firm, to create a false impression that the expert panel was independent.

On September 28, 2016, the "independent" expert panel of 12 scientists published its pre-ordained conclusions in the journal Critical Reviews in Toxicology in a paper titled "A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment."[6] The journal published a special issue dedicated solely to the work of this expert panel which included an introduction/summary article authored by all of the experts, and four papers authored by various subgroups of the panel.[7] On October 11, 2016 these articles were submitted to the EPA to support the re-registration of Roundup and the continued exposure of the American public to Roundup®.

Included as authors are Gary M. Williams, Helmut A. Greim, Larry D. Kier, David J. Kirkland, all of whom have previously participated in ghostwritten Monsanto manuscripts. Prior to the publication of the article the editor of Critical Reviews in toxicology sent an email to Intertek which was forwarded to Monsanto stating the:

> Declaration of Interest sections in all the papers need further attention. I want them to be as clear and transparent as possible. At the end of the day I want the most aggressive critics of Monsanto, your organization and each of the authors to read them and say - Damm, they covered all the points we intended to raise... The remainder of the DOI should make clear how individuals were engaged, ie by Intertek. If you can say without consultation with Monsanto that would be great. If there was any review of the reports by Monsanto or their legal representatives that needs to be disclosed. Trial Ex. 693

William Heydens from Monsanto specifically approved the declaration of interest which was included in the final publication. In the published article submitted to the EPA, the Conflict of Interest statement declares that, "[t]he Expert Panelists. .. were not directly contacted by the Monsanto Company" and that "neither any Monsanto company employees nor any attorneys reviewed any of the Expert Panel's manuscripts prior to submission to the journal." These statements are false. Monsanto directly recruited, contacted and obtained legal approval on the selection of the experts despite the claim that the experts were "not directly contacted" by Monsanto. In a June 2015 email from William Heydens of Monsanto

[6] The ghostwritten Kier and Kirkland study was also published in Clinical Reviews of Toxicology.
[7] http://www.tandfonline.com/toc/itxc20/46/sup1?nav=tocList

to Intertek, he states, "[a]ttached is a slide showing our current thinking on panelists for the Glyphosate Expert: Panel we are working on forming. We have been in contact (asked if they are willing to participate) with everyone on the list except Sam Cohen." Trial Ex. 560.

Additionally, and most egregiously, not only did Monsanto review the manuscripts before they were submitted, they actually wrote parts of the manuscripts; and commented upon and revised parts that they didn't write. Monsanto started drafting the manuscript in August of 2015 before the "independent" experts even had a chance to conclude their meeting. Trial Ex. 568. The independent experts did make edits and contributions to the summary manuscript, however, ultimately it was Heydens who had authority over the content stating "I have gone through the entire document and indicated what I think should stay, what can go, and in a couple spots I did a little editing." Trial Ex. 596. These critical ghostwritten articles are still relied upon by the EPA and other regulatory agencies around the world.

E. Monsanto's Corporate Policy is to Place Profits over Safety

Monsanto had a "Product Safety Center" headed by Dr. Farmer. However, the stated priorities of the safety center were to "Secure the Base," "Defend and maintain the global glyphosate businesses" and "Create Future Growth: Pipeline, Regulatory Approval, Commercial Launch, and Market Expansion." Trial Ex. 693, at 2. These goals are incompatible with human safety and preclude an honest and fair assessment of the findings of independent scientists regarding the genotoxicity and carcinogenicity of GBHs. Rather than actually study the safety of its product at this center, Dr. Farmer helped to spearhead Monsanto's "whack-a-mole" campaign on independent scientists.

For example Dr. Farmer sent her employees to dissuade the authors of the McDuffie (2001) from publishing data about GBHs showing an increased risk of NHL. Trial Exs. 444, 448. Dr. Farmer congratulated John Acquavella and Dan Goldstein for being able to get the glyphosate results out of the abstract. Trial Ex. 23. ("the fact that glyphosate is no longer mentioned in the abstract is a huge step forward – it removes it from being picked up by abstract searches!").

