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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
Case No.: RG17862702

PLAINTIFFS OPPOSITION TO MONSANTO COMPANY'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, SUMMARY ADJUDICATION

BY FAX

Hon. Judge Winifred Smith
Department 21

Hearing Date: March 7, 2019
Time: 10:00 a.m.
Department: 21
Reservation No.: R-2048303

INTRODUCTION

Monsanto's arguments in favor of summary judgment are premised on two fundamental arguments: (1) Plaintiffs' claims are preempted by federal law; and (2) there is insufficient evidence to establish that glyphosate-containing herbicides ("GBHs") cause cancer or that Monsanto knew of the cancer risk prior to Plaintiffs' use of their products. Neither argument is correct.

First, Monsanto has not met its heavy burden to establish federal preemption. Plaintiff's failure-to-warn claims under California law do not impose labeling requirements "in addition to or different from" those required under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). *See* 7 U.S.C. § 136v(a) and (b). Accordingly, courts around the country have uniformly rejected this exact argument. *See Johnson v. Monsanto Co.*, Case No. CGC-16-550128 (Cal. Super. Ct. S.F. Cnty. May 17, 2018); *Hardeman v. Monsanto Co*., 216 F. Supp. 3d 1037, 1038 (N.D. Cal. 2016); *Giglio v. Monsanto Co.*, No. 15CV2279 BTM(NLS), 2016 WL 1722859, at *1-4 (S.D. Cal. Apr. 29, 2016); *Sheppard v. Monsanto Co*., 16-00043 JMS-RLP, 2016 WL 3629074 (D. Haw. June 29, 2016); *Carias v. Monsanto Co*., 15CV3677JMAGRB, 2016 WL 6803780, at *2 (E.D.N.Y. Sept. 30, 2016); *Blitz v. Monsanto Co.*, 317 F. Supp. 3d 1042 (W.D. Wis. 2018). .

Monsanto has also failed to present any evidence whatsoever that the Environmental Protection Agency (EPA) would have rejected warnings of NHL in the labeling of GBHs. EPA's approval of GBHs for sale without a cancer warning is not sufficient to overcome the presumption against preemption. This is especially true where, as here, the EPA has never reviewed the safety of the formulated products being sold to consumers and Monsanto has *never* made any attempt to warn consumers of the safety risk.[1] For implied preemption, Monsanto must show that it was *impossible* under federal law to provide the warnings state law requires. It has not done so.

Second, Plaintiffs have offered opinions from qualified experts on general and case-specific causation. Plaintiff's experts reached their opinions by applying a proper methodology and reviewing the totality of the scientific evidence regarding the association between GBHs and NHL. Thus, summary judgment should be denied as the admissible opinions of Plaintiff's experts create a genuine issue of material fact regarding medical causation.

[1] See Plaintiffs' Separate Statement of Undisputed Facts (PSUF) ¶ 12; Hoke Decl. Ex. 50.

Finally, the Court should also deny Defendant's motion for summary judgment on punitive damages. The evidence in this case is more than sufficient to support an award of punitive damages based on Monsanto's conscious disregard of the rights and safety of consumers, including Plaintiffs Alva and Albert Pilliod (Pilliods or Plaintiffs). The weighing of the evidence and the drawing of legitimate inferences from the facts is properly left to the province of the jury.

STATEMENT OF FACTS

Alberta and Alva Pilliod have been married for over 48 years. Plaintiffs' Separate Statement of Undisputed Facts (PSUF) ¶ 1. The Pilliods purchased a home in Livermore, California in 1982 and began regularly spraying GBHs at their home and other residences until 2017 (35 years) accumulating between 1,080-1,584 days of exposure to GBHs. PSUF ¶¶ 1, 2.

In June 2011, Mr. Pilliod began experiencing worsening pain in his hip and back. PSUF ¶ 3. Following a CT-scan and biopsy, he was diagnosed with diffuse large B-cell lymphoma (DLBCL), a form of NHL. *Id*. In March 2015, Mrs. Pilliod began experiencing vertigo, gait instability and headaches resulting in a fall at her home in Livermore, California. PSUF ¶ 4. 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. PSUF ¶ 5. In July 2016, Mrs. Pilliod was diagnosed with relapsed NHL which again required aggressive chemotherapy. *Id*.

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. Hoke Decl. Ex. 4. Had the Pilliods known of the association between GBHs and NHL, they would have never purchased or used the products. PSUF ¶ 6.

A. 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. It is undisputed that a majority of the initial studies relied upon by Monsanto for the registration of glyphosate were based on fraudulent data. PSUF ¶¶ 21, 22. The EPA had serious concerns and uncertainty about the potential hazards of glyphosate, however, the Agency was

restricted from withdrawing the registration approvals for the pesticides that utilized IBT fraudulent data for its initial approval. PSUF ¶ 22.

