Case No. S264158

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

Dewayne Lee Johnson,
Plaintiff and Respondent / Cross-Appellant,
v.
Monsanto Company
Defendant and Appellant / Cross-Respondent

Petition for Review of a Decision of the Court of Appeal,
First Appellate District, Division One, Nos. A155940 A156706

Superior Court, County of San Francisco
Civil Case No. CGC16550128
Honorable Suzanne R. Bolanos

ANSWER TO MONSANTO'S PETITION FOR REVIEW

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I. Introduction

Monsanto has wholly failed to demonstrate that review is "necessary to secure uniformity of decision or to settle an important question of law." (Rule 8.500.) Instead, Monsanto seeks to re-litigate a routine factual dispute that was easily won by Johnson due to the "abundant" evidence that Roundup caused his cancer. (Opinion 28.) The Court of Appeal issued a detailed, unanimous, and largely unpublished opinion applying the factual record to well-settled California and federal law and concluded that "none of [Monsanto's] arguments are persuasive." (Opinion 15.) The Court of Appeal is correct.

Roundup (a pesticide containing the chemical glyphosate and other carcinogens) was approved by the EPA in 1974 based on fraudulently conducted carcinogenicity and genotoxicity studies resulting in a criminal scandal that "shook the industry and government regulators" and resulted in Monsanto's Manager of Toxicology being imprisoned. (RA 42; *United States v. Keplinger,* (7th Cir. 1985) 776 F.2d 678, 684.) Monsanto has spent the subsequent decades continuing its scientific fraud, concealing the cancer risk, and refusing to appropriately test Roundup. Because of Monsanto's egregious conduct, three juries, five trial judges, and three appellate justices all concur that Monsanto "*consciously disregard[ed]* a *probable* safety risk" of Roundup. (Opinion 80, n. 6; *In re Roundup Products Liability Litigation* (N.D.Cal. 2019) 385 F.Supp.3d 1042, 1046 ["Monsanto deserves to be punished."]) As public health experts note "[t]he Monsanto strategy parallels those used by the tobacco industry..."

to "manufacture doubt" through scientific deception and "aggressive" attacks on independent experts.[1]

Multiple federal and state judges, juries, and appellate justices have uniformly rejected each of the worn out arguments Monsanto makes in its Petition. This unanimous rejection of Monsanto's defenses have led it to settle tens of thousands of claims from Roundup's cancer victims. (Petition 11, n. 1.) Monsanto (now Bayer) represented to its investors that all Roundup cases will settle and there will be "closure to the current Roundup™ litigation in due course."[2] The federal court-appointed mediator Kenneth Feinberg adds "I will be surprised if there are any future [Roundup] trials."[3] No plaintiff requested publication of the Court of Appeal's opinion, so it will have little effect on other Roundup cases.

There is no conflict involving the applicable legal standard of the consumer expectation test.

The Court can begin and end its consideration of Monsanto's petition by denying review of the design defect claims because the verdict stands on Johnson's design defect claims alone. (Opinion 36, 52.) Monsanto does not and cannot plausibly

[1] Samet, "Expert Review Under Attack: Glyphosate, Talc, and Cancer" AJPH, 109, 976_978 (2019) https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2019.305131

[2] https://bit.ly/3kUnkhf

[3] https://www.nytimes.com/2020/06/24/business/roundup-settlement-lawsuits.html)

challenge[4] the Court of Appeal's adherence to the U.S. Supreme Court's dictate that it is "perfectly clear" design defect claims are not preempted by federal law even if they "would surely induce a manufacturer to alter its label..." (*Bates v. Dow Agrosciences LLC* (2005) 544 U.S. 431, 444-446.) This Court has twice rejected petitions from pesticide manufacturers claiming design defect claims are preempted. (*Arnold v. Dow Chemical Co.* (2001) 91 Cal.App.4th 698; *Turner v. Chevron U.S.A. Inc.* 2006 WL 1314013, Cal.App. 2 Dist., May 15, 2006))

The Court of Appeal applied well-settled law on the design defect consumer expectation test to the specific facts of this case. California courts uniformly find that an ordinary consumer can form reasonable minimum safety expectations about pesticides and cancer-causing agents. (Opinion at 22-28; *Arnold,* 91 Cal.App.4th at 717; *Turner,* 2006 WL 1314013, at *2; *Sparks v. Owens-Illinois, Inc.,* (1995) 32 Cal. App. 4th 461; *Boeken v. Philip Morris, Inc.* (2005) 127 Cal.App.4th 1640, 1668; *Jones v. John Crane, Inc.* (2005) 132 Cal.App.4th 990, 1002-03.) This is true even where "expert testimony is required to prove that...[the product] was a...cause of injury." (*Soule v. General Motors*

[4] Monsanto claims that "[t]he design defect claim was also based on a failure-to-warn and therefore is also preempted." (Petition fn. 5) The Court of Appeal correctly ruled this statement was neither true nor timely raised. (Opinion 51-52.) Pursuant to Rule 8.500(c)(1) "...the Supreme Court normally will not consider an issue that the petitioner failed to timely raise in the Court of Appeal." This argument that a "defective design was essentially a 'disguised' failure-to-warn claim" was also rejected by *Bates* (544 U.S. at 436.)

Corp. (1994) 8 Cal.4th 548, 569.) No expert testimony is needed to establish that Johnson reasonably expected Roundup, a widely used weed spray, to not give him cancer, particularly where he was told Roundup was "safe enough to drink." (18B-RT-3229:9-3230:4.) Monsanto's marketing of Roundup was designed to induce people to "shout Glyphosate is Non-toxic[.]'" (6-AA-6556.)

The U.S. Supreme Court has resolved the federal preemption questions under FIFRA.

While there was some conflict among federal and state courts (including this Court) on the scope of preemption of failure-to-warn claims under FIFRA prior to 2005, "*Bates* resolved the conflict." (Opinion 31.) Following the clear mandate in *Bates,* the numerous federal judges considering Roundup labeling claims have reached "*a consensus* ...that FIFRA does *not* preempt claims for damages under state law." (*Blitz v. Monsanto Company* (W.D. Wis. 2018) 317 F.Supp.3d 1042, 1049.) This Court holds that "where the decisions of the lower federal courts on a federal question are 'both numerous and consistent,' we should hesitate to reject their authority." (*Barrett v. Rosenthal* (2006) 40 Cal.4th 33, 58.)

Bates directly applies to safety related failure-to-warn claims and such cases are part of the conflict it "resolve[d]." (Bates, 544 U.S. at 437 fn. 4-5.) In resolving the conflict, *Bates* determined that *Ferebee v. Chevron Chemical Co.* ((D.C. Cir. 1984) 736 F.2d 1529) correctly interpreted FIFRA. (*Id.* at 451.) *Ferebee* held that FIFRA did not preempt a safety related failure-to-warn claim even where, after a review of "extensive scientific

testimony," the EPA did not recognize that the pesticide caused the plaintiff's injury. (*Id.* at 1540.) The U.S. Supreme Court, applying *Bates*, has rejected Monsanto's arguments that safety related failure-to-warn claims caused by its pesticide are preempted under FIFRA. (*Oken v. Monsanto Co.* (2005) 544 U.S. 1012.)

