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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	Case No. 3:16-md-02741-VC MDL No. 2741
This document relates to: *Hardeman v. Monsanto Co., et al.*, 3:16-cv-0525-VC *Stevick v. Monsanto Co., et al.*, 3:16-cv-2341-VC *Gebeyehou v. Monsanto Co., et al.*, 3:16-cv-5813-VC	**PLAINTIFFS' OPPOSITION TO MONSANTO'S (1) MOTION FOR SUMMARY JUDGMENT RE: GROUP 1 PLAINTIFFS ON NON-CAUSATION GROUNDS AND (2) MOTIONS TO EXCLUDE THE EXPERT TESTIMONY OF WILLIAM SAWYER, CHARLES BENBROOK, AND JAMES MILLS**

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INTRODUCTION

Defendant Monsanto Company ("Monsanto") has not established that it is entitled to summary judgment on its arguments applicable to all Group 1 Plaintiffs or its statute of limitations argument in the *Gebeyehou* case.

To begin, federal regulations have not preempted any of the Plaintiffs' claims. With respect to Plaintiffs' warnings claims, "a state-law labeling requirement is not expressly preempted by § 136v(b) if it is equivalent to, and fully consistent with, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) misbranding provisions." *Bates v. Dow AgroSciences, LLC*, 544 U.S. 431, 447 (2005). The test is straight-forward—state law and FIFRA are "equivalent" when a violation of state law would also violate FIFRA's misbranding provisions. *Id.* at 454. Here, the Court already determined that Plaintiffs' claims are equivalent to FIFRA's misbranding provisions. *See Hardeman v. Monsanto Co*., 216 F. Supp. 3d 1037, 1038 (N.D. Cal. 2016). But more importantly, *Bates* instructs that when warnings claims are minimally inconsistent with FIFRA's misbranding prohibition, the solution is not dismissal but rather jury instructions on FIFRA's requirements. *Bates*, 544 U.S. at 454.

Monsanto also challenges all of Plaintiffs' claims under a theory of impossibility preemption. Beyond *Bates'* rejection of every aspect of Monsanto's position, Defendant's argument suffers from a myriad of fatal defects. Most notably, the plain language of FIFRA evinces clear congressional intent to preserve States' broad police powers. *See Bates*, 544 U.S. at 446 ("It is highly unlikely that Congress endeavored to draw a line between the type of indirect pressure caused by a State's power to impose sales and use restrictions and the even more attenuated pressure exerted by common-law suits."); 7 U.S.C. § 136v. As "the purpose of Congress is the ultimate touchstone in every pre-emption case," Monsanto cannot overcome the traditional presumption against preemption under the facts of this case. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quotations omitted). Monsanto relies heavily on preemption cases involving the FDCA to promote its position. In stark contrast to FIFRA, however, the FDCA is a statute that, by express language, displaces the broad police powers. FIFRA, in contrast, expressly reserved those powers to the States. *See* 21 U.S.C. § 301 *et seq.* Accordingly, Monsanto cannot meet its burden and overcome the traditional presumption against preemption. *See Wyeth*, 555 U.S. at 565.

Monsanto fails to meet its obligations on the instant motion. In asserting specific affirmative defenses, Monsanto bears the burden of showing (1) that California law is inconsistent with FIFRA and

(2) that it is impossible for Monsanto to comply with federal and California law. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011). Monsanto does not meet its burden.

Monsanto similarly fails to meet its burden on its other arguments. Plaintiffs' failure to warn claims may proceed because the risks of Roundup® exposure were already known or knowable to the scientific community in the 1980s. By 1999, Monsanto possessed sufficient information about Roundup®'s cancer risks based on a report from Dr. James Parry, a renowned scientist it hired, which indicated risks associated with glyphosate.

Monsanto's argument to bar the assessment of punitive damages must fail as well. Plaintiffs are entitled to punitive damages under California law where, as here, a manufacturer markets a product known to be defective and dangerous to consumers and fails to provide a warning of its risks. Here, Monsanto: (1) continued to market and sell GBFs while failing to warn consumers of a known risk of non-Hodgkin's Lymphoma (NHL); (2) did not conduct studies recommended by its own consultants; (3) did not evaluate its GBF formulations to determine the risks associated with surfactants; (4) elected to continue to market products with a POEA surfactant despite knowledge of safer alternatives; and (5) ghostwrote articles in order to publish positive safety data.

Monsanto raises an unfounded argument that Mr. Gebeyehou's claim is untimely based on purported discovery in 2014—at a time when Mr. Gebeyehou, as a layperson, did not and reasonably could not have discovered that his Roundup® exposure caused his NHL. Mr. Gebeyehou's cause of action arose much later, in March 2016, when he discovered credible facts to support his claims in this litigation. Moreover, the issue of when Mr. Gebeyeheou possessed sufficient facts to know or reasonably be on notice that Roundup® was the cause of his NHL is a question of fact for the jury to decide.

Plaintiffs also oppose Monsanto's motions to exclude the expert testimony of Dr. Charles Benbrook, Mr. James Mills, and Dr. William Sawyer. As discussed below, each individual is well qualified for the area for which they will offer testimony and that testimony will aid and assist the finder of fact at trial. Accordingly, for the detailed reasons below, the Court should deny Monsanto's effort to preclude their testimony and Plaintiffs respectfully request that the Court deny Monsanto's motion for summary judgment in its entirety.

STATEMENT OF FACTS

All Plaintiffs were exposed to Monsanto's Roundup® herbicides prior to developing NHL. *See Ex. 1 Gebeyehou* Dep. at 45:13-16; Ex. 2 *Hardeman* Dep. at 171:4-16; Ex. 3 *Stevick* Dep. at 98:1-19. Roundup®, which combines glyphosate with a surfactant, is designed, marketed and manufactured by Monsanto. ¶¶*Id.* 4. At no point did the labeling, advertising, or marketing for the Roundup® products which Plaintiffs used include a cancer warning or information concerning the risk of NHL. *Id*.

Plaintiffs filed their complaints on February 1, 2016 [Hardeman]; April 29, 2016 [Stevick], and October 7, 2016 [Gebeyehou], respectively, each alleging that exposure to Roundup® substantially contributed to the development and progression of each Plaintiff's NHL.

A. Pesticide Regulation Under FIFRA

Pesticides can be regulated at federal, state, and local levels. *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597 (1991). The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq*. (2012), establishes the federal regulatory component. Under FIFRA, manufacturers register pesticides with the Environmental Protection Agency (EPA) and generally cannot sell their pesticides unless registered. *Id*. § 136a(a). In applying for registration, the manufacturer submits "a complete copy of the labeling of the pesticide." *Id*. § 136a(c)(1)(c); *see also* 40 C.F.R. §152.50(e) (2012). For the most part, FIFRA does not specify the exact language to be used on the labeling; instead, "[t]he registrant must take responsibility for quality control of the product's composition and for adequate labeling describing the product, its hazards and uses." 53 Fed. Reg. 15,952, 15,956 (May 4, 1988).

FIFRA and EPA's regulations establish certain minimum requirements for pesticide labeling, 40 C.F.R. § 156.10(a)(1), but registrants may include non-required information on labels. *Id*. §156.10(a)(2).

EPA will approve the registration of a pesticide if it determines the pesticide's composition warrants claims made for it, its labeling and other materials comply with FIFRA, and it will not generally cause unreasonable adverse effects on the environment when performing its intended function or when used in accordance with widespread and commonly recognized practice. 7 U.S.C. § 136a(c)(5)(A)-(D); *see also* 40 C.F.R. § 152.112.

Both during the registration process and afterwards, the EPA relies on manufacturers to inform it of the product's effects on health. *See* 7 U.S.C 136a(a); 40 C.F.R. § 158.100-158.740. Manufacturers are responsible for drafting labels, requesting the specific classification of the pesticides (for general

use, restricted use, or both), and submitting supporting data. 7 U.S.C. § 136a(c)(1). After registration, if the registrant learns additional factual information about unreasonable adverse health effects, federal law requires the manufacturer to submit that information to the EPA. 7 U.S.C. § 136d(a)(2)(emphasis added).

A manufacturer is responsible for the adequacy of its label at all times. Notwithstanding registration, a pesticide is misbranded if its label contains inadequate directions for use, fails to contain warning statements adequate to protect health and the environment, or is false or misleading in any respect. 7 U.S.C. § 136(q)(1)(A), (F), & (G). Moreover, FIFRA recognizes that, even "when used in accordance with the requirements imposed under this subchapter and as directed by the labeling," a pesticide may "nevertheless cause [] unreasonable adverse effects on the environment," 7 U.S.C. § 136k(b)(3). Although registration is *prima facie* evidence that the pesticide and its labeling comply with FIFRA's registration provisions, FIFRA imposes upon manufacturers a continuing obligation to maintain the safety of registered products. FIFRA expressly provides that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." *Id*. § 136a(f)(1)-(2).

FIFRA anticipates that manufacturers may have to make labeling changes after registration. The onus for deciding whether a labeling change is necessary falls on the registrant, which must draft the revised label and submit it to EPA for review. 40 C.F.R. § 152.44(a). If EPA determines the change will not violate FIFRA, the registration "shall be amended to reflect such change." 7 U.S.C. § 136a(f)(1). Generally, the EPA must approve the application before the manufacturer may sell or distribute the product with amended labeling, 40 C.F.R. § 152.44(a), but certain changes "having no potential to cause unreasonable adverse effects to the environment may be accomplished by notification to the Agency, without requiring that the registrant obtain Agency approval." *Id*. § 152.46(a)(1).

FIFRA also preserves a substantial role for state regulation and specifies that a state "may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited" by FIFRA. 7 U.S.C. § 136v(a). Thus, states may go beyond federal regulation including banning the sale of registered pesticides. FIFRA's only other limitation on states' ability to regulate beyond federal requirements is that "[s]uch State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different

from those required under this Act." 7 U.S.C. § 136v(b). The U.S. Supreme Court has recognized that a state "may ban the sale of a pesticide if it finds, for instance, that one of the pesticide's label-approved uses is unsafe." *Bates v. Dow AgroSciences, LLC*, 544 U.S. 431, 446 (2005).

B. EPA's Review of Glyphosate and Monsanto's Formulations Containing Glyphosate

Glyphosate is a broad-spectrum herbicide that kills annual and perennial weeds. The EPA's Office of Pesticide Programs processed the initial petition and registration application for glyphosate in the 1970's. A majority of the studies submitted for the initial registration of glyphosate were conducted at Industrial Bio-Test Laboratories (IBT) and later found to be invalid. See Ex. 81. Accordingly, Monsanto was required to redo toxicological and carcinogenicity testing on glyphosate.

In 1985, an EPA review of a glyphosate mouse study found that "glyphosate was oncogenic in male mice causing renal tubule adenomas, a rare tumor ...." Ex. 4. During a February 1985 consensus review of the available glyphosate data, a group of EPA scientists classified glyphosate as a "Category C" oncogene: a possible human carcinogen. *Id.* In 1986, a FIFRA Scientific Advisory Panel (SAP) recommended that Monsanto repeat both the mouse and the rat studies to clarify unresolved questions. Monsanto repeated the rat study but did not repeat the mouse study. *Id.* at Ex. 82. The mouse test was not redone, but in 1991, a Carcinogenicity Peer Review Committee reviewed the new rat study and recommended that glyphosate be classified as a Group E chemical: Evidence of Non-Carcinogenicity for Humans. *See* Ex. 83. The Peer Review Committee was divided, with the majority finding that the mouse and rat studies did not demonstrate carcinogenicity. *Id.* The divided Panel cautioned "that designation of an agent in Group E is based on the available evidence at the time of evaluation and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances." *Id.*.

Over the past 40 years, EPA has only reviewed and considered the carcinogenicity of the active ingredient glyphosate. EPA relies on the manufacturer to submit data and has never conducted its own testing on glyphosate or any of Monsanto's formulations using glyphosate. *Id. See Euro-Pro Operating LLC v. Euroflex Ams., No. 08CV6231 (HB),2008 WL 5137060*. EPA has never reviewed whether Monsanto's formulations combining glyphosate with surfactants are carcinogenic in long-term animal studies, and Monsanto has never conducted such tests. *Id. See* Ex. 4.

On March 21, 2015, the International Agency for Research on Cancer (IARC) thoroughly reviewed data relating to glyphosate and concluded that the chemical was a "probable human carcinogen." *See* Ex. 84. In July 2017, the State of California reviewed the IARC classification and similarly concluded that glyphosate is a chemical known to cause cancer.

On September 12, 2016, the EPA's Office of Pesticide Programs published a preliminary issue paper on the carcinogenic potential of glyphosate but did not consider the carcinogenicity of glyphosate-based formulations (GBFs).[1] *See* Ex. 85. The EPA noted that it required additional research to determine whether formulation components, including surfactants, influenced the toxicity of the products. *Id.* at 21. With respect to NHL, the Report found that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data." *Id.* at 22. Nonetheless, EPA ultimately concluded that glyphosate alone was "likely not carcinogenic to humans." *See* Ex. 86.

Prior to the publication of the EPA's issue paper, however, an employee within EPA's Office of Research and Development noted that its scientists would be split on whether glyphosate is carcinogenic with some classifying the herbicide as "likely to be carcinogenic." Ex. 18. Likewise, a FIFRA SAP convened to review the EPA's methodology and report was split with respect to whether glyphosate was a carcinogen with some members concluding that "the weight-of-evidence conclusion based on EPA's 2005 Guidelines naturally leads to suggestive evidence of potential carcinogenic effects." Ex. 87. The SAP further concluded that "the EPA evaluation does not appear to follow the EPA (2005) Cancer Guidelines." *See* Ex. 84.

The EPA still has not issued a final version of its glyphosate review. The terms of its 2005 Guidelines for Carcinogen Risk Assessment dictate the EPA's classification of glyphosate's carcinogenic potential. These terms, however, constitute a non-binding statements of policy that do not establish any substantive rule of law. Ex. 84.

The Roundup® that Plaintiffs used still does not contain any warning or information regarding an association between Roundup® and NHL. *See* Ex. 4.

[1] A revised issue paper was released in December 2017 but did not change the citations made in this motion. *See* U.S. Environmental Protection Agency Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 12-13, 143-44 (Dec. 12, 2017) ("OPP").

3d 1037, 1038 (N.D. Cal. 2016). But more importantly, *Bates* instructs that when warnings claims are minimally inconsistent with FIFRA's misbranding prohibition, the solution is not dismissal but rather jury instructions on FIFRA's requirements. *Bates*, 544 U.S. at 454.

Monsanto also challenges all of Plaintiffs' claims under a flawed theory of impossibility preemption. Aside from the fact that *Bates* implicitly rejected every aspect of Monsanto's position, its argument suffers from a myriad of fatal defects. Most notably, "the purpose of Congress is the ultimate touchstone in every pre-emption case," *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quotations omitted). And here, the plain language of FIFRA evinces clear congressional intent to preserve States' broad police powers. *See Bates*, 544 U.S. at 446; 7 U.S.C. § 136v. But in stark contrast to FIFRA, the FDCA governs the pharmaceutical cases which Monsanto relies upon and the FDCA is a statute that displaces the broad police powers that FIFRA expressly reserved to the States. *See* 21 U.S.C. § 301 *et seq.* Accordingly, Monsanto cannot meet its burden and overcome the traditional presumption against preemption. *See Wyeth*, 555 U.S. at 565.

Monsanto fails to meet its obligations on the instant motion. In asserting specific affirmative defenses, Monsanto bears the burden of showing (1) that California law is inconsistent with FIFRA's and (2) that it is impossible for Monsanto to comply with federal and California law. Monsanto does not meet its burden.