In 2003, the National Cancer Instute Study (NCI) from DeRoos is published showing a statistically significant doubling of the risk of NHL for Glyphosate. Monsanto states that the findings "may add more fuel to the fire for Hardell, et al." Trial Ex. 21. Hardell also found an increased risk of

NHL with glyphosate. Monsanto states "It looks like NHL and other lymphopoetic cancers continue to be the main epidemiology issues both for glyphosate and alachlor." Id. In 2008, the Eriksson study was published showing a statistically significant doubling of the risk of NHL for glyphosate users. Donna Farmer states "[w]e have been aware of this paper for awhile and knew it would only be a matter of time before the activists pick it up" and wanted to know "how do we combat this?" Trial Ex. 18. There was no discussion about warning its customers of these findings.

F. EPA's Office of Pesticide Program's ("OPP") Flawed Review of Glyphosate

The OPP has only reviewed and considered the carcinogenicity of the active ingredient glyphosate and has never reviewed formulated products. EPA relies on the manufacturer to submit data and has never conducted its own testing on glyphosate or any of Monsanto's formulations using glyphosate.[8] Since 1991, the OPP has designated glyphosate as a Group E carcinogen but has cautioned that the designation "should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances." On September 12, 2016, the OPP published a preliminary issue paper on the carcinogenic potential of glyphosate.[9] The EPA noted that additional research would need to be performed to determine whether formulation components, including surfactants influenced the toxicity of the product. With respect to non-Hodgkin's lymphoma, the Report found that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data."

The preliminary findings published in the September 2016 Issue Paper were not uniformly held within the EPA. Prior to publication, an employee within EPA's Office of Research and Development noted that its scientists would be split on whether glyphosate is carcinogenic with some classifying the herbicide as "likely to be carcinogenic." Trial Ex. 398. In December of 2016 an EPA Scientific Advisory Panel ("SAP") was convened to evaluate the OPP's draft assessment of glyphosate. Trial Ex. 1083. The SAP "serves as the primary scientific peer review mechanism of the Environmental Protection Agency (EPA), Office of Pesticide Programs (OPP)." *Id.* at 2. The Panel unanimously concluded that "the EPA

[8] See Plaintiff's Statement of Undisputed Facts Filed in Support of Plaintiff's Motion for Summary Adjudication.

[9] A revised issue paper was released in December 2017 but did not change the citations made in this motion.

evaluation does not appear to follow the EPA (2005) Cancer Guidelines." *Id.* at 18. SAP's critique is consistent with senior EPA officials' concerns about the OPP's assessment raised in a May 2016 email which stated "we're trying to understand how the glyphosate assessment was even in que for posting as we decided last fall that the assessment was not consistent with the Agency's guidelines and we would convene a new group to reevaluate." Trial Ex. 404.

Three members of the SAP panel recently published a meta-analysis of the glyphosate epidemiology and a review of the toxicological data. Trial Ex. 2332. The journal is also run by an EPA toxicologist.[10] These independent scientists conducted an exhaustive independent review of the evidence, including the reviews by EFSA and the EPA, as well as the updated AHS study. *Id*. They concluded that "Overall, in accordance with evidence from experimental animal and mechanistic studies, our current meta-analysis of human epidemiological studies **suggests a compelling link between exposures to GBHs and increased risk for NHL**." *Id.* These opinions are in complete accord with the opinions previously expressed by IARC, Plaintiffs' experts, and leading independent scientists.

The fact that the OPP disregarded its own guidelines in evaluating glyphosate is not surprising in light of the undue influence Monsanto has on OPP employees. In 2015, Monsanto had several discussions with Jess Rowland, then Deputy Director of the OPP Health Effects Division, regarding a review of glyphosate by the Agency for Toxic Substances and Disease Registry (ATSDR), the U.S. agency responsible for assessing toxicity of chemicals. Monsanto was concerned that ATSDR would reach a conclusion on glyphosate similar to IARC. During a discussion with Monsanto, Rowland asked for a contact name at ATSDR and remarked "If I can kill this [the ATSDR review] I should get a medal." Trial Ex. 547.