Bates rejected Monsanto's argument that EPA employees have exclusive authority to determine whether a label is misbranded.[5] (Petition at 24; *Bates,* 544 U.S. at 448 [rejecting argument that FIFRA was intended by "Congress to be interpreted authoritatively by EPA."]) The fact that glyphosate[6] is registered by the EPA without a cancer warning does not help

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[5] The Atlantic Legal Foundation (ALF) submitted an Amicus letter also advancing this rejected argument. ALF, however, fails to disclose its interest in this matter as required by Rule 8.500(g)(2) and its letter should be disregarded. One of Monsanto's lead attorneys in this case and the nationwide Roundup litigation, Joe Hollingsworth, is on the Board of Directors for ALF. (*See e.g.* 1-AA-79; 5-AA-5904; https://atlanticlegal.org/2013/12/24/joe-g-hollingsworth-partner-hollingsworth-llp/) As Hollingsworth LLP's website states its amicus program is used to "independently advance our clients' interests through our memberships in, among others, the...Atlantic Legal Foundation." (https://www.hollingsworthllp.com/firm/supporting-business) Monsanto, likewise, in its brief cites two self-serving articles from law firms that represent Monsanto's parent corporation Bayer as its evidence of nationwide commentary supporting its position.

[6] The EPA evaluates the carcinogenicity of only glyphosate and does not consider the full Roundup formulation used by Johnson. (Opinion 10-11; 22A-RT-3920:16-25; 22A-RT3880:6-10; 21A-RT-3613:21-3616:3.)

Monsanto because "[i]n no event shall registration ... be construed as a defense for the commission of any offense" under FIFRA. (Opinion 45 [quoting 7 U.S.C. § 136a(f)(2).]; *Bates*, 544 U.S. at 438) It is Monsanto's "obligation" to ensure that its label adequately warns consumers of safety risks and to "seek approval to amend its label" if the warnings are inadequate. (*Bates,* 544 U.S. at 438-439.) *Bates* allows a jury to disagree with the EPA's safety assessment of a pesticide holding that "tort suits can serve as a catalyst" in identifying risks not yet recognized by the EPA and "may lead manufacturers to petition EPA to allow more detailed labelling of their products…*" Id.* (*Id.* at 451 [quoting *Ferebee,* 736 F.2d 1529.])

Monsanto falsely claims that the Court of Appeal did not consider the EPA documents that Monsanto submitted for the first time on appeal. (Petition 15.) Over Johnson's objections[7], the Court of Appeal did consider those documents, allowed supplemental briefing; and consistent with the ruling in *Risperdal and Invega Cases* ((2020) 49 Cal.App.5th 942, 959) held that "despite the supplemental information provided by Monsanto, it has established no more than a *possibility* of impossibility." (Opinion at 51.) Monsanto never requested a label change as required under *Merck* and "neither agency musings nor hypothetical future rejections constitute pre-emptive "Laws"

[7] "It is a fundamental principle of appellate law that our review of the trial court's decision must be based on the evidence before the court at the time it rendered its decision." *California School Bds. Assn. v. State of California* (2011) 192 Cal.App.4th 770, 803

under the Supremacy Clause." (*Merck Sharp & Dohme Corp. v. Albrecht* (2019) 139 S.Ct. 1668, 1682.)

The California Attorney General agrees that "[n]either EPA's approval of Roundup's label nor an informal letter disapproving California's efforts to require warnings about glyphosate's carcinogenic properties carries the force of law to preempt state-law warning requirements."[8] This is particularly true where the informal letter was issued in 2019 and thus could not possibly have prevented Monsanto from warning Johnson before 2012. As late as 2017, the EPA permitted other glyphosate manufacturers to add cancer warnings to their glyphosate labels, thereby destroying Monsanto's "impossibility defense." (Respondent's Supplemental Brief 25.)

Monsanto also could have warned Johnson about the risk of cancer without changing the Roundup label. (*Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby* (9th Cir. 1992) 958 F.2d 941, 947 ["manufacturers need not feel pressure to apply for EPA approval of label changes" where they can warn outside of the label.) The U.S. Occupational Safety and Health Administration (OSHA) allows and indeed now requires Monsanto to warn under OSHA about the cancer risk of Roundup on the Material Safety

[8] https://oag.ca.gov/news/press-releases/attorney-general-becerra-files-amicus-brief-lawsuit-against-monsanto-support

Data Sheets[9] relied upon by Johnson. (5-AA-5646-5647; 21A-RT-3637:2-11; 18B-RT-3230:10-3232:4.)

It is implausible that the EPA would refuse a request by Monsanto to add a cancer warning, as the EPA has assured Monsanto "[w]e have Monsanto's back on pesticides regulation..." (XARB 49.) A bipartisan report recently released by 500 former EPA employees including five former EPA Administrators finds that in "recent years" the "EPA has: marginalized the scientific basis for EPA policies and decisions; significantly reduced the credibility of EPA actions and efforts; jeopardized human health and the environment; and provided opportunities for **special interests to have a disproportionate influence on EPA actions**."[10]

The Ninth Circuit recently reversed the EPA approval of a Monsanto pesticide holding that that the EPA's analysis dismissing environmental risks was "fundamentally flawed" because the EPA disregarded quality, independent science in favor of reliance on "Monsanto, and only Monsanto." (*National Family Farm Coalition v. U.S. Environmental Protection Agency* (9th Cir. 2020) 960 F.3d 1120, 1137, 1145.)

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[9] The label approved by the EPA is attached to the actual bottle of Roundup. OSHA has authority over the content of the safety data sheets (also created by Monsanto) which employers are required to provide to employees who use Roundup professionally.

[10] Resetting the Course of EPA, Recommendations from the Environmental Protection Network, August 2020, p. 7 *available at:* https://www.environmentalprotectionnetwork.org/wp-content/uploads/2020/08/Resetting-the-Course-of-EPA-Report.pdf

Here, likewise, an independent Scientific Advisory Panel (SAP) established under FIFRA to peer-review EPA decisions unanimously concluded that for glyphosate, "the EPA [evaluation] does not appear to follow the EPA cancer guidelines;" that it was not "quality science" due to "distortion"; and "many panel members believe that the EPA did not provide convincing evidence of a lack of carcinogenic effects." (RA-123, 202; 14B-RT-2395:6-12; 26B-RT-4640:13-19.) Three SAP members, in a peer-reviewed study, concluded that there was a "compelling link between exposures to [Roundup] and increased risk for NHL [non-Hodgkin Lymphoma]" (XARB 49.) California has deemed the EPA analysis to be "disrespectful of the scientific process."[11]

Congress wisely refused to grant EPA political appointees the sole authority to enforce FIFRA and instead granted "concurrent authority of the Federal and State Governments in this sphere." Bates, 544 U.S. at 451. Therefore, "[n]othing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law." (*Bates*, 544 U.S. at 442; *Hardeman v. Monsanto Company* (N.D. Cal. 2016) 216 F.Supp.3d 1037, 1038 ["the EPA's authority to enforce FIFRA does not prohibit private litigants from also enforcing that statute..."]).