ARGUMENT

A. Monsanto's Express Preemption Argument Does Not Support Summary Judgment.

Plaintiffs' failure to warn claims do not seek to impose requirements in addition to or different from FIFRA. *Hardeman v. Monsanto Co*., 216 F. Supp. 3d 1037, 1038 (N.D. Cal. 2016) (finding that "[t]o the extent Hardeman's failure-to-warn claims attack Roundup's product labeling, they are consistent with FIFRA").[2] But even assuming, *arguendo,* that they did, Monsanto is still not entitled to summary judgment on the basis of express preemption. In *Bates*, the Supreme Court reasoned that the trial court could cure any minimal inconsistencies between parallel warnings claims and FIFRA's misbranding

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

statute in its jury instructions—*not* dismissal under Rule 56. *See Bates*, 544 U.S. at 454 ("If a case proceeds to trial, the court's jury instructions must ensure that nominally equivalent labeling requirements are *genuinely* equivalent.")(emphasis in original); *see also Hardeman,* 216 F. Supp. 3d at 1038 (quoting *Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc.,* 617 F.3d 207, 222 (3d Cir. 2010)) ("*Bates* thus 'established that mere inconsistency between the duty imposed by state law and the content of a manufacturer's labeling approved by the EPA at registration did not necessarily mean that the state law duty was preempted.'"); *Adams v. U.S.,* 449 F. App'x 653, 659 (9th Cir. 2011) ("[t]he instruction need not, however, be 'phrased in the *identical* language as its corresponding FIFRA requirement.'") (citations omitted) (emphasis original).[3]

B. <u>The Supreme Court Rejected Monsanto's Impossibility Preemption Argument</u>

In *Bates*, the majority opinion expressly contemplated that claims parallel to FIFRA's misbranding statute, as well as common-law claims that do not implicate labeling at all, can survive summary judgment and go to the jury. *See Bates* 544 U.S. at 454 ("If a defendant so requests*, a court should instruct the jury* on the relevant FIFRA misbranding standards, as well as any regulations that add content to those standards.") (emphasis added); *see also id.* at 432 ("The proper inquiry calls for an examination of the elements of the common-law duty at issue, not for speculation as to whether a jury verdict will prompt the manufacturer to change its label."). In fact, *Bates* even indicates that a jury verdict *at odds* with EPA findings—the crux of Monsanto's impossibility argument—does not pose a preemption problem. *See Bates*, 544 U.S. at 452 ("While it is true that properly instructed juries might on occasion reach contrary conclusions on a similar issue of misbranding, there is no reason to think such occurrences would be frequent or that they would result in difficulties beyond those regularly experienced by manufacturers of other products that every day bear the risk of conflicting jury verdicts.").

[3] Additionally, the three Plaintiffs and many others in the litigation bring warnings claims that do not concern the Roundup® label at all but instead concern Monsanto's marketing and advertising for its Roundup® branded herbicides. Because these claims do not impose requirements for labeling or packaging at all but instead center upon Monsanto's failures to warn consumer through advertisements and marketing, these claims are not preempted. *See e.g., Hardeman* Am. Compl. ¶101-104; 123-124(a); 124(f); 123(i)-(p); 126-127(h); 173. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013); *In re Incretin-Based Therapies Products Liab. Litig.,* 721 Fed. Appx. 580 (9th Cir. 2017); *Hughes v. Boston Scientific Corp*., 631 F.3d 762, 765 (5th Cir.2011); *Bausch v. Stryker Corp.,* 630 F.3d 546, 549 (7th Cir. 2010); *Coleman v. Medtronic, Inc.,* 167 Cal. Rptr. 3d 300 (Cal. App. Ct. 2014).

Monsanto cannot escape this inconvenient truth by incorrectly claiming that the Court's ruling in *Bates* was limited to express preemption, *see* "Monsanto Company's Notice of Motion and Motion for Summary Judgment Re: Tier 1 Plaintiffs on Non-Causation Grounds, dated Jan. 3, 2019 at 8, fn. 2 (Mot.)—it was not. Both parties in *Bates* addressed impossibility preemption[4] and "the majority opinion indicates that the *Bates* Court rejected impossibility preemption *sub silentio*." *Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270, 1281 (D. Haw. 2015) (citing *Dennis v. Higgins*, 498 U.S. 439 (1991)(noting implicit rejection of argument concerning relief); *Jackson v. Metro. Edison Co*., 419 U.S. 345 (1974)(same); *Ansagay,* 153 F. Supp. 3d at 1281 ("Implied conflict preemption, including impossibility conflict in particular, was indeed before the *Bates* Court," which rejected these arguments). And, as Justice Thomas noted, "[the *Bates*] decision thus comports with this Court's increasing reluctance to expand federal statutes beyond their terms *through doctrines of implied pre-emption*." 544 U.S. at 459 (Thomas concurring in judgment and dissenting in part) (emphasis added). Accordingly, because *Bates* considered and rejected *all* of Monsanto's arguments *sub judice,* save for the "clear evidence" argument, which as discussed below is inapposite, Monsanto's request for summary judgment must be denied.

C. Congress Did Not Intend to Impliedly Preempt Common Law Claims

"[F]ederal preemption is an affirmative defense upon which the defendants bear the burden of proof[.]" *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 251 n.2 (2011) (quoting *Fifth Third Bank ex rel. Trust Officer v. CSX Corp.*, 415 F.3d 741, 745 (7th Cir. 2005)). There are two cornerstones of preemption analysis—Congressional intent and the presumption *against* preemption. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). "In areas of traditional state regulation," such as the regulation of chemical substances, the Court "assume[s] that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'" *Bates v. Dow Agrosciences LLC*, 544 U.S. at 449 (quoting *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 655 (1995)). Indeed, when interpreting federal law, the court has "a duty to accept the reading that disfavors pre-

[4] *See* Brief for Petitioners, *Bates v. Dow AgroSciences, LLC*, 2004 WL 2075750 (U.S.), at 29; Reply Brief for Petitioners, *Bates v. Dow AgroSciences, LLC*, 2004 WL 3017317 (U.S.), at 3, 7; *Amicus Curiae* Brief of the Defense Research Institute in Support of Respondent, 2004 WL 2714007 (U.S.), at 29; Brief for American Chemistry Council as Amicus Curiae in Support of Respondent, 2004 WL 2681683 (U.S.), at 5–6.; *See also Bates v. Dow Agrosciences LLC*, Oyez, https://www.oyez.org/cases/2004/03-388 (last visited Jan 20, 2019).

emption." *Id.* Thus, absent "clear evidence of a conflict," this Court must give force to state law. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 885 (2000).

No court has considered or extended *Wyeth*, *Mensing,* and *Bartlett* in the FIFRA context for good reason—FIFRA's express preemption clause is powerful evidence that Congress did *not* intend to preempt anything other than warning claims that extend beyond FIFRA's misbranding statute. *See Bates*, 544 U.S. at 449; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted."); *Jeffers v. Wal-Mart Stores, Inc.*, 171 F. Supp. 2d 617, 623 (S.D. W.V. 2001) ("The combination of the substantive goals and purpose of FIFRA with its express pre-emption limited to packaging and labeling counsels against finding conflict preemption."); *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 496 (2013) ("Moreover, unlike the federal statute at issue in *Medtronic*, the statute before us contains no general pre-emption clause.") (Breyer dissenting). In fact, Monsanto embraced this position at the outset of this litigation before reversing course in its summary judgment motion. *See Hardeman v. Monsanto Co.*, No. 3:16-cv-005250VC (N.D. Cal. Mar. 22, 2016), ECF No. 30 (Ex. 5) ("*Wyeth* imposed this higher burden for preemption in prescription drug cases precisely because the federal Food, Drug, and Cosmetic act—unlike FIFRA—does not contain an express preemption provision.") (citations omitted). Given that Monsanto has already virtually conceded that FIFRA's express preemption clause forecloses implied preemption, the case against preemption is particularly applicable in the current context.

D. <u>Because Congress Intended to Preserve States' Broad Police Powers Under FIFRA, the Impossibility Analysis Under Prescription Drugs is Inapplicable.</u>

The plain language of FIFRA evinces an unambiguous Congressional intent to preserve states' traditional and broad police powers. *See Bates*, 544 U.S. at 449-450 ("If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly."); 7 U.S.C. § 136v(a) ("A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter."). As explained in *Bates*, FIFRA, by its plain terms, "authorizes a relatively decentralized scheme that preserves a broad role for state regulation. Most significantly, States may ban or restrict the uses of pesticides that EPA has approved, § 136v(a)." *Bates,* 544 U.S. at 450-451. And,

states "may also register, subject to certain restrictions, pesticides for uses beyond those approved by EPA, § 136v(c)." *Id*.

Monsanto's impossibility preemption argument is predicated upon a misplaced assumption that FIFRA and the FDCA are relatively similar statutes. But in stark contrast to FIFRA's decentralized scheme designed to preserve states' police powers—including the express authority to ban the sale of any pesticide outright—the FDCA's regulatory scheme is highly centralized. Through the FDCA, "Congress vested sole authority in the FDA to determine whether a drug may be marketed in interstate commerce." *Gross v. Pfizer, Inc*., 825 F. Supp. 2d 654, 659 (D. Md. 2011) (*citing* 21 U.S.C. § 301 *et seq*.,). Accordingly, the FDCA preempts any state law or tort claim that would prohibit drug manufacturers from selling their FDA-approved products as permitted by FDA. *See, e.g., Zogenix, Inc. v. Patrick*, CIV.A. 14-11689-RWZ, 2014 WL 1454696 at *12 (D. Mass. Apr. 15, 2014) (emergency order banning the ordering, dispensing, and administration of opioid preempted because "if the [State] were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health."); *Gross*, 825 F. Supp. 2d at 659 (requiring a drug manufacturer "to stop production of a drug" "would directly conflict with" FDA's "sole authority ... to determine whether a drug may be marketed in interstate commerce."), *aff'd sub nom., Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014); *c.f.* 7 U.S.C. § 136v. Because FIFRA contemplates that states may ban the sale of pesticides and restrict their uses beyond EPA requirements, it is inconceivable that Congress intended to implicitly preempt state common-law tort suits. Unlike FDCA impossibility preemption, which turns on a manufacturer's inability to comply with federal law in the face of conflicting state requirements, FIFRA expressly contemplates that states can disallow what EPA permits. *See* 7 U.S.C. § 136v.

Nor can Monsanto argue that common-law tort requirements are distinct from the police powers expressly granted to states under § 136v for the purposes of inferring preemptive intent. As the Court explained in *Bates*;

> Under § 136v(a), a state agency may ban the sale of a pesticide if it finds, for instance, that one of the pesticide's label-approved uses is unsafe ... *It is highly unlikely that Congress endeavored to draw a line between the type of indirect pressure caused by a State's power to impose sales and use restrictions and the even more attenuated pressure exerted by common-law suits.*

Bates, 544 U.S. at 446 (emphasis added). This is because immunizing pesticide manufacturers from common law liability is plainly inconsistent with FIFRA. *See id.* at 449-450; 7 U.S.C. § 136j(a)(1)(E); § 136a(f)(1) (a manufacturer may seek approval to amend its label); § 136a(f)(2) (registration not a defense to misbranding); § 136v; 40 C.F.R. §§ 159.184(a), (b) (pesticide manufactures have a duty to report incidents involving a pesticide's toxic effects that may not be adequately reflected in the product's label). Yet, under Monsanto's theory, a manufacturer would have virtually no incentive to correct labeling concerning human health hazards if it could rely on registration to avoid liability. This cannot be right. *See Bates*, 544 U.S. at 450-51 ("...it seems unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability.").

Monsanto, under the instant motion, asks the Court to create a rule that would go even further and bestow blanket immunity upon manufacturers of registered pesticides for not only labeling requirements that parallel FIFRA's misbranding statute, but also *any* common-law requirement promoting product safety. Such a rule would undermine both the goal of FIFRA's regulatory regime and the interests of states in ensuring the safety of their residents. In short, it would be completely antithetical to congressional intent.

E. Even if Impossibility Preemption Applied—Which it Does Not—the Court's Analysis Would Be Guided by *Wyeth* Not *Mensing* or *Bartlett.*

The "clear evidence" standard in *Wyeth*, and not the impossibility analysis in *Mensing* and *Bartlett*, guides the Court's analysis because Monsanto can petition EPA to amend the Roundup® label. *See* 7 U.S.C. § 136a(f)(1).

In *Sikkelee v. Precision Airmotive Corp.*, the Third Circuit undertook an impossibility preemption analysis involving the Federal Aviation Administration (FAA) and held that although some principals of pharmaceutical preemption are applicable to the FAA—a regulatory regime that plainly reserves to the states considerably fewer traditional police powers than does FIFRA—*Wyeth*, and not *Mensing* or *Bartlett*, guides the court's preemption analysis. 907 F.3d 701, 711 (3d Cir. 2018). The Court of Appeals explained that this is because "the defendant generic manufacturers [in *Mensing* and *Bartlett*] were obligated to use the design and labeling of their brand-name counterparts" whereas a defendant manufacturer under the FAA, like Monsanto here, could petition the FAA to change design approvals.

Id. at 713. The Third Circuit applied *Wyeth* even though "[the manufacturer] could not simultaneously comply with federal and state law, where state law would require it to adopt a different design" because there was "no evidence in the record showing that the FAA would not have approved a change." *See id.* at 712-714.

Here, Monsanto's position is analogous to the defendant manufacturers in *Sikelee* and *Wyeth*, not the generic drug manufacturers in *Mensing* and *Bartlett.* FIFRA demands that the manufacturer, and not the EPA, bears primarily responsibility for the content of its label at all times. *See* 7 U.S.C. § 136j(a)(1)(E); § 136a(f)(2); *see also Wyeth*, 555 U.S. at 579 (holding that drug manufacturers, rather than the FDA, are primarily responsible for drug labeling). As no party disputes that Monsanto can petition EPA to implement label and design changes, Monsanto must show sufficient evidence that EPA would have rejected a cancer warning had Monsanto proposed one. *See Wyeth*, 555 U.S. at 571. As discussed below, Monsanto cannot meet its burden.

1. Monsanto Cannot Meet Its Demanding "Clear Evidence" Burden.

Monsanto's burden in proving "clear evidence" is a heavy one. *See Wyeth,* 555 U.S. at 573 (noting that the clear evidence preemption "is a demanding defense."). After previously contending that the "clear evidence" exception to implied preemption is "inapposite" within the FIFRA preemption context, Monsanto now argues the opposite. *See Hardeman v. Monsanto Co*., No. 3:16-cv-005250VC at 6-7 (N.D. Cal. Mar. 22, 2016), ECF No. 30 (Ex. 5) ("Hardeman Preemption Reply."). Monsanto now contends that it must show "[u]nder the circumstances, there is 'clear evidence' that EPA would have rejected a cancer warning had Defendants proposed to add one to the label." Mot. at 14.[5] But Monsanto's problems are multifaceted; first, its product is Roundup® and not glyphosate.[6] Accordingly, it cannot rely on determinations as to a component part to argue that EPA would have nevertheless *rejected* a more stringent label for Roundup®—especially in light of Monsanto's knowledge that glyphosate and

[5] Monsanto's reply in *Hardeman* further supports Plaintiffs' earlier point that FIFRA's express preemption clause creates a strong inference that implied preemption is inapplicable. *See Hardeman v. Monsanto Co*., No. 3:16-cv-005250VC (N.D. Cal. Mar. 22, 2016), ECF No. 30 (Ex. 5) (*"Wyeth* imposed this higher burden for preemption in prescription drug cases precisely because the federal Food, Drug, and Cosmetic act—unlike FIFRA—does not contain an express preemption provision.") (citations omitted).

[6] Even if glyphosate were the subject of the Court's inquiry, Monsanto would still be unable to meet its burden. The Court, however, need not address how EPA would respond to more stringent warning requests for glyphosate alone because that is not at issue.

Roundup® have distinct carcinogenicity risks. Second, Monsanto did not propose a more stringent label or warning. Rather, it expended considerable effort to avoid more stringent labeling requirements. Third, neither Monsanto nor any other company has ever informed the EPA of the risks that GBFs present. Fourth, EPA determinations do not carry the force of law. Under these circumstances, Monsanto cannot show EPA would have rejected its request for a cancer warning and judgment on its "clear evidence" theory must be denied.

2. Glyphosate and Roundup® Are Not the Same Thing.

The Court must consider the manufacturer's knowledge of the risk to determine "clear evidence." *Wyeth,* at 569-70. In *Wyeth*, the Court considered the manufacturer's knowledge and information concerning risks, including incident reports and "accumulating data" received by the company and the company's communication with the FDA. The Court reasoned that because "manufacturers have superior access to information" about their products, "especially in the post marketing phase as new risks emerge" manufacturers "bear primary responsibility for their [product] labeling at all times." *Id.* at 578-79. The same is true with FIFRA, which imposes a "continuing obligation to adhere to FIFRA's labeling requirements." *Bates*, 544 U.S. at 438-439.

Monsanto's detailed knowledge is fatal to its "clear evidence" argument because Monsanto knew that Roundup® is more dangerous than glyphosate alone. In fact, Monsanto was aware "[t]he terms glyphosate and Roundup cannot be used interchangeably" and the distinction between the two was so significant that "you cannot say that Roundup does not cause cancer." Ex. 6 MONGLY00922458. Monsanto toxicologist and oft spokeswoman Donna Farmer explained: "[Monsanto] [has] not done the necessary testing on the formulation to make that statement. The testing on formulations are not anywhere near the level of the active ingredient." *Id.* Moreover, the evidence—especially when viewed in a light most favorable to Plaintiffs—suggests that *if* Monsanto had tested its formulations, the results would have supported a cancer warning. *See* Ex. 7 MONGLY00923065 ("[w]e have to really think about doing [tests of] formulations even if they are not on the market....glyphosate is still in there and could get caught up in some false positive finding."). Nothing in *Wyeth* or its progeny stands for the proposition that a manufacturer can shield itself with a "clear evidence" defense when it knows the data considered by a regulatory body is insufficient to determine the safety of its formulated products.