Unable to remove these products from the market, the EPA required Monsanto to redo toxicological and carcinogenicity studies on glyphosate. In 1983, following its review of a mouse oncogenicity study, the EPA concluded that glyphosate "was oncongenic in male mice causing renal tubule adenomas…in a dose-related manner." PSUF ¶ 23. 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." PSUF ¶¶ 24, 26. Monsanto refused EPA's request to repeat the study and pushed back on the significance of the oncogenicity finding. PSUF ¶ 24. Nonetheless, the EPA concluded that glyphosate was a Category C oncogene: a possible human carcinogen. PSUF ¶25.

Monsanto was acutely aware that the classification of glyphosate as a Class C oncogene would have severe negative economic repercussions. Monsanto found a pathologist to review the slides "in an effort to persuade the agency that the tumors are not related to glyphosate." PSUF ¶ 27. 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. PSUF ¶ 27.

Monsanto's influence prevailed and the Scientific Advisory Panel (SAP), the EPA changed its classification to a Group E carcinogen. However, the SAP did find that the occurrence of three neoplasms in male mice was "unusual" and recommended that Monsanto repeat both the rat and mouse studies. PSUF ¶ 28. The EPA provided Monsanto with specific recommendations regarding the proper design of the study to return proper results. *Id*.. 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. PSUF ¶ 30. Monsanto's chief toxicologist, Dr. Donna Farmer, conceded that these studies "may present an even bigger problem because the studies are with glyphosate and are

on more standard endpoints." *Id*. Publicly, however, Monsanto took a different tone. In a press release, Dr. Farmer wrote:

> Several genotoxicity studies have been conducted on glyphosate…None of these studies have shown any adverse findings. Based on all these results, we are confident that glyphosate herbicide products are not genotoxic and therefore do not present a mutagenic or carcinogenic risk to humans and animals.

PSUF ¶ 31.

Concerned about the genotoxicity studies, Monsanto retained Dr. James Parry ("Dr. Parry") a world renowned expert in genotoxicity to review the data and offer his conclusions. PSUF ¶ 32. 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." PSUF ¶ 33. In other words, "glyphosate is capable of producing genotoxicity both in vivo and in vitro. . ." *Id*. 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. *Id*.

Monsanto decided that it "simply [was not] going to do the studies Parry suggests." PSUF ¶ 35. Monsanto's goal 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. *See* PSUF ¶ 37. Because Dr. Parry never came around to Monsanto's view of the science, Monsanto would not let him speak to regulators and his report was never submitted to the EPA. PSUF ¶¶ 37, 38.

B. Monsanto Refuses To Test Its Formulated Products

Any review by the EPA is limited to the active ingredient glyphosate and does not consider the carcinogenic effect of formulated products. However, consumers, such as the Pilliods, are never exposed to glyphosate alone; they are always exposed to glyphosate and a mix of other ingredients, including surfactants. PSUF ¶ 41. For this reason, published studies have consistently demonstrated that the risks posed by formulated GBHs are considerably greater than with pure glyphosate alone. 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." PSUF ¶ 42.

Over the last decade European regulators forced Monsanto to phase out the use of polyoxyethkene alkylamine (POEA) surfactants in GBHs, but POEA surfactants are still used in several Roundup products in the United States. PSUF ¶ 41. In a PowerPoint created by Monsanto, its scientists recognized that the company must address the toxicity of surfactants. PSUF ¶ 43. Monsanto even 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?" PSUF ¶ 46.

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 any genotoxicity testing on the formulated product i.e. Roundup. In response to European regulators request for genotoxicity studies on the formulation, 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." . PSUF ¶¶ 44, 45. Despite internal concerns regarding the effect of surfactants and other inert ingredients on the safety of the formulations, Monsanto opted to only focus on the carcinogenic potential of glyphosate alone. PSUF ¶ 47. 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"**. PSUF ¶ 49.

C. Monsanto Floods The Scientific Literature With Ghostwritten Articles To Falsely 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[2] 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 articles

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

> 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.

concluding that "Roundup herbicide does not pose a health risk to humans." PSUF ¶ 50. 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. PSUF ¶ 50. EPA has consistently relied on the ghostwritten Williams paper when considering the safety of GBHs. PSUF ¶ 51.

In 2013, Monsanto ghostwrote another article titled "Review of genotoxicity studies of glyphosate and glyphosate-based formulations." PSUF ¶ 55. Monsanto specifically found specialists in the field of genotoxicity to sign off on their paper in order to "help enhance credibility" to their work. PSUF ¶¶ 56, 57. Monsanto identified Dr. David Kirkland as the best candidate." *Id.* Again, the EPA has consistently relied on this ghostwritten article in evaluating 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 that included convening an expert panel to "[p]ublish comprehensive evaluation of carcinogenic potential by credible scientists" that could later be used for litigation support. PSUF ¶ 58. 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."[3] PSUF ¶ 59.

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 needs "further attention" and that if there was any review of the reports by Monsanto that would need to be disclosed. PSUF ¶ 60. 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

[3] The ghostwritten Kier and Kirkland study was also published in Clinical Reviews of Toxicology.

manuscripts prior to submission to the journal." These statements are blatant lies. 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.

