A158228

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT, DIVISION TWO

ALVA AND ALBERTA PILLIOD,
Plaintiffs and Cross-Appellants,

v.

MONSANTO COMPANY,
Defendant and Appellant.

APPEAL FROM ALAMEDA COUNTY SUPERIOR COURT
WINIFRED SMITH, JUDGE • CASE NO. RG17862702

APPELLANT'S OPENING BRIEF

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CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

Defendant and Appellant Monsanto Company is an indirect, wholly-owned subsidiary of Bayer AG, so Bayer AG has a financial interest in a party to this proceeding.

February 7, 2020

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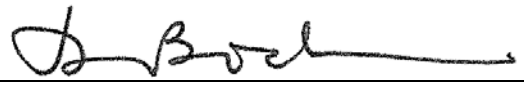
By: 
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INTRODUCTION

Monsanto Company manufactures Roundup Pro®, a glyphosate-based herbicide (hereafter, Roundup), which has been approved as safe for use in the United States for more than 4 years. Over this period, glyphosate has been among the most studied substances in history, and Monsanto's herbicides have been subject to repeated and rigorous scientific scrutiny by health authorities worldwide. Not one national or international regulator has ever concluded that these products cause cancer in humans.

Nevertheless, despite this regulatory scientific consensus, Plaintiffs Alva and Albert Pilliod alleged that their respective exposures to Monsanto's herbicides caused each of them to develop non-Hodgkin's lymphoma (NHL). Over Monsanto's objections, the trial court allowed both Mr. and Mrs. Pilliod to pursue their separate claims together in a lengthy joint trial. The jury ultimately found for both Plaintiffs and awarded over $55 million in compensatory damages and $2 *billion* in punitive damages. The jury concluded that Monsanto should have warned that its herbicides caused NHL, and that these products were "defective" for failing to include a warning because an ordinary consumer would not expect these products to cause cancer.

The jury's verdicts and the damages awarded cannot be reconciled with either the law or sound science.

First, Plaintiffs' liability theories are preempted by federal law under the impossibility and express preemption doctrines. Federal law prohibits a court from imposing liability against a

manufacturer under state law for its failure to warn about an alleged risk or defect that the governing federal regulatory agency has expressly determined is not supported by science, and where the governing federal authority has promulgated rules making it legally impossible for the manufacturer to change the label or the ingredients without prior approval from the regulator.

Regarding the failure to warn claims, the "best scholarship available" at the time Plaintiffs were exposed to Monsanto's herbicides was unanimous in concluding there was insufficient evidence to establish a causal link between NHL and exposure to glyphosate or glyphosate-containing herbicides. As a result, there was no known or knowable risk and therefore no duty to warn under either strict liability or negligence theories. Indeed, much of the trial revolved around a determination in 2015—after all of Plaintiffs' relevant exposures to Roundup had occurred—by the International Agency for Research on Cancer (IARC) that glyphosate is "probably carcinogenic" at some unknown dose. IARC is a nongovernmental consortium of scientists which reached the academic conclusion that glyphosate poses a theoretical cancer hazard detached from any real-world determination that glyphosate poses an actual risk to humans based on its use as an active ingredient in herbicides. After IARC announced its conclusions in 2015, international regulators again reevaluated the science and reaffirmed their findings that glyphosate-based herbicides have not been shown to pose a real-world cancer risk.

There was also no basis for the jury's finding of a design defect under the consumer expectations test, which "is reserved for

cases in which the everyday experience of the product's users permits a conclusion that the product's design violated minimum safety assumptions, and is thus defective regardless of expert opinion about the merits of the design." (*Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 567 (*Soule*), emphasis omitted.) Here, the consumer expectations test does not apply because complex expert testimony is necessary to describe the nature of the product's alleged defect and how it allegedly caused Plaintiffs' injuries. In addition, there was no basis for the jury's findings on Plaintiffs' negligent design theory because the expert testimony offered by Plaintiffs to support that theory lacked foundation, and because there was no evidence that any alleged negligent design of Roundup caused Plaintiffs' harm.

The basic failure of Plaintiffs' warning and design defect claims is also evidenced by the lack of substantial evidence of causation. Plaintiffs' experts failed to account for a number of known alternative causes that have higher risks associated with NHL than even Plaintiffs argued were associated with Roundup. Moreover, because at least 70 percent of NHL cases are of unknown cause (i.e., idiopathic), an expert purporting to testify as to the cause of Plaintiffs' illnesses had to account for unknown causes. Plaintiffs' experts failed to do so. As a result, the expert opinions on specific causation are speculative and entitled to no evidentiary weight.

While each of the foregoing errors require reversal with directions to enter judgment for Monsanto, the trial court's decision to allow both Plaintiffs' claims to be tried together in a

single trial also fatally infected the jury's consideration of the causation issue and independently warrants a new trial. Despite substantial differences in their medical and exposure histories, Plaintiffs were able to blend their causation theory into a prejudicially misleading claim: the mere fact Plaintiffs were married and both developed NHL must mean that their Roundup exposure was the cause of their illnesses.

A new trial is also required because (1) the trial court abused its discretion by admitting highly inflammatory evidence concerning the falsification of test results by a third-party laboratory, and (2) the trial court proceedings were tainted by pervasive and egregious attorney misconduct.

Apart from the substantive errors infecting the jury's liability determination, the jury's award of $2 billion in punitive damages, ultimately remitted to over $69 million, cannot be sustained. The undisputed facts show that Monsanto kept abreast of the most current scientific information and the uniform conclusions of foreign and domestic regulatory agencies that there is no causal link between exposure to Roundup and cancer. Failing to provide a warning for a risk that the governing United States regulatory body (and others worldwide) has duly considered and rejected as not supported by science is not a valid basis for a punitive damages award. (See *Johnson & Johnson Talcum Powder Cases* (2019) 37 Cal.App.5th 292, 333 (*Echeverria*) [reversing award of punitive damages where "it is not universally accepted in the scientific or medical community that [defendant's

product] is even a significant risk factor for" the type of cancer plaintiff developed].)

STATEMENT OF THE CASE

A. Overview of glyphosate and Roundup products

Monsanto Company manufactures Roundup products, which are broad-spectrum herbicides that contain the active ingredient glyphosate. (6 AA 7255.) Glyphosate is registered for use in over 100 countries and is known for being highly effective while low in toxicity and environmental impact. (6 AA 7255-7257.)

Since at least 1991, the U.S. Environmental Protection Agency (EPA)—along with other regulatory agencies worldwide—has repeatedly and consistently concluded that glyphosate does not cause cancer in humans. (See pp. 21-23, 31-34, *post*.) Breaking with the overwhelming worldwide consensus, a working group at the International Agency for Research on Cancer (IARC) in 2015 classified glyphosate as "probably carcinogenic to humans." (24 RT 3911:5-21; see also 13 RT 1926:13-25; pp. 28-30, *post*.) But IARC did not determine whether glyphosate created a real cancer risk to people who actually use glyphosate-based herbicides. (See 14 RT 2214:4-2217:3 [it was "not [IARC's] job" to assess whether glyphosate-based herbicides cause cancer at real-world exposure levels].) Rather, IARC conducted a limited "hazard assessment" to determine if glyphosate was theoretically capable of causing cancer at *any* exposure level. (14 RT 2214:4-2215:25.) By contrast, government regulators, which review a broader array of data than IARC (13 RT 1920:7-11), determine whether an herbicide such as

glyphosate poses a risk of cancer in light of real-world exposures (see 14 RT 2230:3-2232:3 [Plaintiffs' risk assessment expert acknowledging that it was the job of regulatory bodies like EPA and the European equivalents, not IARC, to perform "risk assessments" that determine "whether there's a cancer risk to individuals in their daily lives"]).

After IARC issued its classification in 2015, EPA and other regulatory agencies around the world analyzed and rejected IARC's conclusion. (See 9 AA 9924-9925, 10092-10102, 10213-10214; 13 RT 1927:1-1928:3; see also pp. 31-34, *post*.) Indeed, just last year, EPA announced that including a cancer warning on a glyphosate product in the face of overwhelming data against any such connection would constitute misbranding in violation of federal law because such a warning would be "false and misleading." (EPA Registration Div. Director Michael L. Goodis, EPA Office of Pesticide Programs, Letter to EPA Registrants, Aug. 7, 2019, p. 1 <https://tinyurl.com/y552m94m> [as of Feb. 6, 2020] (hereafter EPA Aug. 2019 Letter).) Still, based on IARC's outlier conclusion, tens of thousands of litigants—including Plaintiffs in this case—have filed suit alleging that Monsanto failed to warn them about the cancer risks of using Roundup.

B. Regulators worldwide, including EPA, have concluded that Roundup is not carcinogenic.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) governs "the use, . . . sale and labeling" of pesticides and herbicides. (*Bates v. Dow Agrosciences LLC* (2005) 544 U.S. 431,

437 [125 S.Ct. 1788, 161 L.Ed.2d 687] (*Bates*); see 7 U.S.C. § 136 et seq.; see also 22 RT 3501:21-3502:2.) FIFRA makes it unlawful for any person to "distribute or sell to any person any pesticide that is not registered" by EPA under the statute. (7 U.S.C. § 136a(a).)

Before registering an herbicide for sale, EPA must determine that the herbicide will not cause "unreasonable adverse effects on the environment" (7 U.S.C. § 136a(c)(5)(C)), including an unreasonable adverse effect on human health (7 U.S.C. § 136(bb)). To carry out this responsibility under the statute, EPA requires a variety of toxicity and carcinogenicity studies to be conducted. (22 RT 3517:4-3518:4; 6 AA 6725-6726, 6946-6947.) EPA reviews an extensive variety of information regarding the product's safety, including animal studies of both short-term and long-term toxicity, epidemiology studies, teratogenicity and mutagenicity studies, and a large number of metabolism studies. (6 AA 6726; 22 RT 3517:13-3518:4.) EPA makes a registration determination only after considering this voluminous scientific data. (7 U.S.C. § 136a(c)(2)(A); see 40 C.F.R. § 158.500 (2019).) As part of the registration process, EPA must approve a pesticide's label, making determinations regarding label provisions necessary to ensure human safety. (7 U.S.C. § 136a(c)(5)(C); 40 C.F.R. § 152.112(f) (2019).) FIFRA requires EPA to re-review a pesticide's registration, including its effects on human health, every 15 years. (7 U.S.C. § 136a(g)(1)(A)(iv).)

EPA first approved Roundup for sale in 1974, and has continually approved Roundup for sale to this day. (6 AA 6725-6726; 22 RT 3516:17-19.) In 1991, EPA classified glyphosate as

non-carcinogenic for humans "based upon [a] lack of convincing carcinogenicity evidence in adequate studies." (9 AA 9979; see 6 AA 7264; 22 RT 3629:3-22.) In 1993, EPA confirmed its finding that glyphosate was not carcinogenic, concluding that glyphosate "will not pose unreasonable risks or adverse effects to humans or the environment." (9 AA 10110.) EPA observed that glyphosate "is of relatively low oral and dermal acute toxicity" and that "[s]everal chronic toxicity/carcinogenicity studies using rats, mice and beagle dogs resulted in no effects based on the parameters examined, or resulted in findings that glyphosate was not carcinogenic in the study." (9 AA 10105.)

Numerous foreign regulatory agencies have also studied the carcinogenicity of glyphosate. Consistent with EPA's findings, none of these agencies have found sufficient evidence that glyphosate is carcinogenic to humans. (13 RT 1977:1-1980:3; see also 11 RT 1476:21-1478:20.) The European Food Safety Authority, European Chemicals Agency, New Zealand EPA, the German health authority, and Canadian, Australian, and Japanese regulators all agree that the evidence does not support a conclusion that glyphosate is a likely human carcinogen. (13 RT 1977:1-1980:3; 25 RT 4081:4-4082:9; 30 RT 5192:21-5194:11; 8 AA 9322-9324, 9339-9341, 9430, 9435; 9 AA 9632-9634, 9810-9813, 9863-9865, 10218-10219, 10223; 10 AA 10722; see also 11 RT 1476:21-1478:20.)

C. The available scientific data demonstrate that glyphosate is not carcinogenic.

Glyphosate is one of the most widely studied substances in the world. (6 AA 6945, 7020; 13 RT 2004:19-2005:24.) Three primary types of science are relevant to assessing whether glyphosate is carcinogenic: epidemiology, toxicology (i.e., animal studies), and mechanistic data (i.e., cell studies). (14 RT 2103:3-15, 2153:5-12.)

1. Epidemiology

Epidemiology is the study of disease in human populations. Epidemiology compares the relative occurrences of disease between exposed and unexposed people to determine a substance's risk ratio. (16 RT 2459:14-2460:7.) Epidemiology is considered the strongest evidence of a substance's likelihood to cause disease because it is the only evidence that measures real-world outcomes in humans based on actual exposures in the field. (13 RT 2003:17-2004:18; 14 RT 2334:8-2335:4; 27 RT 4413:10-4414:14; 29 RT 4929:17-4930:4.)

Large-scale epidemiology studies have found no association between glyphosate use and cancer. The Agricultural Health Study, funded by the National Institutes of Health, is a large-scale cohort study that analyzes whether pesticides increase cancer risk in farmers and commercial pesticide applicators. (27 RT 4443:14-4444:1; 29 RT 4861:25-4863:3; 6 AA 6683.) Participants in the study have been monitored for cancer since enrolling between 1993 and 1997. (16 RT 2633:23-2635:2; 29 RT 4861:25-4863:3.) With

over 50,000 participants, the Agricultural Health Study is the "most robust and reliable data set that we have available." (6 AA 6683; 29 RT 4862:13-18.) In 2018, based upon the results of the Agricultural Health Study, the Journal of the National Cancer Institute published data showing "no association between glyphosate use and NHL overall or any of its subtypes." (16 RT 2627:9-11; 18 RT 2960:5-2961:17; see also 6 AA 6666-6667.) Similarly, the largest and most recent pooled-cohort study available found no evidence of a positive association between NHL and glyphosate exposure. (18 RT 2959:16-2960:4, 2982:6-11; 29 RT 4877:4-11.)[1]

The North American Pooled Project, which is funded by the National Institutes of Health, also addressed whether there is a connection between glyphosate and a risk of NHL. (18 RT 2959:7-15; 29 RT 4859:6-20.) Like the 2018 Agricultural Health Study results, the results of the North American Pooled Project showed no evidence of a positive association between glyphosate exposure and the risk of NHL. (18 RT 2959:10-15; 29 RT 4861:13-20, 4881:14-4884:18; 6 AA 6649.)

The North American Pooled Project and the 2018 Agricultural Health Study results are adjusted for other pesticides and report odds ratios close to 1.0, meaning that those exposed to glyphosate had no higher risk of developing NHL than those who were not exposed. (18 RT 2959:2-9; 27 RT 4444:21-4446:24,

[1] A pooled analysis is one where data is compiled from different studies and analyzed together to increase its power. (16 RT 2487:13-2488:4.)

4452:22-4453:3, 4556:24-4557:6; 29 RT 4861:5-17.)[2] The studies relied upon by Plaintiffs' experts, by contrast, rely in large part on data that is not properly adjusted for other pesticides. (16 RT 2606:10-2609:25; 17 RT 2834:4-9.)

2. Toxicology

Toxicology studies examine the potential effects of substances in laboratory animals who are exposed to doses that are thousands of times greater than what humans are exposed to. (12 RT 1603:12-23; 13 RT 2009:19-2012:18.) For this reason and others, animal data alone is not sufficient to establish whether a

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[2] Epidemiological studies express their results in terms of "relative risk." "When statistical analyses or probabilistic results of epidemiological studies are offered to prove specific causation . . . a relative risk greater than 2.0 is needed to extrapolate from generic population-based studies to conclusions about what caused a specific person's disease. When the relative risk is 2.0, the alleged cause is responsible for an equal number of cases of the disease as all other background causes present in the control group. Thus, a relative risk of 2.0 implies a 50 percent probability that the agent at issue was responsible for a particular individual's disease. This means that a relative risk that is greater than 2.0 permits the conclusion that the agent was more likely than not responsible for a particular individual's disease." (*In re Silicone Gel Breast Impl. Prod. Liab. Lit.* (C.D.Cal. 2004) 318 F.Supp.2d 879, 893; cf. Federal Jud. Center, Reference Manual on Scientific Evidence (3d ed. 2011), Reference Guide on Epidemiology, p. 619 <https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf> [as of Feb. 6, 2020] ["Events are said not to have an association [i.e., occur more or less frequently together than one would expect by chance] when the agent (or independent variable) has no apparent effect on the incidence of a disease (the dependent variable). This corresponds to a relative risk of 1.0."].)

substance causes a specific disease in humans. (13 RT 1892:10-25, 2003:20-2004:1.)

EPA has reviewed numerous long-term rodent carcinogenicity studies of glyphosate. (4 AA 4529; 9 AA 10007, 10027-10028, 10063-10081.) Tumors observed in rodents are analyzed under numerous criteria in EPA's Guidelines for Carcinogen Risk Assessment. (12 RT 1628:1-25.) EPA concluded that "based on [the] weight of [the] evidence," any tumors observed in the rodent studies were not "related" to glyphosate. (25 RT 4056:18-22.) Moreover, tumors found in rodents provide minimal insight for human health risk assessment because the rodents' doses of exposure are orders of magnitude higher than any human would ever be exposed to. (13 RT 2012:10-2013:9.)

