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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	JCCP NO. 4953 ASSIGNED FOR ALL PURPOSES TO JUDGE WINIFRED SMITH DEPARTMENT 21
THIS DOCUMENT RELATES TO: PILLIOD, ET AL. v. MONSANTO CO., ET AL., CASE NO. RG17862702	**DEFENDANT MONSANTO COMPANY'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, SUMMARY ADJUDICATION** Hearing Date: March 7, 2019 Time: 10:00 a.m. Department: 21 Reservation No.: R-2048303

TO THE COURT, ALL PARTIES, AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT that on March 7, 2019 in Department 21 of the above-titled court located at 1221 Oak Street, Oakland, CA 94612, Defendant Monsanto Company will, and hereby does, move this Court for an order granting summary judgment pursuant to Code of Civil Procedure § 437c(a), or in the alternative for summary adjudication pursuant to Code of Civil Procedure § 437c(f), of the following causes of action or issues:

(1) The first cause of action in the Second Amended Complaint ("SAC") for strict liability – design defect on the grounds that it is preempted by federal law and there are no disputed issues of material fact;

(2) The second cause of action in the SAC for strict liability – failure to warn on the grounds that it is preempted by federal law and there are no disputed issues of material fact;

(3) The third cause of action for negligence on the grounds that it is preempted by federal law and there are no disputed issues of material fact;

(4) The fourth cause of action for breach of implied warranty on the grounds that it is preempted by federal law and there are no disputed issues of material fact;

(5) The fifth cause of action for punitive damage on the ground that there are no disputed issues of material fact; and

(6) The sixth cause of action for loss of consortium on the ground that there are no disputed issues of material fact.

This Motion shall be based on this Notice of Motion, the attached Memorandum of Points and Authorities, the concurrently filed declarations and exhibits, the statement of undisputed material facts, Monsanto's *Sargon* motions, and upon such other and further matters that the Court may consider.

Dated February 12, 2019

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INTRODUCTION

Defendant Monsanto Company seeks summary judgment on all claims brought by Plaintiffs Alberta and Alva Pilliod. Plaintiffs are a married couple in their seventies who allege that their exposure to Monsanto's Roundup® herbicide caused them to develop non-Hodgkin's lymphoma ("NHL"). Plaintiffs seek to hold Monsanto responsible for their cancer, asserting six causes of action: (1) strict liability – design defect; (2) strict liability – failure to warn; (3) negligence; (4) breach of implied warranty; (5) punitive damage; and (6) loss of consortium. The crux of these claims is that (1) Roundup's formulation is defectively designed because it allegedly can cause cancer; and (2) Roundup's label is defective because it does not warn users about Roundup's supposed carcinogenetic potential. These claims fail for several reasons.

First, Plaintiffs' claims are preempted by federal law. Plaintiffs' failure-to-warn claims are expressly preempted by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b), because they impose "requirements" that are "in addition to or different from" FIFRA's misbranding requirements for misuse labeling. Plaintiffs' failure-to-warn, design-defect, and breach-of-warranty claims are additionally preempted as a matter of impossibility preemption because the U.S. Environmental Protection Agency ("EPA") specifically requires pre-approval before Monsanto can either change the formulation or the "precautionary statements" on the label.

Second, there is no admissible expert testimony that Plaintiffs' respective subtypes of NHL were proximately caused by their exposure to Roundup for the reasons stated in Monsanto's contemporaneously filed *Sargon* motions to exclude Drs. Weissenberger and Nabhan. Without evidence of causation, none of Plaintiffs' claims can go forward.

Third, Plaintiffs' warnings-based claims fail because it is undisputed that at the time of Plaintiffs' NHL diagnosis it was not "generally accepted in the scientific community" that Roundup caused cancer in humans. CACI 1205; *see also See Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483-84 (1999).

Fourth, Plaintiffs are not entitled to punitive damages because there is insufficient evidence to find that Monsanto acted with malice, oppression, or fraud. *See* Cal. Civ. Code §

3294(c)(1). Rather, Monsanto reasonably relied on global regulatory consensus that glyphosate does not cause cancer as well as leading epidemiology. Moreover, Plaintiffs' evidence does not come close to meeting their burden of proof and in any event involves conduct by employees who were not "managing agents."

STATEMENT OF FACTS

A. Roundup® Herbicide

Roundup® is an herbicide manufactured and sold by Monsanto. Undisputed Material Fact ("UMF") 1. It consists of the active ingredient glyphosate, surfactants that promote the absorption of glyphosate into plants, and water. *See* UMF 2. Glyphosate stops plants from synthesizing amino acids needed for plant growth by inhibiting an enzyme found in plants, but not in human cells.

EPA first approved glyphosate-based herbicides for sale in 1974. Glyphosate has since become one of the most studied substances in the world. EPA classified glyphosate as non-carcinogenic for humans "based on a lack of convincing evidence of carcinogenicity in adequate studies." UMF 9. There is a global regulatory consensus that glyphosate is not a human carcinogen. Regulatory agencies like EPA, the European Food Safety Authority ("EFSA"), and the European Chemicals Agency ("ECHA") have evaluated the safety of glyphosate numerous times and continually found it to be safe. UMFs 9-22, 27-34.