Additionally, and most egregiously, not only did Monsanto review the manuscripts before they were submitted, they actually wrote parts of the manuscripts before the experts concluded their meeting and commented upon and revised the parts that they didn't write. PSUF ¶ 62. Although the independent experts did make edits and contributions to the summary manuscript, it was Monsanto who had ultimate authority over the content. PSUF ¶ 63. Despite universal condemnation of ghostwriting in scientific journals, Monsanto employees take pride in their ghostwriting efforts. PSUF ¶ 64.[4]

D. Monsanto Deliberately Keeps Safety Information From the Public

On May 12, 2000, Monsanto becomes aware of an Abstract from McDuffie, et al., showing an increased risk of NHL from glyphosate in a Canadian epidemiology study. PSUF ¶ 52. Monsanto sent its chief epidemiologist, Dr. John Acquavella, to a conference in August 2000, to speak to Dr. McDuffie regarding the safety of GBHs. At the conference, Dr. Acquavella provided Dr. McDuffie a copy of the ghostwritten Williams (2000) article. *Id.*

Glyphosate is not mentioned in the abstract to the article at the time of publication. The following year, Donna Farmer congratulated John Acquavella and another executive at Monsanto for being able to remove the glyphosate results out of the abstract. *Id.* The fact that glyphosate is not mentioned in the Abstract of this scientific study is significant. Any physician, consumer, or regulator undertaking an "abstract search" for epidemiology regarding an association between glyphosate and cancer is unlikely to locate the McDuffie article based on basic search criteria.

The McDuffie article was not the only epidemiological study linking GBHs to NHL in the early 2000s. In 2002, Monsanto recognized that there were at least six published studies associating GBHs with NHL and that the mounting epidemiology affected the company's "freedom to operate" and that the

[4] In September 2018, the Journal of Critical Reviews in Toxicology issued an "Expression of Concern" after being informed of concerns over the completeness of acknowledged contributions in the declarations of interest provided by the contributors to ghostwritten articles published in their Journal. The Journal note that "we have not received an adequate explanation as to why the necessary level of transparency was not met on first submission." PSUF ¶ 65.

stage was set "for more allegations about human effects associated with glyphosate and other pesticides." PSUF ¶ 53. Despite the mounting scientific evidence, Monsanto never warned consumers of the potential safety risk and continued its efforts to combat these studies.

In 2008, the Eriksson study was published showing a statistically significant doubling of the risk of NHL for glyphosate users. PSUF ¶ 54. Although it was aware of the paper for a significant period of time, Monsanto did not warn consumers about the results. Rather, Monsanto was concerned that "activists" were using the Eriksson study to recommend that people "avoid carcinogenic herbicides .. on lawns by using non-toxic land care strategies that rely on soil health, not toxic herbicides." Donna Farmer wanted to know "how do we combat this?" PSUF ¶ 54.

E. IARC Concludes That Glyphosate is a Probable Human Carcinogen

The International Agency for Research on Cancer (IARC), the cancer research arm of the United Nations World Health Organization, is an intergovernmental entity that exists to "promote international collaboration in cancer research." *See* IARC, Statute Rules and Regulations, Fourteenth Edition (May 2014) at 6. IARC is considered a "critical reference" and "gold standard" for carcinogen identification. PSUF ¶ 13, 14.

Monsanto had long feared that IARC would review glyphosate and conclude it is a probable human carcinogen was possible. PSUF ¶ 17. Monsanto remarked that, with respect to cancer, GBHs had vulnerability in the areas of epidemiology, exposure, genotoxicity and mode of action. PSUF ¶ 18. On March 21, 2015, the International Agency for Research on Cancer (IARC) thoroughly reviewed data relating to glyphosate and concluded that the chemical was a "probable human carcinogen." PSUF ¶ 12.

F. EPA's Review of Glyphosate

EPA 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. PSUF ¶ 66.

Since 1991, EPA 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 EPA's Office of Pesticide Programs (OPP) published a preliminary issue paper on the carcinogenic potential of glyphosate.[5] 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 NHL, the Report found that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data." See EPA Glyphosate Issue Paper at 68.

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." Furthermore, a December 2016 SAP meeting, convened to discuss the methodology used by EPA's Office of Pesticide Programs (OPP) in assessing glyphosate, unanimously concluded "that the EPA evaluation does not appear to follow the EPA (2005) Cancer Guidelines." Numerous panel members concluded that "the weight-of-evidence conclusion based on EPA's 2005 Guidelines naturally leads to suggestive evidence of potential carcinogenic effects."

Likewise, 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. 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). PSUF ¶ 67. Most recently, three of the scientists form the recent SAP Panel published a manuscript in the journal *Mutation Research* finding that:"[o]verall, 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

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

risk for NHL." Zhang, et al. Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence, Mutation Research, (Feb. 5, 2019)

G. Monsanto's Undue Influence on the EPA and Efforts to Undermine IARC's Classification of Glyphosate

Even before the IARC Monograph was published, Monsanto developed a strategy to "Orchestrate Outcry with IARC Decision" through "robust media/social media outreach." PSUF ¶ 19.