FIFRA imposes an affirmative duty on manufacturers to conduct and submit to EPA the necessary data to prove that the benefits of a pesticide outweigh any risks. *See* 7 U.S.C. § 136(bb). And although "[t]he production of data to support a pesticide registration is controlled by the registrant," it is often withheld from the public "as a trade secret." *Burke v. Dow Chem. Co.*, 797 F. Supp. 1128, 1134 (E.D.N.Y. 1992) (*quoting* Tybe A. Brett & Jane E.R. Potter, *Risks to Human Health Associated with Exposure to Pesticides at the Time of Application and the Role of the Courts*, 1 Vill.Envtl.L.J. 355, 363 (1990)). Because of this information imbalance, the burden to ensure the adequacy of the label *always* rests on Monsanto. *See Bates,* 544 U.S. at 438-439 ("[M]anufacturers have a continuing obligation to adhere to FIFRA's labeling requirements."). Therefore, unless manufacturers alert it to the dangers or the need for special restrictions in the use of the product, "it is unlikely that EPA will assume the burden of deciding whether a product should not be sold to the public." *Burke*, 797 F. Supp. at 1135. Under these circumstances, Monsanto's determination to remain willfully ignorant of Roundup®'s cancer risk is irreconcilable with its claim that EPA would have rejected a proposed cancer warning.

Monsanto cannot meet its burden and demonstrate that EPA would have rejected a cancer warning for Roundup® based on EPA's assessments of glyphosate alone because there is no evidence that EPA views glyphosate and GBFs as analogous.[7] Rather, there is considerable evidence EPA views GBFs and glyphosate as distinct. For example, the 2017 EPA OPP report, which Monsanto cites for the proposition that glyphosate is "not likely to be carcinogenic to humans," expressly and repeatedly states that the focus of its review, was limited to glyphosate alone—not GBFs. *See* OPP at 144 ("This evaluation focused on studies on the active ingredient glyphosate; however, additional research could also be performed to determine whether formulation components, such as surfactants, influence the toxicity of glyphosate formulations."); *see also id.* at 70 ("[g]lyphosate formulations contain various components other than glyphosate and it has been hypothesized these components are more toxic than glyphosate alone."). Because EPA acknowledges that GBFs may be more toxic than glyphosate alone, EPA's glyphosate determinations do not provide "clear evidence" that EPA would have rejected a Monsanto proposed

[7] Plaintiffs have alleged since the outset of this litigation that there are material distinctions in the safety profiles of Roundup® and glyphosate. *See Hardeman* Compl. at ¶ 48 ("...glyphosate formulations found in Defendants' Roundup products are more dangerous and toxic than glyphosate alone."); ¶ 62 ("Despite their knowledge that Roundup was considerably more dangerous than glyphosate alone, Defendants continued to promote Roundup as safe.")

cancer warning.

3. Monsanto Never Proposed Adding a Cancer Warning.

Monsanto never attempted to provide a more stringent warning, much less a cancer warning.[8] In fact, Monsanto does not contend that *anyone* proposed a cancer warning at all. The fact that the EPA may not be affirmatively convinced of a causal link between GBFs and NHL does not preclude Monsanto from adding the warning on its own. *See In re Testosterone Replacement Therapy Prod. Liab. Litig*., No. 14 C 1748, 2017 WL 1836435 at *9 (N.D. Ill. May 8, 2017). In drawing all reasonable inferences in favor of Plaintiffs, the Court cannot conclude as a matter of law that the EPA would have rejected a labeling change for NHL without evidence that a warning was ever submitted to or considered by the agency. *See In re Fosamax (Alendronate Sodium) Prod. Liab. Litig*., 852 F.3d 268, 298-299 (3d Cir. 2017). It is certainly reasonable to conclude that the EPA would have accepted a warning in the name of consumer safety even if there was "inherent uncertainty" regarding whether GBFs definitively cause NHL. *In re Fosamax*, 852 F.3d at 299. In both *In re Testosterone* and *In re Fosamax*, preemption was not appropriate where the FDA recognized the possibility of a link between the drug and the side effect even though it ultimately concluded that the available literature did not support an association. *See In re Fosamax*, 852 F.3d at 298; *In re Testosterone*, 2017 WL 1836435 at *9. Accordingly, because the salient question is whether the "EPA would have *rejected* a cancer warning" had Monsanto proposed one, Monsanto has not come close to meeting its burden. Mot. at 14.[9]

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[8] Monsanto relies on case law in support of its clear evidence argument that directly undercuts its argument. *See* Mot. at 12. In every case Monsanto cites, save *Seufert*, a party (typically the manufacturer itself) proposed a more stringent label that the FDA rejected. *See Cerveny v. Aventis, Inc*., 855 F.3d 1091, 1105 (10th Cir. 2017) ("We conclude that the rejection of a citizen petition may constitute clear evidence that the FDA would have rejected a manufacturer-initiated change to a drug label."); *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010) ("The 'clear evidence' in this case is the agency's refusal to require a reference to SJS/TEN on the label of over-the-counter drugs containing ibuprofen, when it had been asked to do so in the submission to which the agency was responding."); *Rheinfrank v. Abbott Labs., Inc*., 119 F. Supp. 3d 749 (S.D. Ohio 2015), *aff'd*, 680 Fed. Appx. 369 (6th Cir. 2017) (same); *But see Reckis v. Johnson & Johnson*, 28 N.E.3d 445 (Mass. 2015) ("The court in *Wyeth* specifically suggested that 'clear evidence' could be established by the FDA's rejection of a drug maker's attempt to give the warning underlying a claim of failure to warn .... That is not to say that the *Wyeth* standard of clear evidence can be satisfied only by the FDA's rejection of a manufacturer's request for an additional warning.").

[9] Additionally, FIFRA expressly contemplates that label approval does *not* foreclose private actions to enforce FIFRA's misbranding prohibition. *See* 7 U.S.C. § 136a(f)(2).

4. Monsanto Never Fully Informed EPA of Roundup®'s NHL Risk.

Additionally, Monsanto cannot meet its clear evidence burden because it has never fully apprised EPA of Roundup®'s cancer risk. Indeed, considerable evidence demonstrates that Monsanto withheld critical information from EPA over the years. For example, after Monsanto hired renowned scientist Dr. James Parry in the 1990's to combat new studies showing GBFs were genotoxic and induced oxidative stress, Dr. Parry's draft report concluded "glyphosate is a potential clastogenic *in vitro*" and the "clastogenic activity may be reproduced *in vivo* in somatic cells." Ex. 8 at 12. Dr. Parry recommended that Monsanto conduct several tests to determine glyphosate's safety, which Monsanto never conducted. Ex. 9 at 116:8-119:24. Monsanto, critically, did not provide the Parry report to EPA, as 40 C.F.R § 159.158 required. *See also Am. Crop Prot. Ass'n v. U.S. E.P.A.*, 182 F. Supp. 2d 89 (D.D.C. 2002). In another example known to the Court, Monsanto employee Dr. William Heydens admitted to ghostwriting and making final edits to an article by Gary Williams. *See* Ex. 10. Monsanto noted in December 2010, that Williams (2000) was "an invaluable asset" for its "responses to agencies; Scientific Affairs rebuttals; and Regulator reviews." Ex. 11 at 12, 16.

The EPA OPP's reliance on ghostwritten papers, seemingly unaware of Monsanto's role in the publications, further impacts Monsanto's failure to inform the agency. For example, the EPA noted that "[t]he CARC evaluated a total of 54 mutagenicity/genotoxicity studies which included studies submitted to the agency, as well as studies reported in the two review articles (Williams et al., 2000, and Kier and Kirkland, 2013)." *See* Office of Pesticide Programs, *Cancer Assessment Document—Evaluation of the Carcinogenic Potential of Glyphosate* at 9 (Oct. 1, 2015) (Monsanto's Exhibit 10). This uncertainty about whether the EPA was aware of Monsanto's role in these publications and whether knowledge of Monsanto's role could have altered EPA's conclusions establishes a disputed issue of material fact that requires denial of summary judgment. *See In re Incretin-Based Therapies Products Liab. Litig.*, 721 Fed. Appx. 580, 584 (9th Cir. 2017) ("Uncertainty about whether the FDA considered the 'new safety information' and whether it would have altered the FDA's conclusion establishes that a disputed issue of material fact should have prevented entry of summary judgment on the defendants' preemption claim.").

5. EPA Registration Does Not Carry the Force of Law.

Monsanto's reliance upon EPA registrations and determinations is likewise unavailing because (1) registration of a pesticide is not a defense to a misbranding claim and (2) "there's no indication that

the EPA's approval of Roundup®'s label had the force of law." *Hardeman*, 216 F. Supp. 3d at 1038-1039. FIFRA expressly contemplates that federal courts and juries, rather than EPA, will have the final say in resolving misbranding claims. 7 U.S.C. § 136n ("The district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this subchapter."); *Hardeman,* 216 F. Supp. 3d at 1039 ("And *Bates* tells us that the EPA's authority to enforce FIFRA—unlike the EPA's authority to approve all pesticide labeling—isn't exclusive."); *Compare Wyeth*, 555 U.S. at 570 (citing 21 U.S.C. §§ 331, 332, 334(a)-(b)) ("Moreover, because the statute contemplates that federal juries will resolve most misbranding claims, the FDA's belief that a drug is misbranded is not conclusive."). This is why, when the EPA brings an enforcement action for misbranding, the EPA's determination of misbranding is not dispositive—ultimately, a jury must decide the question. To hold otherwise would effectively render Section 136a(f) meaningless. It would be legally incoherent for Congress to state that EPA registration is not a defense to misbranding if EPA registration meant the herbicide was, as a matter of law, not misbranded.

6. <u>It Would Not Be Impossible For Monsanto to Warn About the Risk of NHL with Roundup®.</u>

The Office of Pesticide Programs would and currently allows warnings about the risk of NHL associated with glyphosate to be issued to the public. The National Pesticide Information Center (NPIC) is the organization EPA charged with responding to inquiries about the risks of pesticides. The "NPIC is a cooperative agreement between Oregon State University and the U.S. Environmental Protection Agency" that "provides objective, science-based information about pesticides and pesticide-related topics to enable people to make informed decisions about pesticides and their use."[10] The EPA website directs users to the NPIC to find out about the risks of pesticides.[11] Currently, the NPIC advises consumers of the following in a fact sheet available on its website:

> Is glyphosate likely to contribute to the development of cancer?
>
> When high doses were administered to laboratory animals, some studies suggest that glyphosate has carcinogenic potential. Studies on cancer rates in people have provided

[10] Ex. 12, About the NPIC, NPIC website, http://npic.orst.edu/about.html; https://www.epa.gov/safepestcontrol/pesticides-must-be-registered-epa

[11] Ex. 13, EPA website, Information on Health Risks of Pesticides, https://www.epa.gov/safepestcontrol/pesticides-must-be-registered-epa

> conflicting results on whether the use of glyphosate containing products is associated with cancer. **Some studies have associated glyphosate use with non-Hodgkin lymphoma**.[12]

In its guidance to pesticide manufacturers, the EPA allows the manufacturers to direct consumers to the NPIC to obtain information about the health effects of glyphosate.[13] Therefore, not only could Monsanto inform plaintiffs and the public that glyphosate is associated with NHL via the NPIC, the EPA encourages them to do just that.[14]

The IARC working group that evaluated glyphosate included two scientists from the EPA, Peter P. Egeghy and Matthew Martin.[15] The Office of Research and Development Branch of the EPA also reviewed the evidence related to glyphosate and concluded "Bottom line: Based on glyphosate discussions to date among ORD scientists–where we have not formally discussed a classification–I believe we would be split between 'likely to be carcinogenic' and 'suggestive evidence.'"[16] In the present context, where many EPA scientists believe glyphosate is carcinogenic and where the EPA itself warns consumers and physicians that glyphosate is associated with NHL, there is simply no basis to conclude that the EPA would prevent Monsanto from warning that Roundup® is associated with NHL.

Under the facts before the Court, Monsanto's preemption defense fails in all respects. Plaintiffs, accordingly, request that the Court deny Monsanto's motion for summary judgment.

F. Plaintiffs' Warning Claims Survive Summary Judgment Because There is Ample Evidence that Cancer Risks from Roundup® were known or knowable by the Scientific Community at the time of Distribution.

The Court may swiftly reject Monsanto's argument that Roundup®'s cancer risk was not known or knowable. Defendant has predicated its argument on cherry-picked studies and an intentional

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[12] Ex. 14, Glyphosate General Fact Sheet, NPIC website, http://npic.orst.edu/factsheets/glyphogen.html.
[13] Ex. 15, EPA Label Review Manual, Chapter 15: Company Name and Address, 15-3.
[14] Ex. 16, Additionally, in collaboration between the EPA and the Medical University of South Carolina, physicians are also warned of the association between glyphosate and NHL. This publication by the EPA, "Recognition and Management of Pesticide Poisonings," was created "to provide healthcare professionals with current consensus recommendations for treating patients with pesticide-related illnesses or injuries."[14]." In the chapter on chronic diseases, the EPA identifies glyphosate as one of the pesticides that has a "demonstrated risk" of NHL. *Id.* at 222.
[15] Ex. 17, IARC Monograph 112 List of Participants.
[16] Ex. 18, December 7, 2015 email from Vince Cogliano of EPA to Norm Birchfield, EPAHQ_0000204, 208.

distortion of the record in an attempt to misdirect the Court. The relevant test is not whether the scientific evidence uniformly establishes that a cancer risk is known; rather, the standard is whether the potential risk of cancer was "known or *knowable* in light of the generally recognized and prevailing best scientific and medical knowledge at the time of manufacturer and distribution." *Valentine v. Baxter,* 68 Cal. App. 4th 1467, 1483-84 (1999) (emphasis added); *see also* CACI 1205.

Roundup®'s cancer risk was first knowable in the 1980s. EPA initially determined that glyphosate was apossible carcinogen on March 4, 1985.[17] Prior to that in 1982, an EPA review of a glyphosate rat study found a statistically significant increase in lymphocytic hyperplasia and interstitial testicular tumors.[18] By 1999, Monsanto possessed a report from Dr. James Parry indicating potential risks associated with glyphosate. Although epidemiological studies are not a prerequisite to showing that Roundup®'s cancer risk was knowable, the epidemiology showed a cancer risk by 2001, in the McDuffie study.[19] However, in De Roos (2003), the last data collected was in June 1986, demonstrating that Monsanto could have collected a valid epidemiological study in the 1980s. In short, the general causation evidence, with which the Court is already intimately familiar, evinces real risk long before 2013—especially when viewed in a light most favorable to Plaintiffs. *See* Mot. at 14.

G. Punitive Damages are Appropriate Where, As Here, a Manufacturer Failed to Warn or Take Corrective Action Despite Knowledge of a Danger or Serious Injury.[20]

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

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[17] *See* EPA, Office of Pesticide and Toxic Substances, Memo "Consensus Review of Glyphosate," dated Mar. 4, 1985. *Available at:* https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-171.pdf

[18] *See* EPA, Office of Pesticide and Toxic Substances, "Summary of the IBT Review Program Office of Pesticide Programs (July 1983) February 18, 1982 EPA memo re: Lifetime feeding study in rats with glyphosate, *available at* http://www.centerforfoodsafety.org/files/epa-1983_41310.pdf.

[19] *See* Helen H. McDuffie et al., *Non-Hodgkin's Lymphoma and Specific Pesticide Exposures in Men: Cross-Canada Study of Pesticides and Health*, 10 Cancer Epidemiology, Biomarkers & Prevention 1155 (2001).

[20] Remarkably, Monsanto never met to discuss placing a warning re carcinogenicity on labels or press releases before IARC's decision in March 2015. Since then, Monsanto has met 23 times to discuss the topic, yet no warnings have been issued to this day. *See* Monsanto Supplemental Responses to Interrogatory No. 15. Ex. 19.

dangerous consequences of his or her conduct and he or she willfully fails to avoid such consequences. Malice may be proved either expressly through direct evidence or by implication through indirect evidence from which the jury draws inferences." *Pfeifer v. John Crane, Inc.,* 164 Cal. Rptr.3d 112, 135 (Cal. Ct. App. 2013) (quoting *Angie M. v. Superior Court,* 44 Cal. Rptr.2d 197, Cal. Ct. App. 1995).