3. Mechanistic data

Mechanistic studies "provide information concerning the molecular, cellular or physiological mechanisms by which substances exert their effects on living cells and organisms." (*Mechanistic study*, The Free Dictionary By Farlex <https://bit.ly/2XkgsNE> [as of Feb. 6, 2020].) Mechanistic studies can be used to determine the genotoxicity of a particular substance. (12 RT 1700:5-15; 13 RT 1887:24-1888:2, 1888:21-25.)

Genotoxicity refers to damage to a cell's DNA. (13 RT 1982:7-10.) Genotoxicity differs from carcinogenicity; because something is genotoxic does not mean it causes mutations that could result in cancer. (13 RT 1983:5-1984:8, 1989:24-1991:17; 30 RT 5115:20-5117:10, 5119:3-5120:21, 5129:10-24.)

EPA evaluated over 80 genotoxicity studies of glyphosate. (25 RT 4057:18-23, 4058:10-16, 4059:21-4060:8.) After reviewing these studies, EPA found that although there was "limited evidence" of a genotoxic effect in some of the in vitro (i.e., petri dish) studies, there was "no convincing evidence" that glyphosate induces cell changes in the more widely referenced human studies. (25 RT 4058:10-4060:14; 9 AA 9912; see 13 RT 1984:6-14 [the mutagenicity tests for glyphosate are "overwhelmingly negative"]; 30 RT 5115:12-14.)

Despite the consistent results in the epidemiology, toxicology, and mechanistic studies discussed above, Plaintiffs called several experts at trial, including Christopher Portier, Ph.D; Charles Jameson, Ph.D; and Beate Ritz, Ph.D, each of whom opined that glyphosate has the capacity to cause NHL. (See, e.g., 12 RT 1603:4-1606:11 [Dr. Portier]; 14 RT 2178:7-2179:5 [Dr. Jameson]; 16 RT 2462:15-17, 2580:8-13 [Dr. Ritz].)

D. IARC finds a theoretical risk of a cancer hazard at some unknown exposure level.

IARC is an agency of the World Health Organization. (14 RT 2120:15-17.) IARC classifies substances that it studies in either Group 1 ("carcinogenic to humans"), Group 2A ("probably carcinogenic to humans"), Group 2B ("possibly carcinogenic to humans"), Group 3 ("not classifiable as to its carcinogenicity to humans"), or Group 4 ("probably not carcinogenic to humans"). (9 AA 10255-10256; 14 RT 2122:16-2123:6.) IARC has classified only one chemical as "not expected to be or not known to be a . . .

human carcinogen" out of more than 1,000 substances it has evaluated. (14 RT 2123:2-10.) In March 2015, IARC issued Monograph 112 on glyphosate, in which it classified glyphosate in Group 2A as a "probable human carcinogen." (12 RT 1773:6-8; 14 RT 2124:6-10, 2149:13-14.)

"[P]robabl[e] carcinogen[ ]," as that term is used by IARC, has no quantitative significance. (13 RT 1913:4-9.) Indeed, IARC did not assess the probable risk of cancer to humans from exposure to glyphosate, nor did it assess the dose of glyphosate that allegedly could cause cancer. (14 RT 2214:4-2217:3, 2230:18-2231:3; see also 6 AA 6713, 6728-6729; 9 AA 10231 ["the level of human exposure, which determines the actual risk, was not taken into account by IARC"], 10235.) Instead, IARC concluded only that at some unknown dose glyphosate could be a probable carcinogen, not that those using glyphosate-containing herbicides were actually at any potential risk for getting cancer. (14 RT 2226:8-17; see also 9 AA 10235.)

IARC considered only some of the available genotoxicity data, did not analyze several additional relevant rodent studies, and did not consider all of the epidemiological data analyzed by regulators. (13 RT 1915:24-1920:11; 6 AA 7283-7289.) IARC chose not to consider either the Agricultural Health Study or the North American Pooled Project studies discussed above based on the rationale that those data, although largely available to IARC, were not yet published. (6 AA 6646-6651, 6666-6667, 6672.)

IARC considered human epidemiology data, but found it was not sufficient to establish that glyphosate causes cancer. (13 RT

2038:14-2039:6 [classifying the human epidemiological evidence as "limited"]; 6 AA 8853.) Instead, IARC based its Group 2A classification on experimental animal studies concerning tumors in rodents exposed to doses of glyphosate thousands of times greater than those relevant to humans and mechanistic data showing glyphosate can cause non-mutagenic cell changes in petri-dish type experiments. (14 RT 2154:7-2160:6; 6 AA 8853-8854; see 13 RT 1984:6-14, 2009:19-2012:18; 30 RT 5115:12-14.)

Based solely on IARC's classification, Proposition 65 (Prop. 65) (Health & Saf. Code, §§ 25249.5-25249.13), automatically categorized glyphosate as a chemical "known to the state to cause cancer." (21 RT 3416:10-14, 3418:7-19, 3431:20-24; see *Nat. Association of Wheat Growers v. Zeise* (E.D.Cal. 2018) 309 F.Supp.3d 842, 846-847 (*Zeise*).) That classification triggered a state-law requirement to attach a warning label to glyphosate products. (See Health & Saf. Code, §§ 25249.6, 25249.8; Cal. Code Regs., tit. 27, § 25306, subd. (l)(1).)[3]

[3] A district court later enjoined the Prop. 65 glyphosate warning mandate in part because the warning would be "misleading to the ordinary consumer" given that "virtually all other government agencies and health organizations that have reviewed studies on the chemical ha[ve] found there [is] no evidence that it cause[s] cancer." (*Zeise*, *supra*, 309 F.Supp.3d at p. 851.)

E. Following release of IARC's findings, domestic and foreign regulatory agencies reaffirm their conclusion that glyphosate poses no real-world cancer risk.

After IARC announced its Monograph 112 in March 2015, regulatory agencies throughout the world reevaluated glyphosate, considered the latest and most comprehensive datasets—including the data IARC examined—and continued to find insufficient evidence that glyphosate causes cancer in humans.

In October 2015, EPA's Cancer Assessment Review Committee reviewed "63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies," and performed a "[c]arcinogen [r]isk [a]ssessment[ ] based on the weight-of-evidence." (9 AA 10034, 10214.) Based on that assessment, it issued a proposed conclusion that glyphosate is " '[n]ot [l]ikely to be [c]arcinogenic to [h]umans.' " (9 AA 10034.) The committee stated that the "epidemiological evidence at this time does not support a causal relationship. . . ." (*Ibid.*) In September 2016, EPA's Office of Pesticide Programs likewise concluded, based on "a thorough integrative weight-of-evidence evaluation of the available data," that glyphosate is " 'not likely to be carcinogenic to humans.' " (9 AA 9925.) That office reviewed "23 epidemiological studies, 15 animal carcinogenicity studies, and nearly 90 genotoxicity studies," and rejected the contention that the weight-of-the-evidence provided even " 'suggestive evidence of carcinogenic potential.' " (9 AA 9923-9924.) In April 2019—during trial in this case—EPA issued a Proposed Interim Registration

Review Decision, which expressly considered and rejected IARC's finding, and again reiterated its determination that glyphosate is "not likely to be carcinogenic to humans." (EPA, Glyphosate Proposed Interim Registration Review Decision Case Number 0178 (Apr. 2019) pp. 7-8, 19 <https://bit.ly/2xQ7Cwe> [as of Feb. 6, 2020] (hereafter EPA, Glyphosate Proposed Interim Registration Review Decision).)[4] In that decision, EPA also explained that it "thoroughly assessed risks to humans from exposure to glyphosate from all uses and all routes of exposure and did not identify any risks of concern." (EPA, Glyphosate Proposed Interim Registration Review Decision, at p. 19.)

Because of California's Prop. 65 warning requirement, glyphosate registrants asked EPA to approve a change in labeling to include a cancer warning—a change that requires EPA approval. (See 40 C.F.R. § 152.44(a) (2018).) EPA initially approved a limited number of these requests in error. (See Brief for United States as Amicus Curiae Supporting Appellant, *Monsanto Co. v. Hardeman* (9th Cir., Dec. 20, 2019, No. 19-16636) (*Hardeman*) (hereafter U.S. Brief), attached as exh. A to Declaration of Dean A. Bochner in Support of Motion for Judicial Notice, p. 15.)[5] But the agency later issued a letter to all

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[4] The trial court erroneously excluded this document from evidence. (30 RT 5068:24-5070:18.)

[5] The U.S. Amicus Brief in *Hardeman* is the subject of a motion for judicial notice concurrently filed with this brief. When citing to this amicus brief, we cite to the Bates-stamped numbers, which track the page numbers on the PACER heading on each page, rather than the page numbers of the amicus brief.

glyphosate registrants in August 2019 informing them that, "[g]iven EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,'" EPA considers a warning that glyphosate is carcinogenic "to constitute a false and misleading statement" that violates FIFRA's prohibition against "misbranded" substances. (EPA Aug. 2019 Letter, *supra*, at p. 1, citing 7 U.S.C. § 136(q)(1)(A).) The agency instructed registrants to remove any such statement from labels of a glyphosate-based pesticide and to refrain from adding any such statements to the labels of such products in the future. (*Id.* at p. 2.) In making this determination, EPA once again forcefully rejected IARC's findings. In its letter, EPA explained that it "disagrees with IARC's assessment" because "EPA scientists have performed an independent evaluation of available data since the IARC classification" and have concluded that glyphosate is not likely to be carcinogenic. (EPA Aug. 2019 Letter, p. 1.)

EPA has noted that its cancer conclusion is "consistent with other international expert panels and regulatory authorities." (EPA Aug. 2019 Letter, *supra*, p. 1.) Indeed it is:

1. In 2015, the European Union's food safety agency reevaluated and confirmed its earlier conclusion that glyphosate is unlikely to pose a carcinogenic risk to humans. (9 AA 9863.)

2. In 2016, the European Union's chemical safety agency similarly concluded that "[b]ased on the epidemiological data as well as on data from long-term studies in rats and mice, taking a

weight of evidence approach, no hazard classification for carcinogenicity is warranted for glyphosate." (8 AA 9520.)

3. In 2016 and 2017, the Australian government's national pesticide regulator concluded that "exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans." (8 AA 9324, 9341.)

4. In 2016, New Zealand's Environmental Protection Agency re-reviewed the available scientific data in light of IARC's classification and found that "based on a weight of evidence approach, taking into account the quality and reliability of the available data—glyphosate is unlikely to be genotoxic or carcinogenic to humans." (10 AA 10722.)

5. In 2017, the Canadian government's national pesticide regulator, Health Canada, concluded that "[g]lyphosate is not genotoxic and is unlikely to pose a human cancer risk." (9 AA 10223.) Health Canada further concluded that "[a]n evaluation of available scientific information found that products containing glyphosate do not present risks of concern to human health or the environment when used according to the revised label directions." (9 AA 10224.)

F. Nature and progression of NHL

Non-Hodgkin's lymphoma is a common blood cancer of which there are between 60 and 100 different subtypes. (17 RT 2695:14-17, 2788:12-25; 27 RT 4362:1-14; 6 AA 7133.) The average American's risk of developing NHL in his or her lifetime is about 1 in 47. (6 AA 7071.) The incidence of NHL in the United States

began increasing in the 1940s and 1950s—decades before Roundup came on the market. (18 RT 2946:6-12.) Before Roundup was ever manufactured or sold, farmers reported higher rates of NHL than the general population. (6 AA 6637-6638.)

Each subtype of NHL has different causes, treatments, and prognoses. (17 RT 2796:3-15; 30 RT 5177:20-5178:7; 6 AA 7076, 7133.) For most cases of NHL (at least 70 percent), the causes are unknown or "idiopathic." (17 RT 2778:21-2779:7, 2790:25-2792:20; 25 RT 4160:19-4161:9, 4162:8-9, 4163:15-21, 4165:5-4166:12; 27 RT 4360:20-4361:2; 30 RT 5305:15-5306:5; 6 AA 7070-7071.) There are certain risk factors, however, that make it more likely that an individual will develop NHL. (17 RT 2793:3-12.) For instance, NHL, like most cancers, is associated with advanced age. (30 RT 5169:25-5170:6; 6 AA 7099-7100, 7327.) Additionally, autoimmune conditions, obesity, and chronic viral infections can increase the likelihood of a subsequent lymphoma diagnosis. (6 AA 7126, 7130, 7327.) And although some of Plaintiffs' experts opined that smoking was not a risk factor for NHL (18 RT 2996:17-2997:5), research by Plaintiffs' causation expert Dr. Weisenberger demonstrated that smoking can be a significant risk factor for NHL (17 RT 2809:12-2813:18), and Dr. Rubenstein—Mrs. Pilliod's treating physician—agreed with Monsanto's experts that cigarette smoking is "certainly a risk factor" (6 AA 7327). Many of these risk factors far exceed the level of risk Plaintiffs' experts opined was associated with Roundup. (See pp. 77-80, *post*.)

G. Plaintiffs' use of Roundup

Plaintiffs used Roundup on four residential properties. (23 RT 3725:6-8.) They started spraying Roundup on their primary residence in 1982. (23 RT 3695:14-25, 3696:6-3697:5, 3782:4-12.) Mrs. Pilliod estimated that they sprayed about a gallon of Roundup on that property each week, nine months per year, until 2011. (23 RT 3703:22-3704:4, 3706:1-18, 3707:3-8.) They also sprayed Roundup at three other properties throughout the years. (23 RT 3712:4-3713:17, 3720:6-3721:17, 3724:11-3725:8.) Mrs. Pilliod estimated that Mr. Pilliod did approximately 75 percent of the spraying and Mrs. Pilliod did approximately 25 percent. (23 RT 3722:25-3723:6.) Plaintiffs' exposure expert opined that Mr. Pilliod sprayed about three times as much Roundup as Mrs. Pilliod. (19 RT 3270:6-10, 3274:22-3275:3.) Mr. Pilliod stopped spraying Roundup at the time of his NHL diagnosis in 2011. (23 RT 3706:10-18.) Mrs. Pilliod sprayed a "little" after that, but stopped spraying when she became sick in spring 2015. (23 RT 3740:6-3741:18.)[6]

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[6] Plaintiffs' operative complaint alleged exposures to Roundup until 2011, the time that Mr. Pilliod became sick. (1 AA 150.) Mrs. Pilliod confirmed that her husband stopped spraying after 2011. (23 RT 3706:10-18.) Consistent with these admissions, Plaintiffs' experts based their causation analysis on Roundup exposures that occurred up to 2012. (19 RT 3264:7-3265:23, 3272:19-3273:18.) Mrs. Pilliod said she continued to spray a "little" after her husband got sick, but stopped in early 2015 (23 RT 3740:6-3741:18), about the same time the IARC Monograph was published (12 RT 1773:6-8; 17 RT 2752:24-2753:2). Mr. Pilliod testified that he continued to spray until 2016. (23 RT 3796:9-12.) However, before the IARC

(continued...)

H. Mr. Pilliod's medical history

Before being diagnosed with NHL, Mr. Pilliod had a long and complex medical history, including multiple conditions that are significant risk factors for NHL. Mr. Pilliod had an extensive history of skin cancer, multiple episodes of meningoencephalitis, herpes simplex virus, recurrent genital warts, autoimmune disease (ulcerative colitis), a family history of cancer, a 20-year history of smoking a pack of cigarettes per day, multiple brain injuries (in addition to infections), a history of stroke, sleep apnea, high blood pressure, and congenital hemochromatosis. (17 RT 2871:7-2872:5; 30 RT 5139:20-5142:15; 6 AA 7120-7122, 7126-7127, 7130-7131.)

In 2011, at the age of 69, Mr. Pilliod was diagnosed with NHL. (25 RT 4157:23-4158:2; 11 RT 1448:16-17.) He was treated with the standard chemotherapy regimen for NHL (17 RT 2704:2-16; 24 RT 3974:3-24; 6 AA 7123), and has been in remission since 2013 (6 AA 7125, 7140).

I. Mrs. Pilliod's medical history

Mrs. Pilliod also had a 20-year history of smoking cigarettes. (17 RT 2813:22-2815:9; 27 RT 4379:1.) Her medical history also included recurrent bladder cancer, obesity, diabetes, and an

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Monograph was published, Mr. Pilliod had been completely cured and in remission for years (6 AA 7125; 30 RT 5217:4-5) and Mrs. Pilliod had stopped spraying (23 RT 3740:6-3741:18). Any spraying that occurred after the Monograph's publication could not have been a factor in causing their harm.

autoimmune condition affecting the thyroid known as Hashimoto's disease. (27 RT 4378:11-4379:1; 6 AA 7080, 7098, 7146.) In 2015, at age 71, Mrs. Pilliod was diagnosed with and treated for NHL. (27 RT 4378:7-10; 6 AA 6776.) By the end of 2015, Mrs. Pilliod was in remission. (6 AA 7104.) She had a relapse in 2016, but has been in remission since early 2017. (6 AA 6786, 7104-7106; 24 RT 3978:20-21; 27 RT 4392:23-24.)

