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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

| | |
|---|---|
| IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION | MDL No. 2741 |
| | Case No. 3:16-md-02741-VC |
| *Hardeman v. Monsanto Co., et al.*, 3:16-cv-0525-VC<br>*Stevick v. Monsanto Co., et al.*, 3:16-cv-2341-VC<br>*Gebeyehou v. Monsanto Co., et al.*, 3:16-cv-5813-VC | **MONSANTO COMPANY'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT RE: TIER 1 PLAINTIFFS ON NON-CAUSATION GROUNDS**<br><br>**Hearing dates: February 4, 6, and 11, 2019**<br>**Time: 9:30AM** |

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

**PLEASE TAKE NOTICE THAT** beginning on February 4, 2018, in Courtroom 4 of the United States District Court, Northern District of California, located at 450 Golden Gate Avenue, San

Francisco, CA 94102, or as ordered by the Court, Defendant Monsanto Company ("Monsanto") will move this Court for an order, pursuant to Federal Rule of Civil Procedure 56(c), entering judgment in its favor and against Tier 1 Plaintiffs Sioum Gebeyehou, Edwin Hardeman, and Elaine and Christopher Stevick (collectively "Plaintiffs") on the grounds that there is no genuine issue as to any material fact as to any claim for relief of Plaintiff's Complaint, and that Defendant is entitled to summary judgment as a matter of law as to each of the claims asserted therein.

DATED: January 3, 2019

Respectfully submitted,

/s/ *Brian L. Stekloff*

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## INTRODUCTION

Monsanto hereby moves for summary judgment in all of the Group 1 cases on the following grounds: (1) express preemption, (2) impossibility preemption, (3) Plaintiffs' failure to establish a cognizable duty to warn claim, and (4) Plaintiffs' failure to establish the right to seek punitive damages. Monsanto also moves for summary judgment in the *Gebeyehou* case because the claims are time-barred.

**Express preemption.** The express preemption clause contained in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b), preempts Plaintiffs' warning-based claims because those claims impose "requirements" that are "in addition to or different from" FIFRA's misbranding requirements for misuse labeling. While Monsanto recognizes that the Court previously ruled on certain preemption arguments, the Court has not addressed the issue raised here: the conflict between California's broad common law requirement that Monsanto warn against risks based on uses (and misuses) that are "reasonably foreseeable," and FIFRA's more narrow requirement to provide warnings against risks based on uses that are "in accordance with widespread and commonly recognized practice."

**Impossibility preemption.** Plaintiffs' warning-based and design-based claims are preempted as a matter of impossibility preemption because U.S. EPA specifically requires pre-approval before Monsanto can either change the formulation or change the "precautionary statements" on the label. Further, there is now "clear evidence" in the record that EPA would have rejected the formulation or label changes Plaintiffs seek. *Wyeth v. Levine*, 555 U.S. 555, 571-72 (2009).

**Failure to warn.** Plaintiffs' warning-based claims cannot proceed because they cannot establish that the alleged cancer risks they allege Monsanto should have warned about were "known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge at the time of manufacture and distribution." *See Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483-84 (1999). Plaintiffs have admitted that IARC's classification of glyphosate as a cancer hazard in 2015 was "the change in the narrative" that gives rise to their

claims. Dec. 5, 2018 CMC at 59:6-10. But each of the Plaintiffs in this case stopped using Roundup *prior to that date*, in either 2013 or 2014. Throughout their period of exposure, it is indisputable that the "prevailing best scientific and medical knowledge" did not support an association between Roundup and cancer: No epidemiological study using adjusted data, and no regulatory body anywhere in the world, suggested such an association. And even if it were legally relevant (which it is not), IARC's 2015 hazard assessment changes nothing about what was "known or knowable" prior to 2014. As this Court has already observed, IARC's analysis does not address the question whether Roundup actually poses a cancer risk in humans. And the overwhelming scientific and regulatory evidence since IARC's classification was released—including the 2018 Agricultural Health Study by the National Cancer Institute and repeated regulatory re-evaluations of glyphosate—confirm its safety.

**Punitive Damages.** The foregoing analysis also confirms that Plaintiffs are not entitled to punitive damages on any of their claims as a matter of California law. To make such a showing, Plaintiffs would have to prove by clear and convincing evidence that Monsanto acted with malice in producing and marketing glyphosate. As explained further below, California law defines malice as "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). Given the scientific and regulatory consensus described above, Plaintiffs cannot meet that demanding standard. In any event, the evidence they have previously cited also fails to justify punitive damages under California law because it involves conduct by employees that were not "managing agents" of Monsanto, and in any event does not come close to meeting their burden of proof.