Shortly after the publication of the IARC Monograph, Monsanto's stated goals included: (1) invalidating the relevance of IARC; (2) preparing for their litigation defense; and (3) protecting global sales. PSUF ¶ 20. In furtherance of these stated goals, Monsanto also developed unusually close relationships with key officials and scientists at EPA's Office of Pesticide Programs. PSUF ¶ 69-72. 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." PSUF ¶ 70. Monsanto recognized Rowland's efforts in combating the IARC classification. Furthermore, Jack Housenger, Director of the Office of Pesticide Programs worked with Monsanto to put ATSDR's glyphosate review "on hold" and to remove a prominent epidemiologist from the SAP Panel. PSUF ¶ 71, 72.

Monsanto also made true on its campaign to attack IARC and its classification of glyphosate. In February 2018, the House of Representatives Minority Staff Report, Spinning Science and Silencing Scientists: A Case Study in How the Chemical Industry Tries to Influence Science was issued for the House Committee on Science, Space & Technology ("Minority Report").[6] The Minority Report notes Monsanto's efforts to: (1) launch a "disinformation campaign" to undermine IARC's classification of glyphosate; (2) ghostwrite articles on glyphosate; (3) collude with regulators to conduct a biased review of glyphosate; and (4) hire journalists to discredit IARC. The Minority Report concludes that Monsanto's

[6] https://democrats-science.house.gov/news/staff-reports/spinning-science-and-silencing-scientists-case-study-how-chemical-industry

efforts were "aimed at corrupting and disrupting any honest, thorough and complete scientific evaluation of glyphosate and its potential adverse impact on the public's health." PSUF ¶ 74.

LEGAL STANDARD

Summary judgment should be granted only when all the papers submitted demonstrate that there is "no triable issue as to any material fact and that the moving party is entitled to a judgment as a matter of law". Cal. Code Civ. Proc. 437c (2011). Summary judgment is a drastic remedy and should not be used as a substitute for existing methods for the determination of issues of fact. *Dudum v. San Mateo*, 167 Cal. App. 2d 593 (1959). Because of the drastic nature of the procedure, all doubts should be resolved in favor of the party opposing the motion. *Powell v. Standard Brands Paint Co.* 166 Cal.App.3d 357, 362 (1985); *Aguilar v. Atlantic Richfield Co*., 25 Cal 4th 826 (finding that the court must view all evidence and make inferences in the light most favorable to the opposing party). From commencement to conclusion, the party moving for summary judgment bears the burden of persuasion that there is no triable issue of material fact and that he is entitled to judgment as a matter of law. *Id*.

ARGUMENT

A. Federal Law Does Not Preempt Plaintiffs' Failure To Warn Claims

"It is well established that the party who asserts that a state law is preempted bears the burden of so demonstrating." *In re Farm Raised Salmon Cases*, (2008) 42 Cal.4th 1077, 1088, 175 P. 3d 1170. Moreover, the Supreme Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Bates v. Dow Agrosciences LLC*, (2005) 544 U.S. 431, 449 ("*Bates*"). To the contrary, "[i]n areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.' " *Id.* (citation omitted); *In re Farm Raised Salmon Cases*, 42 Cal.4th at 1088 (noting that there is a "strong presumption against preemption.").

The Court must start with the "presumption that Congress does not intend to supplant state law." *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, (1997) 520 U.S. 806, 814. This presumption is heightened "where federal law is said to bar state action in fields of traditional state regulation." *New York State Conf. of Blue Cross & Blue Shld Plans v. Travrs. Ins. Co.*, (1995) 514 U.S. 645, 655. "When faced with two equally plausible readings of statutory text, [courts] 'have a duty to accept the reading

that disfavors preemption.'" *Bruesewitz v. Wyeth Inc.*, (3d Cir. 2009) 561 F.3d 233, 240. This presumption is particularly strong in personal injury tort cases like this one because the states have historically enjoyed expansive powers to protect the "lives, limbs, health, comfort, and quiet of all persons." *Slaughter-House Cases*, (1872) 83 U.S. 36 Monsanto has not met its substantial burden to overcome the strong presumption against preemption.

1. Plaintiffs' Failure to Warn Claims Are Not Expressly Preempted by FIFRA

Plaintiffs' failure to warn claims do not seek to impose requirements in addition to or different from FIFRA. *See Johnson v. Monsanto Co.*, Case No. CGC-16-550128 (Cal. Super. Ct. S.F. Cnty. May 17, 2018); *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1038 (N.D. Cal. 2016) (finding that "[t]o the extent Hardeman's failure-to-warn claims attack Roundup's product labeling, they are consistent with FIFRA").[7] But even assuming, *arguendo*, that they did, Monsanto is still not entitled to summary judgment on the basis of express preemption.

When a statute contains an express preemption clause, the courts "task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62-63, 123 S. Ct. 518, 526 (2002). FIFRA's express preemption clause provides that a State "may regulate the sale or use of any federally registered pesticide or device in the State," but it "shall not impose or continue in effect any requirements for labeling or packaging ***in addition to or different from*** those required" under FIFRA. 7 U.S.C. § 136v(a) and (b)(emphasis added).