California law is clear that "the underlying facts supporting a punitive damages award are for the jury to decide." *Romo v. Ford Motor Co.,* 6 Cal. Rptr.3d 793, 805 (Cal. Ct. App. 2003)113 Cal.App.4th 738, 754 (2003); *Johnson & Johnson v. Superior Ct.,* 121 Cal. Rptr.3d 640, 642 (Cal. Ct. App. 2016) 192 Cal.App.4th 757, 760–61 (2011) (triable issue of material fact existed as to whether petitioners' failure to provide adequate warnings on over the counter medication of risk of rare and skin condition constituted malice so as to justify punitive damages, and rejecting argument that defendant "has at all times marketed and sold Motrin with a label approved by the [FDA] and consistent with the FDA's standards for OTC medications.").

California law has long endorsed the use of punitive damages to deter continuation of a corporation's wrongful conduct. *See Johnson v. Ford Motor Co.* (2005) 113 P.3d 82, 92-93 (Cal. 2005); *Scott v. Ford Motor Co.,* 169 Cal. Rptr.3d 823, 831-32 (Cal. Ct. App. 2014). Under Civil Code section 3294, punitive damages "may be assessed in unintentional tort actions." *Potter v. Firestone Tire & Rubber Co.,* 863 P.3d 795 (Cal. 1993)(citing *Grimshaw v. Ford Motor Co.,* 174 Cal. Rptr. 348 (Cal. Ct. App. 1981). "Marketing a product that is known to be defective and dangerous to consumers supports an inference of malice for purposes of punitive damages." *Karlsson v. Ford Motor Co.,* 45 Cal. Rptr.3d 265, 288 (Cal. Ct. App. 2006). Likewise, a manufacturer's failure to warn of the dangers associated with its products may be "sufficient to show malice so as to support punitive damages." *Johnson & Johnson v. Superior Court,* 121 Cal. Rptr.3d at 648.

California case law contains multiple cases where the court affirmed punitive damages awards when manufacturers acted in conscious disregard for the safety of consumers by failing to warn despite knowing of the risk caused by their products. Even where the risk of harm is relatively slight, and grave injury may only occur to a small fraction of consumers, punitive damages may nevertheless be warranted due to the gravity of the potential harm resulting from a widely used product. *See, e.g.*, *Boeken v. Philip Morris Inc.,* 6 Cal. Rptr.3d 638, 676-77 (Cal. Ct. App. 2005). Nor do punitive damage awards require

absolute certainly; "intentionally marketing a defective product knowing that it *might* cause injury and death is 'highly reprehensible.'" *Id.* (emphasis added; internal quotation marks and citation omitted).

Furthermore, courts have long recognized that punitive damages are warranted when circumstantial evidence supports an inference that a manufacturer put its own interests ahead of its consumers. *See Grimshaw*, 174 Cal. Rptr. at 385 ("While much of the evidence was necessarily circumstantial, there was substantial evidence from which the jury could reasonably find corporate malice where the company proceeded with production of a product with knowledge of negative test results"); *West v. Johnson & Johnson Products, Inc*., 174 Cal.App.3d 831, 869 (1985) (affirming award of punitive damages where evidence showed that adequate testing would have revealed an association between tampon use and toxic shock, that the manufacturer's testing was inadequate, and that the manufacturer decided not to do any further testing even when faced with consumer complaints).

Regulatory approval does not immunize Monsanto. Rather, "the existence of governmental safety regulations does not bar an award of punitive damages for egregious misconduct that they are ineffective in preventing." *Pfeifer v. John Crane, Inc*., 220 Cal. App. 4th 1270, 1301, *as modified on denial of reh'g* (Nov. 27, 2013). In fact, punitive damages are utilized in California "precisely because '[g]overnmental safety standards and the criminal law have failed to provide adequate consumer protection against the manufacture and distribution of defective products." *Buell–Wilson v. Ford Motor Co*., 141 Cal.App.4th 525, 562 (2006), vacated on other grounds in *Ford Motor Co. v. Buell–Wilson*, 550 U.S. 931, 127 S.Ct. 2250 (2007)[21] (citing *Grimshaw*, 119 Cal.App.3d at 810). Punitive damages are appropriate even where "there was a 'reasonable disagreement' among experts" because "[t]he jury is "entitled to" reject the claims of Defendant's experts in reaching a verdict on punitive damages. *Id.* at 559-560.

Nor can the testimony of its employees that they did not believe the results of studies showing that GBFs were genotoxic or carcinogenic absolve Monsanto of responsibility. Monsanto has a duty to "warn of the potential risks" of GBFs and not just the ones its scientists agree with. *See* CACI 1205. "If the sole opinion(s) of one biased actor within that complex system can govern and control the nature, timing, and dissemination of information, and warnings, the system breaks down." *In re Actos*

[21] Although this opinion was vacated with respect to constitutional limits of punitive damage awards, the California Supreme Court continues to cite this case with respect to the availability of punitive damage awards. *Boeken v. Philip Morris USA, Inc*. (2010) 48 Cal. 4th 788, 796.

(Pioglitazone) Products Liab. Litig., 6:11-MD-2299, 2014 WL 5461859, at *47 (W.D. La. Oct. 27, 2014) (rejecting argument that subjective belief of Defendant preclude punitive damages).

1. Monsanto Acted With a Conscious Disregard for Human Life.

The California State trial court found the evidence outlined below to be sufficient in the *Johnson* case both at the summary judgment phase, Ex. 20, and post verdict, Ex. 21, to support punitive damages. Plaintiffs plan to submit this and much more evidence, but cannot summarize the entirety of the evidence due to page constraints.

Plaintiffs intend to offer evidence demonstrating that Monsanto: (1) continued to market and sell GBFs while failing to warn consumers of a known risk of NHL; (2) did not conduct studies recommended by its own consultants; (3) did not evaluate its GBF formulations to determine the risks associated with surfactants; (4) elected to continue to market products with a POEA surfactant despite knowledge of safer alternatives; and (5) ghostwrote articles in order to publish positive safety data. This evidence is sufficient to permit a jury to decide the punitive damages issue.

2. Monsanto's Scientists Prioritized Profits Over Safety.

Monsanto prioritized money over human safety. On March 13, 1985, nine days after the EPA proposed to classify glyphosate as a Class C [possible] oncogene, Monsanto's concern was not about safety, but rather that "the initiation of formal regulatory action would have serious negative economic repercussions." Johnson trial transcript (hereinafter "JT") Tr. at 3851:20-22, 3996:11-13, Ex. 22. EPA eventually reversed that decision after pressure from Monsanto. For example, Monsanto's "Product Safety Center" headed by Donna Farmer was aimed, not at product safety, but at "influencing the scientific literature to prevent [Monsanto's] internal concerns from reaching the public sphere and to bolster its defenses in products liability actions." Johnson Sargon Order at 45-46. Ex. 20. Johnson trial Ex. 23. Rather than safety, the first priority of Monsanto's Product Safety Center was to "Secure the Base," "Defend and maintain the global glyphosate businesses" and "Create Future Growth: Pipeline, Regulatory Approval, Commercial Launch, and Market Expansion." Id. at 2. And as Dr. Kirk Azevedo (a former employee of Monsanto) testified, Monsanto's Vice President told him "we're about making money. So get it straight." JT 1451:20-23. Ex. 22.

The evidence further establishes that, as far back 1999, Monsanto was operating covertly to influence the science to bolster the safety profile of GBFs. A May 26, 1999 email from Dr. Heydens

described Monsanto's scientific outreach planning, which involved maintaining a cohort of "outside scientific experts who are influential at driving science, regulators, public opinion, etc. We would have the people directly or indirectly/behind-the-scenes work on our behalf." Ex. 24 at 1. Additionally, this plan included "[g]et[ing] our data out there so it can be referenced and used to counter-balance the negative stuff. In some cases, we may want to publish specific work in certain world areas to help out in that region. We may use our experts as authors[.]" *Id*.

3. Monsanto Disregarded Risk by Refusing to Conduct Studies Recommended By Its Own Consultants.

In the 1990's, several published studies concluded that glyphosate was genotoxic. Monsanto retained Dr. James Parry, "a recognized genotox expert" to review these independent studies and "[b]ased on his critique of the the genotox papers a decision would be made [by Monsanto] as to expanding or terminating his involvement." Ex. 25 at 2. Before receiving Dr. Parry's report, Dr. Farmer conceded that "[t]here is a concern that the papers by Lioi et al, may present an even bigger problem because the studies are with glyphosate and are on [] more standard endpoints." *Id*. And yet, in the same email, Dr. Farmer drafted a press release stating that "[s]everal genotoxicity studies have been conducted on glyphosate … None of these studies have shown any adverse findings. Based on all these results, we are confident that glyphosate herbicide products are not genotoxic and therefore to not present a mutagenic or carcinogenic risk to humans and animals." *Id*. at 1. It is entirely reasonable for the jury to conclude that these actions constitute deliberate deception aimed at misleading the public.

Monsanto's actions after receiving Dr. Parry's report support submitting punitive damages to the jury. After being presented with findings showing real risk, Monsanto questioned whether Dr. Parry "has ever worked with industry before," Ex. 8, and confirmed that it was not interested in an independent evaluation of the safety data. Ex. 26. Dr. Heydens proclaimed that Monsanto was not "going to do the tests Parry suggests"[22] and elected not to send samples of surfactants to Dr. Parry to conduct his own testing. Ex. 27. Donna Farmer's testimony confirmed that because Dr. Parry never came around to Monsanto's view of the science, Monsanto would not let him talk to regulators on behalf of the company. Farmer Dep. 170:8-170:21, Ex. 28. Dr. Mark Martens, who coordinated with Dr. Parry on behalf of

[22] Monsanto eventually conducts only one of the eight studies which Dr. Parry suggested. JT 1997:19-22, Ex. 22.

Monsanto, confirmed that the company never shared Dr. Parry's report outside of Monsanto. Martens Dep. at 151:6-151:22, Ex. 29. ("Q…Monsanto never shared the Parry report with any regulatory agencies, correct? A. That's correct.").

4. Monsanto Engaged in Unethical Ghostwriting to Influence Regulators and Mislead the Public Regarding the Safety Profile of Roundup.

Monsanto's history of ghostwriting offers strong support for punitive damages because it had the effect of polluting the scientific literature. Monsanto, unhappy with Dr. Parry's report on the genotoxicity of glyphosate, elected to surreptitiously write its own report on the genotoxicity of glyphosate and have "independent scientists" claim authorship. And Monsanto knew this behavior was unethical—as its own consultant, John Acquavella, explained in 2015; "We call that ghost writing and it is unethical." Ex. 30. Dr. Acquavella pointed out the guidelines that "everyone goes by" in determining what is "honest/ethical" in authorship. *Id*. Monsanto repeatedly ignored those guidelines.

Monsanto ghostwrote the Williams paper, rather than continuing with and publishing Dr. Parry's report. In the Williams paper, Monsanto concluded that "under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans." Heydens Dep. at 402:1-4, Ex. 31. The paper does not identify any Monsanto employee as an author even though William Heydens admitted that Monsanto did "the writing" and the experts just "edit and sign their names, so to speak." Ex. 33 at 2.

The Williams paper had an inevitable direct impact on the literature on glyphosate. In a 2010 PowerPoint presentation, Monsanto described the Williams (2000) paper as an "invaluable asset for response to agencies [and] regulatory reviews" and stated that Williams (2000) has "served us well in the past." Ex. 11 at 12, 17. Williams (2000) infected the scientific literature. For example, the only biological plausibility that Monsanto's epidemiology expert, Dr. Lorelei Mucci, reviewed in reaching her opinions in *Johnson* was the summary of studies contained "in the epidemiologic studies." JT. at 4318:1-5, Ex. 22. This is a problem. In De Roos (2003), which shows a statistically significant doubling of the risk of NHL with glyphosate, the results were muted by citation to the Williams (2000) article as evidence that glyphosate is "non-carcinogenic and non-genotoxic." *Id*. at 1888:7-11, Ex. 22.

5. Monsanto Continued its Unethical Ghostwriting.

Monsanto's ghostwriting efforts did not conclude with this single effort. Although Monsanto noted in 2010 that "Williams has served us well in toxicology over the last decade," they needed a

"stronger arsenal of robust papers scientific papers." Ex. 11 at 17. Accordingly in November 2010, Monsanto started ghostwriting sections of the Williams (2012) paper. Donna Farmer, Monsanto's lead toxicologist, confirmed her role, stating: "Attached is the first 46 pages. I added a section in genotox… am working on a section for gasiner in the mechanistic section…Also we cut and pasted in summaries of the POEA surfactant studies." Ex. 34. Donna Farmer confirmed that her name was removed from the list of authors before it was published. Farmer Dep. 118:22-119:06, Ex. 28.

In 2013, Monsanto ghostwrote another article: Kier & Kirkland (2013). Despite the paper's identified authors, Monsanto documents reveal that David Saltmiras, Monsanto's Toxicology Manager for Regulatory Product Safety Center, served as the original author of the paper. In requesting funding for the manuscript, Saltmiras stated that it "will be a valuable resource in future product defense against claims that glyphosate is mutagenic or genotoxic." Ex. 35. However, after the initial draft Monsanto felt that "the manuscript turned into such a large mess of studies reporting genetoxic effects, that the story as written stretched the limits of credibility among less sophisticated audiences." Ex. 36. Therefore, Monsanto determined that a way to "help enhance credibility is to have an additional author on the papers who is a renowned specialist in the area of genotoxicity. Monsanto identified Dr. David Kirkland as the best candidate" and removed David Saltmiras' name. *Id.*

Due to the "severe stigma" of the IARC classification of glyphosate as a 2A carcinogen, Monsanto decided to ghostwrite a new article to "Provide additional support ('air cover') for future regulatory reviews" and for "litigation support." JE. 391 at 3, Ex. 37. Monsanto decided that the "majority of writing can be done by Monsanto." *Id*. at 6. Monsanto's legal department considered this plan "Appealing" and "best if use big names." *Id*. at 11. The ghostwritten article became Williams (2016). In the article, Monsanto lied to the public and regulatory agencies by "claiming that neither any Monsanto Company employees nor any attorneys reviewed any of the expert panel manuscripts prior to submission to the journal." Heydens Dep. at 129:1-130:25, Ex. 31. In fact, Monsanto wrote portions of it and had final say on the edits. *Id.* at 129:1-130:25, 161:3-166:16. Monsanto's extensive involvement in this article is documented in Ex's 11, 38, 39, 40, 41, 42, 43.

6. Monsanto's Ghostwriting Was Specifically Targeted to Combat Repeated Studies Showing that Glyphosate is Genotoxic

On May 12, 2000, Monsanto became aware of an Abstract from McDuffie, et al., showing an increased risk of NHL from glyphosate in a Canadian epidemiology study. Ex. 44. Monsanto Epidemiologist John Acquavella traveled to the conference in August 2000, where he spoke to Dr. McDuffie and gave her a copy of the ghostwritten Williams (2000) (referred to in memo as Cantox glyphosate review). Ex. 45. The next year, Donna Farmer congratulated John Acquavella and Dan Goldstein for being able to get the glyphosate results out of the abstract. Ex. 46 ("the fact that glyphosate is no longer mentioned in the abstract is a huge step forward – it removes it from being picked up by abstract searches!").

In a June 11, 2002 memorandum, Drs. Farmer, Goldstein, and Acquavella discussed the state of science and noted that: "[a]llegations based on results from epidemiologic studies have begun to affect our freedom to operate … localities have cited epidemiologic findings to ban 'non-essential use' of pesticides, usurping federal regulations that are based on toxicologic data. *There are now six published studies that arguably associate glyphosate and other pesticides with lymphopoietic cancers*[.]" *Id*. at 2 (emphasis added). The memorandum further states, "[n]umerous other studies are ongoing in the U.S., Canada, and Europe. The stage is set, therefore, for more allegations about human effects associated with glyphosate and other pesticides." *Id*. at 3 (emphasis added).

In 2003, the DeRoos study was published showing a statistically significant doubling of the risk of NHL after GBF exposure. But Monsanto's concern was not for its at-risk customers, but rather that the findings "add more fuel to the fire for Hardell, et al." Ex. 47. Hardell also found an increased risk of NHL with glyphosate. Monsanto stated, "It looks like NHL and other lymphopoetic cancers continue to be the main epidemiology issues both for glyphosate alachlor." *Id.*

In 2008, the Eriksson study was published showing a statistically significant doubling of the risk of NHL for glyphosate users. Monsanto did not try to warn consumers about this result. Instead Donna Farmer stated "[w]e have been aware of this paper for awhile and knew it would only be a matter of time before the activists pick it up." Ex. 48. Monsanto was concerned that "activists" based on the Eriksson study were recommending that people "avoid carcinogenic herbicides … on lawns by using non-toxic land care strategies that rely on soil health, not toxic herbicides." *Id.* Donna Farmer wanted to know "how do we combat this?" *Id.*

7. Monsanto Failed to Test Its Glyphosate Formulations Despite Knowledge that the Surfactants Were Hazardous and Capable of Promoting Tumors.