**Statute of Limitations in *Gebeyehou*:** Plaintiff Gebeyehou's claims are barred by the two-year statute of limitations in California Civil Procedure Code section 335.1. Gebeyehou's unequivocal testimony and documentary evidence establish that he believed that his NHL was caused by his exposure to Roundup no later than September 24, 2014, the date on which he e-mailed his oncologist that he was "95% sure my cancer is caused by Roundup herbicide" and that

"there is no question that there is a direct link between Round Up and Non-Hodgkin's Lymphoma." (*See* Declaration of Brian Stekloff, Ex. 1, Sioum Gebeyehou Deposition Transcript ("Gebeyehou Tr.") at 58:3-59:15 and Ex. 8 thereto). Accordingly, Gebeyehou's causes of action accrued no later than September 24, 2014, were not tolled, and expired on September 25, 2016. His complaint filed on October 7, 2016, is therefore time-barred.

## SUMMARY OF PLAINTIFFS' CLAIMS

Plaintiffs are California residents. (Ex. 2, Gebeyehou Compl. ¶ 8; Hardeman Am. Compl. ¶ 8; Stevick Compl. ¶ 13). Each Plaintiff asserts the same causes of action under California law against Monsanto derived from Roundup's alleged carcinogenicity: Negligence; Strict Liability Design Defect; Strict Liability Failure to Warn; and Breach of Implied and/or Express Warranties.[1] The crux of these claims amount to: (a) Roundup's formulation is defective in design because it can allegedly cause cancer and (b) Roundup's label is defective because it does not warn users about Roundup's alleged carcinogenetic potential.

## SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate when there is "no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material when it could affect the outcome of the case, and a dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Once the moving party has met its burden, the nonmoving party must come forward with evidence to show there is a genuine issue for trial. *In re Korean Ramen Antitrust Litig.*, 281 F. Supp. 3d 892, 899 (N.D. Cal. 2017).

## ARGUMENT

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

FIFRA's express preemption clause 7 U.S.C. § 136a(c) prohibits States from imposing "any requirements for labeling or packaging" that are "in addition to or different from" the

[1] Christopher Stevick also filed a loss of consortium claim, which is derivative of and dependent on Elaine Stevick's claims. *Calatayud v. California*, 18 Cal. 4th 1057, 1060 n.4 (1998).

requirements imposed by FIFRA. 7 U.S.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. 544 U.S. 431, 444 (2005). First, the state requirement must be a requirement *for labeling or packaging*. Second, the state requirement must impose a labeling or packaging requirement that is *in addition to or different from* FIFRA's requirements. Plaintiffs' failure-to-warn claims satisfy both parts of the *Bates* test because California failure to warn law imposes a labeling requirement to warn for potential risks resulting from "misuses" that are "reasonably foreseeable," which is "in addition to or different from" FIFRA's requirement to warn for potential risks resulting from "misuses" that are "widespread and commonly recognized."

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

*Bates* states the term "requirements" in § 136v(b) "reaches beyond positive enactments, such as statutes and regulations," and "embrace[s] common-law duties." *Bates*, 544 U.S. at 443. Specifically, the Court found that common law failure-to-warn claims "qualify as 'requirements for labeling or packaging'" as defined in § 136v(b). *Id.* at 446. Because Plaintiffs' claims for negligence, strict liability failure to warn, and breach of warranties are all premised on allegations that Monsanto failed to warn about the carcinogenic risk associated with exposure to Roundup, these claims allege deficiencies to Roundup's "labeling or packaging" that satisfy the first prong of the *Bates* test. *See Bates*, 544 U.S. 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) (finding claims of breach of implied warranty, strict product liability, and negligence, among others, which were based on an alleged failure to warn, were expressly preempted). Accordingly, express preemption here turns on the second prong of *Bates's* test.

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

A state-law labeling requirement that is "genuinely equivalent" to FIFRA's labeling requirements is not preempted. *Bates*, 544 U.S. at 454. But courts have made clear that "[s]tate and federal requirements are *not* genuinely equivalent if 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) (emphasis). That standard is met here because Plaintiffs' state law claims impose more expansive labeling obligations concerning product use than FIFRA does.