In July 2015, the International Agency for Research on Cancer ("IARC") issued a monograph ("Monograph 112") that classified glyphosate as Group 2A (probably carcinogenic to humans). UMF 24. IARC found "limited evidence" that glyphosate causes cancer in humans. UMF 25. "Limited evidence" means that IARC found a positive association in epidemiological data between glyphosate and cancer that could result from "chance, bias, or confounding." UMF 26. IARC's classification was largely based on rodent studies that it deemed "sufficient evidence" that glyphosate could cause tumors in rodents and genotoxicity studies that it deemed showed "strong evidence" that glyphosate can cause cell changes in petri-dish type experiments known as "in vitro" studies. IARC's analysis, however, is merely a "hazard assessment," meaning that it

was conducted at a higher level of generality to assess whether glyphosate is potentially capable of causing cancer. *See In re Roundup Prod. Litig.*, 2018 WL 3368534, at *7 (N.D. Cal. July 10, 2018). IARC's hazard assessment did not determine the probability that glyphosate actually causes NHL in humans at real-world exposure levels. *See id.*

Since IARC's classification, EPA re-reviewed the data and again determined that glyphosate is "not likely to be carcinogenic to humans." UMFs 17-21, 27-28. Indeed, just a few weeks ago, EPA reiterated that "it is confident" that "glyphosate is not likely to be carcinogenic" and that its conclusion is consistent with Canadian, EU, German, and Japanese regulators. UMF 28. EFSA likewise reevaluated glyphosate and concluded that it was not carcinogenic to humans. UMF 30.

B. Glyphosate Science

There are three primary types of science relevant to this case: epidemiology, toxicology, and mechanistic data. Epidemiology is the method used to find causes of health outcomes and diseases in human populations. It is the most useful of the three branches of science because it is only one that looks at rates of disease in humans who have been exposed to real-world levels of a substance. *See infra.* Results of epidemiological studies are expressed in ratios: a 1.0 risk ratio means the disease occurred with the same frequency in both the exposed and unexposed groups, whereas a 2.0 risk ratio means the diseases occurred twice as frequently in exposed individuals. A study's confidence interval determines the precision of the ratio's upper and lower interval band.

Toxicology studies take place in a laboratory and look at the toxic effects of substances in experimental animals. As many courts recognize, the value of these studies is limited not only because they test animals, who clearly have a different genetic makeup than humans, but also because they do not use exposure levels similar to those relevant to the real world. *See, e.g.*, *In re Roundup Prods. Liability Lit.*, MDL No. 2741, 2018 WL 3368534, at *5 (N.D. Cal. July 10, 2018); *In re Silicone Gel Breast Implants Prods. Liability Lit.*, 318 F. Supp. 2d 879, 891 (C.D. Cal. 2004). Finally, mechanistic data looks at the mechanism by which a substance may be carcinogenic. It cannot be used alone to determine if a substance actually causes cancer.

The epidemiology relevant to Roundup demonstrates that it is not carcinogenic to humans. The largest epidemiology study of glyphosate-based herbicides to date, the Agricultural Health Study ("AHS"), is a cohort study funded by the National Institutes of Health and EPA designed to analyze if pesticides increase cancer risk in farmers and pesticide applicators. UMF 35. The participants have been monitored for cancer since enrolling in the study between 1993 and 1997. Based on the AHS study, the prestigious *Journal of the National Cancer Institute* in 2018 ("JNCI 2018") published data showing "no associations between glyphosate use and NHL risk overall or any of its subtypes." UMF 35. The paper grouped participants into four tiers based on exposure levels. UMF 38. Each tier showed a risk ratio less than 1.0 and there was no dose-response trend to suggest that cancer was associated with greater glyphosate exposure. *Id.*

The North American Pooled Project ("NAPP") is a project also funded by the National Institute of Health "specifically addressing the hypothesis of glyphosate and NHL risk." UMF 41. NAPP combines case-control data reported in two earlier epidemiology papers McDuffie (2001) and De Roos (2003) and then adjusts the data for other pesticides to improve the validity of the analysis. UMF 42. Like JNCI 2018, the results of NAPP when adjusted for other pesticide use showed "no evidence of a positive association between glyphosate, including higher levels of glyphosate exposure, and the risk of NHL." UMF 43. When the currently available epidemiological evidence is analyzed together in an epidemiological study design called a meta-analysis, the result is that no association is found between Roundup and NHL. UMF 44.

C. Plaintiffs' NHL

NHL is a cancer that consists of more than 60 different subtypes, each of which can have different risk factors. UMF 50. It is undisputed that the majority of NHL cases are idiopathic, meaning there is no known cause. UMF 51. It is also undisputed that the risk of getting NHL, like most cancers, dramatically increases as people age. UMF 52. A man in his 70's is six times more likely to be diagnosed with diffuse large B-cell lymphoma ("DLBCL"), the most common subtype of NHL, than a man in his 50's. *Id.*

Mr. Pilliod was diagnosed with DLBCL, the most common subtype of NHL, in 2012. UMF 53. He was [redacted] UMF 54. Mrs. Pilliod was diagnosed with primary CNS lymphoma ("PCNSL"), a rare DLBCL subtype of lymphoma limited to the CNS, in April 2015, though her symptoms started a few months earlier. UMF 55. She was [redacted] UMF 56. None of Plaintiffs' treating doctors told them that their NHL was caused by Roundup. UMF 57.