Monsanto has failed to identified known carcinogens in formulated Roundup® products on the product label. In 2002, Mark Martens created a power-point stating "Surfactants are biologically not 'inert,' they can be toxic and this must be addressed." Ex. 49. Dr. Martens stated that "[t]his in-vivo genotoxicity finding was cause of concern[.]" Ex. 49 at 15; Martens Dep. at 176:13-16, Ex. 29, ("So now these are your thoughts that the genotoxicity finding in vivo was of concern, correct? A Yes."). But, Monsanto ignored this recommendation and never addressed the carcinogenicity of surfactants. It is undisputed that Monsanto has never conducted an animal carcinogenicity study on Roundup®; and Donna Farmer directed in 2009 that "you [Monsanto's marketing team] cannot say that Roundup does not cause cancer … we have not done carcinogenicity studies with 'Roundup.'" Ex. 50.

In 2008, Europe was beginning to question the safety of tallow amine (the surfactant used in RangerPro). There were internal communications deliberating whether to even defend tallow amine in Europe because "there are non-hazardous formulations, so why sell a hazardous one?" Ex. 51.

Surfactants work with glyphosate through the surfactant's ability to facilitate the absorption of glyphosate, thereby increasing carcinogenicity. In response to questions from European regulators, Monsanto retained TNO, a laboratory in Denmark, to conduct rat skin penetration studies using a Roundup® formulated product. The TNO study revealed that 5% to 10% of the glyphosate was dermally absorbed when tested with the surfactant. As these results were far higher than the information submitted to the EPA, Monsanto elected to immediately stop any further work with TNO as the results could "blow Roundup risk evaluations." Heydens Email, MONGLY03738295, Ex 52. The TNO results were never submitted to the EPA as required under the "adverse effects" reporting requirement in FIFRA, and Monsanto continues to claim that the absorption rate for glyphosate is under 1%. *See* 7 U.S.C. § 136d(a)(2).

8. Monsanto Devoted Enormous Resources to Attacking IARC's Conclusions Instead of Warning The Public of The Cancer Risk.

In October 2014, after Monsanto learned that IARC was going to evaluate glyphosate, Heydens stated that Monsanto had "vulnerabilities" in all the areas considered by IARC, "namely epi, exposure, genotox and mode of action." Ex. 53. In February 2015, a month *before* IARC actually makes a decision on glyphosate, Monsanto started developing a plan to "orchestrate outcry over IARC decision." because

it assumed that data would support either a 2b (possible human carcinogen) or a 2A (probably human carcinogen). Ex. 54 at 1,5. The "outcry" was intended to reach both "IARC panelists" and "Regulators." *Id.*

Instead of devoting resources to informing people about the risk of NHL, or conducting additional tests, Monsanto devoted its vast resources to attacking IARC. This prompted Monsanto employee Steve Gould to exlaim that "We are all over it! More resources than I have seen in my career!" Ex. 55. Enormous resources were devoted to fighting IARC in California because in a Sept. 2015 cost-estimate prepared by Monsanto about the impact of IARC on the sale of Roundup® products to municipalities and school districts, Monsanto projected large losses to business. Ex. 56 at 1. Indeed, Mr. Gould noted that "[c]ustomers that I am aware have already stopped using Glyphosate since the IARC ruling: Irvine Unified School District and several bay area cities and school districts." *Id*.

9. <u>Monsanto Works with EPA to Kill ATSDR Review of the Risks of Glyphosate.</u>

In evaluating glyphosate the EPA failed to follow its own carcinogenicity guidelines. JT. 4607:23-4608:13, 4610:1-4, 4620:25- 4611:11 4613:1-3; 4629:15-20, 4631:23-4632:4, Ex. 22. One of the reasons the EPA failed to follow guidelines was due to inappropriate relationships between certain EPA employees and Monsanto employees. On April 28, 2015, three months before IARC published the full monograph on IARC, Jess Rowland, head of the Office of Pesticide Programs Cancer Assessment Review Committee told Monsanto's regulatory lead, Dan Jenkins, that he would find that glyphosate was not carcinogenic before he even reviewed the data. Ex. 57. Rowland stated that "We have enough to sustain our conclusions. Don't need gene tox or epi …I am the chair of the CARC and my folks are running this process for glyphosate in reg review. I have called a CARC meeting in June" *Id.* at 2. Mr. Rowland further stated that with respect to an ongoing review of glyphosate by the Agency for Toxic Substances and Disease Registry (ATSDR), "If I can kill this [review] I should get a medal." *Id.* Dan Jenkins relates to his coworkers that "Jess doing a nice job at EPA." Ex. 58 at 1. When learning that the National Toxicology Program "appear to have accepted IARC's opinion that glyphosate and its formulations display two characteristics of carcinogens: Genotoxicity and oxidative stress that Ivan Rusyn and Christopher Portier worked so hard to create" Dr. Farmer's colleagues noted that they would have to bring in Capitol Hill to address the development. Farmer Dep 504:4-506:16, Ex. 28. Monsanto also used its political connection to influence the findings of the EPA by getting "some key Democrats

on the hill to start calling jim [jones, Assistant Administrator]" which "shoots across his bow generally that he's being watched." 59 at 8.

In addition to lobbying the EPA, Monsanto hid essential information from the EPA. For example, as a policy, Monsanto did not submit reports of its own employees developing NHL after handling glyphosate. Ex. 60. Monsanto also admitted it did not submit the Parry reports to the EPA. JT. at 1587:15 - 1588:2, Ex 22; Martens Dep. at 151:6-22, Ex. 29.

10. Monsanto's Actions Were Despicable And Support an Award of Punitive Damages.

For forty years, Monsanto was faced with good science demonstrating that there was, at a minimum, a potential risk of cancer with its product. Rather than take these studies seriously, Monsanto actively engaged in a fraudulent campaign to combat this science and try to convince the world that its product was non-toxic. Monsanto continues to this day to claim its product does not cause cancer, when, it knows that you "cannot say that Roundup does not cause cancer'" Ex. 50. In light of this admission, Monsanto's failure to test its widely used Roundup® products warrants punitive damages.

11. There is Clear and Convincing Evidence That Managing Agents at Monsanto Acted with Malice and Oppression.

An employee need not be high ranking to be considered a managing agent. "[P]rincipal liability for punitive damages does not depend on employees' managerial level, but on the extent to which they exercise substantial discretionary authority over decisions that ultimately determine corporate policy." *Major v. W. Home Ins. Co*., 169 Cal. App. 4th 1197, 1221 (2009), as modified on denial of reh'g (Jan. 30, 2009) (claims adjuster for contractor of Defendant considered managing agent). "If there exists a triable issue of fact regarding whether a corporate employee is a managing agent under the *White* test, that factual question must be determined by the trier of fact and not the court[.]" *Davis*, 220 Cal.App.4th at 366. "There is no requirement that the evidence establish that a particular committee or officer of the corporation acted on a particular date with 'malice.' A Corporate defendant cannot shield itself from liability through layers of management committees and the sheer size of the management structure." *Romo v. Ford Motor Co.*, 99 Cal 1115, 122 Cal.2d 139 (2002) *overruled in part on other grounds*.

The relevant question under the managing agent inquiry is whether the corporate employees had significant discretion with respect to the actions that affected the Plaintiff. *Major* 169 Cal. App. 4th 1197, 1221. ("When employees dispose of insureds' claims with little if any supervision, they possess

sufficient discretion for the law to impute their actions concerning those claims to the corporation."). Here, with respect to all of the acts constituting malice claimed by the Plaintiffs, the following employees acted with significant discretion in the key issues relevant to punitive damages, 1) communications with the public meant to conceal the risk of GBFs; 2) Ghostwriting studies and failing to test formulations and; 3) Undue influence over the EPA.

a. Communications with the Public:

Dr. Farmer testified that she has been working at Monsanto for 25 years and has "been one of the spokesperson[s] for the safety of Roundup when it comes to the toxicology." Farmer Tr. 14:11-13; 15:5-7, Ex. 28. She explained, "based on that in-depth knowledge for over those many, yes, I was asked to be -- help defend glyphosate." *Id.* at 19:3-8. And, as described in Ex. 23, her job was to "[d]efend and maintain the global glyphosate businesses[.]" Ex. 23. Steven Gould, the Monsanto employee responsible for providing safety information to San Francisco bay area cities and school districts, stated that he relies on Donna Farmer for this information. Gould Tr. at 23:04-15, Ex. 61.

b. Failure to test and Ghostwriting Articles:

Dr. Heydens is Dr. Farmer's boss. Farmer Tr. at 152:16-19, Ex. 28. Dr. Heydens testified that he is the "product safety assessment strategy lead" Heydens Tr. at 289:23-290:9, Ex. 31. Dr. Heydens is also lead of Monsanto's "product safety center" where he oversaw "the group of scientists … responsible for demonstrating the safety of Monsanto's biotechnology portfolio." *Id.* at 301:13-18. Importantly it was Dr. Heyden's responsibility to "devise the overall testing strategy and sets of studies that we would do to support the safety of that product." *Id.* at 290:7-9.

c. Inappropriate Relationship with EPA Employees:

Daniel Jenkins was Monsanto's U.S. Agency Lead in Regulatory Affairs, and represented Monsanto before various federal agencies. Jenkins Tr. at 36:6-10, Ex. 62. He was responsible for interfacing with regulatory agencies regarding glyphosate data and making strategic decisions about how interact with the EPA and other regulators. *Id.*

The internal documents demonstrate that these witnesses and the other employees identified in the documents were granted significant discretion in dictating what studies were conducted with GBFs and in dictating what information would be shared with the public and regulators. Monsanto has offered no contrary evidence to suggest these employees were acting outside their scope of employment, or that

these employees were acting contrary to the direction of Monsanto executives.

The evidence is clear that long ago Monsanto made a choice to remain willfully ignorant of Roundup®'s cancer risk. Despite knowledge that it was, at a minimum, ignorant of the true Roundup®-cancer risk, Monsanto avoided the ultimate answer to the question of whether Roundup® causes cancer and instead engaged in a decades-long campaign to discredit and obscure. Conduct like Monsanto's is the reason that punitive damages exist in California.

PLAINTIFFS' RESPONSE REGARDING DR. BENBROOK

Dr. Charles Benbrook's testimony is directly relevant to the heart of this case.[23] He has spent his 40-year professional life immersed in pesticide risk evaluation and related regulatory issues and pesticide industry standards of care. Dr. Benbrook has testified before Congress on many of these subjects, advised pesticide companies, presented on them in a number of academic and professional settings and published in both peer-reviewed and non-peer-reviewed literature for decades. Dr. Benbrook has undertaken a painstaking review of the documentary record, and his testimony will assist the jury in understanding these critical issues.

Plaintiffs will not offer expert testimony as a means of regurgitating facts or documents that the jury might otherwise consider directly. Dr. Benbrook is not going to testify as to his interpretation of what Monsanto historically said, his interpretation of Monsanto's intent or his interpretation of Monsanto's reasons for taking certain actions or failing to act. Instead, Dr. Benbrook will provide opinions as to Monsanto's corporate conduct regarding glyphosate-based formulations ("GBFs") vis-à-vis pesticide industry standards of care based on what Monsanto scientists and officials have said about their actions, inaction, and plans regarding GBFs, in light of his extensive experience in and knowledge of the field. As such, Dr. Benbrook's testimony is no different than other "standard of care" experts whose testimony is accepted and presented in the regular course of litigation and will assist the jury's

[23] These issues include the U.S. pesticide regulatory scheme, the interplay of various pesticide regulations, pesticide risk assessment, the chronology of the use, registration and labeling of Monsanto GBFs, Monsanto's conduct regarding the evaluation of and publication about the risks associated with use of its GBFs, Monsanto's public statements through labeling, advertising and marketing regarding its GBFs, the differences between the genotoxicity datasets evaluated by EPA and IARC in their respective evaluations of the carcinogenicity of glyphosate, pesticide industry stewardship/ standard of care, including industry codes of conduct, Monsanto's adoption of those codes of conduct and Monsanto's conduct vis-à-vis those codes of conduct and its GBFs.

understanding of Monsanto's statements and conduct in the context of the then-existing regulations and pesticide industry standards of care adopted by Monsanto.

A. Dr. Benbrook is Highly Qualified to Offer His Designated Opinions.

Dr. Benbrook earned his B.A. in Economics, cum laude, from Harvard University and earned his M. A. and Ph.D. in Agricultural Economics from the University of Wisconsin in 1980. Just prior and then immediately subsequent to graduation, Dr. Benbrook served as an Agricultural Policy Analyst for the Council on Environmental Quality of the Executive Office of the President. Upon President Reagan's election, he served as Staff Director for the U.S. House of Representatives Subcommittee on Department Operations, Research and Foreign Agriculture (DORFA). The DORFA Subcommittee had jurisdiction over pesticide regulation and FIFRA.[24] Dr. Benbrook organized hearings on pesticide regulation conducted by DORFA.[25] In his capacity as Staff Director in the early 1980's, Dr. Benbrook was well versed in and devoted a significant portion of his time reviewing and specifically commenting on the science and policy involved in the regulation of carcinogenic pesticides by the EPA. For example, in 1983, Dr. Benbrook contributed to the public discussion and analysis of the interface of the science of pesticide risk assessment and regulatory policy at the EPA in a Letter to the Editor published in the prestigious journal, Science, in the section, "Carcinogen Policy at EPA."[26] Dr. Benbrook's published letter addressed issues that were precisely the issues facing EPA, at that time, in its evaluation of glyphosate's oncogenicity. Thus, Monsanto's protestations to the contrary, Dr. Benbrook, in real time, was involved with and had expertise in assessing EPA pesticide regulations and the EPA's Office of Pesticide Program ("OPP") assessment of oncogenicity, carcinogenicity, and genotoxicity.

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[24] *See* Kristal Decl, Ex. 63A, Benbrook *Johnson* trial testimony at 3857-3858.

[25] *Id*. at 3859-3860.

[26] *See*, Kristal Decl. Ex. 64B, Benbrook, Carcinogen Policy at EPA, *Science*, Vol. 219, 798 (1983). Dr. Benbrook wrote 36 years ago: "A congressional staff investigation of the pesticide regulatory program in the [EPA]… analyzed the scientific basis for several recent regulatory actions taken by the EPA in an effort to sort out legitimate scientific refinements in regulatory decision-making from changes in policy. The investigations findings, conclusions, and recommendations are contained in a DORFA Subcommittee report …. issued in December 1982….Chapter 6 of the report focuses on regulation of pesticides shown to produce cancer in laboratory animals. *An in-depth review of several case studies, along with dozens of interviews with staff scientists responsible for analyzing available data on pesticide oncogenicity,* led subcommittee staff to conclude that indeed significant changes had been incorporated in the way the EPA balances and juxtaposes experimental evidence under the aegis of the 'weight-of-evidence' decision-making." *Id*. (emphasis added).

Dr. Benbrook's career assessing EPA pesticide regulations, policy and evaluation of cancer risk continued in his next position as Executive Director (1984-1990) of the Board of Agriculture of the National Research Council ("NRC") of the National Academy of Sciences ("NAS"). These highly prestigious organizations were devoted to providing scientific research and guidance to governmental agencies. On a number of occasions, Dr. Benbrook, in his position with the NRC, testified before and at the request of Congress on issues related to pesticide use, management and risks and the interplay of the regulatory schemes controlling the use of pesticides.[27]

In his September 1988 testimony, Dr. Benbrook provided guidance and presented the findings of an extensive study, conducted by the NRC, at the request of and to advise the EPA, regarding procedures to follow when a pesticide (such as Roundup®) had been classified as a "potential oncogene" and was used on crops.[28] This book contains sections on and analyses of the oncogenic risk of pesticides, including a chapter and an appendix on the methodology of estimating oncogenic risks, sections and analyses on the legal basis for regulation of pesticides, including analyses, requirements and discussion of FIFRA, the FDCA, the EPA pesticide registration process, the EPA's classification system for carcinogens, the legislative history of various aspects of pesticide regulation and EPA's application of various pesticide regulations. The NRC study refers to "Glyphosate (Roundup®)" several times and, specifically, as one of the "potentially oncogenic pesticides identified by the EPA."[29] Thus, Dr. Benbrook, more than three decades ago and completely unrelated to litigation, obtained knowledge of glyphosate, its oncogenic potential, its risks, its uses, and the impact of the applicable regulations on its sale and use. When hearings were held, Dr. Benbrook was the person invited to present the findings and policy recommendations and to summarize the findings of the various experts "in agricultural pest control, pesticide development, agricultural economics, cancer risk assessment, public health, food science, regulatory decision making, and law"[30] who contributed to the study.