1. FIFRA's Requirements

Under FIFRA, a pesticide will be registered if, among other things, "its labeling and other material required to be submitted comply with" FIFRA's 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) (emphasis added). To satisfy FIFRA's labeling requirements, a pesticide must not be "misbranded." FIFRA provides, in relevant part, that a pesticide is misbranded 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), which is expressly cross-referenced in both subsections (F) and (G) of FIFRA's misbranding provision, 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

Plaintiffs assert both strict liability and negligence warnings claims. The elements of both claims are set forth in the Judicial Council of California Civil Jury Instructions ("CACI"). CACI No. 1205 directs that 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*." (emphasis added); s*ee also Saller v. Crown Cork & Seal Co.*, 187 Cal. App. 4th 1220, 1230 n.7 (2010). The elements of a negligent failure-to-warn claim are set forth in CACI No. 1222, which states that a manufacturer can be liable for failure to warn if it "*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*." *See also Saller*, 187 Cal. App. 4th at 1240 n.13 (quoting CACI No. 1222 and its elements) (emphasis added).

Accordingly, under California law, a manufacturer can be held liable for a failure to warn of *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.

California failure to warn law imposes labeling requirements that are broader than FIFRA's. 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." Reasonable foreseeability encompasses not only presently existing uses that are widespread and common but also potential and hypothetical future uses that may or may not ever occur. *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. 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.

## II. Plaintiffs' Claims Are Preempted Under Impossibility Preemption.

All of Plaintiffs' claims are preempted under impossibility preemption because FIFRA prohibits Monsanto from making the design and label changes that Plaintiffs seek without first obtaining EPA's approval. 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) ("Conflict preemption analysis examines the federal statute as a whole to determine whether a party's compliance with both federal and state requirements is impossible."). "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). Here, it is impossible for Monsanto to independently comply with both the purported state law requirement to change the design and label of Roundup and FIFRA's regulatory scheme that requires EPA prior approval.

### A. A State-Law Claim Is Barred By Impossibility Preemption If It Requires Defendant to Take Actions that Federal Law Prohibits Without the Prior Approval of a Federal Agency.

Since the Supreme Court decided *Bates* in 2005, it has issued three decisions concerning impossibility preemption pertaining to the Federal Drug and Cosmetic Act ("FDCA"). *Wyeth*, 555 U.S. 555 (2009); *Mensing*, 564 U.S. 604; *Bartlett*, 570 U.S. 472. 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 equally to Plaintiffs' claims, which seek changes that require EPA prior approval.

In *Wyeth*, the Court rejected a brand-name drug defendant's argument that plaintiff's warnings claim was preempted because it found that under FDCA regulations the defendant could make the change sought by plaintiff without FDA prior approval. 555 U.S. at 568. *Mensing* similarly involved state law failure-to-warn claims for damages. Unlike in *Wyeth*, the Court ruled these claims were preempted because generic drug manufacturers are prohibited from making label changes that deviate from the brand label without prior government approval. 564 U.S. at 612-13. Accordingly, "if the manufacturers had independently changed their labels to satisfy their state-law duty" without prior FDA approval, "they would have violated federal law." *Id*. 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. 570 U.S. at 480. The Court 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 the specific FDCA disputes in *Wyeth*, *Mensing*, and *Bartlett*.[2] Indeed, those impossibility preemption principles apply to any product subjected to a rigorous federal pre-

[2] No appellate court has yet considered the application of *Wyeth, Mensing*, and *Bartlett* in the FIFRA context. The District Court of Hawaii, apparently 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.").

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 (finding state law unfair practice claims that required design changes to eye drop dispensers to be preempted). Here, impossibility preemption applies because Monsanto "cannot comply with state law without first obtaining the approval of a federal regulatory agency." *Id.*

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

1. Federal Law Requires Monsanto To Obtain EPA Approval Before Adding a Cancer Warning to the Label.

Similar to the FDCA's scheme for amending a medicine's label, there are several ways Monsanto can amend the Roundup label. First, a company can make certain minor modifications to the label on its own without prior EPA approval, either simply notifying EPA of the change, or in some cases not even having to notify EPA. *See* 40 C.F.R. § 152.44(b)(3) (certain label changes can be effectuated "by notification or non-notification" and do not require EPA prior approval); 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."). Second, a company can make more substantial changes to the label by seeking an amendment to its registration application, which requires prior EPA approval. 40 C.F.R. §§ 152.44 & 152.46. The default rule is that amendment of the registration application and prior EPA approval is required 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 through the notification/non-notification process without prior approval. (*See* Ex. 24, EPA Pesticide Registration Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998) ("PRN 98-10"). 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" through notification or non-notification. *See* PRN 98-10, Section II(N)(3) at pg. 8 (emphasis added). Warnings about human health hazards, such as cancer, are required to appear in the "Precautionary Statements" section of the label. *See* 40 C.F.R. § 156.70(a) ("Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading 'Precautionary Statements . . . .'"). Importantly, PRN 98-10 does not list health warnings as label changes that can occur through notification or non-notification. (*See also* Ex. 3, Benbrook *Hardeman* Dep. at 248:8-13 (agreeing that "in order to change the labeling for a registered pesticide, the registrant must submit it to EPA to review and approve"); 249:10-16 (agreeing that a "registrant can't make a unilateral label change except for minor adjustments to the label")).