J. Relevant procedural history

Before trial, Monsanto moved to sever the claims of Mr. and Mrs. Pilliod based on the significant risk that a jury would assume causation merely because a husband and wife who both used Roundup were diagnosed with NHL, despite the fact that the Pilliods had different exposure histories, risk factors, and diagnoses. (1 AA 194-212; see also 3 AA 3515-3530, 4002-4008.) The trial court denied the motion. (1 AA 271-276; see also 3 AA 4084-4085.)

The joint trial commenced on March 18, 2019. Over Monsanto's objection, the trial court allowed extensive testimony about events that occurred more than forty years ago at Industrial Bio-Test (IBT) Laboratories in which it was revealed that IBT had produced fraudulent data to support the registration of numerous pesticides, including glyphosate. (6 AA 6869; 7 AA 8988.) Monsanto had no involvement in these events, and the data submitted by dozens of companies to EPA were affected. (6 AA 6468; 7 AA 8988; 15 RT 2409:1-16; 22 RT 3625:11-3626:14.)

Monsanto subsequently repeated the affected studies. (6 AA 6869-6870; see 7 AA 8988.)

Throughout trial, the jury was improperly influenced by attorney misconduct, including, among other things, repeated violations of the court's in limine orders and factual and legal misrepresentations in opening statement and closing argument. (See pp. 93-107, *post*.)

Plaintiffs submitted to the jury claims for design defect under the consumer expectations theory, strict liability and negligent failure to warn, negligence, and punitive damages. (6 AA 6573-6577, 6579-6583.) The jury returned a verdict for Plaintiffs on each claim. The jury awarded Mrs. Pilliod $201,166.76 in past economic loss; $2,957,710 in future economic loss; $8 million in past noneconomic loss; $26 million in future noneconomic loss; and $1 billion in punitive damages. (6 AA 6576-6577.) The jury awarded Mr. Pilliod $47,296.01 in past economic loss; $8 million in past noneconomic loss; $10 million in future noneconomic loss, and $1 billion in punitive damages. (6 AA 6582-6583.) Judgment was entered on May 20, 2019. (6 AA 6584-6595.)

Monsanto timely filed motions for new trial and judgment notwithstanding the verdict (JNOV). (6 AA 7347-7353, 8089-8142.) The court conditionally granted the motion for new trial unless Mr. Pilliod agreed to entry of judgment in the amount of $30,736,480 and Mrs. Pilliod agreed to entry of judgment in the amount of $56,005,830. (6 AA 8253-8278.) The reduced awards represented a reduction in compensatory damages based on the trial court's finding that the evidence did not support the jury's

awards of certain compensatory damages, and a reduction in punitive damages to a 4:1 punitive-to-compensatory ratio. (6 AA 8263-8278.) Plaintiffs subsequently accepted the reduced awards. (6 AA 8279-8281.)

Monsanto timely appealed from the judgment and the order denying JNOV. (6 AA 8282-8284.) Plaintiffs cross appealed from the conditional new-trial order reducing their awards of punitive damages. (6 AA 8285-8287.)

STATEMENT OF APPEALABILITY

The judgment and the order denying JNOV are both appealable. (Code Civ. Proc., § 904.1, subd. (a)(1), (4).)

LEGAL ARGUMENT

I. The court should reverse the judgment with directions because Plaintiffs' claims are preempted by federal law.

"The supremacy clause of the United States Constitution . . . vests Congress with the power to preempt state law." (*Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal.4th 929, 935.) " 'Congress may exercise that power by enacting an express preemption provision, or courts may infer preemption under one or more of three implied preemption doctrines . . . .' " (*People ex rel. Harris v. Delta Air*

Lines, Inc. (2016) 247 Cal.App.4th 884, 894.) This case involves both: express preemption, because " 'Congress has made its intent known through explicit statutory language,' " and impossibility preemption, because "simultaneous compliance with both state and federal directives is impossible." (*Viva!*, at p. 936.)

Whether state law claims such as Plaintiffs' are preempted is a question of law and a matter of jurisdiction that may even be raised for the first time on appeal. (See *People v. Salcido* (2019) 42 Cal.App.5th 529, 537; *Town of Atherton v. California High-Speed Rail Authority* (2014) 228 Cal.App.4th 314, 331; *ReadyLink Healthcare, Inc. v. Jones* (2012) 210 Cal.App.4th 1166, 1175; *Sciborski v. Pacific Bell Directory* (2012) 205 Cal.App.4th 1152, 1163.)

For decades, EPA has exhaustively reviewed the science, repeatedly determined that glyphosate does not cause cancer, and consistently approved Roundup for sale with a label that does not warn of cancer. (E.g., 2 AA 2160-2503; 9 AA 9924-9925, 9979, 9981-9982, 10012, 10031-10034, 10121, 10136, 10213-10214; EPA, Glyphosate Proposed Interim Registration Review Decision, *supra*, pp. 7-10; see U.S. Brief, *supra*, at pp. 13-14, 31.) In fact, EPA has determined that adding a cancer warning to glyphosate products such as Roundup would make the product "misbranded" in violation of FIFRA. (EPA Aug. 2019 Letter, *supra*, at p. 1.) These determinations should have defeated Plaintiffs' state-law claims. Express preemption bars any state-law claim that is based on a failure to provide labeling warnings that EPA has determined are not required by FIFRA. And both express and implied

preemption bar any state-law claim that is based on a failure to include in labeling text that federal law prohibits.

A. FIFRA expressly preempts Plaintiffs' warning-based claims.

FIFRA prohibits states from "impos[ing] . . . any requirements for labeling or packaging in addition to or different from those required under this subchapter [i.e., FIFRA]." (7 U.S.C. § 136v(b).) *Bates*, *supra*, 544 U.S. at pages 437-438, 444, established a two-part test for determining whether state law claims are expressly preempted under FIFRA. Under *Bates*, express preemption applies if state law (i) imposes a "requirement" for " 'labeling or packaging,' " and (ii) is " 'in addition to or different from' " a requirement imposed under FIFRA. (*Id.* at p. 444, emphasis omitted.) Both parts of this test are satisfied.

1. Plaintiffs' claims are based on state-law labeling requirements.

In *Bates*, the Supreme Court clarified that the state-law " 'requirements' " subject to FIFRA's preemption provision include not only statutes and regulations but also " 'common-law duties.' " (*Bates*, *supra*, 544 U.S. at p. 443; see *Etcheverry v. Tri-Ag Service, Inc.* (2000) 22 Cal.4th 316, 335 [FIFRA preemption applies to " 'common law damages action[s]' "], overruled in part on another ground in *Bates*, *supra*, 544 U.S. at pp. 436, 452-454.) Plaintiffs' failure-to-warn claims for damages are based on California common-law duties that constitute state-law requirements.

These common-law "requirements" are "for labeling or packaging."[7] A state-law duty is a " 'requirement[ ] for labeling or packaging' " if it "set[s] a standard for a product's labeling." (*Bates*, *supra*, 544 U.S. at p. 446.) Plaintiffs' claims seek to enforce such a "requirement" for "labeling and packaging"—to include cancer warnings on Roundup. (See 3 RT 300:1-6 [Plaintiffs' counsel: "We're not claiming that [Roundup] should be banned. We're just saying that irrespective of any sensible benefits that [glyphosate-based herbicides] will have for the economy, agriculture, and so forth, that did not absolve Monsanto of the obligation to stick a warning label saying that it would cause NHL."]; see also *Bates*, at p. 444 [common-law claims are preempted if they "require[ ] that manufacturers label or package their products in any particular way"].)

2. The purported California law requirement is "in addition to" and "different from" requirements imposed under FIFRA.

FIFRA established a comprehensive statutory scheme for controlling the use, sale, and labeling of pesticides. (*Bates*, *supra*, 544 U.S. at pp. 437-438). Prior to registering a pesticide, EPA must consider data and studies of health risks, including carcinogenicity and toxicity. (7 U.S.C. § 136a(c)(5); 40 C.F.R. § 158.500 (2019).) FIFRA prohibits labeling and packaging that is

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[7] FIFRA defines "labeling" broadly to include "all labels and all other written, printed, or graphic matter [¶] . . . [¶] . . . accompanying the pesticide or device at any time." (7 U.S.C § 136(p)(2)(A).)

"misbranded"—i.e., that is "false or misleading in any particular" or "does not contain a warning or caution statement which may be necessary and . . . is adequate to protect health and the environment." (7 U.S.C. § 136(q)(1)(A), (G); see 40 C.F.R. § 152.112(f) (2019).) EPA will not approve labeling unless it "has determined that the product is not misbranded as that term is defined in FIFRA . . . , and its labeling and packaging comply with the applicable requirements of the Act." (40 C.F.R. § 152.112(f) (2019).)

In its labeling determinations, EPA exercises its expert judgment both about scientific issues and other mandatory label provisions intended to protect applicators and others. (40 C.F.R. § 152.112 (2019).) EPA-mandated labeling provisions include "Human Hazard" and "Precautionary Statement[ ]" warnings about potential health risks and mitigation actions. (*Id.*, §§ 156.60-156.78.) EPA's assessment of those potential health and safety risks, including carcinogenicity, determines what label warnings are warranted and thus required under FIFRA. Thus, in registering a product, EPA determines that the label provisions—including its warnings and precautionary statements—are not false or misleading and contain necessary warnings. EPA's approval of a label in the course of registering and re-registering a product compels the use of that approved label, without deviation. (See 7 U.S.C. § 136j(a); 40 C.F.R. § 152.44 (2019).)

In the case of glyphosate, for decades EPA has concluded, based on its exhaustive review of scientific studies, that glyphosate

poses no cancer risk to humans and that no cancer warning is warranted or appropriate. (See *ante*, pp. 21-23, 31-33; see also U.S. Brief, *supra*, at pp. 18-19 ["EPA has never required a labeling warning of a cancer risk posed by Roundup, and such a warning would be inconsistent with the agency's scientific assessments of the carcinogenic potential of the product"]; 9 AA 9924-9925, 10012, 10031-10034, 10121, 10136, 10213-10214; EPA, Glyphosate Proposed Interim Registration Review Decision, *supra*, p. 7.) By virtue of EPA's authoritative determinations in exercise of its delegated authority, it is a requirement under FIFRA to use the EPA-approved label for glyphosate products—i.e., one with no cancer warning. (U.S. Brief, *supra*, at pp. 6-7 ["Every time EPA reviews and approves [a pesticide's] label," EPA is "making federal law" that is "tailored" to that particular pesticide].)

Indeed, not only does FIFRA not require cancer warnings on glyphosate labeling, but—as EPA expressly confirmed in its August 2019 letter—glyphosate products whose labeling contains a cancer warning are "misbranded pursuant to section 2(q)(1)(A) of FIFRA [7 U.S.C. § 136(q)(1)(A)] and as such do not meet the requirements of FIFRA." (EPA Aug. 2019 Letter, *supra*, at p. 1; see also U.S. Brief, *supra*, at p. 15 [cancer warning on glyphosate products "constituted prohibited misbranding"]; *id.* at p. 23 [a state-law requirement of a "glyphosate cancer warning on a Roundup label" would "not only require[ ] a different label (a requirement preempted by FIFRA)" but "would almost certainly compel Monsanto to produce a misleading label warning very

much at odds with EPA's scientific assessment of the carcinogenic potential of glyphosate"]).

Bates confirms that express preemption applies. In *Bates*, a group of farmers brought a state-law suit against a pesticide manufacturer for failing to warn that the pesticide would stunt their crops. (*Bates*, *supra*, 544 U.S. at p. 435.) The Supreme Court held that a state-law claim can survive preemption only if it "seeks to enforce" what federal law requires, and is "equivalent to, and fully consistent with, FIFRA's misbranding provisions." (*Id.* at pp. 447-448.) Equivalence is a demanding requirement—for instance, if state law requires a pesticide's label to say " 'DANGER' " where EPA decides it should include "the more subdued 'CAUTION,' " the state law requirement "would be pre-empted." (*Id.* at p. 453.) In *Bates*, it was possible that equivalence could be met (a question on which the Court remanded). There, the agency had taken no position on whether the warning sought by the plaintiffs was warranted, in part because EPA had for decades waived any review of "efficacy" warnings. (See *id.* at p. 440.) It was thus plausible that state tort law would reinforce the same substantive misbranding requirements that exist under FIFRA, and thus be permissible under 7 U.S.C. § 136v(b). (*Id.* at p. 447.)

Here the opposite is true. As the United States has explained in no uncertain terms, "FIFRA does not require a warning on Roundup's label that glyphosate causes cancer." (U.S. Brief, *supra*, at p. 24.) In fact, the difference between what FIFRA requires and what California law purportedly requires is far greater than the comparative semantic difference between

"DANGER" and "CAUTION" highlighted in *Bates*; here, Plaintiffs argue that state law requires a warning that glyphosate is carcinogenic, which EPA has determined would be *false*. There cannot be a clearer example of a state-law requirement "different from" and "in addition to" FIFRA's requirements than a claim, like Plaintiffs' here, that would require the defendant to misbrand its product in violation of FIFRA.

B. Impossibility preemption bars Plaintiffs' claims.

Impossibility preemption also applies here, for two reasons: there is clear evidence that EPA would reject any attempt to add a cancer warning to Roundup's labeling, and Monsanto cannot unilaterally alter Roundup's labeling or formulation without EPA's prior approval.

1. Impossibility preemption bars Plaintiffs' claims because there is "clear evidence" EPA would not approve the warning Plaintiffs seek.

Federal law preempts state claims if there is "clear evidence" the federal agency would not have approved the warning purportedly required by state law. (*Merck Sharp & Dohme Corp. v. Albrecht* (2019) 587 U.S. ___ [139 S.Ct. 1668, 1672, 203 L.Ed.2d 822] (*Albrecht*); *Wyeth v. Levine* (2009) 555 U.S. 555, 571 [129 S.Ct. 1187, 173 L.Ed.2d 51] (*Wyeth*).) Clear evidence exists when the regulator is "fully informed" about the alleged risk and the regulator has communicated its rejection of that risk in an agency

action "carrying the force of law." (*Albrecht*, at pp. 1672, 1678-1679.) The Court also clarified that "clear evidence" for purposes of preemption is an issue of law for the court, not the jury. (*Id.* at p. 1679.) Both components of *Albrecht* are satisfied here.

First, EPA itself has confirmed that it is "fully informed." The agency repeatedly has undertaken in-depth scientific reviews of the evidence on glyphosate's safety, concluding it is safe and non-carcinogenic. (E.g., 9 AA 9924-9925, 10012, 10034, 10121, 10136, 10213-10214; EPA, Glyphosate Proposed Interim Registration Review Decision, *supra*, p. 7; see EPA Aug. 2019 Letter, *supra*, at p. 1.) Each of these determinations was based on an extensive review of scientific evidence. (See, e.g., 9 AA 10213-10214.) The most recent determinations include a 227-page evaluation of glyphosate's carcinogenic potential, released in 2016 (2 AA 1704-1930), and a further review of "[a]ll studies of adequate scientific caliber that [EPA] was aware of" (EPA, Glyphosate Proposed Interim Registration Review Decision, *supra*, p. 10). These most recent determinations were made *after* IARC's classification was made public and specifically addressed both the data relied upon by IARC and IARC's findings. (See *ante*, at pp. 21, 31-33.) Indeed, when concluding that glyphosate is not carcinogenic, EPA noted that its review of the scientific literature was more robust than IARC's because "IARC only considered a subset of the studies included in the EPA's evaluation." (EPA, Glyphosate Proposed Interim Registration Review Decision, *supra*, p. 7.) And, in its August 2019 letter, the agency again confirmed that "EPA scientists have performed an independent

evaluation of available data," and that it "considered a more extensive dataset than IARC." (EPA Aug. 2019 Letter, *supra*, at p. 1.) EPA conducted this review with transparency, peer review, and opportunity for public comments, of which it received more than 200,000. (6 AA 7992-7994.)

Second, EPA's decision to register a pesticide and approve its labeling "carr[ies] the force of law." (*Albrecht*, *supra*, 139 S.Ct. at p. 1679.) Indeed, EPA's implementation of FIFRA's misbranding provision—undertaken in the course of formal registration decisions—constitutes agency action with "practical and significant legal effects." (*Reckitt Benckiser Inc. v. E.P.A.* (D.C. Cir. 2010) 613 F.3d 1131, 1138.) Acting pursuant to its delegated authority, the agency has clearly communicated that it would not approve a request to add a cancer warning. (See *Seufert v. Merck Sharp & Dohme Corp.* (S.D.Cal. 2016) 187 F.Supp.3d 1163, 1174 ["The FDA's repeated conclusion that scientific data did not support warning of pancreatic cancer risk coupled with the FDA's statement that product labeling was adequate amounts to clear evidence that the FDA would have rejected a pancreatic cancer labeling change"].)

EPA confirmed that longstanding conclusion in its August 2019 letter, which reiterated what has been true for almost three decades: EPA does not believe glyphosate is a carcinogen, it views a cancer warning in these circumstances as false and misleading, and it "would not approve a change to the [product's] label to include" a cancer warning because that would constitute misbranding under FIFRA and its implementing regulations.