Since serving as Executive Director of NRC, Dr. Benbrook has held appointments with organizations such as the Johns Hopkins University, Bloomberg School of Public Health, the U.S.

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[27] *See*, Kristal Decl. Ex. 65C, Benbrook CV.
[28] *See*, Kristal Decl. Ex. 66D, Benbrook Congressional testimony, September 7, 1988
[29] *Id.* at p.52, Table 3-3, p. 68, Table 3-9, p. 76 Table 3-17, p. 85 Table 3-25.
[30] *Id*. at Preface, p. v.

Department of Agriculture Agricultural Biotechnology Advisory Committee and has served as the Chief Scientist of the Organic Center.[31]

Dr. Benbrook has conducted multiple pesticide label reviews for multiple clients of his private consulting business.[32] He has consulted as a contractor for the EPA.[33] Dr. Benbrook also served as chief scientist for the Organic Center where he was responsible for tracking scientific developments on the safety of food and the impact of pesticides on the environment.[34]

Over the decades, Dr. Benbrook has presented his evaluations of pesticide risk and regulation through the publication of over 40 peer-reviewed articles, many involving issues related to herbicide use, risk and regulation and some, specifically on GBFs.[35] Dr. Benbrook is author of a seminal text on pesticide use and regulation in America, titled *Pest Management at the Crossroads* and published in 1996.[36] Dr. Benbrook has also written a variety of reports, papers and book chapters on the subject of pesticides and pesticide regulations.[37] Dr. Benbrook's current contribution to the scientific discussion relating to pesticide risk and regulation and, specifically to that involving glyphosate/Roundup®, published January 14, 2019, provides a thorough, detailed analysis of the genotoxicity of GBFs and presents the differences in the genotoxicity datasets reviewed by EPA and IARC in their respective glyphosate carcinogenicity reviews.[38]

As the Court is aware, IARC and EPA have reached different conclusions regarding glyphosate genotoxicity. Dr. Benbrook's painstaking analysis demonstrates the differences in the genotoxicity data reviewed by these two agencies and has been accepted as a valuable contribution to the scientific community as a whole. A portion of Dr. Benbrook's expert report and anticipated testimony involves the same subject. Jurors hearing about the differences in conclusions by EPA and IARC would

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[31] See, Kristal Decl. Ex. 65C, Benbrook Curriculum Vitae
[32] *Id*. at 102:6-11.
[33] *Id*. at 69:11-19.
[34] See, Kristal Decl. Ex. 63A, Benbrook *Johnson* trial testimony at 3865-3866
[35]Ex. 65, Benbrook Curriculum Vitae.
[36] *See* Ex. 88 Dr. Benbrook Expert Report dated November 10, 2018 at 35.
[37] For example, for the Cal-EPA, Department of Pesticide Regulation, he authored a report entitled, *Challenge and Change; A Progressive Approach to Pesticide Regulation in California* (1993). For the Consumers Union, he authored a paper, *Pesticide Management at the Crossroads* (1996). For the Organic Center, Dr. Benbrook authored a report *Successes and Lost Opportunities to Reduce Children's Exposure to Pesticides Since the Mid-1990s* (2006). *See*, Kristal Decl. Ex. C, Benbrook CV.
[38] *See* Kristal Decl. Ex. F, Benbrook, *How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides?* Environ Sci. Eur. 31:2, (2019).

certainly be assisted in reconciling these differences and making factual determinations regarding them by hearing the same analysis. Dr. Benbrook's analysis and testimony will greatly assist the jury in evaluating why the conclusions of EPA and IARC regarding the carcinogenicity of glyphosate are different.

B. Dr. Benbrook May Testify About Matters the Jury May Consider in Deciding Monsanto's Intent, Motive, or State of Mind.

Dr. Benbrook will *not* opine on Monsanto's motive, intent, or state of mind. He will provide expert testimony regarding factual matters that properly inform *the jury's own determination* of motive, intent, or state of mind. *See United States v. Pacific Gas and Electric Co.*, 2016 WL 1640462 (N.D. Cal. 2016) (while an expert witness may not opine as to a corporation's intent, he or she may testify about corporate practices and policies that the jury may use to ascertain corporate intent).

Dr. Benbrook is being offered to do precisely what the court permitted in *Pacific Gas*: he will apply his own training and experience to the facts and record and testify regarding Monsanto's practices with respect to GBFs as evidenced in public and internal documents. Dr. Benbrook is not opining as to what Monsanto's documents mean to him. Rather, as he testified, the portions in his report summarizing Monsanto's documents *are not his personal opinions* but are merely statements of fact in the record.[39] Instead of "personal opinions" about emails, Dr. Benbrook's report is based on a systematic review of the source materials.

C. Dr. Benbrook May Reasonably Base His Testimony in Part on Monsanto's Documents and Employee Testimony, and his Opinions that Rely on those Documents and Testimony Will Be Helpful to the Jury.

Monsanto improperly cites *Lopez v. I-Flow, Inc.*, 2011 WL 1897548 (D. Arizona 2011) in challenging Dr. Benbrook. In *Lopez*, the court excluded testimony from plaintiffs' regulatory and labeling expert. However, such testimony was excluded, not because it narrated FDA regulations and guidelines, but because it did so *without any analysis as to how those regulations and guidelines supported her opinions. Id.* at *10. As such, the expected testimony was simply a "narrative of selected regulatory and corporate events and quotations...without sufficient explanation." *Id*. To the contrary, Dr. Benbrook will testify as to how the regulations and guidelines he references and relies on

[39] *See* Kristal Decl. Ex. G Benbrook deposition testimony in *Johnson v. Monsanto Co*., Vol. 2, dated February 9, 2018 at 451-452.

inform his opinions regarding Monsanto's conduct as a pesticide manufacturer. This requires the same "specialized knowledge" which was accepted in *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, 2011 WL 6302287 (S.D. Ill. Dec. 16, 2011). *Yasmin* rejected the argument that regulatory expert's review of corporate emails "does not require the 'specialized knowledge' contemplated by Rule 702, but rather is mere advocacy on plaintiff's behalf." *Id*. at *18.

Most of the documents referenced by Dr. Benbrook do not "speak for themselves," but rather involve technical and scientific information and require expertise to understand their context. Dr. Benbrook must be permitted to assist the jury in understanding documents involving complicated and technical matters. *See Bryant v. Wyeth*, 2012 WL 12844751 at *2 (W.D. Wash. Aug. 22, 2012) ("The Court concludes that the great majority of documents... are complicated and references those documents may or may not support are the legitimate subject of expert testimony. The Court concludes the proposed testimony is more than just a narrative and may assist the jury at trial. Defendants' challenges to these experts are issues for cross examination"); *Straub v. Breg Inc*., 2012 WL 1078335 (D. Arizona, Mar. 30, 2012) (a court may permit an expert to testify as to documents in "explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge.").

Furthermore, there is nothing improper in providing a factual description of the long history of the issues with GBFs as detailed in the regulatory record. Indeed, "to the extent [plaintiff's regulatory expert] is summarizing voluminous records and materials, as appears to be the case, this aspect of his testimony is properly admitted under [R.1006] as well as [R.702] in the sense that he is identifying what he, given his background and expertise, considers to be the most salient aspects of those voluminous materials." *In re Testosterone*, 2017 WL 1836443, *15 (N.D. Ill. May 8, 2017).

The record of Monsanto's failure to act as a reasonable pesticide manufacturer spans decades. In providing *the basis for* his opinions, as he was required to do, Dr. Benbrook's report reflects the extent of the record.

D. Dr. Benbrook May Properly Testify Regarding Monsanto's Duties as a Pesticide Manufacturer and Has Been Permitted to do so in the Past.

Dr. Benbrook will offer opinions concerning complex regulatory frameworks applicable to Monsanto as a pesticide manufacturer, including its interactions with and representations to the EPA. The admission of such expert testimony regarding complicated and highly technical regulatory issues is entirely proper.

In *Adams v. United States*, 2009 WL 1085481 (D. Idaho Apr. 20, 2009), the court addressed this issue *in the context of examining Dr. Benbrook's expert testimony* in that case. The *Adams* court found Dr. Benbrook's testimony proper and admissible as to "(1)...the general roles of the EPA, the registrant, and the state in the registration process for pesticides; (2) the general regulatory framework set up by FIFRA; (3) the industry standards and the stewardship duty; (4) the factual circumstances surrounding the 1995 changes to the label and the obtaining of the 24(c) label; and (4) [his] opinions on whether DuPont's conduct satisfied industry standards and any stewardship duty." *Id*. at *3.[40] [41] Dr. Benbrook intends to testify similarly in this case and there is nothing on this record that should dictate a different result.

Moreover, given the knowledge it had at the relevant times, what Monsanto should have done within the context of these regulations is relevant to the determination of whether Monsanto acted as a reasonably prudent manufacturer. This testimony will aid the fact-finder, and comes nowhere near instructing the jury as to legal obligations.

As Dr. Benbrook notes "….as someone who has worked in this field for many years and has worked on the registration activities of many companies on many different products, there are norms and standards in the industry that Monsanto pledges that it adheres to, as do most of the other major companies, as well as statements that Monsanto has made over many years about the safety and properties of Roundup herbicides and their commitment to doing everything possible to assure that they

[40] *See also*, *Ginena v. Alaska Airlines, Inc.*, 2013 WL 431827 (D. Nevada 2013) (reasoning that in industries with complex regulatory framework, such as the environmental framework at issue in *Adams*, an expert may be permitted to testify as to industry standards and regulations).

[41] In a later memorandum decision, the *Adams* court further explains that Dr. Benbrook has the expertise necessary to render opinions on how companies use the registration process, how they position their products, how they make labeling decisions and how they make marketing decisions regarding those products.

are as effective and as safe as possible. That's the standard to which Monsanto and all pesticide companies ultimately are held in questions and matters such as this one."[42] Furthermore, it is appropriate for Dr. Benbrook to opine, based on the evidence, that Monsanto had a duty to warn consumers of the risk of NHL. As Dr. Benbrook explains the registrant "knows far more about the active ingredient, its properties, its toxicology ... So the agency defers to the registrant and the superior and more in-depth knowledge of the registrant whenever a registrant incorporates in a label amendment a change ...that their face will reduce exposure and risk."[43]

E. CONCLUSION

As described above, Dr. Benbrook brings to this litigation decades of experience in the areas of pesticide risk evaluation, related regulatory schemes, and stewardship/standard of care issues relevant to pesticides. More than thirty years after his first Congressional testimony on pesticide risk assessment and regulation and after a continued career immersed in the review and publication on the use and risk of pesticides and regulation, Dr. Benbrook is certainly qualified to provide expert testimony on these subjects.

Given the Court's role as gatekeeper and not fact-finder, "the gate could not be closed to this relevant opinion offered with sufficient foundation by one qualified to give it." *Primiano v. Cook,* 598 F.3d 558, 568 (9th Cir. 2010). Dr. Benbrook is certainly eminently qualified to testify and assist the jury in performing its required evaluations of the evidence.

PLAINTIFFS' RESPONSE REGARDING DR. SAWYER

A. Dr. Sawyer's Opinions Are Reliable and Admissible.

During the general causation phase of this litigation the Court held that "plaintiffs need not establish any particular level of exposure." *In re Roundup Prod. Liab. Litig.*, No. 16-MD-02741-VC, 2018 WL 3368534, at *5 (N.D. Cal. July 10, 2018). In this phase, it will be helpful for the jury to understand how various factors such as lack of protective gear, the spraying equipment, and the type of surfactant in the Plaintiff's specific formulation affect the exposure routes of Roundup® into the body. In fact, the Ninth Circuit previously determined that a trial court abused its discretion by excluding this

[42] *See Ex. 89*, Benbrook deposition testimony in *Johnson v. Monsanto Co.,* Vol. 1, dated February 8, 2018 at 40.

[43] *See* Ex. 90 Benbrook deposition testimony in *Johnson v. Monsanto Co.*, Vol. 2, dated February 9, 2018 at 476-477.

type of helpful testimony by Dr. Sawyer's that "exposure levels [of a chemical] were "within [a] reasonable range of that known [from several studies] to induce" the alleged injuries" was admissible. *Whitlock v. Pepsi Americas*, 527 F. App'x 660, 661 (9th Cir. 2013). Dr. Sawyer's qualifications are listed in his C.V. and attached Declaration.[44] Ex. Sawyer Decl. ¶¶ 2-8.

B. Dr. Sawyer has not Offered any General Causation Opinions.

Monsanto's contention that Dr. Sawyer is offering general causation opinions in this case is incorrect. Rather, Dr. Sawyer is being offered "to testify on issues concerning the mechanism of absorption of glyphosate-based formulations through the skin and other exposure pathways and the effect of wearing personal protective equipment on the exposure levels." See Ex. 70 Expert Disclosures. Dr. Sawyer confirmed that "I'm not here to speak on general causation at all;" his opinions on "dermal absorption, protective gear, or the co-contaminants within the product, et cetera..." are "directed to all three patients" See Ex. 71 Sawyer *Stevick* Dep. at 19:7-26:22. He is offering a specific causation opinion only with respect to Stevick. *Id.* at 19:15-24. See Ex. 74 Sawyer Decl. at ¶¶ 13, 14.

Dr. Sawyer's testimony regarding absorption and exposure pathways and the effects of wearing personal protective equipment is not a general causation opinion. A general causation opinion must establish that the "substance at issue was capable of causing the injury alleged (general causation). . . ." *Avila v. Willits Envtl. Remediation Tr.*, 633 F.3d 828, 836 (9th Cir. 2011). Here, Dr. Sawyer's testimony is proper. Rule 702 "provides that expert testimony is admissible "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." *Avila*, 633 F.3d at 836-837.

Dr. Sawyer will educate the jury as to how GBFs are absorbed through the skin; how protective clothing can help limit the exposure to GBFs; and how different equipment can affect exposure. *See Ex.* 71 Sawyer Stevick Dep. at 151:8-17 ("...I found that it was not possible to spray it directly down on weeds without encountering overspray on the ankle/lower leg area because the wand is very short...So I would advise not wearing ankle socks or breathable sneakers in using such a device."); 161:21-162:3 (...she constantly had exposure to her hand from the leakage that was wetting her -- her fingers and hand...there was simply no label on the container to recommend the use of gloves and she didn't know

[44] Dr. Sawyer has prepared a declaration to clarify the many misrepresentations of his testimony by Defendant.

any better."). Dr. Sawyer goes over these factors as they apply to all users in great detail in his report. See Ex. 72 Sawyer MDL Rep. 44-114, 113 ("Farmers who did not use rubber gloves had five times more glyphosate in their urine than those wearing protective gloves"). This is objectively useful information for the jury to determine how GBFs actually get into the body and the factors that impact the Plaintiffs' exposures. For instance, because none of the Plaintiffs wore protective gear due to Monsanto's failure to warn, the effect of protective gear on exposure is relevant, helpful information. In short, Dr. Sawyer's testimony directly addresses critical issues relevant to specific causation.

C. Dr. Sawyer's Opinion that Mrs. Stevick's Exposure to GBFs Was Sufficient For her to Develop NHL is Reliable.

Monsanto offers no expert testimony and cites no scientific research that would contradict any of Dr. Sawyer's well-reasoned opinions. Rather, Monsanto's motion is based on willful ignorance and misrepresentations of the opinions that Dr. Sawyer has offered to date.[45]

1. Dr. Sawyer Used Proper Methodology in Assessing Specific Causation.

While Dr. Sawyer did not use the words "differential diagnosis" in his report, he utilized this methodology to reach his specific causation opinion on Mrs. Stevick. "Q: And did you, in fact, perform a differential diagnosis to come to your specific causation conclusion in Mrs. Stevick's case? A: Yes. The only -- the only factor that contributes to her NHL is her age,[46] nothing else." Ex. 71 Sawyer *Stevick* Dep. at 192:23-193:3. As in the *Johnson* trial, Dr. Sawyer will opine that Mrs. Stevick's exposure was sufficient to cause her cancer. Ex. 72 MDL Report at 124. Dr. Sawyer will also testify as to whether other carcinogens were involved and evaluate them on a comparative basis. Ex. 71 Sawyer *Stevick* Dep. 108:12-21, 89:8-90:8.