Furthermore, various communications between Jack Housenger, Director of the Office of Pesticide Programs worked with Monsanto to put ATSDR's glyphosate review "on hold." Trial Ex. 557. On October 13, 2016, a member of Monsanto's lobbying organization, CropLife America, contacted Housenger to discuss the removal of epidemiologist, Peter Infante, from the glyphosate SAP while also inviting Housenger to a retreat with Monsanto and other industry executives at a West Virginia casino

[10] https://www.journals.elsevier.com/mutation-research-reviews-in-mutation-research/editorial-board/david-m-demarini

and resort. Trial Ex. 441. The next day, the OPP announced that it was postponing the SAP hearing 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. Housenger accepted the invite and attended the retreat with Monsanto executives who noted "we had some quality time with EPA OPP Director Jack Housenger to dig into key issues and operational matters at that vital department of EPA." Trial Ex. 610. These meetings and contacts violate EPA regulations which require all meetings with Monsanto employees and lobbyists during the re-registration period of glyphosate to be placed on the public docket. 40 CFR 155.52. These meetings, unfortunately, would have remained secret without discovery in this lawsuit. The EPA's Office of Inspector General is currently investigating collusion between EPA employees and Monsanto in the evaluation of glyphosate. Trial Ex. 1087.

Monsanto's reliance on the findings of federal regulatory agencies have been questioned by scientists around the globe. In March 2016, after the European Food Safety Authority in its Renewal Assessment Report ("RAR") issued its assessment that glyphosate was not likely to pose a carcinogenic hazard to humans, a group of ninety-four eminent scientists published a peer-reviewed article explaining that there were "serious flaws in the scientific evaluation in the RAR, and that the IARC conclusion was correct. Trial Ex. 2136 (Portier, et al., *Differences in the carcinoogenic evaluation of glyphosate between the International Research on Cancer (IARC) and the European Food Safety Authority*, Vol. 70, No. 8J Epidemiol. Community Health 741 (2016)). EFSA failed to follow its guidelines because it simply aligned itself with the OPP. Like the OPP, EFSA *a priori* decided to "disagree with IARC" before it even read the IARC monograph. Trial Ex. 2079. In a series of text messages it was revealed that Monsanto had an off-the-record phone meeting with someone at the EPA ("Spoke to epa re gly") wherein the EPA confirmed that "they aligned efsa on phone call." Trial Ex. 500 at 3250.

G. Evidence Reveals Monsanto's Efforts to Undermine IARC's Classification of IARC

Monsanto had "long been concerned" that IARC would review glyphosate. Trial Ex. 727. Monsanto feared IARC's evaluation because it knew that it was a distinct possibility that finding that glyphosate would be labeled as a probable human carcinogen was possible. Trial Ex. 339. Monsanto remarked that there was vulnerability in the areas of epidemiology, exposure, genotoxicity and mode of

action. *Id*. Therefore, even before the IARC Monograph was published, Monsanto developed a strategy to "Orchestrate Outcry with IARC Decision" through "robust media/social media outreach." Trial Ex. 47. By attacking IARC, Monsanto was trying to protect glyphosate's FTO (freedom to operate). Id. at page 5. The "outcry" was intended to reach both "IARC panelists" and "Regulators." *Id.* As part of the IARC response, Dr. Goldstein ghostwrote editorials for "independent" doctors to dispute the IARC findings. Trial Ex. 1278 (Goldstein Dep. at136:13-137:2.)

Monsanto made true on its campaign dedicated to attacking IARC and its classification of glyphosate. As described by IARC:

> Since the evaluation of glyphosate by the IARC Monographs Program in March 2015, the Agency has been subject to unprecedented, coordinated efforts to undermine the evaluation, the program and the organization. These efforts have deliberately and repeatedly misrepresented the Agency's work. The attacks have largely originated from the agro-chemical industry and associated media outlets. They have taken place in the context of major financial interests relating to: a) the relicensing of glyphosate by the European Commission; b) hundreds of litigation cases in the USA brought by cancer patients against Monsanto, claiming that their malignancies were caused by glyphosate use; c) and the decision by the Californian Environmental Protection Agency to label glyphosate as a carcinogen."

Trial Ex. 2263.

In 2016, Monsanto retained a consulting company to lobby Congress to push the EPA to resolve their decision on glyphosate "sooner rather than later" while emphasizing "the safety and importance of the product." Trial Ex. 692. Monsanto's lobbying efforts also sought to strike funding for IARC. Id. As a result of Monsanto's lobbying efforts, the Committee on Appropriations report "urges the [EPA] to complete its reregistration of glyphosate expeditiously."[11] The evidence reveals that EPA decisions regarding the reregistration of glyphosate are being influenced by political pressure and the influence of industry, the decisions are not being guided by science.