(*Albrecht*, *supra*, 139 S.Ct. at p. 1672; see *ante*, pp. 21, 32-33.) Because EPA would not approve the addition of a cancer warning to Roundup's labeling, a state-law claim that Monsanto should have done so is preempted.[8]

2. Impossibility preemption also bars Plaintiffs' claims because Monsanto cannot unilaterally alter Roundup's EPA-approved labeling or formulation.

"If a private party . . . cannot comply with state law without first obtaining the approval of a federal regulatory agency, then the application of that law to that private party is preempted." (*Gustavsen v. Alcon Laboratories, Inc.* (1st Cir. 2018) 903 F.3d 1, 9; see *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 620 [131 S.Ct. 2567, 180 L.Ed.2d 580] (*Mensing*).) Here, impossibility preemption bars Plaintiffs' state law claims because Monsanto cannot unilaterally change its product's formulation or add a cancer warning to Roundup's label without EPA's approval.

Monsanto cannot alter its product's formulation without EPA's prior approval because such changes would require an amended registration. (See 40 C.F.R. §§ 152.44, 152.46 (2019).) Likewise, unlike a branded pharmaceutical manufacturer's ability

[8] As noted above, EPA acknowledged that it had approved a limited number of glyphosate labels that contained Prop. 65 cancer warnings but explained that these prior approvals "were erroneous because the proposed edits warned of a cancer risk that, according to EPA's assessment, does not exist" and that these "mistakenly approved" warnings have now been corrected. (U.S. Brief, *supra*, at pp. 15, 24, fn. 14; see *ante*, p. 32.)

to change its labeling unilaterally to add safety information (see *Wyeth*, *supra*, 555 U.S. at pp. 568-573), Monsanto cannot add a cancer warning to Roundup's label without first obtaining EPA approval (see 40 C.F.R. §§ 152.44, 152.46, 156.70(a) (2019)).

In *Mensing*, generic drug manufacturers argued it was "impossible" for them to add a warning required by a state-law tort suit because federal law required them to use the exact same label that FDA has approved for the equivalent brand-name drug. (*Mensing*, *supra*, 564 U.S. at pp. 617-618.) The Court agreed because the manufacturers "would have violated federal law" if they "had independently changed their labels to satisfy their state-law duty." (*Id.* at p. 618; see *Mutual Pharmaceutical Co. v. Bartlett* (2013) 570 U.S. 472, 475-476 [133 S.Ct. 2466, 186 L.Ed.2d 607] [design-defect claim barred because generic manufacturers could not unilaterally change their drug's design]; *Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110, 154-155 (*Trejo*) [same for brand-name manufacturer, because " 'once a drug, whether generic or brand-name, is approved, the manufacturer is prohibited from making any major changes' " to its formulation without approval].)

Herbicide manufacturers like Monsanto cannot unilaterally add a cancer warning to their product's labeling. Neither can Monsanto unilaterally alter the formulation of Roundup. (See 2 AA 1283-1294; 40 C.F.R. §§ 152.44, 152.46.) All of Plaintiffs' claims, which are based on either a failure to warn or a reformulation of the product, are accordingly preempted.

II. The court should reverse the judgment with directions because there is no substantial evidence to support the jury's failure-to-warn and design defect findings.

There is no substantial evidence to support either a failure to warn or design defect theory of liability. The warning theory fails because it was not known or knowable to Monsanto that Plaintiffs' use of Roundup could cause cancer. The design defect theory fails because Plaintiffs abandoned the risk-benefit theory of design defect, and instead opted to rely on the wholly inapplicable consumer expectations theory of liability.

A. Plaintiffs' warning claims fail because the prevailing best scientific scholarship concluded that the evidence did not establish a potential cancer risk at the time Roundup was manufactured, sold, and distributed.

A jury's decision should be reversed if it is not supported by substantial evidence viewed in the light most favorable to the prevailing party. (*DiMartino v. City of Orinda* (2000) 80 Cal.App.4th 329, 336, 344.) Substantial evidence " ' "must be reasonable in nature, credible, and of solid value; it must actually be 'substantial' proof of the essentials which the law requires in a particular case." ' " (*Id.* at p. 336.) But substantial evidence " ' "cannot be deemed synonymous with 'any' evidence." ' " (*Bowers v. Bernards* (1984) 150 Cal.App.3d 870, 873.) The evidence here did not come close.

To prevail on their failure-to-warn claims, Plaintiffs had to prove that Roundup "had potential risks that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific community at the time of manufacture, distribution, and sale," and that such risks "presented a substantial danger when" it was used. (32 RT 5485:9-14; see CACI No. 1205; see also *Anderson v. Owens-Corning Fiberglas Corp.* (1991) 53 Cal.3d 987, 1002-1003 (*Anderson*).)[9] Therefore, more than merely establishing that Monsanto could have identified a theoretical risk, Plaintiffs were required to prove that the risk was "known or knowable" based on "the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." (*Anderson*, at p. 1002.)

When a risk is not generally recognized as prevailing in the scientific community, and does not represent the best scholarship available at the time, the risk is not "knowable" and there is no

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[9] The jury was also asked to decide whether Monsanto could be liable under a *negligent* failure-to-warn theory. (32 RT 5487:3-5488:4; 34 RT 5747:4-22, 5749:23-5750:16.) Where, as here, both strict liability and negligent failure-to-warn theories are submitted to the jury, a finding of no liability on the strict liability theory *necessarily* establishes no liability on a negligent failure-to-warn theory based on the same facts. (*Trejo*, *supra*, 13 Cal.App.5th at pp. 132-133 [jury finding that defendant was not liable under strict liability failure-to-warn theory vitiated liability under a negligent failure-to-warn theory]; *Oxford v. Foster Wheeler LLC* (2009) 177 Cal.App.4th 700, 707, 716-721 [jury's finding of no liability on a strict liability failure-to-warn theory was irreconcilably inconsistent with jury's finding of a negligent failure to warn].)

duty to warn. (See *Anderson, supra*, 53 Cal.3d at pp. 1000-1002; accord, *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89, 101 (*Conte*) [strict liability failure to warn requires proof " ' "that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution" ' "]; *Rosa v. City of Seaside* (N.D.Cal. 2009) 675 F.Supp.2d 1006, 1014 ["California courts require that plaintiffs present evidence of '*general* recogni[tion] and *prevailing* best scientific and medical knowledge' to meet the 'known or knowable' element of a strict liability claim"]; see also *Rosa v. Taser Intern., Inc.* (9th Cir. 2012) 684 F.3d 941, 946 (*Rosa*) [rejecting argument that a "knowable" risk includes "any risk that was discoverable through modern technology, no matter how unsubstantiated"].)

The committee that crafted the jury instruction for strict liability failure to warn explained what it means for a potential risk to be "known" or "knowable" for purposes of establishing liability. (CACI No. 1205.) The "committee believes that this standard is captured by the phrase 'generally accepted in the scientific community.' A risk may be 'generally recognized' as a view (knowledge) advanced by one body of scientific thought and experiment, but it may not be the 'prevailing' or 'best' scientific view; that is, it may be a minority view. The committee believes that when a risk is (1) generally recognized (2) as prevailing in the relevant scientific community, and (3) represents the best scholarship available, it is sufficient to say that the risk is

knowable in light of 'the generally accepted' scientific knowledge." (Directions for Use to CACI No. 1205 (2020) pp. 714-715.)

Here, Plaintiffs presented no evidence to satisfy any of these three requirements. The evidence is undisputed that the "best scholarship available" at the time of the sale and distribution of Roundup alleged to have caused Plaintiffs' cancers provided no generally accepted view that exposure to glyphosate posed a carcinogenic risk to humans. Where worldwide regulatory agencies unanimously concluded that there was no evidence of a causal link between NHL and exposure to glyphosate or glyphosate-containing herbicides and that the best prevailing science did not require a cancer warning, that view was not just the majority view, it was the only regulatory view. (See *ante*, pp. 21-23, 31-34.)

In response to the consensus of worldwide regulatory agencies regarding the prevailing science, Plaintiffs offered the IARC Monograph and the post-hoc opinions of their paid experts. Neither can support a failure to warn theory, as none of that information establishes a prevailing scientific view at the time Roundup was sold or distributed to Plaintiffs. The IARC Monograph was not published until March 2015—after both Plaintiffs were diagnosed with cancer and had stopped all relevant spraying of Roundup. (See *ante*, pp. 36-37, fn. 6 [explaining that any spraying of Roundup after the publication of the IARC Monograph could not have caused Plaintiffs' illnesses].) And Plaintiffs' experts did not form their opinions of a link between glyphosate and NHL until after IARC published its Monograph.

(13 RT 1902:2-9 [Dr. Portier, Plaintiffs' expert on general causation, acknowledged that he did not come to the opinion that glyphosate was a carcinogen before 2015]; 16 RT 2592:11-2596:7 [Dr. Ritz, Plaintiffs' epidemiologist, acknowledged that she had never studied a possible link between glyphosate and NHL or begun to criticize the conclusions of the epidemiology studies until after she was hired by Plaintiffs' counsel in 2018].)

The opinions of paid experts at trial and a publication that is not available until *after* a plaintiff's purchase and relevant use of the product are not evidence of what was the " 'generally recognized and prevailing best scientific and medical knowledge' " at the time of the product's manufacture and distribution. (*Rosa*, *supra*, 684 F.3d at pp. 946, 948 [expressing "doubt" that a study that did not become publicly available until after plaintiff's death could constitute "generally accepted medical knowledge"].) The jury therefore had no basis to conclude that Monsanto was liable for failing to warn Plaintiffs, under either a strict liability or negligence theory.

Even if the IARC Monograph had been published earlier, it still would not have provided the substantial evidence Plaintiffs need to prove their failure-to-warn claims. As Plaintiffs' own risk assessment expert, Dr. Jameson, acknowledged, IARC conducted a *hazard* assessment, not a *risk* assessment. (14 RT 2214:4-2215:18.) That means IARC considered only potential harm at any theoretical dose, and not whether exposure to glyphosate-based herbicides in real-world quantities constitutes a potential health risk to human users of glyphosate-based products. (14 RT 2215:23-

2216:17 [a hazard assessment identifies "a potential to cause cancer at some dose," while a risk assessment "looks to the actual level of exposure that humans are exposed to and whether that causes harm"]; see also 14 RT 2230:20-23; 9 AA 10231; 10 AA 10235.) Dr. Jameson conceded that such real-world assessments were in fact not the job of IARC, but instead were and are the job of the worldwide regulatory agencies, such as EPA—all of whom continue to conclude there is insufficient evidence to establish that glyphosate causes cancer. (14 RT 2230:3-2232:3.)

Moreover, long after IARC classified glyphosate as a 'probable' human carcinogen, the view that glyphosate has the potential to cause cancer, much less the potential to cause cancer in actual users of glyphosate-based herbicides, remains at best a minority view. An analysis of the comprehensive Agricultural Health Study, which has been tracking 55,000 agricultural workers over 25 years and was updated in 2018, reported "no increased risk whatsoever." (14 RT 2293:16-2294:25; *ante*, pp. 24-25; 18 RT 2960:5-2961:2 [Plaintiffs' specific causation expert Dr. Weisenburger acknowledged that while he has criticisms of the updated AHS study, the study showed no increased risk of NHL following glyphosate exposure].) Recent data from the North American Pooled Project, a pooling of several epidemiology studies in multiple states, also showed no statistically significant increased risk. (18 RT 2946:17-2947:6, 2959:2-15.) Consistent with these findings, the worldwide regulatory and public health agencies that reviewed IARC's Monograph and the available science concluded there is no evidence of a real-world cancer risk

to users of Roundup. (13 RT 1895:2-1901:2, 1938:11-1942:8 [Plaintiffs' expert Portier acknowledged that European regulators (EFSA) concluded after IARC "that there's not a carcinogenic risk" with glyphosate]; see also *ante*, pp. 21-23, 31-34.)

Monsanto's obligation was to warn of a known or knowable risk to users of Roundup, not to warn of an after-the-fact minority view that did not reflect the best prevailing science. (See Directions for Use to CACI No. 1205 (2020) pp. 714-715.)

In denying Monsanto's post-trial motions, the trial court acknowledged that "[a] plaintiff cannot rely on a minority or outlier theory to support a failure to warn claim." (6 AA 8262.) But that is precisely what Plaintiffs did here. The trial court excused Plaintiffs' lack of evidence of a majority view by asserting—with no references to the factual record—that because Monsanto was purported to have "successfully sought to influence the generally recognized and prevailing best scientific and medical knowledge to minimize scientific discovery or recognition of a risk, then the jury [could have] reasonably infer[red] that the scientific information would probably have been adverse to [Monsanto]." (*Ibid.*) To reach that conclusion, the trial court relied on the spoliation instruction in CACI No. 204 that the jury "may consider whether one party intentionally concealed or destroyed evidence" and if it did, then the jury "may decide that the evidence would have been unfavorable to that party." (CACI No. 204; see 6 AA 8262, 8271 [concluding that Monsanto made "efforts to impede, discourage, or distort the scientific inquiry about glyphosate" and that such evidence could have "earn[ed] an Evidence Code [section] 413 and

CACI [No.] 204 suppression of evidence instruction"].)[10] The trial court's conclusion is devoid of support in law or fact.

Notably, the trial court did not instruct the jury on CACI No. 204. Had there actually been evidence to support such an instruction, presumably the trial court would have given it—thus, neither the trial court (nor this court) can draw any inference from the mere fact Plaintiffs asserted that Monsanto "influenced" the science. In fact, there was no basis for giving such an instruction. (See *In re Roundup Products Liability Litigation* (N.D.Cal. 2019) 385 F.Supp.3d 1042, 1047 ["[Plaintiff] did not present evidence that Monsanto hid evidence from the EPA or, alternatively, that it had managed to capture the EPA. While [plaintiff] presented evidence that Monsanto had a cozy relationship with particular EPA employees, he did not present any evidence that would reasonably support an inference that this relationship rendered invalid the EPA's approval process for Roundup."].) There is not a shred of evidence that Monsanto misled any of the worldwide regulatory agencies, or more importantly, that any information

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[10] The trial court also purported to rely on the instruction in CACI No. 203 that the jury can disregard certain "weaker" evidence if a party fails to put on "stronger" evidence. (CACI No. 203; see 6 AA 8262.) The trial court, however, refused to read CACI No. 203 to the jury because it concluded the instruction did not apply. (28 RT 4792:16-22.) Moreover, that instruction does not relieve Plaintiffs of their burden to produce actual evidence of a prevailing scientific view that supports their theory of causation. Plaintiffs' own experts repeatedly acknowledged that there was no such prevailing view, and opined only that they disagreed with all of the regulatory agencies that had reviewed the science. (See, e.g., 13 RT 1893-1902, 1929-1933, 1977-1980, 2007-2022; 16 RT 2646-2649.)

Monsanto purportedly withheld would have made any difference in the conclusions of these agencies. (See *ibid.*; *Echeverria*, *supra*, 37 Cal.App.5th at pp. 332-335 [where the defendant defended its product to a committee evaluating cancer risks, punitive damages were unavailable as a matter of law where there was no evidence the defendant's efforts changed the committee's "ultimate conclusion"].)

Plaintiffs emphasized Monsanto's purported "ghostwriting" of some scientific articles, which the trial court noted as a basis for denying JNOV on the failure to warn claims. (11 RT 1375:1-1376:21; 6 AA 8269.) Plaintiffs pointed to the Williams article in 2000, and other articles addressing IARC. (11 RT 1374:7-1376:21; 32 RT 5509:9-5517:12.) But the evidence showed that Monsanto's contributions were either recognized in the "acknowledgements" section, such as in the Williams article, or did not rise to the level warranting authorship or recognition. (6 AA 6871-6885; see also 6 AA 6806-6812.) Importantly, there is no evidence that these "ghostwritten" papers were scientifically inaccurate or that the articles in any way compromised (or influenced) the decisions of worldwide regulatory agencies that did their own independent reviews of the science. Indeed, even today regulators have not changed their assessments of the risks of glyphosate, despite Plaintiffs' allegations of concealment.

Plaintiffs also complained that Monsanto failed to fully disclose and follow-up on the internal conclusions of its independent consultant, Dr. James Parry, who, after conducting a preliminary review of toxicology studies, opined that glyphosate

may be potentially genotoxic and recommended that eight additional studies be done to confirm these conclusions. (11 RT 1364:22-1373:25; 6 AA 6972-6977, 6989-6993.) The trial court, in denying JNOV, seized upon this allegation to conclude that Monsanto failed to "look further when there were indications that glyphosate might cause cancers" and that it "retained Dr. Parry as a consultant to investigate glyphosate, but then engaged in a campaign to discredit him when it disagreed with what his research indicated." (6 AA 8269.) But the evidence showed, in fact, that Monsanto did "look further" when Dr. Parry suggested follow-up studies on genotoxicity: it conducted the relevant studies that Dr. Parry recommended in accredited labs and submitted them to the EPA and/or published their results. (6 AA 7024-7031.)[11] Moreover, the fact that Monsanto was critical of the method and form of Dr. Parry's initial conclusions, and its decision not to submit those to EPA, constituted nothing more than the normal scientific process (6 AA 7004-7008)—indeed, after Monsanto conducted and provided additional studies, Dr. Parry ultimately agreed that glyphosate is not genotoxic and that some of the additional studies he had initially recommended were not necessary (6 AA 7028-7031). These events hardly constitute suppression of scientific evidence. And, even if Dr. Parry's preliminary conclusions had been shared with EPA and other regulators, there is no evidentiary basis to presume that these

[11] Monsanto was reluctant to allow Dr. Parry to perform the studies because his lab was not accredited for good laboratory practices and because his department was not well-equipped to complete all the necessary assays. (6 AA 6995-6997, 7031.)

initial musings would have changed any of the regulators' view of the science.