Thus a "state-law labeling requirement is not pre-empted by section 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005) ("*Bates*"). Under this "parallel requirements" test, a state may permit a cause of action for violating FIFRA's own requirements, even if the state's remedies go beyond those allowed under FIFRA. *Id.* at 447-48. To survive preemption, state law requirements "need not be phrased in the identical

[7] Every federal court to consider FIFRA preemption in the context of Roundup and NHL followed the *Hardeman* decision. *See e.g., Giglio v. Monsanto Co.*, No. 15CV2279 BTM(NLS), 2016 WL 1722859, at *1-4 (S.D. Cal. Apr. 29, 2016); *Sheppard v. Monsanto Co*., 16-00043 JMS-RLP, 2016 WL 3629074 (D. Haw. June 29, 2016); *Carias v. Monsanto Co*., 15CV3677JMAGRB, 2016 WL 6803780, at *2 (E.D.N.Y. Sept. 30, 2016); *Blitz v. Monsanto Co.*, 317 F. Supp. 3d 1042 (W.D. Wis. 2018).

language as the corresponding FIFRA requirement; indeed, it would be surprising if a common law requirement used the same phraseology as FIFRA." *Id.* at 454.Since *Bates,* courts have consistently held that FIFRA does not preempt state-law failure to warn claims or other product liability claims. *See Johnson v. Monsanto Company,* Case No. CGC-16-550128 (Cal. Super. Ct. S.F. Cnty. May 17, 2018); *Hardeman v. Monsanto Company,* (N.D. Cal. 2016) 216 F. Supp. 3d 1037; *Carias v. Monsanto Company,* (E.D.N.Y. 2016) 2016 WL 6803780; *Gucciardi v. Bonide Products, Inc.,* (E.D. Pa. 2014) 28 F. Supp. 3d 383; *Indian Brand Farms, Inc. v. Novartis Crop Protection, Inc.,* (3d Cir. 2010) 617 F.3d 207, 221-25; *Wuebker v. Wilbur-Ellis Co.,* (8th Cir. 2005) 418 F.3d 883, 886; *Hardin v. BASF Corp.,* (E.D. Ark. Dec. 15, 2005) 2005 WL 6151334, at *2.

Here, Plaintiffs' failure to warn claims under California law parallel requirements imposed by FIFRA's misbranding prohibitions. FIFRA prohibits the sale or distribution of any pesticide that is misbranded. 7 U.S.C. § 136j(a)(1)(E). It is a matter of black letter law that when an herbicide manufacturer misbrands its product, it has violated FIFRA and EPA approval of the label is not a valid defense. 7 U.S.C.A. § 136a ("In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter."). Accordingly, FIFRA imposes a requirement upon herbicide manufacturers not to misbrand its product, consistent with those sought by Plaintiff.

The labeling for Roundup has never included any warning or information regarding the risk of Non-Hodgkin's lymphoma. The basis for Plaintiff's failure-to-warn claims, i.e. the failure to provide an adequate warning necessary to protect human health, also amounts to a violation of the generalized duty imposed by FIFRA. As the court in *Johnson* succinctly held in denying Monsanto's preemption argument:

> Substantively, Monsanto's express preemption argument depends on the premise that Monsanto is immune from FIFRA liability so long as it uses a label that has been approved by the EPA or is otherwise consistent with the EPA's factual findings. That's not true.

See Johnson v. Monsanto Company, Case No. CGC-16-550128 (Cal. Super. Ct. S.F. Cnty. May 17, 2018).

Under the plain language of FIFRA "registration does not provide a defense to the violation of the statute." 7 U.S.C. § 136a(f)(2). "[T]he mere fact that the EPA has approved a product label does not prevent a jury from finding that that same label violates FIFRA." *Hardeman,* 216 F. Supp. 3d at 1038.

FIFRA contemplates that pesticide labels will evolve over time and "tort suits can serve as a catalyst in this process." *Bates*, 544 U.S. at 451. The EPA's approval of a label is solely for the purposes of gaining federal approval to market the product, it does not, however, "represent a finding that the [product] as labeled, can never be deemed unsafe by later federal action, or as in this case, the application of state law." *Wyeth* 555 U.S. at 592 (Thomas, J., concurring in the judgment).

EPA approval of a proposed label provides only a "floor of safe conduct" it does not provide "a ceiling on the ability of states to protect their citizens." *Ferebee v. Chevron Chemical Co.* (D.C. Cir. 1984) 736 F.2d 1529, 1541-1542; *Euro-Pro Operating LLC v. Euroflex Americas, No*. (S.D.N.Y. Dec. 8, 2008) 2008 WL 5137060, at *6.

a. California Law Does Not Impose Requirements that are Different or in Addition to FIFRA'S Requirements

Courts have uniformly agreed that express preemption under FIFRA does not bar failure-to-warn claims for Monsanto's failure to warn of the risks of NHL. Nonetheless, Monsanto now argues that the findings from a 1989 case before the EPA's Office of the Administrator somehow support express preemption. See Mot. for SJ at 7-8; *citing In re Protexall Prods. Inc*., 1989 WL 550929 at *3. Monsanto's reliance on this case is misguided and amounts to a deliberate misrepresentation of the judicial officer's findings in order to confuse the issues before this Court.