SUMMARY JUDGMENT STANDARD

A motion for summary judgment "shall be granted if all the papers submitted show 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. Civ. Proc. Code § 437c(c). The pleadings serve as the "outer measure of materiality" on summary judgment. *Hutton v. Fidelity Nat'l Title Co.*, 213 Cal. App. 4th 486, 493 (2013). The defendant need not conclusively negate Plaintiff's claim, it must merely show that the plaintiff cannot establish at least one element of the cause of action. *Aguilar v. Atlantic Richfield Co.*, 25 Cal. 4th 826, 853 (2001).

ARGUMENT

I. Plaintiffs' Warning-Based Claims Are Expressly Preempted.

FIFRA's express preemption clause prohibits States from imposing "any requirements for labeling or packaging" that are "in addition to or different from" FIFRA's requirements. 7 U.S.C. §§ 136a(c), 136v(b). In *Bates v. Dow Agrosciences LLC*, the Supreme Court established a two-part "parallel-requirements" test to determine whether a state-law claim is pre-empted by FIFRA: (1) the state requirement must be *for labeling or packaging*, and (2) it must impose a labeling or packaging requirement that is *in addition to or different from* FIFRA's requirements. 544 U.S. 431 (2005). Plaintiffs' claims satisfy both parts of the *Bates* test and are expressly preempted.

A. Plaintiffs' Warnings Claims Impose Requirements for Labeling or Packaging.

The *Bates* Court specifically found that common law failure-to-warn claims "qualify as 'requirements for labeling or packaging'" as defined in § 136v(b). *Bates*, 544 U.S. at 446. Here, Plaintiffs' claims for negligence, strict liability failure to warn, and breach of warranties allege deficiencies to Roundup's "labeling or packaging" and satisfy the first prong of the *Bates* test

because they are all premised on allegations that Monsanto failed to warn about the carcinogenic risk associated with exposure to Roundup. *Id.* at 443; *see also Wilgus v. Hartz Mountain Corp.*, No. 3:12-CV-86, 2013 WL 653707, at *6 (N.D. Ind. Feb. 19, 2013) (expressly preempting claims of breach of implied warranty, strict product liability, and negligence based on an alleged failure to warn). Accordingly, express preemption here turns on the second prong of the *Bates* test.

B. Plaintiffs' Failure-to-Warn Claims Impose Requirements that Are "In Addition to or Different From" FIFRA's Requirements.

Plaintiffs' state-law claims impose more expansive labeling obligations concerning product use than FIFRA does, and are therefore expressly preempted because "a manufacturer could be held liable under the state law without having violated the federal law." *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) (citing *Bates*, 544 U.S. at 453-54).

1. FIFRA's Requirements

FIFRA requires that a pesticide's "labeling and other material required to be submitted comply with" its requirements and "when used in accordance with *widespread and commonly recognized practice* it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5) (emph. added). Under FIFRA, a pesticide must not be "misbranded," which FIFRA explains occurs if:

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

7 U.S.C. § 136(q)(1)(F), (G).

Section 136a(d) provides the criteria by which EPA determines if a pesticide should be classified for general use, restricted use, or both. Section 136a(d) states EPA must consider whether the pesticide will "cause unreasonable adverse effects on the environment" when the pesticide is used "*in accordance with a widespread and commonly recognized practice*." *See also*

In re Protexall Prods., Inc., FIFRA Docket Nos. 625, et al., 2 E.A.D. 854 (E.P.A.), 1989 WL 550929, at *3 (July 26, 1989) ("Thus, it is not merely the label directions that determine the manner of use of the product to be considered in the risk analysis; instead, where 'widespread and commonly recognized practice' differs from use as indicated on the label, the risk to be evaluated is the risk created by that actual use of the product."). Because pesticide labels must contain EPA's appropriate use classification to avoid being misbranded, FIFRA thus requires the label to warn about uses that are widespread and commonly recognized. *See* 40 C.F.R. § 156.10(a)(1) & (j) (requiring the contents of a pesticide's label to include the "use classification(s) as prescribed in paragraph (j) of this section"); 7 U.S.C. § 136(q)(1)(F), (G).

2. Failure-To-Warn Claims Under California Law

Under California law, a manufacturer can be held strictly liable if it failed to warn of "potential risks that were known or knowable in light of the scientific and medical knowledge" and that "presented a substantial danger when the product is used or misused in an intended or reasonably foreseeable way." Judicial Council of Cal. Civ. Jury Instr. ("CACI") No. 1205; s*ee also Saller v. Crown Cork & Seal Co.*, 187 Cal. App. 4th 1220, 1230 n.7 (2010). A negligent failure to warn claim requires that a manufacturer "knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner." CACI No. 1222; *see also Saller*, 187 Cal. App. 4th at 1240 n.13. Accordingly, for strict liability and negligent failure to warn claims, a manufacturer can be held liable only for *reasonably foreseeable* uses (and misuses) of its product.

3. California Failure-to-Warn Claims Impose Requirements that Are Different From and In Addition to FIFRA's Requirements.