In light of this regulatory framework, Monsanto cannot amend its Roundup label to add a cancer warning to the "Precautionary Statements" of the label without prior EPA approval. Rather, Monsanto can only amend the Roundup label to add a cancer warning 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 defendants 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. Federal Law Requires Monsanto To Obtain EPA Approval 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 non-notification, notification, or registration amendment criterion as label changes. See 40 C.F.R. §§ 152.44, 152.46; *see also* PRN 98-10. Although EPA in PRN 98-10 permits the registrant to change the source of a product ingredient through a notification, the guidance document does not allow the manufacturer to change the actual active (glyphosate) or inert ingredients (surfactants) through the notification or non-notification procedures, nor is such a change permissible under the language of 40 C.F.R. §§ 152.44, 152.46. PRN 98-10, § III(A), III(B)(1) at pp. 8-9. 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." (*See also* Ex. 3, Benbrook *Hardeman* Dep. at 242:17-21 (agreeing that "[e]very time that Monsanto changes a glyphosate-based formulation, it has to submit an application to EPA to get approval of that new formulation")).

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.

**C. <u>Plaintiffs' Claims Are Additionally Preempted Because There is Clear Evidence EPA Would Have Rejected the Formulation and Label Changes</u>**

Plaintiffs' claims are additionally preempted under impossibility preemption because there is "clear evidence" that EPA would reject any attempt by Monsanto to add a cancer warning to the applicable Roundup label or change its formulation. In *Wyeth*, the Supreme Court rejected the defendant's impossibility preemption argument because FDA regulations allowed the defendant to make unilateral changes to its drug label before receiving FDA approval, *see* 555 U.S. at 568, and defendant also lacked "clear evidence" that the FDA subsequently would have rejected the label change at issue in the lawsuit, *see id*. at 571-72. Courts applying this "clear evidence" standard have 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. *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).

Here, there is clear evidence that EPA would reject any attempt by Monsanto to add a cancer warning to the applicable Roundup label or 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." (Ex. 4, EPA, *Reregistration Eligibility Decision (RED) Glyphosate* at 14 (Sept. 1993)).
- 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." (*Id.* at viii.).
- In 1997, EPA again found that "[d]ata indicate that glyphosate is a group E carcinogen (evidence of noncarcinogenicity for studies in humans . . . )." (Ex. 5, *Glyphosate; Pesticide Tolerances*, 62 Fed. Reg. 17,723, 17,728 (Apr. 11, 1997) (to be codified at 40 C.F.R. pts. 180, 185 and 186)).
- In 2002, in response to a challenge to glyphosate's safety, the EPA found "[n]o evidence of carcinogenicity" of glyphosate. (Ex. 6, *Glyphosate; Pesticide Tolerances*, 67 Fed. Reg. 60,934, 60,935-43 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180)).
- In 2004, the EPA found that "[g]lyphosate has no carcinogenic potential." (Ex. 7, *Glyphosate; Pesticide Tolerance*, 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180)).

- 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." (Ex. 8, *Glyphosate; Pesticide Tolerances*, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180)).
- In 2013, "EPA . . . concluded that glyphosate does not pose a cancer risk to humans." (Ex. 9, *Glyphosate; Pesticide Tolerances*, 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180)).
- 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." (Ex. 10, EPA, Office of Pesticide Programs, *Cancer Assessment Document—Evaluation of the Carcinogenic Potential of Glyphosate* at 77 (Oct. 1, 2015) ("CARC")).
- 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." (Ex. 11, Glyphosate Issue Paper at 137, 141).
- In December 2017, EPA concluded that scientific evidence provides "strongest support" for the descriptor "not likely to be carcinogenic to humans." (Ex. 12, EPA, Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 143-44 (Dec. 12, 2017)).
- 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.'" (Ex. 12, EPA, *Glyphosate—Health Human Risk Assessment* at 3 (Dec. 12, 2017)).