IV. Scientific Evidence Demonstrates that Roundup Was a Substantial Cause of the Pilliods' NHL

Plaintiff's experts have reviewed the underlying studies considered by IARC; additional data available through discovery and through post-IARC literature searches; the IARC monograph; and regulatory reviews. Plaintiff's experts possess impressive credentials, apply reliable and consistent

[11] https://www.congress.gov/congressional-report/114th-congress/senate-report/281/1

methodologies, and thoroughly and objectively consider the available data to conclude that glyphosate and glyphosate-based herbicides ("GBH") more likely than not causes NHL and caused NHL in the Pilliods. The data reviewed and explained by Plaintiffs's experts is consistent and compelling. 12 long term animal studies show that glyphosate causes several tumors including ***malignant lymphomas*** in three different mice studies; Scores of peer-reviewed studies across multiple species show that glyphosate and GBHs demonstrate two key characteristics of carcinogens, genotoxicity and oxidative stress. Two studies in humans directly exposed to GBHs through aerial spraying that show ***genotoxicity in lymphocytes and human blood cells.*** Finally, the peer-reviewed epidemiology studies s***how increased risks of NHL in humans.***

The qualifications of Plaintiff's experts are impeccable and the following experts may be called upon at trial in support of Plaintiff:

Dr. Beate Ritz M.D., Ph.D. is the Chair of the Epidemiology Department at UCLA, which is one of only a few positions specifically assigned to the Center of Occupational and Environmental Health (COEH) mandated by the State of California to conduct research, teaching, and service to communities in California on occupational and environmental health. Dr. Ritz will testify that GBHs cause NHL.

Christopher J. Portier. received his PhD in Biostatistics. For over 32 years, Dr. Portier held prominent leadership positions with the federal government that combined the disciplines of toxicology, statistics, and epidemiology, including: Associate Director of the National Institute of Environmental Health Sciences (NIEHS) National Toxicology Program and thus the nation's chief toxicologist. Dr. Portier will testify that GBHs cause NHL.

Chadi Nabhan, M.D. is a board-certified clinical medical oncologist and past Assistant Professor of Medicine at the University of Chicago. Currently, Dr. Nabhan serves as Medical Director of Cardinal Health. His clinical practice and academic research for the past 17 years has focused on lymphomas, treating approximately 30 lymphoma patients per week. Dr. Nabhan regularly relies on both epidemiology and toxicology studies in his clinical practice and is well versed in the etiology, background, and treatment of NHL. Dr. Nabhan will testify that GBHs were a substantial cause of the Pilliods' NHL.

Dennis D. Weisenburger M.D. is Chair of the Pathology Department of the City of Hope Medical Center. He specializes in the studies of the hematopoietic and immune systems, with a special interest in NHL that has spanned nearly 40 years. Dr. Weisenburger will testify that GBHs cause NHL and were a substantial cause of the Pilliods' NHL.

Dr. Charles W. Jameson Ph.D. completed a Ph.D. in Organic Chemistry in 1975. He has worked for National Institutes of Health's National Cancer Institute (NCI) as a senior chemist for the NCI's Rodent Bioassay Program. Dr. Jameson worked on the NTP's Report on Carcinogens (RoC) and is the Senior Author for 69 NTP RoC Background Documents. Dr. Jameson was the IARC subgroup chair for the group evaluating the animals carcinogenicity of glyphosate.

William Sawyer, Ph.D. "is a highly qualified toxicologist - currently chief toxicologist of Toxicology Consultants and Assessment in New York. He is Board Certified in forensic medicine, toxicology and pharmacology and is well published."[12] He has more than 28 years of experience in public health and forensic toxicology including five years of governmental service. Dr. Sawyer will testify about routes of exposure of GBHs and will testify that the Pilliods were exposed to a sufficient amount ofRoundupto cause them to develop NHL.

Charles Benbrook, Ph.D., "a Ph.D. in agricultural economics. In the early 1980s, he was Staff Director for the House subcommittee with jurisdiction over FIFRA, and worked for 6 years with the National Academy of Sciences on, among other things, pesticide use." Since 1990 he has been hired by federal and state government agencies, among others, to complete numerous projects involving the health effects and regulation of pesticides. Dr. Benbrook will provide expertise on pesticide regulation and its application to GBHs manufactured by Monsanto.