As set forth above, FIFRA requires label information only for uses that are "widespread and commonly recognized." 7 U.S.C. § 136(q)(1)(F), (G); *In re Protexall Prods., Inc.*, 1989 WL 550929, at *3. Conversely, California law requires manufacturers to consider all uses (and misuses) that are "reasonably foreseeable." Reasonably foreseeable uses encompass a much broader category of uses than just uses that are widespread and common. *See, e.g.*, *Bunch v.*

Hoffinger Indus., Inc., 123 Cal. App. 4th 1278, 1303 (2004) (applying California's reasonable foreseeability test, which requires a manufacturer to "anticipate" potential and hypothetical uses of its product when deciding on appropriate label). Because California law imposes broader labeling requirements on manufacturers than FIFRA does, a manufacturer could be held liable under California law without having violated FIFRA. For example, if a use (or misuse) was reasonably foreseeable but not widespread and commonly recognized, the manufacturer would be liable under California law, but not FIFRA. Plaintiffs' failure to warn claims are therefore expressly preempted by FIFRA.

II. Plaintiffs' Claims Are Preempted Under Impossibility Preemption.

Federal law preempts state law "where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); s*ee also Whistler Invs., Inc. v. Depository Tr. & Clearing Corp.*, 539 F.3d 1159, 1166 (9th Cir. 2008). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011).

Since 2005, the Supreme Court has issued three opinions concerning impossibility preemption pertaining to the Federal Drug and Cosmetic Act ("FDCA"). *Wyeth*, 555 U.S. 555 (2009); *Mensing*, 564 U.S. 604 (2011); *Bartlett*, 570 U.S. 472 (2013). Under *Wyeth*, *Mensing*, and *Bartlett*, a state tort claim is preempted if the claim seeks to have a manufacturer make product changes that require the prior approval of a federal regulatory agency. *See Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 9 (1st Cir. 2018) ("If a private party … cannot comply with state law without first obtaining the approval of a federal regulatory agency, then the application of that law to that private party is preempted."). This impossibility preemption analysis applies to Plaintiffs' claims because they seek changes requiring EPA prior approval.

First, the *Wyeth* Court recognized this analysis and rejected a preemption argument because it found that the defendant could make the change sought by plaintiff without FDA prior approval. 555 U.S. at 568. In contrast, the *Mensing* Court found preemption because "if the manufacturers had independently changed their labels to satisfy their state-law duty" without prior

FDA approval, "they would have violated federal law." 564 U.S. at 618 (citing 21 C.F.R. § 314.150(b)(10)). Because defendants could not satisfy their alleged state duties "without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency," they could not "independently do under federal law" what state law required. *Id*. at 620, 623-24. *Bartlett* extended *Mensing*'s reasoning to defective design claims and explained that where state law imposes a duty on a manufacturer to take "certain remedial measures" prohibited by federal law without prior FDA approval, it is "impossible for a private party to comply with both state and federal requirements," giving rise to preemption. *Id*. (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

Lower courts recognize that impossibility preemption applies in factual and regulatory contexts beyond FDCA disputes.[1] Indeed, those impossibility preemption principles apply to any product subjected to a rigorous federal pre-approval process and to which post-approval design or label changes require agency approval. For example, the Third Circuit acknowledged that impossibility preemption principles articulated in *Mensing* apply to the Federal Aviation Act. *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 703-04 (3d Cir. 2016). *But see Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 714 (3d Cir. 2018) (split panel finding that it was not impossible for defendant to comply with both plaintiff's claims and FAA). Similarly, the First Circuit, citing *Mensing*, recently recognized that "[i]f a private party (such as the manufacturers here) cannot comply with state law without first obtaining the approval of a federal regulatory agency, then the application of that law to that private party is preempted." *Gustavsen*, 903 F.3d at 9. Here, Plaintiffs' claims are preempted because it is impossible for Monsanto to

[1] No appellate court has considered the application of *Wyeth, Mensing*, and *Bartlett* in the FIFRA context. The sole federal court to have considered the issue incorrectly found impossibility preemption categorically inapplicable to FIFRA. *Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270, 1280 (D. Haw. 2015). *Bates* cannot properly be read as foreclosing the impossibility preemption analysis articulated years later in *Wyeth, Mensing*, and *Bartlett* nor was impossibility preemption before the Court in *Bates*. *Cf. Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1595 (2015) ("Since the parties have argued this case almost exclusively in terms of field pre-emption, we consider only the field pre-emption question.").

independently comply with both the purported state-law requirement to change the design and label of Roundup and FIFRA, which requires EPA prior approval to make such changes.

A. Plaintiffs' State-Law Claims Are Preempted Because Monsanto Cannot Make the Label and Design Changes Plaintiffs Seek Without Prior EPA Approval.

1. EPA Approval is Required Before Adding a Cancer Warning to the Label.

Similar to the FDCA's scheme for amending a medicine's label, there are different categories of amendments for a pesticide label, and some minor modifications may be made without prior EPA approval. *See* 40 C.F.R. § 152.44(b)(3) (certain label changes can be effectuated "by notification or non-notification"); 40 C.F.R. § 152.46(a) & (b) (label changes permitted by "notification" and "without notification" are "certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment"). But substantial changes require an amendment to the registration application, which needs prior EPA approval. 40 C.F.R. § 152.44 & 152.46. This is the default rule for "any modification in the composition, labeling, or packaging of a registered product." 40 C.F.R. § 152.44(a).

EPA provides express regulatory limitations as to what types of label changes can be made without prior approval. UMF 4. Pesticide Registration Notice ("PRN") 98-10 prohibits a "change in the ingredients statement, signal word, use classification, *precautionary statements*, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use." UMF 5. Warnings about health hazards, like cancer, are required to appear in the "Precautionary Statements" section of the label. *See* UMF 6; 40 C.F.R. § 156.70(a). Importantly, PRN 98-10 does not list health warnings as label changes that can occur without EPA approval. UMF 7.