[11] https://oehha.ca.gov/proposition-65/general-info/oehha-statement-regarding-us-epas-press-release-and-registrant-letter

The California Attorney General agrees that the "EPA's failure to regulate glyphosate doesn't...preempt California from requiring that consumers be informed of the risks of cancer-causing products...California protects its residents from dangerous pesticides, and we shouldn't be forced to put our heads in the sand simply because the EPA won't do its job."[12]

The carcinogenicity of Roundup was both known and knowable by Monsanto

Monsanto's challenge, in issue three, to the Court of Appeal's correct recitation of established California law on strict liability failure-to-warn merits no consideration. Monsanto ignores the findings by the jury, the trial court[13], and the Court of Appeal that Johnson satisfied the higher burden of proving scienter under punitive damages based on clear and convincing evidence that Monsanto was "*consciously disregarding* a *probable* safety risk" of Roundup. (Opinion 80 fn. 2.) The Court of Appeal thus expressly refutes Monsanto's false claim that the punitive damage finding was based on a "possibility" of harm standard. (*Id.*)

This Court established that a manufacturer is required to warn of a "potential risk" of it product. (*Anderson v. Owens-*

[12] https://oag.ca.gov/news/press-releases/attorney-general-becerra-files-amicus-brief-lawsuit-against-monsanto-support

[13] Monsanto inappropriately cites a tentative opinion by the trial court on punitive damages, but a "tentative opinion has no relevance on appeal." (*Wilshire Ins. Co. v. Tuff Boy Holding, Inc.* (2001) 86 Cal.App.4th 627, 638.)

Corning Fiberglas Corp. (1991) 53 Cal.3d 987, 991.) The Court of Appeal applied *Anderson* and the jury received the standard CACI 1205 strict liability instruction to consider whether the carcinogenicity of Roundup was "known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific community..." (29A-RT-5047:3-6.)

Monsanto raises no conflict or unsettled area of law; it simply wishes to reargue its evidence that the Court of Appeal noted "is underwhelming." (Opinion 18-19.) The Court of Appeal correctly focused its attention on the "quality"[14] of the scientific evidence presented and found that Johnson presented "abundant—and certainly substantial—evidence that glyphosate, together with the other ingredients in Roundup products, caused [Johnson's] cancer." (Opinion 17-18, 29 [citing notes to CACI 1205 which requires manufacturers to use the "best scholarship available."] Almost the entirety of the "abundant" evidence supporting a jury finding that Roundup "more likely than not" caused Johnson's NHL was available to Monsanto prior to and during Johnson's use of Roundup. (RB-XAOB 28-41, 49-60.) The abundant evidence that Roundup causes cancer represented not a minority view, but the inevitable conclusion that occurs when qualified, independent scientists utilize the best available scientific methodologies.

[14] Even in terms of quantity, the number of scientists and studies supporting Johnson's petition far outnumber those cited by Monsanto.

II. Statement of Facts

From June 2012 until January 2016, Johnson sprayed thousands of gallons of Roundup as the Integrated Pest Manager at the Benicia Unified School District. (Opinion 3-7) Monsanto never informed Johnson that Roundup was carcinogenic. (*Id.* at 4-6, 76-77.) Instead, the Roundup sales representative told him that it was "safe enough to drink." (18B-RT-3229:9-3230:4.) The Roundup label states that "the active ingredient in this product inhibits an enzyme found only in plants." (6-AA-6918.)

In August of 2014, Johnson was diagnosed with NHL. (17A-RT-2861:5-9.) On November 11, 2014, Johnson called Monsanto and a Monsanto employee reported " ... He is just trying to find out if [his cancer] could all be related to such a large exposure to Ranger Pro[15]...He is looking for answers." (6-AA-6516 [emphasis added.]) No one called Johnson back to tell him Roundup could be causing his cancer. (5-AA-5616-5617; 18B-RT-3274:5-3275:6.) Johnson thus continued spraying Roundup and again called on March 27, 2015, twelve days after the International Agency for Research on Cancer ("IARC") issued its findings that glyphosate is a probable human carcinogen:

> [Johnson] has concerns about continuing to use Roundup as part of his job and questions if Roundup could be a source of his cancer... **The caller's level of fear is rising over his continued use of Ranger Pro** ... **MRPC discussed the product toxicity. The symptoms are not an expected response from the product.**

[15] RangerPro is the same as Roundup, but utilizes a different name for marketing purposes.

(6-AA-6519; 5-AA-5621-5623) Again no one called Johnson back, and instead directly contradicted IARC's findings and failed to convey them to Johnson. (18B-RT-3282:4-3283:5.) Consequently, Johnson kept spraying Roundup and in September 2015 his cancer transformed into an aggressive and incurable variant which will drastically shorten his life expectancy. (17B-RT-2882:21-2884:3.)

Prior to 2012, Monsanto was well aware of abundant evidence that Roundup was capable of causing NHL. The major epidemiology studies relied on by Johnson's experts were published before 2008 and "were done in different contexts, different populations, different countries under different circumstances…across all the studies, they were consistently positive" showing an association between Roundup and NHL. (16B-RT-2644:17-20.) The animal studies on the active ingredient glyphosate were completed by 2010, and included five mouse studies which each showed an increase in the incidence of lymphomas lending strong support to causality of NHL in humans. (12B-RT-1825:19-1837:14.) Genotoxicity studies conducted before 2009 demonstrated that Roundup damaged DNA in the blood cells and lymphocyte cells in humans, a mechanistic precursor to NHL. (13A-RT-1975:4-1979:10; 6-AA-6870.)

Johnson's experts' review of this abundant data, applying the Bradford-Hill methodology, led to the conclusion "that there is indeed a causal association between glyphosate and NHL."

(16B-RT-2642:22-2646:23; 13A-RT-2023:3-5.) The Bradford Hill methodology is "well accepted in the medical field for making causal judgments." (*Wendell v. GlaxoSmithKline LLC* (9th Cir. 2017) 858 F.3d 1227, 1235, fn. 4.)

The opinions of Johnson's experts are supported by the findings of IARC. IARC, an agency of the United Nation's World Heath Organization, is the "prime arbiter" in determining whether a chemical is carcinogenic. (16A-RT-2550:12-17.) After months of carefully evaluating the available data, an IARC panel of seventeen experts convened in March 2015 and unanimously determined that Roundup is a probable human carcinogen. (12A-RT-1760:4-6.) These seventeen experts included Dr. Mathew Martin from the U.S. EPA; Dr. Lauren Zeise, Head of California's Office of Environmental Health Human Assessment (OEHHA); and renowned epidemiologist Dr. Aaron Blair, retired chief of cancer epidemiology at the National Cancer Institute. (12A-RT-1724:4-1726:6.) IARC's assessment was based on real-world exposures to applicators such as Johnson and represents a real risk to human health. (12-RT-1741:21-24; 16A-RT-2600:8-2601:21.) IARC's findings should "raise a red flag to those charged with protecting Public Health" and should "trigger immediate remedial action" such as "labeling of carcinogenic hazards." (16A-RT-2604:7-18.)