Plaintiffs further complained that Monsanto allegedly misrepresented to EPA mouse study data in the mid-1980s that purportedly showed Roundup was a potential carcinogen. (11 RT 1346-1354.) But even accepting Plaintiffs' characterization of these events, the record is clear that this rodent study information did not have a material impact on EPA or other worldwide regulatory agencies' ultimate conclusions about glyphosate. Glyphosate is one of the most studied substances on earth. (6 AA 7020.) EPA has reviewed no less than 12 long-term rodent carcinogenicity studies on glyphosate. (4 AA 4529; EPA, Glyphosate Proposed Interim Registration Review Decision, *supra*, p. 7.) At a minimum, since at least 1991, EPA and other agencies have repeatedly concluded based upon all of these animal studies—including Monsanto's—that there is insufficient evidence that glyphosate is carcinogenic. (See *ante*, pp. 21-23, 27, 31-34.) There was no showing that the earlier 1983 mouse study, as spun by Plaintiffs, did make or would have made any difference to their conclusions. Plaintiffs had an obligation to establish *some* evidence of a prevailing view of the scientific community considering exposure to glyphosate to be potentially carcinogenic to humans. (32 RT 5485:9-15; see *Anderson*, *supra*, 53 Cal.3d at pp. 1002-1003.) Because they did not present any such evidence, and because the evidence established that the prevailing view at all relevant times has been otherwise, Plaintiffs' failure to warn claims fail as a matter of law.

Finally, even if this court were to credit the trial court's unsupported rationale that Monsanto misled or defrauded regulatory agencies to maintain approval to sell Roundup without a cancer warning, that accusation cannot support a failure to warn cause of action as a matter of federal law. (See *Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341, 347-348 [121 S.Ct. 1012, 148 L.Ed.2d 854] [because "[p]olicing fraud against federal agencies" is not a matter within traditional state regulation and rather "the relationship between a federal agency and the entity it regulates is inherently federal," "fraud-on-the-FDA claims" are preempted by federal law]; *Nathan Kimmel, Inc. v. DowElanco* (9th Cir. 2002) 275 F.3d 1199, 1207 [noting that it was "troubled" that a California state court could judge illegal under state law "an applicant's disclosures [to EPA]"]; *Giglio v. Monsanto Company* (S.D.Cal., Apr. 29, 2016, No. 15cv2279 BTM(NLS)) 2016 WL 1722859, at p. *3 (*Giglio*) [nonpub opn.] [finding that "[u]nder *Kimmel*" claims that Monsanto "failed to adequately warn the EPA of the dangers of Roundup and concealed information from and/or misrepresented information to the EPA . . . are preempted by FIFRA" (citation omitted)].) These "concerns expressed by the Supreme Court in *Buckman* hold true not only where there is a separate fraud-on-the-FDA [or EPA] claim but also where a plaintiff seeks to prove fraud on the FDA [or EPA] in order to bring a traditional state-law torts suit." (*In re Trasylol Products Liability Litigation* (S.D.Fla. 2010) 763 F.Supp.2d 1312, 1325; see *id.* at pp. 1326-1327 [collecting cases that agree].) It is for EPA pursuant to federal law, and not a California court or jury, to

determine "the propriety of disclosures" Monsanto made to EPA about Roundup.

In sum, relying only on Plaintiffs' mischaracterization of a handful of events, the trial court improperly relieved Plaintiffs of their burden to present *any* evidence of a generally accepted and prevailing view within the scientific community that exposure to glyphosate-based herbicides posed a potential cancer risk to humans at the time Monsanto sold or distributed the Roundup used by Plaintiffs that allegedly caused their NHL. Instead, the record shows the unanimous conclusions of EPA and numerous foreign regulatory agencies that there is insufficient evidence to establish that glyphosate-based herbicides pose a risk of cancer. Because the risk that glyphosate causes cancer was not a generally accepted, prevailing view in the scientific or regulatory community, the risk was not known or knowable and Monsanto had no duty to warn. (See *Anderson, supra*, 53 Cal.3d at pp. 1000-1002; *Conte*, *supra*, 168 Cal.App.4th at p. 101; *ante*, pp. 21-28, 31-34.)

B. The jury's design defect findings based on the consumer expectations test and negligence are both legally and factually unsupported.

Plaintiffs' design defect theory does not fit the case or the evidence. (See 3 RT 300:1-6.) As made clear below, the consumer expectations theory does not apply merely because the plaintiff asserts she did not expect to be injured by the product. (*Trejo*, *supra*, 13 Cal.App.5th at p. 159.)

California recognizes two tests for establishing a product design defect independent of a warning claim: the consumer expectations test and the risk-benefit test. (See *Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 435.) Plaintiffs opted to proceed only on a consumer expectations theory, abandoning the traditional risk-benefit theory because they wanted the jury to be wholly ignorant of the benefits of Roundup in determining whether the product had a purportedly defective design. (See 3 RT 300:13-20 ["We will want to proceed with the consumer expectation test. . . . [Monsanto] can't defend against the consumer expectation test by saying look at all the great benefits of Roundup."].)

But the consumer expectations theory of liability is a limited one, not a wholesale replacement for the risk-benefit test. The test was created to ease the burden of proof on injured consumers in " 'res ipsa-like cases' " where expert testimony is unnecessary because the product obviously did not perform as an ordinary consumer would expect. (*Pruitt v. General Motors Corp.* (1999) 72 Cal.App.4th 1480, 1484 (*Pruitt*).) The consumer expectations theory is "reserved for cases in which the *everyday experience* of the product's users permits a conclusion that the product's design violated *minimum* safety assumptions, and is thus defective *regardless of expert opinion about the merits of the design*." (*Soule*, *supra*, 8 Cal.4th at p. 567; *Morson v. Superior Court* (2001) 90 Cal.App.4th 775, 785 (*Morson*) [the test applies only where the ordinary consumer actually has " 'legitimate, commonly accepted minimum safety assumptions' " derived from his or her *use* of the product.]) The test thus *does not apply* where the circumstances

of the alleged defect are so complex that the jury cannot decide liability without considering expert testimony. (*Soule*, at pp. 568-569.)

The key factor in determining the applicability of the test is not the complexity or simplicity of the product itself, but rather the complexity of the alleged circumstances of the plaintiff's injury: "[u]nder *Soule* the consumer expectations test can be applied even to very complex products, but only where the circumstances of the product's failure are relatively straightforward." (*Morson*, *supra*, 90 Cal.App.4th at p. 792.) Thus, where a plaintiff alleges he was injured based on nonobvious technical or mechanical consequences of a product's design and use, the risk-benefit test, not the consumer expectations test, is the appropriate test to determine whether the product is defectively designed. (See, e.g., *Soule*, *supra*, 8 Cal.4th at pp. 556, 570 [consumer expectations test did not apply where the parties "assumed that quite complicated design considerations were at issue, and that expert testimony was necessary to illuminate" whether a steering wheel that collapsed during a crash was defective].)

Trejo and *Morson* are particularly instructive because they involve products that allegedly injured plaintiffs through a complex biochemical mechanism that was not readily apparent to any ordinary user and that required expert testimony to establish. In *Morson*, plaintiffs suffered an allergic reaction to defendant's latex gloves. (*Morson*, *supra*, 90 Cal.App.4th at p. 778.) The Court of Appeal concluded that the consumer expectations test did not apply because plaintiffs' case depended on the specifics of the

product's chemical composition and the specialized knowledge surrounding it. (*Id.* at p. 793.) As the court explained, plaintiffs erroneously viewed the latex product "as a simple one that can give rise to simple consumer expectations of safety that have nothing to do with the chemical composition of the material from which the product is manufactured, or any other design characteristics for which specialized knowledge is required for understanding or taking appropriate precautions." (*Ibid.*)

Similarly, the plaintiff in *Trejo* suffered a rare reaction to over-the-counter Motrin, and the Court of Appeal held the trial court erred in applying the consumer expectations test. (*Trejo, supra,* 13 Cal.App.5th at pp. 116, 158-159.) The court concluded that "[t]he circumstances of Motrin's failure involve technical details and expert testimony regarding 'the effect of the product upon an individual plaintiff's health,' " and required balancing the product's risks and benefits. (*Id.* at p. 160, quoting *Morson*, *supra*, 90 Cal.App.4th at p. 792.) Therefore, the consumer expectations test "should not have been applied." (*Ibid.*)

The trial court here never should have submitted the consumer expectations theory to the jury because, as in *Morson* and *Trejo*, the circumstances of Roundup's alleged failure involve expert testimony and technical details about its chemical composition and effect on Plaintiffs' health. No ordinary user could develop an expectation about whether Roundup could cause cancer based on its mere everyday use. (See *Trejo*, *supra*, 13 Cal.App.5th at p. 160 [consumer expectations test inappropriate where "[t]he circumstances of [the product's failure] involve technical details

and expert testimony regarding 'the effect of the product upon an individual plaintiff's health' "].) Indeed, Plaintiffs had to present testimony from a multitude of experts who described the complex medical and technical reasons why Roundup allegedly caused harm. First, these epidemiologists, toxicologists, oncologists, and other experts (contrary to the regulatory consensus) offered their views on the extensive scientific and regulatory literature concerning whether glyphosate-containing herbicides even have the potential to cause cancer. (See, e.g., 12 RT 1606:9-11 [Dr. Portier testified to his opinion based on the review of extensive literature that Roundup "probably" causes NHL]; 13 RT 1893:11-1901:1 [Dr. Portier acknowledges he reached that opinion by disagreeing with the conclusions of the majority of regulatory agencies and authors of epidemiology studies]; 16 RT 2578:6-18, 2614:5-2628:24 [Dr. Ritz concluded it is "biological[ly] plausib[le]" that Monsanto's products cause NHL, but acknowledged she reached that conclusion by criticizing several epidemiology studies].)

Second, these experts' opinions on how or why "the circumstances of [Roundup's] failure" "probably caused" Plaintiffs' NHL were *anything but* "relatively straightforward." (*Morson*, *supra*, 90 Cal.App.4th at p. 792.) These experts described a complex process by which purported cancer-causing chemicals are absorbed through the skin, aided by surfactants that allegedly cause a "synergistic effect" by promoting a novel theory of dermal absorption of glyphosate. (19 RT 3164:25-3165:25; see also 19 RT 3185:1-3189:24; 32 RT 5607:16-18, 5525:22-5526:1.)

Where, as here, complex expert testimony is necessary to describe the nature of the product's alleged defect and how it could cause the plaintiff's injury, the consumer expectations test does not apply. (*Soule*, *supra*, 8 Cal.4th at pp. 556, 570; *Trejo*, *supra*, 13 Cal.App.5th at p. 159; *Morson*, *supra*, 90 Cal.App.4th at pp. 779, 788.)

In deciding to instruct the jury on the consumer expectations theory, the trial court acknowledged that "unpacking glyphosate" was "complex" (28 RT 4760:1-5), but surmised (incorrectly) that such complexity "doesn't necessarily make the product itself so complex that the jury can't figure out whether or not the warnings were sufficient, or any of the other issues that follow the use of Roundup in the ordinary course of weed-fighting or however else they use it on their property" (28 RT 4760:6-11). That analysis, while perhaps justifying a failure to warn instruction, does not support a consumer expectations instruction for design defect liability.

Once the trial court gave Plaintiffs the green light to submit the consumer expectations theory to the jury, Plaintiffs did not even attempt to demonstrate how an ordinary consumer would form such minimum safety expectations, and the trial court refused to let the jury determine whether Roundup is the type of product about which an ordinary consumer could form such expectations.[12] (See 28 RT 4793:17-4794:21; Directions for Use to

[12] If the court does not conclude that Monsanto is entitled to judgment on the consumer expectations claims, at a minimum the court should reverse and remand for a new trial on the consumer (continued...)

CACI No. 1203 (2020) p. 704 [where the court determines that the consumer expectations test "may, but not necessarily does, apply . . . [,] modify the instruction to advise the jury that it must first determine whether the product is one about which an ordinary consumer can form reasonable minimum safety expectations"].) Instead, Plaintiffs relied on the wholly improper, but all too common basis for advocating the consumer expectations test: they asserted that they did not expect to get sick. As Plaintiffs' counsel argued in closing, " '[d]id Roundup fail to perform as safely as an ordinary consumer would have expected?' Of course it did. It causes cancer." (32 RT 5607:12-14.) Of course, "it could be said that any injury from the intended or foreseeable use of a product is not expected by the ordinary consumer." (*Trejo*, *supra*, 13 Cal.App.5th at pp. 158-159.) That, however, is, as a matter of law, not a basis to apply the consumer expectations theory of liability because if that "were the end of the inquiry, the consumer expectation[s] test always would apply and every product would be found to have a design defect." (*Id.* at p. 159.)

Equally unavailing is any reliance on inapplicable asbestos cases as the basis for upholding the use of the consumer expectations test here. Asbestos cases are "of limited value . . . due to the problem of comparing apples and oranges in such fact-specific circumstances." (*Morson*, *supra*, 90 Cal.App.4th at p. 786.)

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expectations claims because the trial court erroneously refused to allow the jury to determine whether Roundup is the type of product about which an ordinary consumer could form minimum safety expectations. (See Directions for Use to CACI No. 1203 (2020) p. 704.)

In the asbestos cases, courts concluded that seemingly innocuous products fail to meet a consumer's minimum safety assumptions if they are manufactured in a way that allows them to release a *known* toxin like asbestos in the presence of product users. (See, e.g., *Saller v. Crown Cork & Seal Co., Inc.* (2010) 187 Cal.App.4th 1220, 1229, 1232-1233, 1238; *Sparks v. Owens-Illinois, Inc.* (1995) 32 Cal.App.4th 461, 474-475 (*Sparks*).) But a product containing an ingredient like glyphosate, which scientific and regulatory authorities across the world have concluded is *not* a known carcinogen, raises no similar issues.

Finally, Plaintiffs will likely rely on *Arnold v. Dow Chemical Co.* (2001) 91 Cal.App.4th 698 (*Arnold*) as purportedly authorizing the consumer expectations theory in cases involving pesticides. But in *Arnold*, the primary issue was federal preemption, not the applicability of the consumer expectations theory. (*Id.* at p. 702.) The respondents raised the consumer expectations issue for the first time on appeal. (*Id.* at p. 727.) In a single paragraph without any analysis, the court held the consumer expectations test was not necessarily foreclosed with respect to a claim alleging injury from pesticides sprayed in and around the plaintiff's home. (*Id.* at pp. 703, 727.) However, the two cases cited by the *Arnold* court do not support the conclusion that the consumer expectations test should apply here. (*Id.* at p. 727, citing *Sparks*, *supra*, 32 Cal.App.4th at pp. 474-475, and *Bresnahan v. Chrysler Corp.* (1995) 32 Cal.App.4th 1559, 1568.) *Sparks* is an asbestos case, which is inapposite for the reasons discussed above, and *Bresnahan* discusses the consumer expectations test only in dicta

that has been expressly rejected by other appellate courts. (See *Pruitt*, *supra*, 72 Cal.App.4th at p. 1485 [explaining that "[t]he discussion of the consumer expectations test in both *Bresnahan* opinions is clearly dicta" and declining to follow those opinions].)

Construing *Arnold* or the asbestos cases to permit a consumer expectations claim on these facts is inconsistent with binding Supreme Court precedent in *Soule*, and the well-reasoned opinions of several Courts of Appeal. *Soule* makes clear that where expert testimony is needed to establish the dangers of a product, the risk-benefit test, and not the consumer expectations test, applies. (*Soule*, *supra*, 8 Cal.4th at p. 567; *Pruitt, supra,* 72 Cal.App.4th at pp. 1483-1485.) That is particularly true where, as here, expert opinion was needed not just to establish that Monsanto's products caused Plaintiffs' injuries, but also to establish the very nature of those products' alleged defects. Because expert testimony is the *only* way for a jury to conclude that Roundup is defective, the consumer expectations theory does not apply as a matter of law.

Plaintiffs may argue that even if the consumer expectations theory should not have been submitted to the jury, the verdict can be supported by the jury's finding that Roundup was negligently designed. But in order to prevail on such a theory, Plaintiffs were required to establish that the purported negligent design was a substantial factor in causing their NHL. (32 RT 5486:11-13.) Plaintiffs provided no such evidence. Plaintiffs made no claim that manufacturing an herbicide containing glyphosate constituted negligence. Instead, their negligent design theory was based solely

on the testimony of a single expert, Dr. Sawyer, who claimed that the inclusion of the surfactant POEA made Roundup more toxic than an herbicide containing glyphosate alone. (19 RT 3160:15-3162:2, 3171:20-3172:7, 3250:15-3251:19; 26 RT 4303:2-4306:11.)