Most recently, 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.'" (Ex. 13, Testimony of Anna B. Lowit, Science Advisor, Office of Pesticide Programs, EPA, Before the H. Comm. on Sci., Space, & Tech. at 7 (Feb. 6, 2018)). 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." (Ex. 3, Benbrook *Hardeman* Dep. at 250:4-9; *see generally id.* at 249:24-250:22). 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).

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' Warnings Claims Should Be Dismissed Because the Alleged Cancer Risks Were Not Known or Knowable by the Scientific Community at the Time of Distribution.

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 at the time of manufacture and distribution." *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). The "known or knowable in light of" language for strict liability "at a minimum encompasses" claims for negligent failure to warn. *Id.* ("[A] reasonable manufacturer would not be charged with knowing more than what would come to light from the prevailing scientific and medical knowledge."). A failure to provide proof on this element necessitates entry of summary judgment for Monsanto on the warnings claims.

The Group 1 Plaintiffs stopped using Roundup in 2013 (Mr. Hardeman) and 2014 (Mr. Gebeyehou and Ms. Stevick), meaning that the last potential "time of distribution" was in 2014. At that time (and, to be clear, up through today), there was no "known" or "knowable" cancer risk associated with glyphosate, because the "prevailing best scientific and medical knowledge" confirmed its safety.

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 2014 supported the non-carcinogenicity of glyphosate. Most significantly, the largest, longest, and most comprehensive epidemiological study on the carcinogenic risk to humans of using GBHs—the Agricultural Health Study ("AHS")—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. (Ex. 14, Andreotti, G. et. al., *Glyphosate Use and Cancer Incididence in the Agricultural Health Study*, 110 J. Nat'l Cancer Inst (2017) ("AHS Study")). 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, Monsanto was not alone in concluding, based on the totality of the evidence, that glyphosate was safe. Regulatory agencies around the world have evaluated studies not just of epidemiology, but also of the potential genotoxicity, mutagenicity, and carcinogenicity of glyphosate. And prior to Plaintiffs' last exposure, those agencies uniformly concluded that glyphosate was safe. EPA addressed the matter time after time, as noted above. And to name just one international example, the European Commission for Health and Consumer Protection found that there was "no evidence of carcinogenicity" in its 2002 review of glyphosate. (Ex. 15).

Further, there is no new scientific evidence from after the Plaintiffs' exposure that changes what was "known or knowable" in 2014. Plaintiffs repeatedly emphasize IARC's decision to classify glyphosate as a probable human carcinogen in 2015. But as this Court has recognized, IARC's assessment was not the same as the one the jury will have to make in this case as a matter of California law—IARC "is a public health assessment, not a civil trial." GC SJ Op. 2. And in any event, IARC's pronouncement was not a game-changer in any relevant sense. In 2018, a further analysis of the broad-ranging epidemiological data from the AHS was published in the prestigious *Journal of the National Cancer Institute* and was supported by the Special Studies Institutional Review Board of the National Cancer Institute. (Ex. 14, AHS Study). For this later publication, the additional time afforded researchers the ability to follow up with study participants and evaluate the health effects of glyphosate at 5, 10, 15, and 20 years. (*Id.*). The results were again conclusive: The researchers "observed *no associations* between glyphosate use and overall cancer risk or with total lymphohematopoietic cancers, including NHL." (*Id.*).

In a similar vein, regulators worldwide have looked at glyphosate's safety again post-IARC and have come to the same conclusions as before. As noted above, IARC's assessment prompted EPA's Cancer Assessment Review Committee ("CARC") to begin its own reassessment of glyphosate's safety. (Ex. 10, CARC at 7). Based on its assessment of all available epidemiological data, 11 animal studies, and 54 mutagenicity and genotoxicity studies, the CARC concluded that glyphosate should continue to be classified as "not likely to be carcinogenic to humans." (*Id.* at 10). EPA has reasserted these findings several more times. 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." (Ex. 16, ECHA at 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." (Ex. 17, New Zealand at 16). 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." (Ex. 18, JMPR at 13). 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." (Ex. 19, International Programme on Chemical Safety ("IPCS"), Enviornmental Health Criteria 159 (1994); Ex. 20 World Health Organization (WHO), *Glyphosate and AMPA in Drinkking-water: Background Document for Development of WHO Guidelines for Drinking-water Quality*, WHO/SDE/WSH/03.04/97 (June 2005)). While these assessments likewise arose in different contexts from a "civil jury trial," they further demonstrate that IARC does not speak authoritatively on glyphosate.