The consensus among independent scientists is that IARC uses state-of-the-art methodology and that Roundup is carcinogenic. In 2015, 125 independent scientists co-authored a peer-reviewed article supporting the scientific methodology

utilized by IARC. (16A-RT-2606:20-2609:19.) Monsanto's consultant who monitored the glyphosate proceedings stated that "the meeting followed the IARC guidelines." (5-AA-5739.) 94 independent scientists co-authored a peer-reviewed article supporting IARC's assessment of Roundup; and concluding that Roundup is a probable human carcinogen. (13A-RT-2016:3-2019:25.)

The IARC classification was published in March 2015, while Johnson was still using Roundup and before his cancer became terminal. (RB-XAOB 28-43.) Regarding the studies relied on by IARC, 77% were published before 2013; and 97% were published before 2015. (6-AA-6903-6916.) Even before IARC reached its conclusion, Monsanto knew Roundup would be classified as a carcinogen. On October 15, 2014, Monsanto internally acknowledged that Roundup had "vulnerabilities" in all the areas considered by IARC. (6-AA-6432.) In February of 2015, Monsanto drafted a plan to "orchestrate outcry" against IARC knowing that IARC would have to classify Roundup as a possible or probable human carcinogen based on the data. (6-AA-6426, 6430.)

The political regulatory reviews relied on by Monsanto are highly flawed. Those agencies (including the EPA) are restricted to only evaluating one ingredient in Roundup, the chemical glyphosate, whereas IARC evaluates the entire formulation (including the genotoxic surfactants in Roundup). (22A-RT-3920:16-25.) The EPA acknowledges that "glyphosate formulations are hypothesized to be more toxic than glyphosate

alone." (7-AA-7244.) Indeed, Monsanto's own scientists wondered why they continued to sell the "hazardous" U.S. Roundup formulation when "non-hazardous" alternatives were available. (6-AA-6563.) And yet, EPA's evaluations are limited to "the genotoxic potential of glyphosate technical." (*Id.*)

The SAP unanimously concluded that the EPA repeatedly violated its own carcinogenicity guidelines in its draft assessment of glyphosate. (14B-RT-2395:6-19; 26B-RT-4607:23-4613:1-3; 26B-RT-4629:15-4632:4.) The former EPA Assistant Administrator reviewed the work of the EPA scientists that evaluated glyphosate and concluded that the "assessment was not consistent with the Agency's guidelines." RA-116. In December of 2015, the scientists at the EPA's Office of Research and Development, the "scientific research arm of EPA"[16] concluded that glyphosate should be labelled as "likely to be carcinogenic" to humans or having "suggestive evidence" of carcinogenicity in humans. RA-231-232. Those views were dismissed in the current review of glyphosate. European regulatory agencies' decisions were likewise flawed. In Europe, Monsanto was allowed to write the first draft of the carcinogenicity review utilized by the European regulatory agencies. 13A-RT-2012:5-2014:23.

These regulatory decisions are not the result of scientific scholarship, but instead they result from Monsanto's influence on government regulators. Monsanto engaged in a massive campaign targeted at "Regulators" to "Orchestrate Outcry with

[16] https://www.epa.gov/aboutepa/about-office-research-and-development-ord

IARC Decision." (6-AA-6430; 6-AA-6596-6598.) Monsanto received commitments by EPA employees to conclude that glyphosate was not carcinogenic prior to a review being conducted (6-AA-6601); used its connections to get "key democrats on the hill" to pressure the EPA and let them know "they're being watched" (6-AA-6589), and used its EPA contacts to delay and kill other government regulatory agency reviews of glyphosate that were likely to agree with IARC. (6-AA-6601). Monsanto "deliberately and repeatedly misrepresented [IARC]'s work" to government regulators. (16A-RT-2597:15-18.)

Monsanto actively sought to suppress the "abundant" evidence that Roundup was carcinogenic both prior to and during Johnson's use of Roundup. In 2001, Monsanto pressured an author to remove an epidemiological finding that Roundup doubles the risk of NHL from an abstract to keep that data from being picked up in online abstract searches. (AA-6469-6475; 5-AA-5629.) In 2003, Monsanto internally acknowledged that "[i]t looks like NHL and other lymphopoetic cancers continue to the main epidemiology issues ... for glyphosate." (6-AA-6481.) In 2008, another study showed Roundup doubled the risk of NHL, and Monsanto internally 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" and wonder "how do we combat?" (6-AA-6623.)

In1985, the EPA concluded that a mouse study demonstrated that glyphosate was a possible carcinogen. (12B-RT-1817:23-1818:12; RA85-93.) Monsanto refused to update the

label and refused to conduct additional testing recommended by the EPA, as Monsanto was "concerned that even the initiation of formal regulatory action would have serious negative economic repercussions." (22A-RT-3851:20-22, 3895:16-3897:17.)

In 1999, Monsanto hired world-renowned toxicologist Dr. Parry to conduct an independent review of the genotoxicity of Roundup. (6-AA-6387.) After Dr. Parry concluded that Roundup was likely genotoxic and more testing was needed, Monsanto buried Dr. Parry's report, concealed it from the EPA and concluded "we simply aren't going to do the tests Parry suggests." (RB-XAOB 52-53.)

In 2000, Monsanto employees began ghostwriting articles where "independent" experts just "sign their name so to speak" that concluded, contrary to Dr. Parry's findings, that Roundup was not genotoxic or carcinogenic. (6-AA-6529.) These ghostwritten articles became an "invaluable asset for response to agencies [and] regulatory reviews" (RA336, 341.) In 2012 Monsanto began ghostwriting a new article to serve as "a valuable resource in future product defense" and to explain away a "a large mess of studies reporting genotoxic effects" with Roundup. (6-AA-6604; 6-AA-6610.) In 2015, due to the "severe stigma" of IARC, Monsanto planned another ghostwritten article to "[p]rovide additional support ('air cover') for future regulatory reviews" and for "litigation support." (RA344.) Monsanto hand-delivered copies of this ghostwritten manuscript to the EPA. (6-AA-6524, 6-AA-6546.)

Roundup is more dangerous than glyphosate alone and contains several other chemicals including a surfactant and other known carcinogens. (21A-RT-3609:3-3610:16; 22A-RT3880:6-30.) Surfactants are genotoxic and enhance glyphosate's penetration through human skin. (21A-RT-3609:14-3618:13.) Monsanto has long been aware that "[s]urfactants are biologically not "inert", they can be toxic and this must be addressed" and that "surfactant[s] played a role" in promoting tumors. (6-AA-6564; 6-AA-6535-6538; 6-AA-6300.) In 1999, Dr. Parry informed Monsanto that Roundup could be ten times more genotoxic than pure glyphosate. (5-AA-5551, 5823.) Safer formulations of Roundup are sold in Europe without the toxic surfactants and Monsanto scientists internally concede that "there are non-hazardous formulations, so why sell a hazardous one?" (21A-RT-3626:15-3627:16; 6-AA-6563). The surfactant in Roundup sold to Johnson is now banned in Europe. (5-AA-5781.)