But this testimony does not support the jury's verdict on negligent design, for at least two reasons. First, although Dr. Sawyer purported to opine that Roundup was the cause of Plaintiffs' NHL, he acknowledged that he never even considered other potential causes because he deferred to Plaintiffs' other experts on that issue. (19 RT 3258:20-3259:21.) Absent such consideration, his purported specific causation opinion (to the extent it actually was a specific causation opinion) wholly lacked any foundation. (See pp. 74-84, *post*.) Second, even if the jury had credited Dr. Sawyer's specific causation opinion, neither he nor any other expert opined that the inclusion of POEA in Roundup's formulation (as opposed to the existence of glyphosate alone) was a substantial factor in causing Plaintiffs' NHL. Indeed, Dr. Sawyer conceded that nobody has ever studied the long-term carcinogenicity of POEA (19 RT 3163:2-12), so no expert did, or could have, reached such a conclusion. Because Plaintiffs' presented no evidence that the alleged negligent design of Roundup caused their NHL, the negligent design theory fails as a matter of law.

III. The court should reverse the judgment because the jury's causation findings are legally flawed.

A. The court should reverse the judgment with directions because there is no reliable foundation for the specific causation opinions of Plaintiffs' experts.

To constitute substantial evidence, expert testimony must have a reliable foundation. (See, e.g., *Sargon Enterprises, Inc. v. University of Southern California* (2012) 55 Cal.4th 747, 770 (*Sargon*); *Lockheed Martin Corp. v. Superior Court* (2003) 29 Cal.4th 1096, 1110; *Lockheed Litigation Cases* (2004) 115 Cal.App.4th 558, 563-564; *Jennings v. Palomar Pomerado Health Systems, Inc.* (2003) 114 Cal.App.4th 1108, 1117.)

To prove that Roundup exposure caused their NHL, Plaintiffs offered the testimony of Dr. Chadi Nabhan and Dr. Dennis Weisenburger. (See, e.g., 17 RT 2687:9-18; 24 RT 3882:5-11.) Plaintiffs' experts concluded that Roundup was the most likely cause of Plaintiffs' NHL based upon a "differential etiology," a process of "ruling in" possible causes and "ruling out" competing causes in order to determine "the probability that a given agent was the cause of an individual's disease." (Federal Jud. Center, Reference Manual on Scientific Evidence, *supra*, Reference Guide on Epidemiology, pp. 617-618; see 17 RT 2768:19-2769:6; 24 RT 3961:25-3962:2.)

For a differential etiology to have evidentiary value, there must be not only a reliable basis for ruling in a product as a

possible cause, but also a reliable basis for ruling out plausible alternative causes. (See, e.g., *Bland v. Verizon Wirele*ss*, (VAW) L.L.C.* (8th Cir. 2008) 538 F.3d 893, 897 (*Bland*) ["Even if [the expert] were able to link [the illness] to [exposure to defendant's product], [the expert] must also rule out other possible causes"]; *Cooper v. Takeda Pharmaceuticals America, Inc.* (2015) 239 Cal.App.4th 555, 585-586, 594 (*Cooper*); *Jones v. Ortho Pharmaceutical Corp.* (1985) 163 Cal.App.3d 396, 403 ["A possible cause only becomes 'probable' when, *in the absence of other reasonable causal explanations*, it becomes more likely than not that the injury was a result of its action. This is the outer limit of inference upon which an issue may be submitted to the jury." (emphasis added)].)

Here, however, Plaintiffs' experts had no reliable methodology for "ruling in" Roundup as the cause of either of the Plaintiffs' NHL, in light of the overwhelming epidemiological evidence that there is no statistically significant association between exposure to Roundup and NHL, nor for "ruling out" all of a host of known alternative risk factors despite overwhelming evidence of highly significant statistical associations between these alternative risk factors and NHL. Nor did they have a reliable methodology for disregarding the undisputed fact that in the vast majority of cases (at least 70 percent) the cause of NHL is simply advanced age or unknown. As a result, Plaintiffs' expert testimony on the causal relationship between exposure to Roundup and each Plaintiff's NHL is speculation entitled to no evidentiary weight.

As previously noted (see *ante,* pp. 24-26), large-scale epidemiology studies have found no association between glyphosate use and cancer. Moreover, it is undisputed that the incidence of NHL has not increased as the use of Roundup has increased. (30 RT 5184:16-5189:3 [incidence of lymphomas increased in the 1980s through the early 1990s due to the AIDS epidemic, but then plateaued in the mid-1990s just as the use of glyphosate-based pesticides increased dramatically], 5296:19-24 ["There's no question at all" in the scientific community that "the rate of [NHL] has plateaued in this country"]; see also 16 RT 2536:2-2537:18 [glyphosate-based herbicides were used sporadically in 1993, but their use had increased dramatically by 2013]; 24 RT 3931:15-16.) As one expert explained, if glyphosate-based herbicides "were a major cause or a cause of [NHL], I should have seen the rate of new [NHLs] going up, just as I saw the rate go up when something new called HIV came along. But I don't see that." (30 RT 5188:20-5189:3.)

Nonetheless, Dr. Nabhan and Dr. Weisenberger ruled in Roundup exposure as a potential cause of Plaintiffs' NHL. They did so by (a) disregarding large-scale epidemiology studies and regulatory findings that there is no statistically significant association between Roundup exposure and NHL (13 RT 1983:16-24, 2049:10-23, 2050:6-2052:2, 2061:1-6, 2062:22-2063:1; 14 RT 2291:1-8, 2294:22-25; 16 RT 2635:5-14; 18 RT 2959:2-2961:17, 2964:19-25, 2966:14-21, 2967:1-5, 2980:7-2982:11; 24 RT 3913:20-3914:2, 3915:15-21, 3929:2-3933:3; 25 RT 4057:3-12, 4058:17-25, 4059:21-4060:20, 4061:20-4062:7, 4078:12-4080:12, 4090:18-

4091:13; *ante*, pp. 21-27, 31-34), (b) relying upon epidemiological studies that largely fail to account for the possible role of other pesticides and do not satisfy the minimum 2.0 relative risk ratio for epidemiology to be probative of specific causation (*Cooper*, *supra*, 239 Cal.App.4th at 593; 16 RT 2606:24-2607:10, 2607:18-25, 2609:5-7, 2643:10-17; 17 RT 2833:1-25, 2834:4-9, 2835:9-16, 2910:23-2911:5; 24 RT 3917:12-17, 3918:8-12, 3923:10-14, 3924:6-12; 25 RT 4098:4-4099:4),[13] and (c) failing to comprehensively review all of the relevant scientific data (17 RT 2892:10-2893:24; 25 RT 4055:19-4056:11).

At the same time that major epidemiological studies show no meaningful association between exposure to Roundup and NHL, Plaintiffs' medical history revealed multiple risk factors that have been shown to have a demonstrated association with Plaintiffs' forms of NHL.[14] Plaintiffs' experts, however, had no methodology for excluding these alternative factors.

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[13] In analyzing epidemiology studies, it is critical to consider potential confounders. (6 AA 6638; 29 RT 4851:11-4852:9, 4887:18-4889:8.) Confounding occurs when there is some other factor that is associated with both the tested substance and the outcome, and that if controlled for, may explain some of the results. (13 RT 2039:14-19.) To avoid confounding, epidemiologists mathematically adjust or control for potential confounders, such as other pesticides, to isolate the effect of the studied substance versus the effect of potential confounders. (29 RT 4856:4-15.) Data that is adjusted for confounders is preferred over unadjusted data because it is more accurate and less subject to finding a misleading connection. (17 RT 2906:10-23.)

[14] As discussed above, Monsanto presented compelling evidence at trial that there is no positive association between glyphosate exposure and the risk of NHL. (See *ante*, pp. 21-28, 31-34.) But (continued...)

Mrs. Pilliod. Mrs. Pilliod had an extensive history of smoking cigarettes. (17 RT 2813:22-2814:8, 2814:20-24, 2815:7-9.) According to Dr. Weisenburger's own research, cigarette smoking is associated with a *doubling* of the risk of NHL for the type of tumor that Mrs. Pilliod had. (17 RT 2811:8-23, 2815:10-16, 3047:22-3048:6; 17 RT 2803:11-13, 2813:19-21; 2805:22-2806:9, 3050:8-12.) The same study found that herbicide use, by contrast, was not associated with this type of tumor. (17 RT 2800:3-9, 2803:1-6, 2806:12-17, 3019:19-21, 3049:13-16.)

Therefore, according to Dr. Weisenburger's own research, smoking was a far more likely cause of Mrs. Pilliod's NHL than Roundup. Yet Plaintiffs' experts provided no explanation why they entirely ruled out Mrs. Pilliod's history of smoking as an alternative explanation for Mrs. Pilliod's NHL. Indeed, neither expert considered cigarette smoking as a possible cause when conducting their differential etiologies. (See 17 RT 2997:4-5; 24 RT 3962:5-3968:23.)

Mrs. Pilliod also had other significant risk factors for NHL that her experts improperly dismissed: obesity and autoimmune (Hashimoto's) disease. (24 RT 3955:11-13; 3966:11-17; 3967:15-17.) Notably, Hashimoto's disease is associated with a tripling of the risk of NHL. (17 RT 2854:9-22; 27 RT 4386:24-4388:21.) Yet both of Plaintiffs' specific-causation experts ruled out Hashimoto's

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even crediting Plaintiffs' experts' opinions that studies show a statistically significant positive risk ratio of 1.4 for glyphosate exposure and NHL (see 17 RT 2732:11-2733:10), those experts certainly had *no basis* to exclude risk factors that had significantly higher associations with NHL.

disease as a likely cause of Mrs. Pilliod's NHL. (See 17 RT 2854:23-2855:11; 18 RT 3024:8-13, 3025:3-12; 25 RT 4142:8-4146:6.) The experts attempted to justify this opinion by claiming that the data for Hashimoto's was limited to thyroid lymphomas (see 17 RT 2855:8-11; 18 RT 3024:2-13, 3025:3-12; 24 RT 3966:23-3967:3) despite evidence that Hashimoto's is associated with other types of lymphomas as well (see 25 RT 4144:12-4145:18; see also 17 RT 2854:14-20, 2855:12-14; 18 RT 3046:2-25).[15]

Mr. Pilliod. Nor did Plaintiffs' specific-causation experts adequately explain how they could discard several risk factors for Mr. Pilliod, each of which (unlike Roundup) have been shown to have a demonstrated association with Mr. Pilliod's form of NHL.

- *Personal history of skin cancer.* Epidemiology data confirms a substantially increased risk of NHL (relative risk ratios between 2.0 and 3.0) in patients with recurrent skin cancer. (17 RT 2872:6-11, 2874:11-15, 2875:18-21, 2877:17-22, 2878:2-10, 2879:1-3.) It was undisputed that Mr. Pilliod had more than 20 skin cancers throughout his lifetime. (17 RT 2871:4-2872:5, 2876:8-17; see 6 AA 7130-7131, 7146.) Yet both of Plaintiffs' specific causation experts dismissed skin cancer as a causative risk factor for NHL. (See 18 RT 3032:1-4; 24 RT 3956:19-3957:7.)

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[15] The experts also inexplicably ruled out Mrs. Pilliod's personal history of cancer (see 6 AA 7080, 7098, 7146-7147), despite the fact that one of the very studies they relied upon to rule in Roundup also showed that a personal history of cancer more than doubles the risk of later developing NHL (17 RT 2829:12-14, 2846:4-6, 2850:5-2852:11; 24 RT 3962:21-3963:4).

- *Ulcerative Colitis.* Ulcerative colitis poses an "overall risk" for developing NHL in men that is "statistically significant." (17 RT 2863:22-2864:13.) However, Dr. Weisenburger did not "rule in" ulcerative colitis when performing his differential etiology because he did not believe Mr. Pilliod had that disease. (17 RT 2784:1-15, 2829:21-22, 2856:2-5, 2859:16-22, 2861:22-25; 18 RT 3028:20-21, 3029:5-6, 3031:6-9, 3032:8-9.) Dr. Nabhan, by contrast, recognized that ulcerative colitis was a risk factor that applied to Mr. Pilliod and could not be ruled out as a possible cause. (24 RT 3949:11-12, 3951:7-21, 3952:16-23, 3955:19-3956:6; see 6 AA 6790, 7126.)

- *Genital warts.* Studies have shown a very high, statistically significant risk of NHL (relative risk ratios of 3.0 and 3.1) in men like Mr. Pilliod, who have experienced recurrent genital warts. (17 RT 2884:5-12, 2885:13-16, 2887:22-2888:3.) Nonetheless, Dr. Weisenberger discounted the role of genital warts (18 RT 3025:20-23, 3027:16-20, 3032:10-13), and concluded that Mr. Pilliod's risk of contracting NHL without exposure to Roundup "would have been no higher than yours or mine" (17 RT 2889:22-23). Similarly, Dr. Nabhan dismissed genital warts as a possible cause. (24 RT 3945:23-3946:23.)

Advanced age and idiopathy. Finally, Plaintiffs' experts' differential etiologies did not—and could not—properly rule out the possibility, indeed likelihood, that the cause of Plaintiffs' NHL was either advanced age or is simply unknown (idiopathic).

- *Age.* The experts agreed that age increases the risk of contracting NHL because, as humans age, mutations can occur

that ultimately lead to cancer. (See 17 RT 2770:12-13, 2865:9-11, 2866:11-18, 2867:7-12; 24 RT 3938:15-18; 25 RT 4134:7-11, 4161:10-4162:2.) Both Dr. Weisenberger and Dr. Nabhan, however, dismissed this risk factor as "not causative." (17 RT 2770:20-21; 18 RT 2989:9-11; 24 RT 3939:4-5; 25 RT 4133:16-17.) But their explanation that age does not actually cause cancer misses the point that, because of their advanced age at the time of diagnosis, both Mr. and Mrs. Pilliod were at a much greater risk of developing NHL than the general population, regardless of whether they had ever been exposed to Roundup. For Plaintiffs' experts to conclude that Roundup must have caused Plaintiffs' cancers without explaining why Plaintiffs were not just as likely to develop cancer because of their advanced age, is speculation.[16]

- *Idiopathy*. For a differential etiology to be valid where the cause of an illness is unknown in the majority of cases, an expert must explain why idiopathic causes can be ruled out, which is why a differential etiology is usually insufficient to support a finding of causation under these circumstances. (See *Bland*, *supra*, 538 F.3d at p. 897 ["Where the cause of the condition is unknown in the majority of cases, [an expert] cannot properly conclude, based upon a differential diagnosis, [that exposure to

[16] The experts' ruling out age was inconsistent with how they treated obesity, which both experts considered a risk factor that they could not rule out, even though it is not understood whether obesity actually *causes* NHL or is merely *associated* with NHL. (17 RT 2777:11-22; see also 24 RT 3966:3-3967:12; 25 RT 4144:23-4145:6 [Hashimoto's disease is a potential cause that cannot be ruled out for Mrs. Pilliod even though an association between Hashimoto's disease and NHL is not necessarily causative].)

defendant's product] was 'the most probable cause' of [plaintiff's illness]. As a practical matter, [the expert's] causation opinion could not possibly be based upon a reasonable degree of medical certainty. [¶] . . . Even if [the expert] were able to link [the illness] to [exposure to defendant's product], [the expert] must also rule out other possible causes."]; *Hall v. Conoco Inc.* (10th Cir. 2018) 886 F.3d 1308, 1314-1315; *Milward v. Rust-Oleum Corp.* (1st Cir. 2016) 820 F.3d 469, 475-476; *Tamraz v. Lincoln Elec. Co.* (6th Cir. 2010) 620 F.3d 665, 675; *Kilpatrick v. Breg, Inc.* (11th Cir. 2010) 613 F.3d 1329, 1343 (*Kilpatrick*); see also *Echeverria, supra*, 37 Cal.App.5th at pp. 331-332; *Henricksen v. ConocoPhillips Co.* (E.D.Wash. 2009) 605 F.Supp.2d 1142, 1162 (*Henricksen*); Federal Jud. Center, Reference Manual on Scientific Evidence, *supra*, Reference Guide on Epidemiology, p. 618 ["for diseases for which the causes are largely unknown, . . . a differential etiology is of little benefit"].)

Here, it is undisputed that the vast majority of NHL cases are caused by factors that are currently unknown, i.e., idiopathic, or simply have no external cause. (17 RT 2778:24-2779:7, 2791:9-20, 2792:2-16; 24 RT 3909:13-15, 3937:15-20; 25 RT 4160:19-22, 4166:3-12; 27 RT 4360:25-4361:2; 30 RT 5305:15-22; see also 6 AA 6772, 7070-7071, 7109-7110, 7128.) Yet Plaintiffs' experts made no attempt to explain why idiopathic causes could be excluded from consideration. Instead, they made a speculative leap from Plaintiffs' Roundup exposure to the conclusion that because an allegedly known cause—Roundup—could be ruled in as a potential cause, it must have been *the* cause. (See 17 RT 2777:11-2779:21,

2890:12-14, 2891:2-4; 24 RT 3953:13-21, 3954:6-7, 3956:7-10.) In effect, Plaintiffs' experts concluded that ruling in exposure to Roundup as a possible cause meant they could automatically rule out other causes. As a result, they collapsed the "ruling in" and "ruling out" steps of a differential etiology into a single finding, and evaded the need to independently explain why unknown causes can be excluded, no matter how likely the unknown causes are to be the actual cause of Plaintiffs' illnesses.