With respect to other carcinogens, Dr. Sawyer properly considered the totality of the evidence. Dr. Sawyer conducted a thorough review of Mrs. Stevick's family history, age; prior work history; operational hazards; home hazards; alcohol, tobacco, and drug history; and medical history as stated in

[45] Dr. Sawyer testified at length at his deposition that he does not hold any general causation opinions. What he intends to testify to the jury in *Hardeman*, *Gebeyehou*, and *Stevick* are the toxicological mechanism effects of the glyphosate with respect to absorption, excretion, co-formulates and contaminants. Deposition of Dr. Sawyer, Dec. 20, 2018 at 23: 21-24: 2, 25: 9-17, 194:2-7.

[46] Dr. Sawyer did note that the epidemiology studies were age-stratified and there is still an increased risk in NHL, so that would put Stevick's risk above the background risk for her age-group. Ex. *Id.* at 246:25-247:12; Ex. MDL Report at 27

his deposition. Ex. 72 MDL Report at 1-16; Ex. 71 Sawyer *Stevick* Dep. at 89:8-90:8, 108:12-21. Furthermore, Dr. Sawyer reviewed all relevant medical records. Ex. 71 MDL Report at 1-10. Dr. Sawyer conducted a phone interview with Mrs. Stevick to get details on her exposure to Roundup® and other carcinogens. *Id.* at 9. Dr. Sawyer read Mrs. Stevick's deposition testimony. *Id*. at 10. Dr. Sawyer compared Mrs. Stevick's exposure to GBFs to the exposure of subjects in epidemiological studies and explained how he will calculate Mrs. Stevick's dose at trial using the UK POEM methodology. Ex. 71 Sawyer *Stevick* Dep. at 43:2-11. Dr. Sawyer also took into account idiopathic causes[47] of Mrs. Stevick's cancer when preforming his differential diagnosis. Ex. 71 Sawyer *Stevick* Dep. at 197:22-198:1.

After "ruling in" the totality of the evidence, Dr. Sawyer then "ruled out" on a differential basis all other non-trivial possible causes of a Mrs. Stevick's NHL:

> "The second thing was to determine on a differential basis if I could find any health factors, family history, drug use, smoking, any type of pharmaceuticals such as long-term cortisone or implanted tissues which require an immunosuppressant drug, family history, genetic disorders. You know, I looked at all those things and found nothing, including her occupational exposures that were sufficient enough to be of merit.

Ex. *Id*. at 89:8-90:8, 195:10-18. Dr. Sawyer further opined that the dosage of GBF received by Mrs. Stevick was clearly within the range of the human epidemiologic studies of applicators. Ex. 71 *Id*. at 45:1-3; 198:19-199:10.

Disregarding these facts, Monsanto contends that Dr. Sawyer failed to "rule out" Ms. Stevick's exposure to other non-GBF carcinogens such as radiation, benzene and mecoprop. Ex. 72 MDL Report at 1-16; Ex. 71 Sawyer *Stevick* Dep. at 89:8-90:8, 108:12-21. And although Dr. Sawyer did not rule out age as a contributing factor, he was not required to do so. *See Cooper,* 239 Cal. App. 4th at 578.

As to exposure to radiation, Dr. Sawyer testified during deposition that the "13 times or 30 times" that Mrs. Stevick was exposed to radiation while wearing an "apron and a collar" was nowhere near enough "millirems to be of any risk." Ex. 71 Sawyer *Stevick* Dep. 120:3-15. A topic that Dr. Sawyer is "intimately familiar with." *Id*. at 120:22. Dr. Lorelei Mucci's Textbook of Cancer Epidemiology states "there is no evidence that ionizing radiation causes NHL." Ex. 73. Likewise, Dr. Sawyer took into

[47] Dr. Sawyer also took into account idiopathic causes of Mrs. Stevick's cancer when performing his differential diagnosis based on the epidemiological studies. Ex. Sawyer Stevick Dep. at 197:22-198:1. To the extent his consideration of idiopathy is based on epidemiology, he is relying on the epidemiologists. Ex. 74 Sawyer Decl. at ¶¶ 45-48

account a host of other possible carcinogen exposures: WD-40, GUNK, CRC Lectra cleaner, Armor All, Scotch Super Adhesive, Cleaning duster, and Liquid Wrench, etc. that Ms. Stevick walked by occasionally. Ex. Sawyer *Stevick* Dep. 108:12-15. Moreover, it is very much disputed that Ms. Stevick was exposed to benzene and mecoprop. Dr. Sawyer stated "it's just ridiculous to insinuate that any of these chemicals contained enough benzene to have any relevance." *Id.* at 108:12-21. Ms. Stevick did not use mecoprop; her husband did. Id. 155:10-156:9; Ex. Sawyer Decl. at ¶¶ 76-79.

2. Dr. Sawyer is Qualified to use Epidemiology Studies to Form his Opinions.

Dr. Sawyer is trained in epidemiology and uses epidemiology in his practice. Sawyer Aff. at ¶ 86. Ex. 74 And although Dr. Sawyer has been qualified to offer epidemiology opinions in other cases, here, Dr. Sawyer will only make use of the epidemiology studies as a means of comparing Stevick's dose to the dose in the epidemiology studies. Ex. 71 Sawyer *Stevick* Dep. 241:13-17. He will be deferring detailed opinions on the epidemiology studies to epidemiologists. Ex. 71 Sawyer *Stevick* Dep. at 241:11-19. (*Johnson v Monsanto Co.*, No. CGC-16-550128, 2018 WL 2324413, at *15 (Cal.Super. May 17, 2018)) (allowing Dr. Sawyer to testify that Plaintiff's exposure was consistent with the epidemiology).[48]

3. Dr. Sawyer's Dose Calculation is Sufficiently Reliable.

Dr. Sawyer bases his dose calculation on a generally accepted pesticide modeling technique, the UK Predictive Operator Exposure Model. (UK POEM). Monsanto presents no evidence that this model is unreliable. *See, e.g.*, *Nw. Coal. for Alternatives to Pesticides (NCAP) v. U.S. E.P.A.*, 544 F.3d 1043, 1048–49 (9th Cir. 2008) (rejecting argument that pesticide exposure modeling [a different model then UK POEM] is unreliable where "Petitioners have presented no evidence that modeling does not yield reliable data. There is nothing inherently unreliable about the use of models...").

Monsanto, itself, utilizes the UK POEM modeling on glyphosate when making regulatory submissions. Ex. 72 MDL Report at 18-21. Dr. Sawyer and Monsanto scientists use the UK POEM in

[48] To the extent Dr. Sawyer's opinions related to the epidemiological are dependant upon other experts, this is entirely proper. *See Pulse Med. Instruments, Inc. v. Drug Impairment Detection Servs., LLC*, 858 F. Supp. 2d 505, 512 (D. Md. 2012) ("[A]n expert may rely on the work of others when preparing an expert report, particularly when it is the sort of work that is reasonably relied upon by experts in the relevant area of expertise"); *Beck v. Koppers, Inc.,* No. 3:03 CV 60 P D, 2006 WL 270260, at *10 (N.D. Miss. Feb. 2, 2006) ("[Dr. William] Sawyer's dosage and risk assessment testimony (as long as the latter is based on Dahlgren's general causation testimony) meets the threshold requirements of Rule 702.").

assessing the exposure of glyphosate because the model is designed for all pesticides. As Dr. Sawyer explained, "[t]he data I relied upon is using actual spray and measurements of that spray on the body. Now, whether it's glyphosate or a similar chemical of molecular weight and velocity doesn't matter." Ex. 75 Sawyer *Hall* Dep. at 438. In fact, the European Food Safety Authority (EFSA) in its 2015 glyphosate evaluation (which Monsanto relies upon) used the UK POEM to estimate operator exposure to glyphosate.[49] And, the 2015 Greim article cites the UK POEM, too, stating, "Systemic exposure of operators, as assessed for the EU reapproval of glyphosate, is predicted to be between 0.0034 (German BBA model, tractor-mounted ground-boom sprayer) and 0.226 mg/kg bw/day (UK POEM, hand-held-spraying to low targets, data not shown)."[50]

The UK POEM is recognized by EFSA as an available and reliable exposure modeling technique. Sawyer Decl. at 64. The latest regulatory body to review the UK POEM notes that it "is an internationally developed model based on a robust dataset." *Id.* at 67.

In direct contradiction to Monsanto's allegation that Dr. Sawyer put the wrong inputs into some of his POEM calculations, Dr. Sawyer actually presents a range of dermal absorption rates from 1% to 10%. It is Dr. Sawyer's opinion that the absorption rate ranges from 3 to 10 percent based on the findings of two in vivo primate studies; one human skin study and one rat skin study.[51] Ex. 71 MDL Report at 59-66; 119-120. Ex. 74 Sawyer Decl..

In arriving at this absorption range, Dr. Sawyer correctly applies generally accepted guidelines from the OECD that "[t]he current default approach taken by nearly all regulatory agencies is to determine the dermal absorption value by adding the absorbed dose and the chemical remaining in the skin, following washing" Ex. 72 MDL Report at 93. As Dr. Sawyer notes, Monsanto studies demonstrate that "much of the test material [glyphosate] may in some way bind to or in the skin and cannot be removed by washing" Ex. 72 MDL Report at 60. Monsanto scientists internally confirmed Dr. Sawyer's opinion.

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[49] EFSA, "Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate", p. 41 (2015) available at: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4302

[50] Greim, et al., "Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies" Crit Rev Toxicol. 2015 Mar 16; 45(3): 185–208. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4819582/

[51] The TNO rat study was not deemed unreliable, rather, Monsanto prohibited the study from continuing because "of the potential for this work to blow Roundup risk evaluations (getting a much higher dermal penetration than we've ever seen before.)" *Id.* 108-110.

For example, a Monsanto toxicologist stated in a 2003 email that "we know now, 5-20% of the dose of glyphosate could be stored in the skin...I think we should be really happy if the regulators allow us to use the 3% derm pen values." Ex. 72 MDL Report at 22. MDL Report at 22. Dr. Sawyer does not agree that human cadaver skin studies referenced by Monsanto more closely approximates the human experience. Ex. Sawyer MDL Rep. at 58, 67-88. Dr. Sawyer extensively explained why these studies fail to follow established guidelines. *Id.*

Finally, Dr. Sawyer uses the UK POEM, not to establish a threshold dose for causation, but to compare whether Ms. Stevick's exposure to glyphosate is similar to that of professional users. Under the UK POEM based on studies examining professional and amateur applicators, home users are shown have a higher rate of exposure than professional users due to the equipment used and lack of protective gear. Ex. 74 Sawyer Decl. at 71; Ex. MONGLY01075506, Appendix 8-14 (Under the UK POEM methodology based on a 3% absorption, professional users have a range of doses from 0.066 to 0.67 mg/kg over 6 hours (0.011 - 0.11 mg/kg/hr) compared to a dose of 0.12 mg/kg for residential users after 30 minutes (0.24 mg/kg/hr.) ; Ex. 77 Sawyer Johnson Rep. 151-152 (*highest* doses for professional users at 3% and 6 hours use is 1.38 mg/kg/hr (0.23 mg/kg/hr). Ex. 71 Sawyer Stevick Dep. at 132:13-17 (Stevick dose at 0.239 mg/kg/hr).

D. Dr. Sawyer May Rely on and Explain Technical Details Contained in Internal Monsanto Documents.

Plaintiffs agree that Dr. Sawyer will not testify about Monsanto's corporate intent, but Dr. Sawyer will discuss the scientific findings, opinions and data contained in internal Monsanto documents. Experts may rely on and discuss corporate documents if the documents are relevant to their opinions. *See In re Seroquel Prod. Liab. Litig.*, No. 6:06-MD-1769-ORL-22D, 2009 WL 3806436, at *4 (M.D. Fla. July 20, 2009). Also, there is "nothing particularly unusual, or incorrect, in a procedure of letting a witness relate pertinent information in a narrative form as long as it stays within the bounds of pertinency and materiality." *In re Yasmin,* 2011 WL 6302287, at *18.

The emails cited by Dr. Sawyer in his report are filled with technical knowledge that would not be easily comprehended by a lay juror. For example, the following phrases need expert explanation:

> Even though we can absorb additional 'uncertainty factors' in our risk assessment based on our biomonitoring results, I feel uncomfortable with this discussion. This approach by

> Spain sets a precedent and contradicts the fact that we always claimed to fully understand the glyphosate pharmacokinetics. The Wester IV experiment suggests that almost the entire 'systemically' available dose was excreted in urine. The low dose topical in vivo experiment suggests that almost the entire dose (82%) that was absorbed through the skin was excreted in feces (3.6% feces versus 0.8% in urine).

Ex. 71 MDL Report at 96.

E. Dr. Sawyer May Testify About Ethics in Toxicology.

Sawyer is qualified to explain that toxicologists are "ethically bound to perform certain duties, regardless of the outcome of the specific test," and not to "adjust the evidence to meet a predetermined outcome." Ex. 74 Sawyer Aff. Dr. Sawyer can opine on the effect of the failure of Monsanto scientists to follow the ethical code of toxicologists. *Johnson v Monsanto* Co., No. CGC-16-550128, 2018 WL 2324413, at *16 (Cal. Super. May 17, 2018) (denying Monsanto's motion to exclude Dr. Sawyer's testimony; "with respect to the impact of non-compliance with the ethical obligations owed by toxicologist, Monsanto has not demonstrated that Dr. Sawyer disclaimed any such opinions."); *see also MAR Oil Co. v. Korpan*, 973 F. Supp. 2d 775, 785 (N.D. Ohio 2013) (Testimony pertaining to breaches of ethical codes is admissible).

F. Dr. Sawyer Properly Revised His Calculation.

Dr. Sawyer did decide that 50 kg was a reasonable measure for Stevick's weight based on Sullivan's report and the fact that Stevick's current weight of 55 kg was due to the fact that she gained weight around the time of her cancer; after using GBFs. Ex.71 Sawyer Stevick Dep. at 222:6-223:20. Furthermore it has little bearing on his opinion as it affects the dose by only 10%. Ex. 74 Sawyer Decl. at ¶¶ 98-99. There is nothing inappropriate in revising his calculations in such a manner. Contrary to Monsanto's allegations, "There is no stigma attached to such error correction, nor should there be. If anything, it strengthens the quality of the expert report." *Crowley v. Chait*, 322 F. Supp. 2d 530, 540 (D.N.J. 2004); *United States v. Tarwater*, 308 F.3d 494, 505 (6th Cir. 2002); *Davis v. United State*s, No. CV 07-00461 ACK-LEK, 2009 WL 10702627, at *5 (D. Haw. Apr. 24, 2009).

PLAINTIFFS' RESPONSE REGARDING JAMES MILLS

Monsanto's financial circumstances are a relevant consideration for punitive damages under California law. While the math involved is not overly complex, an understanding of the data requires expertise to assist the jury. Indeed, jurors are unfamiliar with and therefore unable to interpret many of the ordinary, but complicated, financial documents relevant to Monsanto's finances. This is the very

conclusion other courts have made in similar major product liability litigations. *See In re Yasmin,* 2011 WL 6732819, at *7 (S.D. Ill. Dec. 16, 2011); *In re E. I. Du Pont De Nemours and Company C-8 Personal Injury Litigation*; 2015 WL 13767600, at *8-9 (S.D. Oh. Aug. 11, 2015).

A. James Mills is Qualified to Testify.

Monsanto incorrectly claims that James Mills is not qualified to testify as an expert witness. Mr. Mills has a Master of Arts degree in applied economics. He is a senior economist with Robert W. Johnson & Associates and belongs to various professional associations. He has been qualified and has testified as an expert economist in many cases. Because Mr. Mills demonstrates expertise in the field of economics he is qualified to discuss Monsanto's major financial information.

B. Mills' Report and Opinions

Mr. Mills was retained to frame the financial condition of Monsanto based upon its financial data including 10-K reports, proxy statements, 8-K report, and news releases. Should the jury find evidence sufficient to warrant punitive damages, Mr. Mills will provide the information he gleaned from the financials, which includes net worth, cash on hand, research and development expenditures, advertising expenditures, and the cost of the recent acquisition of Monsanto by Bayer. He will explain to the lay jury the definitions and interpretations of these indicators. This data will provide the jury with a financial picture of Monsanto for consideration in assessing the total amount of punitive damages.