A. Epidemiological Studies Show An Increased Risk of NHL

Numerous peer-reviewed epidemiological studies showing glyphosate increases the risk of NHL. In Hardell (1999), a case-controlled study out of Sweden demonstrated an Odds Ratio of 2.3 (0.4–13) in a univariate analysis and an Odds Ratio of 5.8 (0.6–54) in a multivariate analysis. Trial Ex. 1538. The odds ratio ("OR") is a measure of the likelihood that exposure to a chemical was associated with the

[12] Mary B. FLEMING, Plaintiff, v. NICHOLLS-WILCOX, INC., Defendant., 2005 WL 5419258

disease. An OR of 2.3 means that a glyphosate users risk of developing NHL is 2.3 greater than a non-glyphosate user.

McDuffie (2001) was a Canadian population-based study authored by seven independent scientists and published in a peer-reviewed journal Cancer Epidemiology, Biormarkers & Prevention. Participants who used GBHs greater than 2 days per year, had a statistically significant (CI 1.20-3.73) doubling of NHL (OR=2.12). Trial Ex. 1568.

Hardell (2002) involved a pooled analysis of two Swedish case-control studies. The peer-reviewed study, published in the journal Lymphoma & Leukemia, revealed a statistically significant (CI 1.08-8.52) OR of 3.04, controlling for age, study, county and vital status in the univariate analysis. Trial Ex. 1575.

DeRoos (2003) was a study by the National Cancer Institute which pooled data from three case-control studies on NHL conducted in the 1980s. The study was published in the peer-reviewed journal Occupational and Environmental Medicine. The study revealed a statistically significant elevated risk between glyphosate use and NHL (OR 2.1) using the logistical regression approach. Trial Ex. 1588.

Erickson (2008) is a peer-reviewed, population-based case-control study published in the well-respected International Journal of Cancer. Overall, the study reported a statistically significant increase in NHL risk with glyphosate exposure (OR 2.02). The study results demonstrate a dose-response effect. For those with greater than 10 days use, the risk was higher (OR=2.36, CI 1.04-5.37). Trial Ex. 1703.

The North American Pooled Project (NAPP) (2015). The NAPP is an ongoing analysis that has pooled data previously analyzed in De Roos (2003) and McDuffie (2001) to examine glyphosate and NHL. In a peer-reviewed abstract NAPP reported an elevated risk of all NHL with any glyphosate use (OR=1.43, 95% CI:1.11,1.83) and a dose-response effect was seen with greater use (>2 days/year, OR=2.42, 1.48-3.96). Trial Ex. 2065.

The numerous individual, peer-reviewed studies, showing a statistically significant elevated risk, are confirmed in peer-reviewed meta-analyses. The first meta-analysis included 2,928 cases from 6 studies and reported a statistically significant (CI 1.1-2.0) increase (OR 1.5) in NHL risk with any glyphosate exposure. Trial Ex. 2006 (Shinasi&Leon (2014)). IARC conducted the second meta-analysis

and examined the same six studies but adjusted the data from Hardell (2002) and Eriksson (2008) and showed a statistically significant (CI 1.03-1.65) increased risk of GBH exposure (OR 1.3). Trial Ex. 1019.

The third meta-analysis was sponsored by Monsanto and conducted by Exponent, Inc. Trial Ex. 2106. The models yielded the following results: OR 1.27 (CI 1.01-1.59), OR 1.3 (CI 1.03-1.64), OR 1.32 (1.00-1.73), and OR 1.37 (CI 1.04-1.82). For both the IARC and Monsanto meta-analyses, four of the six studies adjusted for other pesticides. Id. at 21.