Despite its knowledge of the genotoxicity of surfactants, Monsanto has never conducted a carcinogenicity test on the surfactants or the formulated Roundup product. (21A-RT-3614:11-3615:16; 22A-RT-3850:8-17.) Monsanto internally acknowledges, "you cannot say that Roundup does not cause cancer … we have not done carcinogenicity studies with 'Roundup.'" 6-AA-6466. Monsanto has also refused to report cases of NHL among its glyphosate manufacturing employees to the EPA or conduct a study of those individuals to see if they have a higher rate of NHL despite recommendations by its own epidemiologist. (6-AA-6236; 5-AA-5657.) The lack of such a study

as "a critical data-gap" by the SAP. (RA-135.) Monsanto, to this day, continues to hide this critical data.

III. Argument – Monsanto's Petition Should Be Denied

A. There is substantial evidence to support the jury's verdict for Johnson's design defect claim, and there is no conflict with other courts rendering further review superfluous.

The jury was provided the standard, well-established CACI 1203 instruction on the design defect consumer expectation test and there was substantial evidence to support its verdict. (28-RT-4758:22-4759:2.) "A product design may be found defective if...the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." (*Webb v. Special Electric Co., Inc.,* (2016) 63 Cal.4th 167, 180). "[I]mplicit in a product's presence on the market is a representation that it is fit to do safely the job for which it was intended." (*Johnson v. United States Steel Corp.* (2015) 240 Cal.App.4th 22, 32.) "[T]he jury can rely on its own expectations of safety in applying the test." *Id*. "[T]he inherent complexity of the product itself is not controlling on the issue of whether the consumer expectations test applies." (*Mansur v. Ford Motor Co.* (2011) 197 Cal.App.4th 1365, 1374.) Plaintiffs are not required to "prove that there was a safer alternative design." (*Sparks,* 32 Cal. App. 4th 461, 473.)

To invoke the consumer expectation test, a plaintiff must provide evidence of: (1) plaintiff's exposure to the product; (2) the circumstances surrounding plaintiff's injury; and (3) the objective

features of the product relevant to evaluating its safety. (*Saller v. Crown Cork & Seal Co., Inc.* (2010) 187 Cal.App.4th 1220, 1236.) The consumer expectation has repeatedly and uniformly been held applicable in cases involving carcinogens. In *Boeken*, the consumer expectation test was appropriate where "studies have shown that most smokers believe that light cigarettes are safer than regular cigarettes..." (127 Cal.App.4th at 1668.) In *Sparks,* the consumer expectation test was applicable where ordinary workers exposed to asbestos in the 1960s "did not expect to develop a fatal disease from simply breathing" sawdust. (32 Cal.App.4th at 476; *Saller*, 187 Cal.App.4th at 1234 ["Several cases have applied the consumer expectations test to asbestos-containing products."]) Relying on this Court's opinion in *Soule, Arnold* authorizes the consumer expectations theory in cases involving pesticides. (*See Arnold,* 91 Cal.App.4th 698). In *Arnold*, the Court concluded that an ordinary consumer may "reasonably believe that pesticides are designed to eliminate pests within homes occupied by humans, without causing significant harm to the humans." *Id.* at 717.

Here, Johnson offered detailed testimony about his reasonably foreseeable use of Roundup; the circumstances of his injury; and the objective features of the product relevant to its safety. Johnson sprayed the same formulation of Roundup sold, over-the-counter, to ordinary consumers for use around their home. (21A-RT-3607:15-3608:8.) Johnson mixed and sprayed Roundup using common and well-accepted methods. (18B-RT-3253:11-3256:7-10; 21A-RT-3597:11-16; 22A-RT-3937:7-21; 23A-

RT-4097:9-15.) Johnson would experience significant "spray drift" resulting in direct exposure of Roundup to his face, cheek, ears, and neck. (18B-RT-3240:17-3243:6; 3315:12-3316:2.) Monsanto's own expert testified that Johnson's exposure to Roundup was not only foreseeable, but that Johnson "did a good job" reducing his exposure. (28-RT-4903:3-8.)

Johnson testified that he understood Roundup to be safe and would not have sprayed Roundup if he knew it could harm humans; particularly at a school. (18B-RT-3234:20-3235:5; 3283:6-11.) The Roundup sales representative told him that Roundup was "safe enough to drink;" Johnson was informed that glyphosate affects enzymes "only in plants" not humans, and Monsanto's representatives told him over the phone that cancer was not an "expected" side effect from Roundup; and Monsanto sought to convince consumers that Roundup was "non-toxic." (18B-RT-3229:9-3230:4; 6-AA-6918; 6-AA-6519; 6-AA-6556.) This non-expert evidence mandates a conclusion that Johnson like the plaintiffs in *Arnold*, could "reasonably believe" that Roundup was designed to be toxic only to plants "without causing significant harm to the humans." (91 Cal.App.4th at 717.)

Monsanto misleads the Court about the nature of Johnson's expert testimony. (Petition 34.) Johnson's experts explained in detail how Roundup caused cancer and how the design increased that risk of cancer, but they did not testify as to the safety expectations of an ordinary consumer. It is long-settled that "[t]he fact that expert testimony was required to establish legal causation for plaintiffs' injuries does not mean than an ordinary

user of the product would be unable to form assumptions about the safety of the products." (*Saller*, 187 Cal.App.4th at 1235; *Soule,* 8 Cal.4th at 569 fn. 6.)

The cases Monsanto cite do not represent a conflict among the Court of Appeals as to the applicable law, but simply represent different fact patterns and different evidence applied to the same legal principle. *Morson* arose in the context of the HIV/AIDs epidemic which mandated a public health need for effective latex gloves for healthcare workers. (*Morson v. Superior Court* (2001) 90 Cal.App.4th 775, 782.) Defendants presented expert testimony that changing the design to reduce the danger of allergies "might lead to defects in barrier protection" and thereby increase the danger of healthcare workers contracting diseases. *Id.* at 788. Thus, expert testimony about the complex weighing of risks and benefits was required and precluded application of the consumer expectation test. With some public health products such as latex gloves or Tylenol "it is simply impossible to eliminate the balancing or weighing of competing considerations in determining whether a product is defectively designed or not....' [Citation.]" (*Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110, 160 [quoting *Soule,* 8 Cal.4th at 562–563.])