To be sure, the Court has already concluded that there is a jury question in this case as to whether glyphosate can cause cancer at doses to which humans might be exposed. But the relevant question for purposes of this motion is not whether there is some science that could support that point—it is whether there was a "known or knowable" risk about which Monsanto should have warned prior to 2014 given the "generally recognized and prevailing best scientific and medical knowledge." In light of the overwhelming consistency and direction of the scientific evidence, the answer to that question is no.

## IV. 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. Federal courts look to California law on punitive damages when evaluating state law claims. *E.g.*, *Morgan v. Woessner*, 997 F.2d 1244, 1259 (9th

Cir. 1993); *Chronicle Publ'g. Co. v. Legrand*, No. C-88-1897-DLJ, 1992 WL 420808, at *2 (N.D. Cal. Sept. 3, 1992). 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").

The elements of liability for punitive damages bear out this background principle. Plaintiffs must prove that Monsanto is guilty of "oppression, fraud, or malice" to justify a punitive damages award. Cal. Civ. Code § 3294(a) (emphasis added).[3] The California Code defines malice as "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). Despicable conduct, in turn, is conduct that is so "vile, base, contemptible, miserable, wretched or loathsome" that decent ordinary people would look down upon and 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, the 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 above, Plaintiffs cannot meet these standards in connection with Monsanto's decision to develop, market, and sell Roundup. Relying

[3] While § 3294(a) permits recovery of punitive damages for "fraud," plaintiffs' complaints do 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).

on overwhelming epidemiological evidence and consistent regulatory approval of glyphosate is reasonable corporate conduct. In all events, 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.

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 only liable for the actions of an employee 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 only show an employee is a managing agent 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).

The evidence Plaintiffs have highlighted thus far does not meet this standard. It largely involves conduct by Donna Farmer (Senior Toxicologist), William Heydens (Product Safety Assessment Strategy Lead), Daniel Goldstein, (Medical Sciences and Outreach Lead), and John Acquavella (Senior Fellow, Epidemiology). Plaintiffs provide no evidence that any of these individuals 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.

In any event, the limited evidence involving these individuals that Plaintiffs previously cited in support of punitive damages does not establish malice. In the *Johnson* trial, Plaintiffs highlighted 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 in fact, 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. (Ex. 21, Heydens, W. et al., *Genotoxic Potential of Glyphosate Formulations: Mode-of-Action Investigations,* 56 J. Agric. Food Chem. 1517 (2008); Hotz, K., *A Study of the Short-Term Effects of Mon 3050 in Male CD-1 Mice,* Monsanto Study MSL-16949, Monsanto Co. (July 26, 2002) (unpublished study) (on file with Monsanto Co.). And the evidence shows that upon review of those results, Dr. Parry agreed that GBHs were not genotoxic. Plaintiffs also accused Monsanto of "ghostwriting" a handful of scientific articles, including Williams (2000),[4] and Kier and Kirkland (2013).[5] But in every case, Monsanto's contributions were either publicly identified or did not rise to the level warranting authorship or recognition. 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." (Ex. 22). 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 same is true for Kier and Kirkland (2013): The acknowledgement section references the contributions of "David Saltmiras

[4] Ex. 22, Gary Williams, Robert Kroes, and Ian Munro, *Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans,* Regulatory Toxicology and Pharmacology (2000).

[5] Ex. 23, Larry D. Kier and David J. Kirkland, *Review of Genotoxicity Studies of Glyphosate and Glyphosate-based Formulations,* Critical Reviews in Toxicology (2013).

(Monsanto Company)" for "his invaluable service in providing coordination with individual companies and the Glyphosate Task Force." (Ex. 23). 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.

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.

## V. Gebeyehou's Claims Are Time Barred By California's Two-Year Statute of Limitations.

California law is clear that Gebeyehou was required to bring his claims for personal injury within two years of accrual. Cal. Civ. Proc. Code § 335.1; *Henderson v. Pfizer, Inc.*, 285 F. App'x 370, 372 (9th Cir. 2008). California's two-year statute of limitations applies to all claims of personal injury caused by an alleged product defect, regardless of the particular legal theory invoked. *Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085, 1094 (C.D. Cal. 2011) (citing *Soliman v. Philip Morris, Inc.*, 311 F.3d 966, 971 (9th Cir. 2002)).