Monsanto ignores these multiple peer-review studies demonstrating that glyphosate causes NHL and will seek emphasize the Agricultural Health Study ("AHS"). However, The study was not sufficiently well-designed to detect the increased risk in NHL overall. Prior to this litigation, former Monsanto employee John Acquavella stated, that "[t]he exposure assessment in the AHS will be inaccurate" and "[i]naccurate exposure classification can produce spurious results" Trial Ex. 429 at 3-5. Similarly, Dr. Donna Farmer, Monsanto's head toxicologist, prepared a presentation in 1999 characterizing the AHS as a "flawed study" and "junk science." Trial Ex. 41. Scientists from the Harvard School of Public Health also reviewed the AHS's design in 1999. The Harvard scientists raised concerns that the exposure misclassification in the AHS would "reduce the power of the study to detect any genuine cause-effect relationships and…reduce[s] the validity of findings." Trial Ex. 362 at 58. The authors of the AHS study in 2011 concluded that flaws in the study "may diminish risks estimates to such an extent that no association is obvious, which indicates false negative findings might be common." Trial Ex. 1833.

For these reasons, neither Plaintiff's experts nor IARC considered the AHS strong enough to outweigh the multiple positive case-control studies. In responding to Monsanto's "unprecedented, coordinated efforts to undermine" IARC, which included accusations "that results from the AHS were withheld from the IARC Monograph evaluation and that recent results would have led to a different evaluation," IARC responded that the AHS:

> ...null finding did not outweigh the positive associations found in other epidemiological studies. The most recent analysis from the AHS only became available in 2017 - 30 months after the Monograph evaluation - and was consistent with the prior results included in the Monograph, except that new data on increased leukemia risk with glyphosate exposure were not available to

> the Working Group in 2015... The lengthy court testimony given by Dr. Blair does not support any change in the classification of glyphosate consequent to the latest AHS publication. Trial Ex. 2263.

In fact, when including the high exposure groups from the AHS in the most recent meta-analysis, Zhang, et al. found a statistically significant relative risk of 1.41. Trial Ex. 2332. Along with this data and toxicological data, the authors concluded that there was a "compelling link" between NHL and Roundup. *Id.*

B. The Toxicology Data Demonstrates that GBHs are Carcinogenic

1. Glyphosate is Carcinogenic in Animals.

Toxicology supports Plaintiffs' experts' opinions that glyphosate and GBHs cause cancer in humans. "[E]pidemiological findings of an adverse effect in humans represent a failure of toxicology as a preventive science or of regulatory authorities or other responsible parties in controlling exposure to a hazardous chemical or physical agent. ... The two disciplines complement each other, particularly when the approaches are iterative." Reference Manual at 660. The animal studies show an increased risk of multiple tumors in multiple species, including replicated findings of malignant lymphomas in mice**.** These findings strongly support causation in conjunction with the findings of NHL in human epidemiological studies and the findings of genotoxicity in human lymphocytes. Rodent studies are the only available method to *test* the carcinogenicity of a pesticide in a clinically controlled manner and adds strength to the conclusion that the increased risk of NHL in epidemiological studies is not the result of confounding. *See* Reference Manual at 640.

It is important to note that the animal carcinogenicity studies involved only pure glyphosate and did not include the surfactant which increase the toxicity of glyphosate and facilitate "penetration of glyphosate through animal cell membranes." Trial Ex. 1237 at 77-81. Therefore these studies underestimate the carcinogenic effect of GBHs in rodents. Trial Ex. 2332. Still, significant increases in malignant lymphoma were seen in three mouse studies. *Id.* Peer-reviewed literature consistently accepts that lymphomas found in mice exhibit similar pathological features to those in humans, such that they

"exhibit enough parallels to suggest they represent the same disease but in a different species."[13] The publications support the coherence criteria of Bradford-Hill because of "the increased risk of malignant lymphomas in CD-1 mice, the marginal increase in these tumors in Swiss mice and the strong similarity between malignant lymphomas in mice and NHL in humans." Trial Ex. 2215 (Portier Rep. at 7, 74, 97) Here, the cancers (including lymphoma) seen in the animal bioassays enhances causation.

2. Mechanistic Studies Show that GBHs are genotoxic.

Mechanistic data provide evidence of how a chemical causes cellular changes that progress to cancer. The mechanistic evidence here is especially strong because it includes evidence of genotoxicity in human lymphocytes and blood samples following real-world GBH exposure. Moreover, mechanistic data are probative and relevant in considering biological plausibility and coherence as important parts of the Bradford-Hill criteria, particularly where the epidemiology corroborates the carcinogenic effects of GBHs in exposed humans. "[W]ith improved understanding of the mechanism of action of chemical carcinogens, there has been increased use of mechanistic data." Reference Manual at 656.