Here, Monsanto presented no expert testimony about the "competing considerations" of the design of Roundup. (Opinion 23.) Roundup is not a public health product that requires a weighing of competing considerations, particularly when used to control weeds at school districts. Indeed, by the time of trial

"several bay area cities and school districts" "already stopped using Glyphosate since the IARC ruling." (6-AA-6425.) After the verdict, Johnson's school district also stopped using Roundup.[17]

B. Under well-settled U.S. Supreme Court precedent, Johnson's failure-to-warn claims are not preempted.

Bates forecloses Monsanto's arguments that the Johnson's state law claims are expressly or impliedly preempted by federal law (FIFRA). Instead, *Bates* recognizes and emphasizes the important role of jury trials "as a catalyst" in identifying risks of pesticides not yet recognized by the EPA. (*Bates,* 544 U.S. at 451 [citing *Ferebee,* 736 F.2d 1529.]) FIFRA is "aimed at protecting citizens from the hazards of modern pesticides," it is not a "subsidization of the pesticide industry that command[s] states to accept the use of EPA-registered pesticides." (*Ferebee,* 736 F.2d at 1541-1542.) Courts presiding over Roundup claims, have unanimously rejected Monsanto's preemption arguments.[18]

The California Attorney General agrees that "FIFRA does not preempt state rules that are fully consistent with federal

[17] https://beniciaheraldonline.com/busd-city-discontinue-use-of-glysophate-products/

[18] (*Blitz,* 317 F.Supp.3d at 1049);(*In re Roundup,* 364 F. Supp. 3d 1085); (*Beyond Pesticides v. Monsanto Co.* (D.D.C. 2018) 311 F. Supp. 3d 82, 92); (*Blitz v. Monsanto Company* (W.D.Wis. 2018) 317 F.Supp.3d 1042)*; (Hernandez v. Monsanto* (C.D. Cal. 2016) 2016 WL 6822311); *(Sheppard v. Monsanto* (D. Hawaii, 2016) 2016 WL 3629074)*; (Mendoza v. Monsanto* (E.D. Cal. 2016) 2016 WL 3648966)*; (Giglio v. Monsanto* (S.D. Cal. 2016) 2016 WL 1722859)

requirements to warn workers and consumers about chemical risks, even if EPA disagrees that a particular chemical poses a risk." In 1999 the EPA argued to this Court that "preemption of state tort law would strongly conflict with the central purpose of the 1972 FIFRA amendments — providing increased public protection against pesticides."[19]

FIFRA evinces an unambiguous Congressional intent to preserve states' traditional and broad police powers. (*See Bates*, 544 U.S. at 449-450.) "The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption" and "emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." (*Bates* 544 U.S. at 449-450.)

1. Johnson's failure-to-warn claims are not preempted by the express preemption doctrine.

Bates has explicitly rejected the argument that FIFRA's misbranding provisions and FIFRA itself were "intended by Congress to be interpreted authoritatively by EPA." (*Bates*, 544 U.S. at 448.) In enacting FIFRA, Congress preserved a state's right to "regulate the sale or use of any federally registered

[19] https://www.citizen.org/wp-content/uploads/usetcheverrybrief.pdf p. 9. *Bates* cited this EPA brief when it rejected the United States' "particularly dubious" position in 2004 that FIFRA expressly preempts "all state requirements concerning labeling," noting the U.S. had taken a contrary position "just five years ago." See (544 U.S. at 449 & n.24.)

pesticide..." 7 U.S.C. § 136v(a.) "Generally, **the intent of the provision is to leave to the States the authority to impose stricter regulation on pesticides** uses than that required under the Act." (Sen.Rep. No. 838 92d Cong., 2d Sess. 30 (1972) reprinted in 1972 U.S.Code Cong. & Admin.News 4021 [emphasis added.]) FIFRA authorizes "concurrent authority of the Federal and State Governments in this sphere." *Bates,* 544 U.S. at 451. "[P]rotection of pesticide users and victims by *both* federal and state law lies at the center of the Act's design." (*Ferebee,* 736 F.2d at 1543).

FIFRA's only limitation on state authority is set forth in the Act's express preemption clause, which provides that states "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.) However, "[n]othing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law." *Bates,* 544 U.S. at 442. There is a two-part test for determining whether FIFRA preempts state law claims: "First, it must be a requirement '*for labeling or packaging* '...Second, it must impose a labeling or packaging requirement that is '*in addition to or different from'* those required under this subchapter.'" *Id.* at 444.

a. Johnson's failure-to-warn claims based on statements outside of the label and the OSHA safety data sheet are not preempted.

As the EPA explained in 1999 "FIFRA cannot be read to preempt state damages actions for failure-to-warn based on representations made outside a pesticide label, such as claims made orally or in advertising."[20] (*see also In re Dicamba Herbicides Litigation,* (E.D. Mo. 2019) 359 F.Supp.3d 711, 735 ["claims for non-label-related marketing efforts are not preempted, even to the extent that those claims are based in part on failure-to-warn."]; *Indian Brand Farms, Inc. v. Novartis Crop Protection Inc.* (3d Cir. 2010) 617 F.3d 207, 218) [marketing brochure does not qualify as "labeling."]; *New York State Pesticide Coalition, Inc. v. Jorling* (2d Cir. 1989) 874 F.2d 115, 119 [state "Notification requirements such as cover sheets, signs, and newspaper advertisements do not impair the integrity of the FIFRA label."]) For example, "[M]anufacturers need not feel pressure to apply for EPA approval of label changes so that they can comply with Proposition 65. Point-of-sale signs are sufficient to satisfy the California requirements." (*Allenby*, 958 F.2d at 947.)

Here, in addition to the label, Johnson relied on the Safety Data Sheet mandated by OSHA that is not attached to the product; he relied on the sales representative who said Roundup was "safe enough to drink;" and he relied on Monsanto employees directly when he called to ask if Roundup could cause cancer. (5-AA-5646-5647; 21A-RT-3637:2-11;18B-RT-3229:9-3232:4; 6-AA-6918; 6-AA-6519) Monsanto could have warned Johnson through

[20] https://www.citizen.org/wp-content/uploads/usetcheverrybrief.pdf, p.42.

any of those means of communication. In fact, OSHA provides that "manufacturers ... **must treat** ... **IARC monographs**, "as establishing that a chemical is a carcinogen *or potential carcinogen* for hazard communication purposes." *Styrene Information & Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal.App.4th 1082, 1099 (citing 29 C.F.R.1910.1200 (d)(4) (2012)). Under OSHA, Monsanto should have applied the same criteria IARC uses and added a cancer warning prior to 2012. (*Id.* at APPENDIX A.6.)

b. Johnson's common law failure-to-warn claims are equivalent to FIFRA misbranding provisions and are therefore not preempted.

Johnson's failure-to-warn claims are also not "in addition to or different from' those required under" FIFRA. (*Bates,* 544 U.S. at 444.) State law and FIFRA are "equivalent" when a violation of state law would also violate FIFRA's misbranding provisions. *Id.* at 454. FIFRA requires manufacturers to provide a warning that "is adequate to protect health." 7 U.S.C. § 136(q)(1)(G). "California law...is consistent with this requirement." (*In re Roundup Products Liability Litigation* (N.D. Cal. 2019) 364 F.Supp.3d 1085, 1087; Opinion 45.)

EPA approval of a label is irrelevant to an equivalency analysis. (*Indian Brand Farms,* 617 F.3d at 222.) A court must look to the equivalency of "the claim and the statutory text." (*Id.* [emphasis added.]) A court then determines if there are "any EPA regulations that further refine those general standards in any way that is relevant to petitioners' allegations." *Id.*

Monsanto does not and cannot point to any statute or regulation that in anyway preempts Johnson's failure-to-warn claims. Monsanto only points to an opinion by EPA officials about the carcinogenicity of glyphosate, but opinions are not statutory text or a regulation.