### A. Statement of Material Facts

Gebeyehou alleges that he began using Roundup on a regular basis in 1988. (Ex. 2, Compl. ¶¶ 7-8, 109-110). He was diagnosed with NHL in or about January 2014. (*Id.* ¶ 111). Sometime in 2014, Gebeyehou started using the product only occasionally until he ceased using Roundup all together in 2016. (Ex. 1, Gebeyehou Tr. 54:7-25). At deposition, Gebeyehou testified he reduced the amount of Roundup he used in 2014 because of "rumor[s] going out all over that Roundup causes cancer," which he saw on the internet after conducting Google searches for terms such as "roundup and cancer." (*Id.* at 54:12-13, 63:4-12). Then later in 2014, he watched a Dr. Oz television show in September regarding an alleged link between Roundup and cancer. (*Id.* at 63:9-12, 55:23-56:1). Plaintiff recalls that the presenters on the Dr. Oz show described the type of exposure to Roundup that allegedly can cause cancer, and that it was "exactly the same way [he] was applying it, having no gloves and wind and by no cover and

everything." (*Id.* at 59:16-24). This show "made [him] sure – certain that they were talking about [him]." (*Id.* at 59:24-60:1).

On September 24, 2014, Plaintiff e-mailed his oncologist, stating:

> BTW, **I am 95% sure that my cancer is caused by Roundup herbicide**. It was all over on Dr OZ about the connection on this week show too. This is just to send you advance material, and will chat with you the specifics on our next meeting.
>
> **There is no question that there is a direct link between Round Up and Non-Hodgkins Lymphoma**. Click on the following link and read the article entitled, **"Roundup Chemical Doubles Your Risk of Lymphoma"**. http://www.rodalenews.com/roundup-lymphoma

(*Id.* at 58:3-59:15 and Ex. 8) (emphasis added).

In addition to the title itself—"Roundup Chemical Doubles Your Risk of Lymphoma" —the article Plaintiff sent his oncologist contained numerous assertions that Roundup was unsafe and was linked to cancer, and specifically NHL. (*Id.* at 65:22-66:3, Ex. 9). The article claimed:

- "A major new review finds this 'safe' weed killer is anything but harmless."
- "There's been a striking increase in the number of non-Hodgkin's lymphoma cases over the past three decades, and a major new scientific review suggests chemical pesticides—particularly glyphosate, the active ingredient in the popular weedkiller Roundup—are playing an important role in fueling cancer."
- "The Roundup-Lymphoma Connection"
- "The International Agency for Research on Cancer researchers found that exposure to glyphosate doubled a person's risk of developing non-Hodgkin's lymphoma."

The article then offered an alternative "[t]o avoid Roundup in your home: Use safer weed-killing products, like Burnout." (*Id.*).

Plaintiff did not file his Complaint until October 7, 2016, more than two years after coming to the view that Roundup had caused his NHL. Plaintiff's contemporaneous communications in 2014 and subsequent sworn testimony demonstrates that he had knowledge of a purported link between his NHL and Roundup as early as September 2014.

**B. The Statute of Limitations Accrued No Later Than September 24, 2014—More Than Two Years Before This Action Was Filed.**

1. Gebeyehou Had Actual Knowledge, or at the Very Least Constructive Knowledge, of Defendant's Purported Wrongdoing by September 24, 2014.

"There is a general, rebuttable presumption that a plaintiff has knowledge of the wrongful causes of an injury." *Pooshs v. Philip Morris, USA, Inc.*, 51 Cal. 4th 788, 795 (2011); *see also Doe v. Roman Catholic Bishop of Sacramento*, 189 Cal. App. 4th 1423, 1434 (2010) (plaintiff "is charged with presumptive knowledge of the injury when it occurred"). "A plaintiff is held to her actual knowledge as well as knowledge that could reasonably be discovered through investigation of sources open to her." *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1109 (1988). "If a person becomes aware of facts which would make a reasonably prudent person suspicious, he or she has a duty to investigate further and is charged with knowledge of matters which would have been revealed by such an investigation." *Mangini v. Aerojet-Gen. Corp.*, 230 Cal. App. 3d 1125, 1150 (1991); *see also Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 808-09 (2005) ("[A] potential plaintiff who suspects that an injury has been wrongfully caused must conduct a reasonable investigation of all potential causes of that injury.").

The Court here does not need to inquire as to what a reasonable person may have done because *Gebeyehou himself* admitted that he was "95% sure that [his] cancer is caused by Roundup herbicide" on September 24, 2014. (Ex. 1, Gebeyehou Dep. Ex. 8). On that same day, he wrote "[t]here is no question that there is a direct link between Round Up and Non-Hodgkins Lymphoma." (*Id.*). Based on this uncontroverted evidence of Gebeyehou's direct knowledge of the alleged cause of his injury, his causes of action expired on September 24, 2016—prior to the filing date of his Complaint on October 7, 2016.