In *In re Protexall*, the EPA sought to cancel the registration of a pesticide used to kill ants due to the risks posed to children. 1989 WL 550929 at *1. The manufacturers of the pesticide included a specific warning in their labeling that the product "should be kept out of the reach of children and may be fatal if swallowed." *Id.* at *5. However, despite the warning, the Administrator was considering whether to remove the product from the market due to the risk of accidental exposures *Id*. at *2-3. The case did not involve inadequate labeling or the failure to warn of a known or knowable safety risk associated with the product. *Id*. at *2-3.

In re Protexall does not stand for the proposition that FIFRA requires label information only for uses that are "widespread and commonly recognized" as Monsanto suggests. See Mot. for SJ at *7. The misbranding provisions of FIFRA under 7 U.S.C. § 136(q)(1)(F) and (G) for inadequate warnings are completely separate and distinct from the classification of pesticides by the Administrator under 7 U.S.C.

§ 136a(d) or cancellation by the EPA under 7 U.S.C. § 136d(b). As explained in *Bates*, supra, tort suits can serve as a "catalyst" to assure that pesticide labeling evolves in light of new safety information.

2. Congress Did Not Intend to Impliedly Preempt Failure-to-Warn Claims

The existence of an express preemption clause should inform the court's "analysis of the existence of any implied preemption." *In re Farm Raised Salmon Cases,* (2008) 42 Cal.4th 1077, 1092, 72 Cal.Rptr.3d 112, 175 P.3d 1170 . "An express definition of the pre-emptive reach of a statute "implies"—i.e., supports a reasonable inference—that Congress did not intend to pre-empt other matters....' *Paduano v. Am. Honda Motor Co*., (2009) 169 Cal.App.4th 1453, 1478-79, 88 Cal. Rptr. 3d 90, 112. "While an express clause does not foreclose an inquiry into implied conflict preemption in all cases, deference should be paid to Congress's detailed attempt to clearly define the scope of preemption under the [relevant statutory scheme]. *Id*. (internal citations omitted).

Preemption is a question of congressional intent "and when Congress has made its intent known through explicit statutory language, the court's task is an easy one." *Am. Meat Inst. v. Leeman,* (2009) 180 Cal.App.4th 728, 746, 102 Cal.Rptr.3d 759, 772. In enacting the express preemption provision of FIFRA, Congress made clear that the only claims that are preempted under the statute are those involving labeling requirements in addition to or different from those required under FIFRA. *See Johnson v. Monsanto* at 41 (finding that under FIFRA "Congress has spoken"). Any analysis of conflict preemption must be considered in light of this express preemption provision. Here, Monsanto has not provided sufficient evidence to contradict the inference that Congress intended a narrow interpretation of the scope of preemption under FIFRA.

With respect to FIFRA, Congress expressed its intent of the limited circumstances in which state law claims will be preempted. As this provides a reliable indicium of congressional intent with respect to state authority, the court need not engage in implied preemption analysis in this instance.

a. Monsanto Has Not Proved that it was Impossible to Warn Consumers of the Risk of NHL

Federal preemption under FIFRA is not appropriate even if the Court undertakes an analysis of implied conflict preemption under *Wyeth*. A product manufacturer bears a heavy burden when arguing that federal requirements made it impossible to strengthen its label. *See Chavez v. Blue Sky Natural Beverage Co*., 268 F.R.D. 365 (N.D. Cal. 2010) *citing Wyeth v. Levine* 555 U.S. 555, 573, 129 S. Ct.

1187, 1199 (2009). A court may only grant summary judgment on the basis of preemption where, resolving all questions of fact in the plaintiff's favor, there is "clear evidence" that the EPA would have rejected attempts by Monsanto to include a warning of NHL on its labeling. *Wyeth*, 555 U.S. at 571; *In re Actos (Pioglitazone) Prods. Liab. Litig*., 2014 WL 4364832, *21-22 (holding that, in preemption analysis, court's role is not "to substitute its judgment for the jury's or to weigh evidence, make credibility calls, or to select which interpretation of the evidence presented might be more desirable. . ."). Monsanto has failed to meet its burden of showing that it was impossible to comply with both federal and state requirements as there is no "clear evidence" that the EPA would have rejected a change to the labeling warning of NHL. *See Wyeth*, 555 U.S. at 571.