"[T]he EPA's authority to enforce FIFRA does not prohibit private litigants from also enforcing that statute." (*Hardeman,* 216 F.Supp.3d at1038.) A state jury is entitled to conclude that the "EPA failed to enforce FIFRA correctly when it approved that label. And *Bates* tells us that the EPA's authority to enforce FIFRA...isn't exclusive." (*Id.* at 1039.) "The Supremacy Clause gives priority to 'the Laws of the United States,' not the criminal law enforcement priorities or preferences of federal officers." (*Kansas v. Garcia* (2020) 140 S.Ct. 791, 807*)*

Monsanto cannot escape the directive from Congress that "[i]n no event shall registration of [a pesticide] be construed as a defense for the commission of any offense under this subchapter." (7 U.S.C. § 136a(f)(2).) Furthermore, "if the EPA's registration decision is not preemptive, it follows that the factual findings on which it relied in making that decision also are not preemptive." (*Hernandez,* 2016 WL 6822311, at *8; *Ferebee,* 736 F.2d at 1540.)

Under *Bates*, it is Monsanto's "obligation to adhere to FIFRA's labeling requirements." (544 U.S. at 438.) If glyphosate is registered without a cancer warning, then it provides no "defense;" but rather obliges Monsanto to request that a warning be added to the label. (*Id.*) What Monsanto "cannot do, however, is to force states, under the purported aegis of a statute aimed at

protecting against the hazards of modern pesticides, to accept the use of [Roundup] and to tolerate uncompensated injuries to that state's citizens." (*Ferebee,* 736 F.2d at 1543.) The EPA cannot strip California of its sovereign power to protect its citizens from pesticides, expressly reserved to them by Congress. California is not required to put its head "in the sand simply because the EPA won't do its job."[21]

2. Consistent with well-settled law the Court of Appeal correctly ruled that Monsanto failed to meet the heavy burden required to establish an impossibility preemption defense.

Monsanto's burden in proving it would be impossible[22] for it to have added a cancer warning to the label through a formal request to the EPA "is a demanding defense." (*See Wyeth,* 555 U.S. at 573.) To establish an impossibility preemption defense. A defendant must show by clear evidence that: 1) "...it fully informed the [Agency] of the justifications for the warning required by state law; 2) "that the [Agency], in turn, informed the []manufacturer that the [Agency] would not approve changing the drug's label to include that warning;" 3) The proposed warnings

[21] https://oag.ca.gov/news/press-releases/attorney-general-becerra-files-amicus-brief-lawsuit-against-monsanto-support

[22] Johnson disagrees that impossibility preemption can be applied under FIFRA, but the disagreement is academic because the linchpin under either express or implied preemption is whether Congress acted with the "force of law" to or authorized the EPA to implement regulations that make it impossible for Monsanto to comply with state law. (Opinion 48-51.) Neither situation is present here.

must constitute "any and all warnings to the drug label that would satisfy state law;" and 4) the agency action rejecting the warning must carry the "force of law..."(*Merck,* 139 S.Ct.at 1678.) The "possibility of impossibility" is not enough. (*Id.* at 1678-1679.) As the Court of Appeal held, after reviewing the evidence Monsanto submitted post-trial, Monsanto can't surmount any of these hurdles (Opinion 51) and the failure to satisfy even one element dooms such a defense.

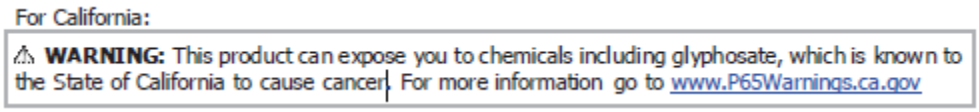
First, Monsanto has never requested a label change and the language from *Merck* "implies that the manufacturer must have actually requested a change and that the FDA rejected it." (*Dolin v. GlaxoSmithKline LLC* (7th Cir. 2020) 951 F.3d 882, 890.)[23] Monsanto cannot say it fully informed the EPA of the basis for a label change or the cancer risk associated with Roundup. Rather than submitting Dr. Parry's report to the EPA, and reports of its employees with NHL, Monsanto submitted ghostwritten reports and aggressively advocated against a label change.

Monsanto cannot claim that the EPA is fully informed where it has still not conducted adequate testing of its product.

[23]Monsanto misrepresents the holding in *Dolin*, and cites two cases that suggest an FDA's formal rejection of a citizen's petition submitted pursuant to FDA regulations (21 C.F.R. § 10.30.) is sufficient to demonstrate clear evidence that the FDA would reject a proposed warning. The EPA has no similar regulations that allow third parties to initiate formal reviewable proceedings to change a pesticide label. Furthermore, a drug manufacturer must still show that a citizen's petition letter fully informed the FDA of all adverse data and contained the proposed warning advocated by the plaintiff. (*Risperdal,* 49 Cal.App.5th at 959.) Monsanto made no attempt to make those showings.

Wyeth, 555 U.S. at 570 ["Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug."]) Monsanto has *admitted* "you cannot say that Roundup does not cause cancer … we have not done carcinogenicity studies with 'Roundup.'" 6-AA-6466. Monsanto has never conducted the epidemiology study on its manufacturing workers identified as "a critical data-gap" by the EPA SAP in 2017. (RA-135.) Monsanto has never conducted necessary tests recommended by Dr. Parry in 1999. (13A-RT-1997:19-22.)

Second, the EPA has never informed Monsanto that it "would not approve changing" the label to include a cancer warning. **(***Merck,* 139 S.Ct. at 1678-1679.) In 2017, the EPA **approved a request** by a glyphosate manufacturer to add the following warning to its label:



(Respondent's Supplemental Brief 25.) Because the EPA has "Monsanto's back on pesticides regulation..." it would likely comply with a request by Monsanto to add a cancer warning. (XARB 49.)

Third, the EPA's 2019 letter has no relevance to this case because a court's preemption analysis must be limited to the events at the time of the injury. (*Martin v. PacifiCare of California* (2011) 198 Cal.App.4th 1390, 1410.) "[I]nformal policy opinion[s]" made "only after [plaintiff's] injuries" have no

preemptive effect. (*Fellner v. Tri-Union Seafoods, L.L.C.* (3d Cir. 2008) 539 F.3d 237, 355.). The letter also fails to carry Monsanto's burden of showing that EPA would have rejected "any and all" warnings as required by *Merck*. The EPA letter applies only to (post-2019) warnings **"exclusively on the basis that it contains glyphosate."**[24] However, Johnson claims that the formulated product Roundup more likely than not causes NHL. The EPA only considers whether glyphosate is carcinogenic, not the full product. (22A-RT-3920:16-25; Opinion 10-11.) The EPA letter applies only to the exact language that glyphosate "is known to the State of California to cause cancer." The EPA confirms its August 2019 letter reflects a belief that only "a **strong** glyphosate cancer warning on a pesticide label is misbranding." (EPA Amicus Brief at 26.) California law does not require the strong warning that Roundup is known to cause cancer, Monsanto need only provide "sufficient warnings of potential risks." (29A-RT-5047:3-8)