The undisputed evidence also establishes that Gebeyehou had both actual and constructive knowledge of his claims based on the many sources he admittedly saw in September 2014 regarding an alleged link between Roundup and NHL, including:

- Seeing warnings "all over" the internet after running Google searches such as "Roundup and cancer." (Ex. 1, Gebeyehou Tr. 63:4-12).
- After hearing these "rumors," watching a Dr. Oz television show, which Gebeyehou refers to as a "credible" source (*Id.* at 56:15-20), that detailed a purported connection between Roundup exposure and cancer and "[t]he definition of their exposure … was the way [Plaintiff] was applying it." (*Id.* at 60:6-12).

- Finding an article entitled "Roundup Chemical Doubles Your Risk of Lymphoma," which Gebeyehou sent to his oncologist. (*Id.* at 58:3-59:15 and Ex. 8).

Indeed, Gebeyehou actually investigated the cause, concluding that he was "95% sure that [his] cancer is caused by Roundup herbicide" on September 24, 2014. (Ex. 1, Gebeyehou Dep. Ex. 8).

The undisputed evidence thus demonstrates that Gebeyehou actually did suspect that Roundup was the cause of his NHL. *See, e.g.*, *Jolly*, 44 Cal.3d at 929-30 (finding constructive knowledge at the time plaintiff was told she may have been injured by a drug ingested by her mother); *Erickson*, 846 F. Supp. 2d at 1095 (finding constructive knowledge at the time "a reasonable person in Gebeyehou's position may have asked his doctor why removal and replacement [of pacemaker] was necessary after such an unexpectedly short time"); *Norgart v. Upjohn Co.*, 21 Cal. 4th 383, 406 (1999) (finding constructive knowledge at the time plaintiffs suspected daughter's death from prescription drug overdose was caused by some "force or action" of a third party). There are no questions of material fact. Gebeyehou's cause of action accrued at least as early as September 24, 2014.

2. Gebeyehou's Claims Were Not Tolled.

Gebeyehou cannot seek refuge behind his threadbare equitable tolling allegations that he "had no knowledge of the his [*sic*] NHL was caused by the glyphosate in the Roundup he regularly used over the years or was no[t] aware of any fact sufficient to place him on inquiry notice of the glyphosate causing NHL and related medical conditions until just April 2016 when he for the first time read the IACH article which was published on or about October 2015." (Compl. ¶ 114). First, that allegation is demonstrably false, as the discovery record has confirmed. Gebeyehou admits that he (1) reviewed internet sources regarding "roundup and cancer," (2) watched a Dr. Oz television show detailing the connection between Roundup and cancer based on exposure that was "exactly" the same as his, and (3) e-mailed his oncologist that he was 95% certain Roundup caused his NHL and provided a link to an article about Roundup doubling the risk of lymphoma—all more than two years before he filed this lawsuit.

Gebeyehou's only response is to claim that he only read the title of the article he sent to his oncologist and not the substance of the article itself. (*See, e.g.*, Ex. 1, Gebeyehou Tr. 71:9-24). But this implausible and self-serving excuse cannot save his claims from dismissal. Even taking this assertion as true, the title of the article itself, "Roundup Chemical Doubles Your Risk of Lymphoma," is sufficient to give rise to a suspicion of wrongdoing here and trigger Gebeyehou's duty to investigate and at a minimum read the article—particularly in light of the other information he had catalogued and sent to his doctor at that time. Indeed, Gebeyehou admits the title caught his attention as it is the reason he sent the article to his oncologist. (*Id.* at 65:11-20).

Given Gebeyehou's own admissions regarding his knowledge in September 2014, and his inaction thereafter, he cannot meet his burden to establish facts "showing that he was not negligent in failing to make the discovery sooner and that he had no actual or presumptive knowledge of facts sufficient to put him on inquiry." *Hobart v. Hobart Estate Co.*, 26 Cal. 2d 412, 437 (1945). The Court should grant summary judgment in favor of Monsanto.

## CONCLUSION

For the foregoing reasons, Monsanto respectfully requests that the Court grants its motion for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure and dismiss these cases in their entirety with prejudice.

DATED: January 3, 2019

Respectfully submitted,

/s/ Brian L. Stekloff

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 3rd day of January 2019, a copy of the foregoing was filed with the Clerk of the Court through the CM/ECF system which sent notice of the filing to all appearing parties of record.

/s/ Brian L. Stekloff