Monsanto, therefore, can amend the Roundup label to add a cancer warning only by submitting "an application for amended registration" to EPA, which "must be approved by [EPA] before the product, as modified, may legally be distributed or sold." 40 C.F.R. § 152.44(a). Because Monsanto could not unilaterally change the label "without the Federal Government's

special permission and assistance, which is dependent on the exercise of judgment by a federal agency," *Mensing*, 564 U.S. at 620, 623-24, Plaintiffs' warning-based claims are preempted.

2. EPA Approval is Required Before Changing the Design of the Formulation.

Like the label change Plaintiffs seek, Monsanto cannot change the EPA approved Roundup formulation (and thus Roundup's design) without EPA's prior approval. All registered products "must have a single, defined composition." 40 C.F.R. § 152.43(a). It is illegal under FIFRA for Monsanto to sell "any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration." 7 U.S.C. § 136j(a)(1)(C). It is also unlawful to sell a pesticide that is adulterated. 7 U.S.C. § 136j(a)(1)(E). Adulterated products include a pesticide where "(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold; (2) any substance has been substituted wholly or in part for the pesticide; or (3) any valuable constituent of the pesticide has been wholly or in part abstracted." *Id.* § 136(c).

Changes to EPA-approved product formulations are governed by the same criterion as label changes. UMF 8. PRN 98-10 specifically states that "[a] registrant may NOT make the following active ingredient related changes by notification, but must submit an application for amendment" including a chance for an "[a]ddition, deletion, or substitution of an active ingredient or decrease in the amounts of existing acting ingredient." *Id.* at § III(A), at pp. 8-9. Section V of PRN 98-10 further states that "a formulation change may only be accomplished through submission of any application for amended registration." Because Monsanto cannot alter glyphosate or the surfactants in the Roundup formulation without EPA's prior approval, Plaintiffs' design-defect claims are preempted as a matter of impossibility preemption.

B. Plaintiffs' Claims Are Additionally Preempted Because There is Clear Evidence EPA Would Have Rejected the Formulation and Label Changes

Many courts have additionally held that claims are preempted when the evidence shows that the federal regulatory agency had considered the safety risk but nevertheless rejected concerns

about that risk.[2] *See, e.g.*, *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 816 (7th Cir. 2018) ("As a matter of law, this is what [*Wyeth*] called 'clear evidence' that the FDA would have rejected the warning that plaintiff seeks under Illinois law."). Here, there is clear evidence that EPA would reject any attempt to add a cancer warning to the applicable Roundup label or to change the formulation. EPA has considered glyphosate's safety time after time, and has repeatedly made findings of non-carcinogenicity:

- On June 26, 1991, EPA classified glyphosate as non-carcinogenic for humans "based on a lack of convincing evidence of carcinogenicity in adequate studies." UMF 10.
- In 1993, glyphosate was registered again, and EPA again concluded in its Reregistration Eligibility Decision ("RED") that there was "evidence of non-carcinogenicity in humans." UMF 11.
- In 1997, EPA again found that "[d]ata indicate that glyphosate is a group E carcinogen (evidence of noncarcinogenicity for studies in humans . . .)." UMF 12.
- In 2002, in response to a challenge to glyphosate's safety, the EPA found "[n]o evidence of carcinogenicity" of glyphosate. UMF 13.
- In 2004, the EPA found that "[g]lyphosate has no carcinogenic potential." UMF 14.
- In 2008, EPA found that "[t]here is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant." UMF 15.
- In 2013, "EPA . . . concluded that glyphosate does not pose a cancer risk to humans." UMF 16.
- In 2015, after IARC released its classification of glyphosate as a likely carcinogen, EPA's Office of Pesticide Programs re-evaluated the chemical and again classified it as "[n]ot [l]ikely to be [c]arcinogenic to [h]umans." UMF 17.
- In September 2016, EPA concluded that "the available data and weight-of-evidence clearly do not support the descriptors 'carcinogenic to humans,' 'likely to be carcinogenic to humans,' or 'inadequate information to assess carcinogenic potential'" and that scientific evidence provides "strongest support" for the descriptor "not likely to be carcinogenic to humans." UMF 18.
- In December 2017, EPA concluded that scientific evidence provides "strongest support" for the descriptor "not likely to be carcinogenic to humans." UMF 19.

[2] *See Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir. 2017); *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010); *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 766, 769-70 (S.D. Ohio 2015), *aff'd*, 680 F. App'x 369, 384-88 (6th Cir. 2017); *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1173-74, 1177 (S.D. Cal. 2016).

- That same month, EPA also published a draft Human Health Risk Assessment in support of the registration review for glyphosate where it concluded that "glyphosate should be classified as 'not likely to be carcinogenic to humans.'" UMF 20.

In February 2018, the Science Advisor of EPA's OPP testified before the House Committee on Science, Space, and Technology that "[b]ased on the comprehensive analysis of all available data and reviews, the EPA concludes that glyphosate is 'not likely to be carcinogenic to humans.'" UMF 21.