1. Monsanto's Financial Condition is Relevant to Punitive Damages.

Monsanto's financial condition is an issue for the jury to consider when determining the amount of punitive damages. In assessing punitive damages, a jury must consider the impact of the award on the defendant "in light of the defendant's financial condition," because the deterrent function of punitive damages will not be served if the financial condition of a defendant allows it to "absorb the award with little or no discomfort." *Adams v. Murakami*, 54 Cal.3d 105, 113 (1991). *See also Bertero v. Nat'l. Gen. Corp.*, 13 Cal.3d 43, 65 (1974).

The consideration of "financial condition" under California law does not involve any rigid focus on any one indicator of financial condition. "Various measures of a defendant's ability to pay a punitive damages award have been suggested," but the Supreme Court has declined "to prescribe any rigid standard for measuring a defendant's ability to pay." *Adams*, 54 Cal.3d at 110, 116 n.7. A jury may assess a defendant's ability to pay by reference to the defendant's past profits from the wrongdoing and its

current gross or net wealth, sales or income, as well as its net worth. *See, e.g.*, *Vallbona v. Springer* (4th Dist. 1996) 43 Cal.App.4th 1525, 1540-41 & n.19; *Vossler v. Richards Mfg. Co*. (5th Dist. 1983) 143 Cal.App.3d 952, 967-68 (noting relevance of "figures on gross sales, gross income, or gross wealth"); *Bankhead v. ArvinMeritor, Inc.* (2012) 205 Cal. App. 4th 68, 85, 139 Cal. Rptr. 3d 849 (upholding a punitive damage testimony beyond net worth including 10-K reports, proxy statements, cash flows, sales, and executive compensation). Thus, California courts strongly support presentation of the full financial condition of a company instead of simply stipulating to "net worth."

2. Mr. Mills' Opinion is Reliable and Helpful For the Jury.

Monsanto argues that Mr. Mills is performing no function beyond reading simple documents that are comprehensible to a layperson and that Mr. Mills relies on "publicly available" information. *Id*. However, the "public" or "private" nature of a document has no bearing on whether it is within the understanding of a layperson. Moreover, because Monsanto was a publicly-traded company at all relevant times, it is to be expected that the vast majority of its financial data is "publicly available."

Interpretation and analysis of the type of financial information Mr. Mills analyzed in this litigation is a technical and specialized field. The average juror would not be able to review Monsanto's Securities and Exchange Commission (SEC) filings, proxy statements, and news releases, to reach an informed conclusion as to the company's financial condition. In particular, Mr. Mills safeguards the jury from misinterpreting such information and specifically summarizes data that California courts have found relevant to the punitive damages inquiry.

The Southern District of Illinois decision in *In re Yasmin*, illustrates the value of Mr. Mills' expert testimony regarding the financial condition of a large company. 2011 WL 6732819, at *7 (S.D. Ill. Dec. 16, 2011). In *Yasmin*, Robert Johnson, a colleague of Mr. Mills, offered similar testimony regarding the financial condition of Bayer. *Id*. *7. Bayer sought to exclude Mr. Johnson's testimony on the same grounds Monsanto asserts here, arguing that it was unhelpful to the jury. *Id*. The court rejected the argument and held:

> Clearly, it is generally more helpful to the trier of fact and efficient for the Court to present voluminous information in the form of a summary. However, the jury requires someone in possession of the necessary knowledge and expertise to explain the relevant summaries and charts.
> Although concededly comprehensible, the Court finds Johnson's report assists the trier of fact in its analysis of issues relevant to the dispute. As explained previously, evidence of

> Bayer's total wealth is relevant and admissible as it pertains to a possible punitive damages award in each individual plaintiff's case. Accordingly, to allow the jury to assess Bayer's wealth with any level of accuracy, an expert is required to determine Bayer's total wealth and explain his or findings in a manner helpful to the trier of fact. Thus, the Court finds Johnson's report is helpful to the trier of fact as it converts currency forms of various documents and then uses generally-accepted economic formulas to determine Bayer's total wealth; a task not within the general ability of a layperson. Therefore, Johnson's report satisfies the requirements of Fed. R Evid. 702 and Daubert. As such, it is admissible."

Id. (citations omitted). Similarly, Mr. Mills' qualifications allow him to select, review, and summarize the documents that identify Monsanto's financial condition and aid the jury in their interpretation.

Monsanto, relying upon *Voilas v. Gen. Motors Corp*., argues that Mr. Mills' testimony will invade the province of the jury. 73 F.Supp.2d 452 (D.N.J.1999). But in *Voilas*, the court excluded expert testimony offering three different calculations of punitive damages. *Id*. Here, Mr. Mills intends to solely discuss Monsanto's financial condition; his testimony does not entail a punitive damages calculation. Ex. 78, 31:9-12. ("So it's my understanding that an amount of punitive damages -- if punitive damages were found -- would be within the purview of the trier of fact."). Accordingly, because Mr. Mills will not make a recommendation as to as appropriate punitive damages award in this case, his testimony does not usurp the role of the jury.

Further, Monsanto argues that Mr. Mills' testimony should be excluded because the figures he seeks to present are not representative of Monsanto's actual ability to pay. However, this only illustrates why Mr. Mills' testimony is helpful to a jury: he has the expertise and specialized knowledge to select and analyze the relevant financial metrics and put this information into a context that enables the jury to evaluate Monsanto's ability to pay. According to Monsanto's logic, the jury would be better off if Plaintiffs simply handed the jury all of Monsanto's publicly-available financial information without any guidance or contextual analysis. And, to the extent Monsanto disputes Mr. Mills' selection (and non-selection) of certain financial numbers and metrics, Monsanto's appropriate recourse is to challenge Mr. Mills' choices on cross-examination—not seek to exclude his entire testimony. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 596 (1993).

PLAINTIFFS' RESPONSE REGARDING MR. GEBEYEHOU

A. Mr. Gebeyehou's Claims Are Not Time-Barred.

Monsanto's contention that Mr. Gebeyehou's personal injury claims accrued based on purported discovery in 2014 is simply unfounded. The 2014 time period Monsanto identifies is *before* the IARC assessment and the publication of the Greim paper which, for the first time, made public the toxicological data generated by industry related to glyphosate. As explained below, Mr. Gebeyehou, as a layperson, did not and reasonably could not have discovered that his Roundup® exposure caused his illness until he received some credible confirmation of his suspicion. Whether the Court applies the statute of limitations under Cal. Civ. Proc. Code § 335.1 (for personal injury claims) or Cal. Civ. Proc. Code § 340.8 (exposure to hazardous materials or toxic substances), the outcome is the same. Moreover, the issue of Mr. Gebeyehou's discovery of the salient facts supporting his claims is a question of fact that should be resolved by the jury. Thus, summary judgment on this argument is inappropriate.

1. Mr. Gebeyehou Did Not and Could Not Have Discovered the Association Between NHL and Roundup® in 2014.

a. Cal. Civ. Proc. Code § 340.8 Applies to the Instant Case.

Contrary to Monsanto's argument, the applicable statute of limitations in this case is not Cal. Civ. Proc. Code § 335.1, but Cal. Civ. Proc. Code § 340.8. "Nothing in the statute limits its provisions to environmental hazards." *See Nelson v. Indevus Pharm., Inc.,* 142 Cal. App. 4th 1202, 1209 (2006) (noting, in a pharmaceutical case, that according to the clear language of the statute, [CCP 340.8] applies to "any" civil action "for injury or illness based upon exposure to a hazardous material or toxic substance.") (internal citation and quotation marks omitted).

Cal. Civ. Proc. Code § 340.8 provides that a civil action for personal injuries based on exposure to a hazardous or toxic substance must be commenced:

> no later than either two years from the date of injury, or two years after the plaintiff becomes aware of, or reasonably should have become aware of, (1) an injury, (2) the physical cause of the injury, and (3) sufficient facts to put a reasonable person on inquiry notice that the injury was caused or contributed to by the wrongful act of another, whichever occurs later.

Mr. Gebeyehou sued Monsanto within the above-proscribed time frame: Mr. Gebeyehou did not know, nor did he have sufficient facts reasonably to put him on notice of, the causal connection between his Roundup® use and NHL diagnosis until March 2016 when his physician friend sent him an email about the IARC Monograph 112. Ex. 80 *Gebeyehou* Dep. 55:1-6.

Monsanto bases its entire argument on three purported facts: (1) that Mr. Gebeyehou saw an episode of the Dr. Oz show in September 2014 that raised his suspicion that Roundup® use could cause cancer; (2) that he conducted Internet research and found an article linking cancer and Roundup® use, and sent it to his oncologist asking if his Roundup® use could have caused his NHL; and (3) that he reduced his Roundup® use after hearing "rumors" about Roundup®'s potential carcinogenicity. (MSJ at 21-25). None of these facts supports accrual of the statute of limitations.

First, the September 22, 2014 Dr. Oz episode Monsanto references was not about Roundup®; the episode was about a "brand-new GMO pesticide" called Enlist Duo manufactured by Dow, which is a combination of glyphosate and 2,4-D. Season 6, Episode 11: New GMO Pesticide Doctors Are Warning Against (aired: 9-22-2014) (https://www.doctoroz.com/episode/new-gmo-pesticide-doctors-are-warning-against?video_id=3794878213001). The episode's purpose appears to have been to provide general information to the public about the ways in which the agrochemical, biotechnical, and pesticide industries pose dangers to human health and the environment. Importantly, the show did not address a correlation between Roundup® use and NHL.

Second, Mr. Gebeyehou's September 24, 2014 email to his oncologist, attaching an article about Roundup® use and cancer, again shows only that, at that time, Mr. Gebeyehou was undertaking a reasonable inquiry about whether there was a plausible link between Roundup® use and NHL. Rodale, Inc., the publisher of the article, was a health and wellness magazine that is no longer in business. It was not a scientific journal, the article was not written by a doctor or scientific researcher, and there are no citations to the papers referenced in the article for Mr. Gebeyehou to access and review. He thus sent an inquiry to the only person he believed could provide the answer—his oncologist, *see* Ex. 80 *Gebeyehou* Dep. 126:19-25—who rejected Gebeyehou's suspicion. Mr. Gebeyehou testified that the statement in his email that he was 95% certain that Roundup® caused his NHL was an exaggeration to get his oncologist's attention. Ex. 80 *Gebeyehou* Dep. 57:15-19. Further, Monsanto omits the undisputed fact that Dr. Pai, his oncologist, responded to Mr. Gebeyehou's email about other matters

but did not respond to or address Mr. Gebeyehou's comment about Roundup® and NHL. Ex. 79 *Pai* Dep. at 48:15-49:5. Indeed, Dr. Pai essentially dismissed Mr. Gebeyehou's concern altogether: "Typically, my common response to most of my patients usually is that there's a difference a lot of times between association and causation, and at this point, just from our scientific journals where I get most of my information from, there isn't any -- there wasn't any obvious link [between Roundup® and NHL] that I was aware of at the time." Ex. 79 *Pai* Dep. at 50:8-13. Dr. Pai also did not tell Mr. Gebeyehou to stop using Roundup®. Ex. 79 *Pai* Dep. at 51:19-21. Mr. Gebeyehou had no independent scientific information or any reason to question his physician's response. Thus, Mr. Gebeyehou's inquiry in 2014 was unsubstantiated and he continued to use Roundup®.

Third, Mr. Gebeyehou's reduced use of Roundup® in 2014 is irrelevant. If Mr. Gebeyehou had reasonably believed Roundup® likely caused his NHL in 2014, he would have ceased using it altogether as he did in 2016 when his suspicion was confirmed. And Mr. Gebeyehou's reduced Roundup® use in 2014 is neither surprising nor relevant to the discovery inquiry given his illness. For example, during the 2014 summer, he could hardly walk 150 yards. Ex. 80 *Gebeyehou* Dep. at 121:1-4.

b. Even If Cal. Civ. Proc. Code § 335.1 Applies, Mr. Gebeyehou's Cause of Action Did Not Accrue in 2014.

Even if the Court were to apply Cal. Civ. Proc. Code § 335.1 as Monsanto argues, "[p]roduct liability claims brought under either negligence or strict liability theories are [also] subject to delayed accrual under the discovery rule." *Fox v. Ethicon Endo-Surgery, Inc.,* 35 Cal. 4th 797, 809 (2005) (citations omitted). It is well settled that "under the delayed discovery rule, a cause of action accrues and the statute of limitations begins to run when the plaintiff has reason to suspect an injury and some wrongful cause." *Id.* at 803. California courts are clear that in order to bring a cause of action, "plaintiff must be aware of her injury, its factual cause, and sufficient facts to put her on inquiry notice of a negligent cause of action." *Clark v. Baxter Healthcare Corp.,* 83 Cal. App. 4th 1048, 1057-59 (2000) (noting that plaintiff who suffered an adverse reaction to latex gloves in 1993 did not have notice of the defendant's wrongdoing until 1995 when she received a flyer regarding latex allergy litigation despite consulting an allergist in 1994 who suggested she may be allergic to latex gloves).

The same arguments above apply to the discovery rule applicable to Cal. Civ. Proc. Code § 335.1. Mr. Gebeyehou did not and could not reasonably have obtained sufficient facts to know that

Roundup® was the cause of his illness prior to the IARC's classification of glyphosate as a 2A carcinogen on March 20, 2015. More specifically, Mr. Gebeyeheou did not actually discover the facts supporting his cause of action prior to the IARC Monograph 112, which he only learned in March 2016 when a physician friend sent him an email about it. Ex. 80 *Gebeyehou* Dep. 55:1-6.

2. Monsanto's Fraudulent Concealment Tolls the Statute of Limitations.

California's fraudulent concealment doctrine also tolled the statute of limitations on Mr. Gebeyehou's claims. "In order to establish fraudulent concealment, the complaint must show: (1) when the fraud was discovered; (2) the circumstances under which it was discovered; and (3) that the plaintiff was not at fault for failing to discover it or had no actual or presumptive knowledge of facts sufficient to put him on inquiry." *Baker v. Beech Aircraft Corp.,* 39 Cal. App. 3d 315, 321 (1974) (citation omitted). Mr. Gebeyeheou's case satisfies all three prongs. *See* Gebeyehou Compl. ¶¶ 115-118.

The basis of the fraudulent concealment doctrine is that "the defendant, having by fraud or deceit concealed material facts and by misrepresentations hindered the plaintiff from bringing an action within the statutory period, is estopped from taking advantage of his own wrong." *Baker*, 39 Cal. App. 3d at 322-23 (internal quotation marks and citation omitted). There is voluminous evidence that Monsanto ghostwrote scientific papers to confront an increasing body of science, including the IARC assessment, that glyphosate causes cancer.[52] After consistently promoting the safety of its Roundup® products for years, via its website, advertisements, commercials and labels, and withholding scientific data concerning the carcinogenicity of glyphosate and GBFs from the EPA and the public generally, Monsanto cannot now claim that Mr. Gebeyehou ought to have somehow discovered the facts underlying his claim in 2014.[53] This is especially the case here, where Mr. Gebeyehou regularly visited Monsanto's website where he was likely subject to Monsanto's deceptive representations. *See* Ex. 80 Gebeyehou Dep. 159:1-9.

[52] Evidence of Monsanto's ghostwriting is outlined in Plaintiffs' Response to Monsanto's Motion *In Limine* No. 2: Ghostwriting and incorporated herein.

[53] For the same reasons, Monsanto is equitably estopped from arguing that Mr. Gebeyehou should have discovered the cause of his NHL when Monsanto, to this day, manipulates the science about glyphosate and touts Roundup's®safety. See, e.g., Lomeli v. Costco Wholesale Corp., No. 11-CV-2508-MMA(KSC), 2012 U.S. Dist. LEXIS 55913 (S.D. Cal. Apr. 20, 2012).

B. Summary Judgment Is Unavailable Because Material Facts Are Disputed.

The crucial issue of when Mr. Gebeyehou sufficient facts to know or reasonably be put on notice that Roundup® was the cause of his NHL is, at minimum, a question of fact for the jury to decide and necessitates denial of Monsanto's summary judgment motion. "When a plaintiff reasonably should have discovered facts for purposes of the accrual of a cause of action or application of the delayed discovery rule is generally a question of fact, properly decided as a matter of law only if the evidence (or, in this case, the allegations in the complaint and facts properly subject to judicial notice) can support only one reasonable conclusion." *Stella v. Asset Mgmt. Consultants, Inc.,* 8 Cal. App. 5th 181, 193 (2017) (citations omitted). Based on the relevant material disputed facts, the Court cannot decide on summary judgment which side to believe.

Dated: January 25, 2019

Respectfully Submitted,

/s/Aimee H. Wagstaff

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ECF ATTESTATION

Pursuant to Civil L.R. 5-1(i)(3), the filing attorney attests he has obtained concurrence regarding the filing of this document from the signatory above.

Date: January 25, 2019

By: */s/ Leland H. Belew*
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