Were the reliance of Plaintiffs' experts on exposure to Roundup sufficient to excuse the need to address idiopathic causes, a differential etiology could rest solely on an expert's juxtaposition of the plaintiff's exposure to a product and the occurrence of an illness, without regard to alternative causes that are as likely, and here even more likely, to be the actual cause of that illness.[17] Such a speculative leap is neither sound science nor substantial evidence. The opinions of Plaintiffs' specific-causation experts are, in short, at best a guess entitled to no evidentiary weight and at worst an outcome-driven conclusion stripped of methodological

[17] Both experts conceded that Plaintiffs could have developed the same type of cancer at the same time, with the same features, whether or not they had ever been exposed to Roundup. (17 RT 2788:6-11, 2889:19-22; 25 RT 4168:11-23.) Nonetheless, because their claims were tried together, Plaintiffs were able to exploit the fact that they both contracted NHL to suggest that Roundup exposure necessarily caused both Plaintiffs to develop NHL. (See 24 RT 3882:5-3884:6, 3887:3-3888:7, 3957:8-3961:23, 3963:5-11.) Dr. Nabhan went so far as to conclude it was "common sense" that Roundup was the cause of Plaintiffs' NHL simply because both Plaintiffs contracted NHL. (24 RT 3882:24-3883:6, 3883:22-3884:1; see p. 87, *post*.)

coherence. (See *Henricksen*, *supra*, 605 F.Supp.2d at p. 1162 ["It seems the only reason cited for distinguishing [plaintiff's] disease from one of 'no known cause' was the existence of a known risk factor, namely exposure to benzene. Standing alone, the presence of a known risk factor is not a sufficient basis for ruling out idiopathic origin in a particular case, particularly where most cases of the disease have no known cause."]; see also *Kilpatrick*, *supra*, 613 F.3d at p. 1343 [" '[S]imply because a person [is exposed to a product] and then suffers an injury does not show causation' "].)

* * *

Plaintiffs' experts failed to account for a host of alternative causes of Plaintiffs' NHL. They did so because, in their view, exposure to Roundup is always the cause of NHL and thus, these alternative causes are irrelevant. But the mere presence of what those experts consider to be a known risk factor (contrary to all of the major epidemiological evidence) is not any basis, much less a reliable basis, for disregarding the many other and far more likely risk factors in this case. The result is that the specific causation opinions of Plaintiffs' experts are not substantial evidence that can support a finding that Roundup more likely than not caused Plaintiffs' injuries. (See *Sargon, supra*, 55 Cal.4th at pp. 770-771.)

B. Alternatively, the court should reverse and remand for a new trial because the trial court's refusal to sever Plaintiffs' cases for trial fatally infected the jury's consideration of the causation issue.

Although Plaintiffs had different medical histories, different risk factors, different treatment histories, different exposures, and different forms of NHL (see 1 AA 194-212; 3 AA 3515-3530), the trial court nonetheless found Plaintiffs' claims were properly joined (1 AA 271-276; 3 AA 4084-4085). In so doing, the trial court allowed Plaintiffs to conflate the central issue of causation and thereby abused its discretion in refusing to order severance in "the interests of justice" under Code of Civil Procedure section 379.5.

Joinder of plaintiffs for trial is proper under Code of Civil Procedure section 378 only where the plaintiffs' injuries arise from the same transaction or series of transactions (see, e.g., *Anaya v. Superior Court* (1984) 160 Cal.App.3d 228, 233) and even then, considerations of court " 'convenience and economy must yield to a paramount concern for a fair and impartial trial' " (*In re Repetitive Stress Injury Litigation* (2d Cir. 1993) 11 F.3d 368, 373). Here, the refusal to sever Plaintiffs' claims provided Plaintiffs with a windfall opportunity to use joinder of their claims to unfairly bolster their case for proof of causation.

Both of Plaintiffs' specific causation experts conceded that Plaintiffs could have developed the same type of cancer at the same time, with the same features, whether or not they had ever been exposed to Roundup. (17 RT 2788:6-11, 2889:19-22; 25 RT

4168:11-23.) Nonetheless, through joinder of their claims for trial, Plaintiffs were able to claim that the mere fact they were married and developed NHL must mean that their Roundup exposure was the cause of their illnesses. (24 RT 3882:5-3884:1, 3957:8-3961:23.)

But Plaintiffs had radically different medical histories. Mr. Pilliod's history included skin cancer, genital warts, ulcerative colitis, stroke, high blood pressure, and smoking, among others, whereas Mrs. Pilliod's history included obesity, diabetes, Hashimoto's disease, bladder cancer, and smoking. (See *ante*, pp. 37-38, 78-80.) These conditions present different risk factors for developing NHL. (See 3 AA 3522-3524.) Moreover, there were major differences in the quantity and quality of Plaintiffs' usage. Mr. Pilliod sprayed Roundup 75 percent of the time, used both ready-to-use spray and mixed concentrate, and wore long-sleeved shirts, while Mrs. Pilliod only used Roundup 25 percent of the time, never mixed concentrate, and wore a tank top while spraying. (3 AA 3525; 23 RT 3705:1-17, 3722:25-3723:6; 28 RT 4645:9-4646:22; *ante*, p. 36.)

Joined together, Plaintiffs encouraged the jury to ignore these many important differences by claiming that the mere fact they were married and developed NHL must mean that their Roundup exposure was the cause. (24 RT 3882:5-3884:1, 3957:8-3961:23.) This argument pervaded the trial:

- *Opening Statement:* "[I]f you do the probability of both of them getting it just by chance, just by random chance alone, not because of Roundup, because of something else, it's 1 in 20,000." (11 RT 1314:22-25.) "When we asked [Mrs. Pilliod], 'What do you

think caused it?' She says, 'Well, this is so unlikely, it must be an environmental exposure, a chemical, Roundup.' " (11 RT 1315:4-7.)

- *Dr. Nabhan:* It is "common sense" that the Pilliods' cancers were both caused by the same factor. (24 RT 3882:24-3884:1; 3957:17-3958:10.)

- *Dr. Nabhan:* "Q. . . . [I]f you multiply [the likelihood that Mrs. Pilliod would get the disease] with [the likelihood that Mr. Pilliod would get the disease], it gets 15,876. So is that the odds of the two of them both coming down with it? A. And that would be conservative, but I'll take that, that's fine." (24 RT 3888:3-7; see 24 RT 3886:8-3888:2.)

- *Closing Argument:* "So assuming that there was no risk factors or anything, we can actually calculate the probability that two genetically unrelated people would actually get lymphoma. And we got around 1 in 15, 1 in 20,000." (32 RT 5580:11-15.) It is "rare, very rare" for "two genetically unrelated people to get the same" type of cancer. (32 RT 5580:18-21.)

This parade of testimony and lawyer argument, made possible only by the denial of severance, enabled the jury to avoid evaluating the circumstances of each Plaintiff and instead reach a verdict simply because they believed Roundup can cause cancer generally, without regard to whether Roundup actually caused each Plaintiff's individual cancer. (See *Rubio v. Monsanto Co.* (C.D.Cal. 2016) 181 F.Supp.3d 746, 757-758 [joinder of two plaintiffs, who both used Roundup, was not in the interests of justice where "there are significant factual differences in the circumstances under which Roundup was applied by Plaintiffs;

frequency, duration, and amount of exposure; concurrent exposures to other products; timing of exposure, location, and medical histories . . . ."].)

The trial court's refusal to sever Plaintiffs' cases for trial gave Plaintiffs an overwhelming advantage they never would have had if their claims had been tried separately—i.e., the ability to use the coincidence of their marriage to persuade the jury to ignore the many crucial differences between them to conclude that Roundup must have been the cause of both of their illnesses. Thus, at the very least, Monsanto is entitled to a new trial that will permit the issue of causation to be tried on a level playing field.

IV. The court should reverse and remand for a new trial because the trial court abused its discretion by admitting irrelevant and highly prejudicial evidence about fraud committed at IBT, a third-party testing laboratory.

The trial court's decision to permit Plaintiffs to introduce evidence of a third party's fraud at the IBT laboratory tainted the evidence with irrelevant and prejudicial testimony. Plaintiffs exploited the evidence about IBT to improperly suggest that Monsanto itself had engaged in fraud in connection with Roundup's original registration by EPA.

IBT, an independent laboratory based in the United States, contracted with various manufacturers and other entities, including EPA itself, to perform toxicology tests on their products. (22 RT 3625:11-3625:24.) Monsanto was among the dozens of

companies whose products IBT tested. (22 RT 3625:25-3626:8.) In 1976, the U.S. Food and Drug Administration (FDA) discovered discrepancies in some toxicology tests IBT performed. (7 AA 8988.) Following this discovery, EPA demanded an audit of all IBT studies, which were used to support pesticide registration. (*Ibid*.)

The audit revealed that some of IBT's studies could not be validated, including studies conducted on glyphosate and used in connection with glyphosate's original registration with EPA in 1974. (12 RT 1785:17-1786:12; 22 RT 3562:20-3565:25.) Monsanto, following communications with EPA, ultimately repeated all of the studies at issue in accordance with EPA guidelines. (6 AA 6869-6870.) No data from IBT studies is used in support of glyphosate's current registration with EPA. The discovery of impropriety in connection with IBT's work also led to a criminal investigation. One former IBT employee eventually prosecuted for conduct at IBT, Dr. Paul Wright, had previously worked at Monsanto, left to work at IBT by August 1971, and then returned to work at Monsanto in October 1973. (6 AA 7185; see also 3 RT 476:3-19.) But as Plaintiffs' counsel acknowledged, the fraud for which Wright was prosecuted and convicted when he worked at IBT did not relate to glyphosate; it concerned entirely different products. (3 RT 476:15-25, 477:6-15.)

Before trial, Monsanto moved to exclude all testimony and evidence about IBT as irrelevant and unduly prejudicial. (3 AA 3489-3493.) Plaintiffs claimed that evidence about IBT demonstrated that Monsanto was negligent and further argued that the facts "implicate Monsanto explicitly or implicitly in the

s[c]andal" and that "the jury will need to decide for themselves[ ] if Monsanto really did have nothing to do with the IBT fraud." (3 AA 3860.)

The trial court granted in part and denied in part the motion, holding only that the "*history of the Industrial Bio-Test research may be relevant*." (6 AA 6468.) But, the court held, "*Plaintiffs may not argue or imply that Monsanto was in any way involved*." (*Ibid.*; see also 3 RT 471:22-472:1; 15 RT 2409:1-16 [court rules that Plaintiffs cannot suggest that Monsanto, through Dr. Wright, was involved in the fraud at IBT].)

Despite the trial court's ruling, Plaintiffs repeatedly invited the jury to infer that Monsanto itself was involved in fraud at IBT. Nowhere was this more clear, or impactful, than in Plaintiffs' closing when Plaintiffs' counsel argued that Roundup was "literally born in fraud" which they characterized as the first step in what they described as "40 years of misconduct." (32 RT 5500:14-5502:16; see also 32 RT 5502:18-20.) Counsel also improperly suggested that Monsanto, through Dr. Wright, was involved in the fraud at IBT, and that Dr. Wright was involved in fraudulent glyphosate studies when he worked at IBT. (32 RT 5501:4-21.) Although neither is true, Plaintiffs left the undeniable implication that Monsanto itself played a role in and should be held responsible for IBT's conduct.

Plaintiffs hardly missed an opportunity to bring up fraud and Monsanto any time IBT's name came up. Plaintiffs' counsel brought it up in their opening, referencing the IBT "scandal" and that IBT and Dr. Wright, who had worked at Monsanto, "engaged

in widespread scientific fraud." (11 RT 1344:12-1346:21.) Plaintiffs elicited testimony from five separate witnesses about IBT, Monsanto, and fraud. (6 AA 6804-6805 [Heydens], 7184-7185 [Reeves]; 12 RT 1785:17-1787:24 [Portier]; 22 RT 3519:17-3532:8, 3562:20-3565:21, 3634:9-3635:19 [Benbrook]; 27 RT 4469:14-4470:11 [Bello].)

Indeed, Plaintiffs made the IBT issue a centerpiece of their factual presentation. Plaintiffs' principal witness on IBT, Dr. Benbrook, described IBT as "probably the largest sort of scandal . . . in the history of pesticide regulation in the U.S." (22 RT 3520:13-15), and went on to testify that IBT conducted four out of five mutagenicity studies on glyphosate that Monsanto had submitted to EPA (22 RT 3523:17-24), and that EPA later deemed all of those studies to be invalid as a result of IBT's conduct (22 RT 3527:9-12). Although Dr. Benbrook agreed that Monsanto later repeated the IBT studies (22 RT 3529:19-3530:2), he repeatedly stressed that Monsanto did not remove Roundup from the market, or issue a warning, between 1976, when the "scientific fraud" at IBT was first discovered, and 1983, when Monsanto received results from the repeat tests (22 RT 3527:13-15, 3529:10-18; see also 22 RT 3530:18-22, 3531:6-11), and that Dr. Wright worked at Monsanto before his tenure at IBT (22 RT 3634:18-3635:13).[18] In short, Plaintiffs deliberately made a supposed connection between

[18] The trial court sustained Monsanto's objection to a question by Plaintiff's counsel that Dr. Wright worked at Monsanto before IBT and struck Dr. Benbrook's answer, but the damage of course was already done. (22 RT 3635:11-17.)

Monsanto, Roundup, and IBT's fraud into a pervasive theme at trial.

Evidence about IBT was irrelevant and, therefore, should have been excluded. (Evid. Code, §§ 210, 350.) The conduct that occurred at IBT, an independent laboratory, had no bearing whatsoever on whether Monsanto's failure to warn caused Plaintiffs' NHL. To the contrary, it was undisputed that Monsanto itself was not involved in IBT's conduct, that Monsanto was one of dozens of victims of IBT's conduct, that Monsanto repeated the studies IBT performed that were deemed to have been tainted, and that Roundup's current registration does not rely on any IBT studies. The IBT evidence is irrelevant precisely because it has "no tendency in reason to prove or disprove any [material] fact." (*Velasquez v. Centrome, Inc.* (2015) 233 Cal.App.4th 1191, 1212.)[19]

Nor could Plaintiffs connect evidence about IBT to their specific claims. First, Mrs. Pilliod testified that she would not have used Roundup in 1982 if she had known that its registration depended in part on studies that could not be validated by EPA. (23 RT 3751:2-7.) But this testimony does not make evidence about IBT relevant given that (a) Monsanto itself was not responsible for the tainted studies, (b) new studies were performed and reached the same result, and (c) Roundup's current registration did not depend on any studies tainted by IBT's involvement. (6 AA 6869-6870; 7 AA 8988; see also 5 AA 5241-5315; 6 AA 6483.) Second,

[19] This evidence was irrelevant for the additional reason that claims based on fraud on the EPA are preempted by FIFRA. (See *Giglio*, *supra*, 2016 WL 1722859, at p. *3; see *ante*, pp. 63-64.)

Plaintiffs argued that evidence about IBT demonstrated Monsanto's negligence in failing to disclose for a period of time that some of the studies used for its registration could not be validated. But since any such studies were later repeated and submitted to EPA in support of Roundup's current registration, the sale of Roundup in the interim period—with the full authorization of EPA—is hardly evidence of negligence.

Moreover, even if evidence about IBT had some relevance to Plaintiffs' claims, it was outweighed by its unduly prejudicial effect on Monsanto. (Evid. Code, § 352.) From the very outset of trial through its conclusion, Plaintiffs used the court's limited permission to introduce facts about IBT to suggest that Monsanto itself was somehow responsible for fraud. The jury never should have been permitted to infer that Monsanto itself was actively involved in fraud and evidence about IBT therefore should have been excluded.

V. The court should reverse and remand for a new trial because the verdict is the product of prejudicial attorney misconduct.

Throughout the trial, Plaintiffs' counsel engaged in egregious and pervasive misconduct that "was carefully contrived and calculated . . . to arouse and inflame the jury [so] that it would render a large verdict." (*Love v. Wolf* (1964) 226 Cal.App.2d 378, 394 (*Love*).)

A. Counsel improperly told the jury that this case is "historic."

In opening statement, Plaintiffs' counsel repeatedly characterized this case as a "*historic* fight against Monsanto." (11 RT 1309:16, emphasis added; see 11 RT 1429:13 [telling the jury that their participation in "this *historic* case means everything to [Plaintiffs]" (emphasis added)].) Counsel also suggested that a verdict for the Pilliods might cause EPA to change its view on the carcinogenicity of glyphosate: "[T]he EPA hasn't issued its final ruling yet. They're still considering it. . . . But the most recent iteration of their opinion is that it doesn't cause cancer. That's where the EPA . . . stands right now. Although *they could change after -- well, after this trial. Who knows?*" (11 RT 1404:6-16, emphasis added.)

Monsanto objected that these statements improperly suggested the jury should accord this case "historic" significance (11 RT 1430:5-13) and that the jury could play a role in regulating public health by using its verdict to persuade EPA to change its glyphosate classification (11 RT 1436:24-1437:11; see *Regalado v. Callaghan* (2016) 3 Cal.App.5th 582, 599 ["telling the jury that its verdict had an impact on the community and that it was acting to keep the community safe [was] improper"]).