EPA has also approved labels for glyphosate-based herbicides without cancer warnings both before IARC's classification, as well as after learning of IARC's position concerning glyphosate as shown by EPA approval letters issued in October 2016 for Roundup Custom® Herbicide and February 2018 for Roundup QuikPRO®. Plaintiffs' expert Dr. Benbrook even admitted that "[d]espite EPA's awareness and review of the IARC monograph finding that glyphosate-based herbicides are a probable carcinogen, the agency has continued to approve labels that do not include a warning about carcinogenicity." *See* Benbrook *Hardeman* Dep. at 250:4-9; *see gen id.* at 249:24-250:2 (attached as Exhibit 8 to the Declaration of Eugene Brown). Dr. Benbrook further testified that "since 1991 there have been numerous approvals of glyphosate-based formulations," EPA has never required carcinogenicity warnings on those formulations, and "EPA's approval of the product labels on glyphosate-based formulations is consistent with its determination that glyphosate is not likely to be carcinogenic to humans." (*Id.* at 240:23-241:12, 242:7-21; 250:18-22).

Courts have held that a regulatory agency's repeated and consistent conclusion that a particular product does not pose a particular risk constitutes "clear evidence" that the regulatory agency would have rejected a proposed warning related to that risk. *See Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1169 (S.D. Cal. 2016) ("The FDA's repeated conclusion that scientific data did not support warning of pancreatic cancer risk coupled with the FDA's statement that product labeling was adequate amounts to clear evidence that the FDA would have rejected a pancreatic cancer labeling change."); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1276-77 (W.D. Okla. 2011) (the FDA's "repeated conclusions . . . that there was no scientific evidence to

support a causal connection between [selective serotonin reuptake inhibitors] and suicidality in adult patients" constituted "clear evidence that the FDA would have rejected" an expanded warning for suicide).

In short, EPA has repeatedly rejected any finding that would require a cancer warning to be added to Roundup's label. And in light of EPA's repeated consideration of the totality of scientific evidence, there is no basis for arguing that the agency simply overlooked (or remained ignorant of) the risk that a plaintiff claims should have been added to the label. Under the circumstances, there is "clear evidence" that EPA would have rejected a cancer warning had Defendants proposed to add one to the label.

III. Plaintiffs Cannot Prove that Roundup Caused their NHL.

To prevail on any of their claims, Plaintiffs must prove that Roundup was the proximate cause of their NHL through reliable expert testimony. *Trejo v. Johnson & Johnson,* 13 Cal. App. 5th 110, 125 (2017).[3] Plaintiffs must prove to a reasonable medical ***probability*** that the formulation caused their respective NHL subtypes. *Jones v. Ortho Pharm. Corp.*, 163 Cal. App. 3d 396, 403 (1985). Mere possibility alone is insufficient. As stated in Monsanto's concurrently filed *Sargon* motions as to Drs. Nabhan and Weissenberger, Plaintiffs have failed to submit reliable and therefore admissible testimony that their NHL resulted from their exposure to Roundup. Plaintiffs' experts performed a "differential diagnosis" in name only and failed to articulate any sound scientific reason for settling on Roundup, as opposed to the numerous other risk factors or unknown causes, as the cause of Plaintiffs' NHL. With no evidence to support causation, Plaintiffs cannot prevail on any of their claims, and summary judgment must be granted in favor of Monsanto.

[3] "With cancer the question of causation is especially troublesome . . . it is frequently difficult to determine the nature and cause of a particular cancerous growth." *Trejo*, 13 Cal. App. 5th at 125. As a result, "'the unknown and mysterious etiology of cancer' is beyond the experience of laymen and can only be explained through expert testimony. Such testimony, however, can enable a plaintiff's action to go to the jury only if it establishes a reasonably probable causal connection between an act and a present injury." *Id.*

IV. Plaintiffs' Warnings Claims Should Be Dismissed Because the Alleged Cancer Risks Were Not Known or Knowable by the Scientific Community.

For Monsanto to have a duty to warn under California law, Plaintiffs must present competent evidence showing that Roundup's alleged risks of cancer were "known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge" when the product that allegedly harmed the plaintiff was manufactured, distributed, or sold. *See Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483-84 (1999) (quoting CACI 1205 (plaintiff must prove "the [product had risks] that were [known/[or] knowable in light of the [scientific] knowledge that was generally accepted in the scientific community at the time of [manufacture/distribution/sale]")); *accord Brown v. Superior Court*, 44 Cal. 3d 1049, 1069 (Cal. 1988). A failure to provide proof on this element necessitates entry of summary judgment for Monsanto on the strict liability and negligence claims based on failure to warn.

The last potentially relevant "time of distribution" for Plaintiffs would be prior to the onset of their respective NHLs in 2011 and early 2015. At that time—and still today—there was no "known" or "knowable" cancer risk associated with glyphosate because the "generally accepted" and "prevailing best scientific and medical knowledge" confirmed its safety.

Regulatory agencies around the world have evaluated more than a hundred epidemiology, carcinogenicity, and genotoxicity studies and concluded time and time against that glyphosate is not a carcinogen. *See* UMFs 9-22, 28-34. Prior to Plaintiffs' NHL onset, those agencies had uniformly determined that glyphosate is not likely to cause cancer in humans. Indeed, Plaintiffs' own experts admitted in their depositions, taken this year, that there is no general acceptance that Roundup causes DLBCL. Nabhan Dep. 290:25-291:6 (attached as Exhibit 3 to the Declaration of Eugene Brown).