Wyeth and its progeny establish that the "clear-evidence test is a 'demanding defense' meant to represent a longstanding 'presumption against pre-emption.'" *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 852 F. 3d 268, 286 (3d Cir. 2017). In applying *Wyeth*'s clear-evidence test, courts have routinely held that manufacturers do not satisfy their heavy burden of establishing impossibility preemption by merely showing that a regulatory agency has considered the risk and did not require a labeling change. In *Mason v. Smithkline Beecham Corp.*, 596 F. 3d 387 (7th Cir. 2010), the Seventh Circuit made clear that, under *Wyeth*, the test for manufacturers seeking to establish FDA preemption is a stringent one. In *Mason, the* court rejected GlaxoSmithKline's ("GSK") assertions that it would have been impossible to add a warning about the risk of suicide to the Paxil label prior to 2003. *See Mason*, 596 F.3d at 387. In reaching its conclusion, the court was unpersuaded by the record evidence that the FDA had approved Paxil without a warning about suicide in 1989, and that over the years, the FDA had considered the data and concluded there was insufficient evidence to support a warning about the risk of suicide. *See id.* at 394-96. The Court found it was still not clear the FDA would have rejected a CBE labeling change to add a warning about suicide to the Paxil label before 2003.

The fact that the EPA may not be affirmatively convinced of a causal link between GHBs and NHL does not preclude Monsanto from adding the warning on its own. *See In re Testosterone Replacement Therapy Prod. Liab. Litig*., 2017 WL 1836435 at * (N.D. Ill. May 8, 2017). In drawing all reasonable inferences in favor of Plaintiffs, the Court should not conclude as a matter of law that the EPA would have rejected a labeling change for NHL without evidence that such a warning was ever

submitted or considered by the agency. *See In re Fosamax (Alendronate Sodium) Prod. Liab. Litig*., 852 F. 3d 268, 298-299 (3d Cir. 2017). It is certainly reasonable to conclude that the EPA would have accepted a warning in the name of consumer safety even if there was "inherent uncertainty" regarding whether GHBs definitively cause NHL. *Id*. at 299. In both *In re Testosterone* and *In re Fosamax*, preemption was not appropriate as the FDA recognized the possibility of a link between the drug and side effect even though it ultimately concluded that the available literature did not support an association. *In re Fosamax*, 852 F. 3d at 298; *In re Testosterone*, 2017 WL 1836435 at *9.

As noted earlier, the EPA's 2016 review in this case was limited to glyphosate. The EPA specifically noted that additional research would be needed to determine the effect of surfactants on the toxicity of the products. Furthermore, while the EPA's publication concluded that generally glyphosate was "likely not carcinogenic to humans" the agency's specific conclusion regarding NHL was that the risk "cannot not be determined based on the available data." These conclusions are far from "clear evidence" that the EPA would have rejected a labeling change specific to NHL. Indeed, if EPA's primary goal was "one of protecting the public health" there is no reason why the EPA would preclude Monsanto from warning consumers of the potential risk of NHL following exposure to formulated products.

Unlike the FDCA that does not contain an express preemption provision, there is an inference that Congress did not intend to pre-empt other matters under FIFRA. In applying the "clear evidence test" the court should pay deference to the clearly defined scope of FIFRA preemption. Unless there is an express denial of proposed labeling by the EPA, a state law claim seeking remedy for inadequate instructions or warnings would be consistent with FIFRA's misbranding provisions. Thus, Plaintiff's claims against Monsanto are not pre-empted.

B. Monsanto Is Not Entitled to Summary Judgment as Plaintiff has Introduced Reliable and Admissible Evidence of Causation

Plaintiff's experts possess impressive credentials and applied reliable methodologies to conclude that GBHs more likely than not caused their NHL. The data reviewed and explained by Plaintiffs' experts is consistent and compelling. The causation evidence, viewed in its entirety, weighs heavily in favor of admissibility. Monsanto cannot dismiss Plaintiffs' claims by simply ignoring the overwhelming weight of the evidence by piecemeal rejection of individual studies and reliance on the EPA. This approach is anathema to the standards of expert admissibility in California.

For the reasons set forth in Plaintiff's Opposition to Monsanto's *Sargon* Motions, Plaintiffs have offered admissible expert testimony on medical causation. Accordingly, Monsanto's motion for summary judgment must be denied.

C. Plaintiffs' Warning Claims Survive Summary Judgment Because There is Ample Evidence that Cancer Risks from Roundup® Were Known or Knowable by the Scientific Community at the Time of Distribution.

Monsanto's argument that Roundup®'s cancer risk was not known or knowable is predicated upon cherry-picked studies and an intentional distortion of the record. The relevant test is not whether the scientific evidence uniformly establishes that a cancer risk is known; rather, the standard is whether the "*potential* risk" of cancer was "known or *knowable* in light of the generally recognized and prevailing best scientific and medical knowledge at the time of manufacturer and distribution." *Valentine v. Baxter*, 68 Cal. App. 4th 1467, 1483-84 (1999) (emphasis added): CACI 1205.

Roundup®'s potential cancer risk was first knowable in the 1980s. In fact, EPA first determined that glyphosate was a possible carcinogen on March 4, 1985.[8] Prior to that in 1982, an EPA review of a glyphosate rat study found a statistically significant increase in lymphocytic hyperplasia and interstitial testicular tumors. By 1999, Monsanto possessed a report from Dr. James Parry indicating potential risks associated with glyphosate. And although epidemiological studies are not a prerequisite to showing that Roundup®'s cancer risk was knowable, the published epidemiology showed a cancer risk by 2001 in the McDuffie study. However, in De Roos (2003) the last data collected was in June 1986, demonstrating that Monsanto could have conducted a valid epidemiological study in the 1980s. In short, the general causation evidence, with which the Court is already intimately familiar, evinces real risk long before 2013—especially when viewed in a light most favorable to Plaintiffs. *See* Mot. at 14.