There are dozens of studies demonstrating genotoxicity of GBHs in animal and human cells. IARC monograph. The results of peer reviewed *in vivo* studies (Paz-y-Mino 2007 and Bolognesi 2009) demonstrate genotoxicity in blood and lymphocyte cells ***in living humans*** following exposure. Trial Exs. 1690, 1725. In light of the human mechanistic data, opinions extrapolating the results of other genotoxicity experiments to humans are substantiated. Bolognesi 2009 and Paz-y-Mino 2007[14] examined the genotoxic effect of aerially sprayed GBHs on the blood and lymphocyte cells of humans living in the sprayed areas. The Pilliods were subjected to a much higher and more frequent dose of GBHs than the study participants. Dr. Matthew Ross, from the IARC working group, confirmed the importance of the

[13] Trial Ex. 2025, D. Begley, et al., *Finding mouse models of Human Lymphomas and Leukemia's using the Jackson Laboratory Mouse Tumor Biology Database*, 99 EXPERIMENTAL AND TOXICOLOGIC PATHOLOGY 533-536, 534 (2015); Ex. 101. J. Ward, *Lymphomas and Leukemias in Mice*, 57 EXPERIMENTAL AND TOXICOLOGIC PATHOLOGY 377-381 (2006).

[14] A follow-up study cited by Defendants, conducted two years after the aerial spraying of GBHs was banned, showed the health of the population improved and that the GBH-induced DNA damage healed. The authors re-affirmed their 2007 findings stating that "the results suggest that the individuals exposed to the broad spectrum herbicide suffered a genotoxic effect." Trial Ex. 1826, Paz-y-Mino et al., *Baseline determination in social, health, and genetic areas in communities affected by glyphosate aerial spraying on the northeastern Ecuadorian border*, 26 REV ENVTL. HEALTH 45 (2011).

Bolognesi study, stating "looking at exposed populations to an agent and seeing evidence of DNA damage is strong evidence that it is occurring, that it can occur."[15]

Responding to Monsanto's question "What strong evidence was presented in the IARC monograph working group 112 that carcinogenesis observed in experimental animals is mediated by a mechanism that also operates in humans?" Dr. Ross explained:

> The mechanistic evidence that was deemed strong was the genotoxicity and the oxidative stress classification. . . .. The important thing, in terms of operable in humans, is the fact that exposed humans showed evidence of genotoxicity, and cultured cells of human origin showed evidence of genotoxicity. Those were -- those then showed that this mechanism may operate in humans.[16]

Importantly, IARC's finding of strong evidence of oxidative stress and genotoxicity mirror the findings in the Parry report from 15 years earlier. The same Parry report that was buried by Monsanto.

C. The Totality of the Evidence Demonstrates that GBHs were a Substantial Cause of the Pilliods' NHL

In considering all of the above data, Plaintiffs' experts on causation appropriately applied the Bradford-Hill Criteria to come to their opinion that GBHs can cause NHL. 4/17/2018 Order re: Sargon Motions, p. 20. Dr. Nabhan, an oncologist, Dr. Weisenburger, a pathologist, and Dr. Sawyer, a toxicologist, have further applied their general causation opinions (including the multiple studies showing a doubling of the risk of NHL) in examining the Pilliods' case and have concluded that Roundup was a substantial cause of the Pilliods' NHL.

Dr. Nabhan, Dr. Weisenburger and Dr. Sawyer all carefully examined the Pilliods' exposure to Roundup and concluded that both Mr. and Mrs. Pilliod were highly exposed. The Pilliod have been married and shared the same residences for over 40 years in Alameda County. Trial Ex. 1242 (Nabhan Rep. at 31). Studies have shown that married couples are at an increased risk of NHL likely due to shared environmental exposures such as pesticides. *Id.* Mr. and Mrs. Pilliod were extensive users of Roundup®. They sprayed Roundup together at four different properties over the course of thirty years and 1500 total days. *Id.* at 8-10. During this time they did not wear protective gear such as gloves or impermeable clothing based on representations by Monsanto that such gear was unnecessary. *Id.* at 10, 26.

[15] Trial Ex. 1259, Deposition Transcript of Dr. Matthew Ross, 202:15-18.
[16] *Id.* ., 104:7-105:10.