Even after IARC's July 2015 monograph regulators worldwide have reanalyzed glyphosate's safety and come to the same conclusions as before. IARC's assessment prompted EPA's Cancer Assessment Review Committee ("CARC") to begin its own reassessment of glyphosate's safety. UMF 17, 29. Based on its assessment of all available epidemiological data,

11 animal studies, and 54 mutagenicity and genotoxicity studies, CARC concluded that glyphosate should continue to be classified as "not likely to be carcinogenic to humans." UMF 29. EPA has reasserted these findings several more times including in a 2016 EPA Office of Pesticide Program report that looked at substantial amounts of data. UMF 29. And regulatory agencies worldwide have reached the same conclusion. To take just a few of many examples, the European Chemicals Agency concluded in 2017 that "[b]ased on the epidemiological data as well as the data from long-term studies in rats and mice, taking a weight of the evidence approach, no classification for carcinogenicity is warranted." UMF 31. And the New Zealand Environmental Protection Authority, weighing all the available evidence, found: "glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification as a carcinogen or mutagen." UMF 32. No governmental agency in the world has concluded otherwise.

Notably, the WHO—of which IARC is a part—has itself since disagreed with IARC's classification of glyphosate as a probable human carcinogen. In 2016, the Joint Meeting on Pesticides Residues Report concluded "glyphosate in unlikely to pose a carcinogenic risk to humans via exposure from diet." UMF 33. That was not the only time WHO assessed glyphosate: In 1994, the International Programme on Chemical Safety ("IPCS") conducted an Environmental Health Criteria and concluded that "no adverse effects were found" in workers using GBFs, and in 2005, the WHO Guidelines for Drinking-Water Quality concluded in 2005 that "the presence of glyphosate . . . in drinking-water does not represent a hazard to human health." UMF 34.

These regulatory findings are supported by the underlying scientific data. The "best scientific" evidence of a chemical's safety in humans is epidemiological evidence, because it studies actual risk in humans. *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005) ("epidemiology is the best evidence of general causation"); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1198 (11th Cir. 2002) (Epidemiology is "generally considered to be the best evidence of causation in toxic tort actions"); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 532 (W.D. Pa. 2003) ("Epidemiology is the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or a

disease." (internal quotations and citation omitted)). And the epidemiological evidence available prior to 2015 supported the non-carcinogenicity of glyphosate. Most significantly, AHS—the largest, longest, and most comprehensive epidemiological study on the carcinogenic risk to humans of using GBHs—confirmed glyphosate's safety. AHS is a prospective cohort epidemiological study that followed more than 54,000 professional pesticide applicators and continued to track their progress for more than 20 years. UMFs 35-40 It represents the largest population of glyphosate users ever studied and the largest study in which researchers controlled for other pesticide use in order to isolate the effects of glyphosate on the study population. *Id.* When researchers first published results from this population in 2005, they concluded that "[t]here was no association between glyphosate exposure and all cancer incidence or most of the specific cancer subtypes we evaluated, including NHL." *Id.*

Further, there is no new scientific evidence from after the Plaintiffs' harm that changes what was "known or knowable" prior to the onset of their diseases. Plaintiffs emphasize IARC's decision to classify glyphosate as a probable human carcinogen in 2015. But IARC's pronouncement was not a game-changer in any relevant sense. IARC was merely a hazard assessment that reviewed previously available data. And, in any event, subsequent publications have cast doubt on IARC's conclusion.

In short, the evidence does not support that there was a "known or knowable" risk about which Monsanto should have warned that was "generally accepted" given the "generally recognized and prevailing best scientific and medical knowledge."

V. Plaintiffs Have Not Demonstrated a Right to Seek Punitive Damages in this Case.

The foregoing analysis also establishes that Monsanto is entitled to summary judgment on Plaintiffs' request for punitive damages. California law "does not favor punitive damages and they should only be granted with the greatest of caution," *Dyna-Med, Inc. v. Fair Empp't & Hous. Comm'n.*, 43 Cal. 3d 1379, 1392 (1987), and in the "clearest of cases," *Henderson v. Sec. Nat'l. Bank*, 72 Cal. App. 3d 764, 771 (1977). *See also Lackner v. North*, 135 Cal. App. 4th 1188, 1210,

(2006) (Punitive damages are appropriate only when the Defendant's actions are "reprehensible, fraudulent or in blatant violation of law or policy").

Plaintiffs must prove that Monsanto is guilty of "oppression, fraud, or malice" to justify a punitive damages award. Cal. Civ. Code § 3294(a).[4] Malice is "conduct which is *intended* by the defendant to cause injury to the plaintiff or *despicable conduct* which is carried on by the defendant with a *willful and conscious disregard of the rights or safety of others*." Cal. Civ. Code § 3294(c)(1) (emphasis added). Conduct is "despicable" only when it is so "vile, base, contemptible, miserable, wretched or loathsome" that decent ordinary people would despise it. *Mock v. Michigan Millers Mut. Ins. Co.*, 4 Cal. App. 4th 306, 331 (1992). And to prove "conscious disregard" of the rights or safety of others, a plaintiff must prove that there was "actual knowledge" and "in the face of that knowledge, [the defendant] fail[ed] to take steps it knows will reduce or eliminate the risk of harm." *Ehrhardt v. Brunswick, Inc.*, 186 Cal. App. 3d 734, 742 (1986). Further, Plaintiffs must establish these showings by clear and convincing evidence, which requires proof that "leave[s] no substantial doubt [and is] sufficiently strong to command the unhesitating assent of every reasonable mind." *In re Angelia P.*, 623 P.2d 198 (Cal. 1981); *Shade Foods, Inc. v. Innovative Prod. Sales & Mktg., Inc.*, 78 Cal. App. 4th 847, 891 (2000).