D. Plaintiff Are Entitled to Punitive Damages as a Result of Monsanto's Reckless Indifference to the Rights of Others

"In order for a jury to award punitive damages, it need only find that the defendant acted with malice, oppression or fraud." (Civ.Code, § 3294, subd. (a); *Major v. Western Home Ins. Co.*, 169 Cal.App.4th 1197, 1225–26 (2009). Under the statute, "malice does not require actual intent to harm.

[8] March 4, 1985 memo re: glyphosate consensus review. *Available at:* https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-171.pdf

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. Malice may be proved either expressly through direct evidence or by implication through indirect evidence from which the jury draws inferences." *Pfeifer v. John Crane, Inc.,* 220 Cal.App.4th 1270, 1299 (2013) (quoting *Angie M. v. Superior Court,* 37 Cal.App.4th 1217, 1228 (1995)).

Plaintiffs are not required to "prove" a case for punitive damages at summary judgment. *Johnson & Johnson v. Superior Court* (2011) 192 Cal. App. 4th 757, 762, 121 Cal. Rptr. 3d 640, 643. The question of whether the defendant's conduct "will support an award of punitive damages is for the trier of fact, since the degree of punishment depends on the peculiar circumstances of each case." *Id.*; *Romo v. Ford Motor Co*. (2003) 113 Cal.App.4th 738, 754 (finding that "the underlying facts supporting a punitive damages award are for the jury to decide."); *Egan v. Mut. Of Omaha Ins. Co*. (1979) 24 Cal.3d 809, 821 ("It is well established that liability for punitive damages is a question of fact."). Summary judgment on the issue of punitive damages is only appropriate in the rare instance when "no reasonable jury could find the plaintiff's evidence to be clear and convincing proof of malice, fraud or oppression." *Id*. As stated by the court in *West v. Johnson & Johnson Products, Inc.* (1985) 174 Cal.App.3d 831:

> Determinations related to assessment of punitive damages have traditionally been left to the discretion of the jury . . . [T]he existence of 'malice' – in the sense of 'conscious disregard for the safety of others' – has been held to be a question of fact for the jury to determine. Similarly, in the field of negligence it has been held that whether reasonable testing and inspection would have disclosed a product defect is a question of fact for the jury to decide."

Id. at 867-68.

In order to grant Monsanto's motion for summary adjudication on the issue of punitive damages, the Court would be required to weigh the evidence and construe the facts in a light most favorable to Monsanto. This is not appropriate at summary judgment. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for summary judgment or for a directed verdict." *Am. Airlines, Inc. v. Sheppard, Mullin, Richter & Hampton,* (2002) 117 Cal. Rptr. 2d 685, 709 "Where reasonable minds could differ as to whether the evidence would support punitive damages, the resolution of the conflicting inferences and the weighing of opposing evidence is for the jury; for the court to grant a

[summary adjudication] would be to usurp the jury's unction". *Hoch v. Allied-Signal, Inc.*, (1994) 29 Cal. Rptr. 2d 615, 619-20.

The evidence in this case, as detailed above, is more than sufficient to support a jury's award of punitive damages based on Monsanto's reckless disregard for the safety of others, including Plaintiffs. Plaintiffs have offered evidence demonstrating that Monsanto: (1) continued to market and sell GHBs while failing to warn consumers of a known risk of NHL; (2) did not conduct studies recommended by the EPA and its own consultants that would have helped evaluate the carcinogenicity risk of GHBs; (3) did not evaluate its GHB formulations to determine the risks associated with surfactants; (4) elected to continue to market products with a POEA surfactant despite knowledge of safer alternatives; (5) withheld information from the EPA regarding dermal absorption and consultant recommendations; and (6) ghostwrote articles in order to publish positive safety data. Based on this evidence, a reasonable jury could find that Monsanto's exhibited a conscious and callous disregard of public safety in order to maximize corporate profits.

In denying Monsanto's motion for summary judgment on punitive damages, the Honorable Curtis Karnow summarized pertinent evidence that, when viewed in the light most favorable to the Plaintiff, would support a reasonable jury's finding that punitive damages are warranted:

> 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.*,127 Cal.App.4th 1640, 1690 (2005). After hearing all of the evidence relating to Monsanto's conduct, a reasonable jury did, in fact, find that there was clear and convincing evidence that Monsanto acted with malice and fraud. Monsanto's actions warrant the imposition of punitive damages.

CONCLUSION

For the foregoing reasons, Plaintiffs ask this Court to deny Monsanto's company's Motion for Summary Judgement relating to federal preemption, all causes of action, and punitive damages.

DATED: February 21, 2019

Respectfully submitted,

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