Based on this extensive exposure history, Dr. Nabhan ruled in Roundup as a potential cause of Mrs. Pilliod's NHL because she "had extensive exposure to RoundUp over 3 decades using it in her residences. Her exposure is above the threshold that had been described in the epidemiologic studies and scientific literature." *Id.* at p. 22. He likewise ruled in Roundup as a potential cause for Mr. Pilliod, because he used it even more than Mrs. Pilliod. *Id.* at p. 26. Weisenburger he ruled in Roundup® because "He used it for many years, I think 28 years, prior to developing his non-Hodgkin's lymphoma. He used it frequently. He used it in large quantities." Weisenburger Dep at 38:9-38:11. Weisenburger stated that both Mr. and Mrs. Pilliod are within the "high-risk category of exposure" to Roundup®. *Id.* at 229:12-20.

Dr. Sawyer will testify that "Mrs. Pilliod wore shorts and flip flops with a tank top or t-shirt when spraying. Mr. Pilliod wore jeans, tennis shoes, long-sleeved cotton shirt or T-shirt and a straw hat" and that "[t]hese practices facilitated enhanced absorption." Trial Ex. 1243. (Sawyer Rep. at 117). Dr. Sawyer will also testify that "acute exposure doses were sometimes left on the skin for prolonged periods of time as they did not shower immediately after application, which contributed to dosage." *Id.* Furthermore, the spraying device designed by Monsanto increased exposure because "the spray is coming out not far from the hand and it has that propensity to drift onto the body." Sawyer Dep. at 122. Dr. Sawyer conducted comparative dose analyses between the Pilliods and professional applicators and stated that there exposure was consistent with professionals noting "[y]ou could actually have a professional applicator working seven hours --that is, if that person is wearing PPE -- a lower exposure than a home gardener working for one hour." Id. at 242.

Dr. Weisenburger and Dr. Nabhan conducted exhaustive reviews of the Pilliods medical and social history, interviewed the Pilliods and conducted a differential etiology in determining the cause of the Pilliods NHL. Both concluded that Roundup® was the most substantial factor in causing the Pilliods' NHL. Dr. Nabhan explained that "[i]n order to reach a sound and clear conclusion on the causes of Mrs. Pilliod's NHL, I considered all of the potential causative and risk factors for NHL and then determined whether such factors were relevant to Mrs. Pilliod's case." Trial Ex. 1242 (Nabhan Rep. at 12-13). Weisenburger likewise explained that "I did a – an exhaustive evaluation of the ... things that cause non-

Hodgkin's lymphoma and the kinds of diseases and exposures that Mr. Pilliod [and Mrs. Pilliod] had. In other words, I did what's called a differential diagnosis, or better called a differential etiology." Hoke Decl. Ex. 4 (Weisenburger Dep. at 37:14-38:1). The most substantial contributing cause of the Pilliods' NHL is not unknown (idiopathic); it was Roundup. Because the Pilliods sprayed Roundup® together for 1500 days, Dr. Nabhan testified "we're dealing here with a husband and wife who lived together, who shared all of their residences, and they both have the same exact disease. So how could anybody say this is idiopathic is beyond me." 3/6/19 Hearing Transcript at 134:15-25

V. CONCLUSION

The remaining issues in this case are mainly factual issues to be determined by the jury. The facts that will be admitted at trial will strongly support a jury finding for plaintiffs

Respectfully Submitted,

Dated: March 14, 2019

The Miller Firm, LLC

By: _/s/ Michael J. Miller__
Michael J. Miller, Esq.
Attorneys for Alva and Alberta Pilliod

PROOF OF SERVICE

I, Jeffrey A. Travers, declare as follows:

I am a citizen of the United States and am employed in Orange County, Virginia. I am over the age of eighteen years and not a party to the within action. My business address is The Miller Firm, LLC, 108 Railroad Avenue, Orange, Virginia 22960. On **March 14, 2019**, I served the following documents by the method indicated below:

1. **PLAINTIFFS' TRIAL BRIEF**

☑ **By Electronic Service:** A true and correct copy of the document(s) described above was electronically served via e-mail to counsel for Monsanto Company:

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on this **March 14, 2019** at Orange, Virginia.

/s/ Jeffrey A. Travers
Jeffrey A. Travers,
Declarant