In light of the scientific and regulatory evidence, Plaintiffs cannot meet these standards in connection with Monsanto's decision to develop, market, and sell Roundup, or its failure to warn consumers of alleged carcinogenicity. Monsanto's reliance on regulatory safety-consensus and epidemiology that in total showed no causal association was reasonable corporate conduct and nothing close to the "despicable" conduct required to support punitive damages. Such evidence precludes any possible finding that Monsanto "intended" to cause harm to anyone, or that it actually knew of a risk about which it failed to take ameliorative steps.

Additionally, the evidence Plaintiffs have highlighted in other Roundup cases to support primitives is far from sufficient to establish malice. It largely involves conduct by Donna Farmer

[4] While § 3294(a) permits recovery of punitive damages for "fraud," Plaintiffs' complaint does not assert an underlying fraud claim. As a result, Plaintiffs cannot rely on fraud to seek punitive damages. *Gawara v. U.S. Brass Corp.*, 63 Cal. App. 4th 1341 (1998).

(Senior Toxicologist), William Heydens (Product Safety Assessment Strategy Lead), Daniel Goldstein (Medical Sciences and Outreach Lead), and John Acquavella (Senior Fellow, Epidemiology). For example, Plaintiffs have pointed to an email from Dr. Heydens in which he allegedly stated that Monsanto would not perform additional toxicological studies recommended by Dr. James Parry, an independent researcher. But Monsanto *did* complete tests in an accredited laboratory in response to Dr. Parry's recommendations and either submitted them to the EPA or, in some instances, published the results in peer-reviewed journals. UMF 48. And the evidence shows that upon review of those results, Dr. Parry agreed that GBHs were not genotoxic. UMF 49.

Plaintiffs also accused Monsanto of "ghostwriting" a handful of scientific articles, including Williams (2000), Williams (2012), and Kier and Kirkland (2013). But in every case, Monsanto's contributions were either publicly identified or did not rise to the level warranting authorship or recognition. UMF 45-47. The acknowledgements section of Williams (2000) thanks "the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions." UMFs 45. It then names the specific toxicologists who had assisted the authors and gives credit to the company for giving the authors "complete access" to a large volume of valuable data. *Id.* The Williams (2012) publication also acknowledges Monsanto for "funding and for providing its unpublished glyphosate and surfactant toxicity study reports." UMF 46. The same is true for Kier and Kirkland (2013): The acknowledgement section references the contributions of "David Saltmiras (Monsanto Company)" for "his invaluable service in providing coordination with individual companies and the Glyphosate Task Force." UMF 47. Notwithstanding their rhetoric, Plaintiffs cannot point to any instance where Monsanto purposely wrote an article and put someone else's name on it in order to deceive the public as to authorship.

Plaintiffs' claim for punitive damages also fails for a separate reason: they cannot identify any wrongdoing by Monsanto's officers, directors, or managing agents. Under California law, an employer is liable for the actions of an employee only if the employer "authorized or ratified the wrongful conduct" on which the damages claim is based. Additionally, for a corporate defendant,

the employee whose actions are at issue must be "an officer, director, or managing agent of the corporation." Cal. Civ. Code §3294(b). The California Supreme Court has defined "managing agent" under section 3294(b) to be an employee with "broad discretion" that "determines corporate policy." *Egan v. Mutual of Omaha Ins. Co.*, 24 Cal. 3d 809, 822-23 (1979). The *Egan* court specifically determined that to be a "managing agent," an employee must possess "ultimate supervisory and decisional authority regarding the disposition of all claims [like that at issue]." *Id.* at 823. Since *Egan*, the California Supreme Court has further narrowed this standard, holding that plaintiffs can show an employee is a managing agent only by proving he or she "exercised substantial discretionary authority over significant aspects of a corporation's business." *White v. Ultramar, Inc.*, 21 Cal. 4th 563, 572, 577 (1999); *see also Kelly-Zurian v. Wohl Shoe Co.*, 22 Cal. App. 4th 397, 422 (1994) (supervisory employee is not a "managing agent" unless he or she also has authority to establish or change the company's business policies).

Plaintiffs provide no evidence that any of the individuals they identify were "managing agents" of Monsanto, exercising "substantial discretionary authority" over any portion of Monsanto's business. Cal. Civ. Code § 3294; *White*, 21 Cal. 4th at 572, 577. Nor can they. Each employee worked in Monsanto's regulatory or science group. While they contributed to the company through their expertise in their respective scientific disciplines, not one can fairly be characterized as having the authority over business affairs required by the California punitive damages statute to hold Monsanto liable.

Because the scientific and regulatory consensus establishes that Monsanto acted reasonably, and because Plaintiffs have produced no contrary evidence involving any managing agents of Monsanto, the Court should grant summary judgment to Defendants on punitive damages.

CONCLUSION

For the foregoing reasons, Monsanto respectfully requests that the Court grants its motion for summary judgment or, in the alternative, summary adjudication.

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