Fourth, the EPA letter does not carry the "force of law"[25] sufficient to preempt Johnson's claims. Agency actions must be conducted through "congressionally delegated authority" to have any preemptive effect, such as through "notice-and-comment rulemaking setting forth labeling standards." (*Merck,* 139 S.Ct. at

[24] https://www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf

[25] Glyphosate's registration without a cancer warning does not carry the "force of law" because Congress expressly stated registration cannot be "construed as a defense." (Opinion 45; *Crespo v. S.C. Johnson & Son, Inc.* (E.D.N.Y. 2019) 394 F.Supp.3d 260, 271)

1679.) Agency letters that eschew statutory requirements have no preemptive effect. (*Reid v. Johnson & Johnson* (9th Cir. 2015) 780 F.3d 952, 964.) In *Fellner*, the Third Circuit held that a letter from the FDA to California stating that a Prop 65 warning on defendant's product would be false and misleading had no preemptive effect on a plaintiff's failure-to-warn claim against that defendant. (539 F.3d at 254.) An agency "must actually exercise its authority in a manner in fact establishing the state warning as false or misleading under federal law" to have preemptive effect. (*Id.* at 255.)

If the EPA believes that glyphosate labels with Prop 65 warnings are misbranded, then there is "a detailed, multi-step process that EPA *must* follow" which provides for notice-and-comment, hearings, and judicial review. (*Reckitt Benckiser, Inc. v. Jackson* (D.D.C. 2011) 762 F.Supp.2d 34, 42-43; 7 U.S.C. § 136a(c)(6), § 136d, § 136n.) The EPA has not even commenced this congressionally mandated process to establish a Prop 65 warning is misbranded. If Monsanto acted with even a modicum of concern for public safety, it would have petitioned for a label change, like the two other companies that successfully added a cancer warning to the glyphosate label, and used these procedural safeguards to ensure the EPA-label contained a cancer warning.

C. There is no conflict as to the appropriate standard for strict liability failure-to-warn claims.

As found by the jury, the trial court and the Court of Appeal, clear and convincing evidence supported a finding that

Monsanto was liable for "*consciously disregarding* a *probable* safety risk" of Roundup (Opinion 80 fn. 2.) The "abundant" evidence that Roundup *more-likely-than-not* causes NHL was available to Monsanto even before Johnson started using Roundup. Because the Court of Appeal agreed that Johnson proved Monsanto was aware of the "probable" risk of cancer, it is meaningless to review whether Johnson was required to prove Monsanto's awareness of only a "potential" risk of cancer under failure-to-warn claims.

Nonetheless, this Court holds that a duty to warn under strict liability arises when the "*potential* risk" of cancer was "*knowable* in light of the generally recognized and prevailing best scientific and medical knowledge at the time of manufacturer and distribution." (*Anderson*, 53 Cal.3d at 991, 1002.) "[R]easonably scientifically knowable…refers to knowledge obtainable 'by the application of reasonable, developed human skill and foresight" (*Id.* fn. 13). The jury was properly instructed on this standard using the standard CACI 1205 and the Court of Appeal applied the facts of this case to that standard. (Opinion 15-20; 29A-RT-5047:3-6.)

The jury properly determined that the methodology used by IARC and Plaintiff's experts represent the "best scientific" knowledge. Monsanto's own expert agrees that IARC and Bradford-Hill represent the best scientific techniques for assessing causation. (24B-RT-4331:22-4337:14.) One hundred twenty-five scientists published a peer-reviewed article endorsing IARC's methodology; and 95 scientists co-signed a letter

endorsing IARC's finding that Roundup was a carcinogen. (13A-RT-2016:3-2019:25, 16A-RT-2606:21-2609:18.) Both federal and California courts consider IARC to be an "authoritative" and "well-respected" scientific body. (The Federal Judicial Center's Reference Manual on Scientific Evidence (3rd. Ed. 2011) pp. 20, 565; *California Chamber of Commerce v. Brown* (2011) 196 Cal.App.4th 233, 258.)

Monsanto did not have to wait until IARC's review to warn Roundup could cause NHL. "[M]onsanto could have reached this conclusion on its own had it investigated the issue responsibly and objectively." *In re Roundup,* 364 F.Supp.3d at 1089. When Monsanto learned IARC was planning to evaluate Roundup, Monsanto had little doubt that IARC would classify Roundup as carcinogenic. (6-AA-6432; 6-AA-6426.)

Johnson provided abundant evidence that the regulatory agencies' conclusions with respect to glyphosate were highly flawed. (RB-XAOB 39-41, 60-62.) The jury agreed the EPA did not use the "best scientific" knowledge as the EPA failed to follow even their own scientific guidelines. (*Id.*) A jury is entitled to "disagree with [an agency's] conclusions." (*Trejo,*13 Cal.App.5th at 144.)

Instead of citing a conflict among the Courts of Appeal, Monsanto cites two other cases that agree with the Court of Appeal's opinion here. (*Johnson & Johnson Talcum Powder Cases* (2019) 37 Cal.App.5th 292, 297("Echeverria"); *Valentine v. Baxter* (1999) 68 Cal.App.4th 1467, 1483-84.) Monsanto simply disagrees with established law.

Monsanto's challenge to the punitive damage verdict bears little discussion as its premised on a misreading of the Court of Appeal's opinion. The Court of Appeal applied a "probable" risk standard to its affirmation of the trial court's new trial order on punitive damages. (Opinion 80, fn. 6.) There is also no conflict with the punitive damage ruling in *Echeverria* because "the evidence here is also far different from the facts in recently decided *Echeverria*." (Opinion 77-79.) The Court of Appeal noted that whereas the plaintiff in *Echeverria* only established a "possible" link to her injury, Johnson established a "probable" link to his injury. (*Id.*)

IV. CONCLUSION

Monsanto fails to demonstrate that review should be granted under Rule 8.500, therefore its petition should be denied.

September 17, 2020

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CERTIFICATE OF WORD COUNT

(Cal. Rules of Court, rule 8.504(d)(1))

The text of this brief consists of 8,398 words as counted by the Microsoft Word version 2013 word processing program used to generate the brief.

Dated: September 17, 2020

_____

Jeffrey A. Travers

CERTIFICATE OF SERVICE

Court: California Supreme Court

Case Numbers: Court of Appeal, First Appellate District, Division One, No. A155940

Superior Court, County of San Francisco Civil Case No. CGC16550128

I am employed in the County of Orange, Commonwealth of Virginia. I am over the age of 18 years and not a party to the within action. My business address is 108 Railroad Avenue, Orange, VA 22960.

On September 17, 2020, I served the foregoing documents described as Answer to Petition for Review on all interested parties in this action as follows:

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Via the Court's TrueFiling Electronic Filing System.

On September 17, 2020, I will serve the foregoing documents described as Petition for Review on:

Hon. Suzanne R. Bolanos
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400 McAllister St, Department 504
San Francisco, CA 94102
Trial Judge
[Case No. CGC16550128]

Via Fedex.

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

Executed on September 17, 2020, at Orange, VA.

Jeffrey A. Travers