The trial court overruled Monsanto's objections. (11 RT 1437:19-1438:6.) The judge said the suggestion that EPA might change its glyphosate classification after the resolution of this case "got close to the line" and "almost got [her] to [her] feet," but everything else was "just hyperbole." (11 RT 1437:12, 1438:10-18.)

By the end of trial, however, the judge had changed her mind: outside the jury's presence, she admonished Plaintiffs' counsel not to use the term "historical" in closing argument "because this [case] is about the Pilliods" and to "enlist them in some sort of movement" would be "prejudicial." (31 RT 5432:8-20.)

These were not isolated statements. Indeed, Plaintiffs' counsel knew these comments were improper before he made them because he was admonished for making similar statements at trial in another Roundup case, *Johnson v. Monsanto Company* (A155940 & A156706, app. pending) (*Johnson*), a few months earlier. (See Motion for Judicial Notice, Bochner Decl., exh. C, p. 37:17-22 [in opening statement, the same lawyer told the jury: "You . . . are actually part of something really important. . . . [E]ach one of you, whether or not you want to be . . . , are actually *part of history*." (emphasis added)], pp. 38:1-5, 39:22-40:1, 41:6-23 [after similar statements in closing argument, trial court in *Johnson* admonishes Plaintiffs' counsel for making "really inappropriate" comments and gives the jury a curative instruction].) Nonetheless, Plaintiffs' counsel proceeded with the same line of improper argument here.

B. Counsel repeatedly violated the trial court's rulings.

1. Counsel violated the court's ruling prohibiting references to the presence of glyphosate in sources other than Roundup.

An attorney commits misconduct by repeatedly violating the trial court's rulings. (See *Hawk v. Superior Court* (1974) 42 Cal.App.3d 108, 126-127, 130; see also *Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, 295 (*Bigler-Engler*); *Martinez v. Department of Transportation* (2015) 238 Cal.App.4th 559, 567-568 (*Martinez*).)

In this case, before trial, Monsanto moved in limine to exclude any evidence or argument that glyphosate is present in food, breast milk, or any other sources unrelated to Plaintiffs' alleged route of exposure. (3 AA 3484-3488.) Monsanto explained that Plaintiffs allege injury only from exposure to glyphosate by spraying Roundup on weeds, and Plaintiffs' exposure expert based his opinions only on dermal exposures that occurred during the Roundup application process. (3 AA 3485-3486.) The trial court granted the motion, stating: "References to exposure to glyphosate will be limited to those on which experts base their opinions. Opening the door to all possible exposures would be time consuming and confusing to the jury." (6 AA 6468.)

Nevertheless, Plaintiffs' counsel repeatedly violated this ruling in opening and closing arguments, and during the presentation of evidence. In his opening statement, counsel said

that glyphosate is "ubiquitous" and "pervasive" and that "finding people who haven't been exposed . . . is actually fairly difficult." (11 RT 1331:1-13.) When Monsanto objected, Plaintiffs' counsel insisted he did not violate the court's ruling because he did not "mention it being in food." (11 RT 1433:3-7.) But Plaintiffs' counsel did exactly that in closing argument, stating: "[P]eople are exposed to glyphosate outside of spraying it, right? *It's in the food. It's all over the place.*" (32 RT 5557:20-22, emphasis added.) Monsanto again objected and moved for a mistrial (32 RT 5612:16-22, 5614:7-10), but the trial court denied the motion, concluding that these and other improper statements in closing argument did not "rise[ ] to the level of mistrial" (32 RT 5616:14-16).

Counsel also violated this ruling during the presentation of evidence. While questioning his own expert in front of the jury, Plaintiffs' counsel read the following statement from a report: " 'Given that more than 6 billion-kilograms of Roundup have been applied in the world in the last decade, *glyphosate may be considered ubiquitous in our environment*.' " (16 RT 2559:6-14, emphasis added.) Monsanto objected and moved to strike the statement. (16 RT 2559:15-17.) The trial court sustained the objection and granted the motion to strike, and Plaintiffs' counsel withdrew the statement. (16 RT 2559:16-20.) But the damage was done.

2. Counsel violated the trial court's ruling limiting evidence and argument about IBT.

As discussed above, Plaintiffs' counsel repeatedly violated the trial court's in limine ruling prohibiting Plaintiffs from arguing or implying that Monsanto "was in any way involved" in the fraud that occurred at IBT. (6 AA 6468, emphasis omitted; see *ante*, pp. 88-93.) We incorporate by reference that argument here. (See *ante*, pp. 88-93.)

3. Counsel violated the trial court's ruling prohibiting references to the *Johnson* and *Hardeman* cases.

Before trial, Monsanto moved in limine to exclude evidence, testimony, or argument related to any prior or current litigation involving Monsanto, arguing that references to other litigation are irrelevant and should be excluded under Evidence Code section 352. (3 AA 3480-3483.) The trial court partially granted and partially denied this motion. (6 AA 6468.) Specifically, the motion was granted, except the court agreed with Plaintiffs (over Monsanto's objection) that Roundup lawsuits pending at the time of the Pilliods' exposure were relevant to show Monsanto's knowledge and notice. (3 RT 457:13-459:6, 463:6-16.) The court also allowed the parties to ask experts about how much they have been paid in other litigation. (3 RT 463:19-466:19.) At the in limine hearing, Plaintiffs' counsel acknowledged that the jury returned its verdict in the *Johnson* case after the Pilliods' exposures took place, and that therefore *Johnson* would not be

relevant to Monsanto's corporate conduct in this case. (3 RT 461:14-18.)

Nonetheless, during trial, Plaintiffs' counsel asked a witness about her testimony "at the *Johnson* trial." (29 RT 4834:3-5.) Defense counsel objected and the court sustained the objection. (29 RT 4834:6-10.) At the next break, the court told Plaintiffs' counsel he can ask witnesses about their testimony in prior proceedings but he may *not* mention the *Johnson* or *Hardeman* cases specifically by name. (29 RT 4865:19-4866:21.) Later, while questioning another witness, Plaintiffs' counsel mentioned the *Hardeman* case by name. (30 RT 5106:8.) Defense counsel objected and moved for a mistrial, arguing that Plaintiffs' repeated references to the *Johnson* and *Hardeman* cases violate the court's prior rulings and are prejudicial. (30 RT 5106:10-12, 5123:23-5124:11.) Plaintiffs' counsel claimed he was instructed only not to say the word "trial," but the court insisted she was "very clear" when she directed counsel not to refer to those cases by name. (30 RT 5124:17-5127:4.) Nonetheless, the court yet again denied the mistrial motion. (30 RT 5127:4-6.)

C. Counsel made inflammatory statements about EPA and other regulatory agencies in closing.

In closing, Plaintiffs' counsel argued that "EPA, EFSA, all these different regulatory bodies, they've been saying Roundup is safe for 40 years. If it turns out that they're wrong, *there's literally blood on their hands. Literally*." (32 RT 5569:12-16, emphasis added.) The trial court sustained Monsanto's objection, stating,

"no 'blood on their hands.' " (32 RT 5569:17-24; see also 32 RT 5612:23-24.) Moments later, Plaintiffs' counsel made more improper statements about EPA: "[F]rankly, EPA has a bad track record. . . . How many things have been cancer causers that it took a lawsuit to find the truth of?" (32 RT 5572:20-25.) Defense counsel again objected, which the trial court sustained. (32 RT 5573:1-2; see also 32 RT 5612:25-5613:4.)

By arguing that regulatory agencies like EPA would have "blood on their hands" if their glyphosate determinations turned out to be wrong, Plaintiffs' counsel suggested that the jury also would have "blood on [its] hands" if it reached the same conclusion as EPA about the carcinogenicity of glyphosate. This statement was inflammatory and improper. (See *United States v. Johnson* (E.D.La. 2010) 713 F.Supp.2d 595, 634-639 [prosecutor's statement that returning a verdict other than death would be like " 'wash[ing] the blood from his hands' "]; *Deaton v. Commonwealth* (Ky.Ct.App. 1932) 55 S.W.2d 47, 49 [prosecutor's statement that " '[i]f any one of the jury want to hang the jury and acquit the defendant, let the blood of [the victim] be on his hands' "]; *State v. Gilstrap* (S.C. 1944) 32 S.E.2d 163, 165 [defense counsel's statement that the jurors " 'would have the blood of [defendant's mother] on their hands' " if they convicted his client].)

The same is true of counsel's comment that "EPA has a bad track record" and his question asking "[h]ow many things have been cancer causers that it took a lawsuit to find the truth of?" (32 RT 5572:20-25.) These comments were not only false and inflammatory, they also assumed facts not in evidence—i.e., there

was no evidence that "it took a lawsuit" to reveal that an agent caused cancer despite a prior EPA determination of non-carcinogenicity. (32 RT 5572:24; see *Cassim v. Allstate Ins. Co.* (2004) 33 Cal.4th 780, 796 (*Cassim*) [in closing argument, counsel " 'may not assume facts not in evidence or invite the jury to speculate as to unsupported inferences' "].)

D. Counsel misstated the law in closing argument.

Plaintiffs' counsel argued: "One of the things that I think is really important to understand how the law works is that the obligation to warn rests with Monsanto, not California EPA, not the EPA. *What that label says and what it does not say is their choice and their choice alone*." (32 RT 5532:1-5, emphasis added.) This statement is false: the content of the Roundup label is not Monsanto's choice alone. As discussed above, Monsanto cannot add a cancer warning to the Roundup label without first obtaining EPA review and approval of the warning. (See *ante*, pp. 22, 32-33, 41-51.) Indeed, Plaintiffs' own expert, Dr. Benbrook, admitted that Monsanto cannot legally sell a product unless the label is approved by EPA. (22 RT 3617:13-22.) Thus, Plaintiffs' counsel misstated the law and misled the jury when he argued that the law requires Monsanto *alone* to determine the content of the Roundup label. Yet the trial court overruled Monsanto's objection to this argument, stating she essentially agreed with Plaintiffs' counsel that "how Monsanto chose to present the product was up to them." (32 RT 5616:14-5617:3; see 32 RT 5612:2-15.)

E. Counsel stoked the jury's fears by wearing gloves when handling and spraying a Roundup bottle that contained only water.

During trial, in front of the jury, Plaintiffs' counsel put on gloves to handle a Roundup bottle that contained only water. (See 19 RT 3130:14-22, 3254:16-3255:1; 23 RT 3780:17-24, 3781:17-20.) While questioning Mr. Pilliod, counsel sprayed the bottle. (See 23 RT 3781:15-20.) The entire demonstration was simply a tactic to scare the jury. The tactic worked: one juror later asked the court, "Why [did] the lawyer put[ ] on gloves if only water [was] in the Roundup container?" (6 AA 6480; see also 23 RT 3805:1-5.)

The trial court observed that the juror's question suggested he was concerned about his own safety. (23 RT 3804:19-24 [trial court: "I don't want the jurors to think they were in any danger at all. When you came out with the gloves and everything, clearly that's a sign you need the gloves. You wouldn't put them on if you didn't think you needed them, or whatever reason you put them on."], 3805:4-6 ["I think implicit in [the juror's question] is that he wondered if it was safe"], 3806:1-2 ["I'm worried that he's concerned"].) To try to allay any concerns, the trial court instructed the jury that the bottle contained only water. (23 RT 3805:13-14, 3806:14-16 [court instructs jury: "the earlier bottle of Roundup that Mr. Wisner was using, only contained water, and there's no reason to be concerned, okay?"].) The court also told Plaintiffs' counsel not to handle the Roundup bottle during closing argument. (31 RT 5423:7-20.)

Counsel's demonstration was an improper ploy to frighten the jury. (See *People v. Fields* (1983) 35 Cal.3d 329, 361-362 [appeals to jurors' fears are improper]; *People v. Jones* (1970) 7 Cal.App.3d 358, 363 [same]; see also *People v. Zurinaga* (2007) 148 Cal.App.4th 1248, 1259-1260 [prosecutor committed misconduct in closing argument by discussing 9/11, which "continue[s] to invoke fear, dread and anger"].)

The trial court recognized that Plaintiffs' counsel engaged in misconduct and even cautioned that such conduct ran " 'a grave and unjustifiable risk of sacrificing' " a potential recovery. (6 AA 8258, quoting from *Bigler-Engler*, *supra*, 7 Cal.App.5th at p. 298.) The trial court ultimately decided that the misconduct was not prejudicial (6 AA 8258-8259), but that was an error.

F. The misconduct was prejudicial.

Attorney misconduct is prejudicial if it is " 'reasonably probable' " that the appellant would have achieved a more favorable result absent the misconduct. (*Cassim*, *supra*, 33 Cal.4th at p. 800.) The bar is not high: " 'a "probability" in this context does not mean more likely than not, but merely a *reasonable chance*, more than an *abstract possibility*.' " (*Ibid.*) Even "a single instance of misconduct can justify reversal." (*Id.* at p. 803.) A reviewing court "makes an independent determination" whether attorney misconduct is prejudicial in light of the record. (*Martinez*, *supra*, 238 Cal.App.4th at p. 568; see *City of Los Angeles v. Decker* (1977) 18 Cal.3d 860, 872 (*Decker*).)

In assessing prejudice, courts generally consider the nature and seriousness of the misconduct, the likelihood of actual prejudice on the jury, the efficacy of objections or admonitions, and the general atmosphere, including the judge's control, of the trial. (*Garcia v. ConMed Corp.* (2012) 204 Cal.App.4th 144, 149 (*Garcia*); *Martinez*, *supra*, 238 Cal.App.4th at p. 568.)

Here, the misconduct was serious, deliberate, and pervasive. Plaintiffs' counsel twice ascribed "historic" significance to this case in front of the jury, even though he had been previously admonished that such comments are "really inappropriate." (11 RT 1309:16, 1429:13; Motion for Judicial Notice, Bochner Decl., exh. C, pp. 37:17-22, 38:1-5, 39:22-40:1, 41:6-23.) Indeed, the trial court here recognized (albeit belatedly) that this case "is about the Pilliods" and to "enlist them in some sort of movement" by invoking the "historical" nature of the case would be "prejudicial." (31 RT 5432:8-20.) Plaintiffs' counsel also preyed on the jury's fears by telling them, in violation of a court order, that glyphosate is "ubiquitous," "pervasive," "in the food," and "all over the place" (11 RT 1331:1-13; 32 RT 5557:20-22), and by wearing gloves while handling and spraying a Roundup bottle that contained only water. These are just a few examples of the egregious misconduct that took place at trial (see *ante*, pp. 93-103), the cumulative effect of which requires reversal (see *Martinez*, *supra*, 238 Cal.App.4th at p. 570; *Simmons v. Southern Pac. Transportation Co.* (1976) 62 Cal.App.3d 341, 355 (*Simmons*)).

Second, it is very likely that Monsanto suffered actual prejudice from the misconduct. The jury's outrageous verdict

establishes prejudice: $2 *billion* in punitive damages and $55 million in compensatory damages to an elderly couple whose cancer is in remission. (See *Kenworthy v. State of California* (1965) 236 Cal.App.2d 378, 401 [a "grossly excessive verdict" indicates "a verdict tainted by bias and resulting from prejudice"].) There is certainly " 'a *reasonable chance*, more than an *abstract possibility*' " that Monsanto would have obtained a more favorable verdict—at least a significantly lower award—if the jury's passions had not been inflamed by counsel's misconduct. (*Cassim*, *supra*, 33 Cal.4th at p. 800; see *Love*, *supra*, 226 Cal.App.2d at p. 394 ["When a skillful lawyer . . . strives advertently to achieve a given result and where the result is in fact achieved, how can a court reasonably say that his conduct played no role in the result?"].)

Indeed, the trial court recognized that the jury's punitive and compensatory awards were excessive, which she attempted to cure by ordering a remittitur. (6 AA 8263-8266, 8273-8278.) But "excessive damages resulting from passion or prejudice which might also affect the issue of liability *cannot be cured by a remittitur*." (*Sabella v. Southern Pac. Co.* (1969) 70 Cal.2d 311, 316, fn. 2 (*Sabella*), emphasis added; see *Minneapolis etc. Ry. v. Moquin* (1931) 283 U.S. 520, 521 [51 S.Ct. 501, 75 L.Ed. 1243] (*Moquin*) ["no verdict can be permitted to stand which is found to be in any degree the result of appeals to passion and prejudice"].)

Here, the misconduct clearly affected both liability and damages issues. As to liability, for example, the misconduct sought to improperly influence the jury's determinations on whether glyphosate was carcinogenic (see, e.g., *ante*, pp. 99-100

["blood on their hands"], 102-103 [wearing gloves while handling bottle], 98-99 [references to other glyphosate litigation]); whether Monsanto sought to distort the science (see *ante*, pp. 88-93, 98 [IBT fraud]); and whether Monsanto was liable for failure to warn (see *ante*, p. 101 ["What that label says and what it does not say is their choice and their choice alone"]). Under these circumstances, a new trial, not a remittitur, is the proper remedy. (See *Sabella*, *supra*, 70 Cal.2d at p. 316, fn. 2; *Moquin*, *supra*, 283 U.S. at p. 521; see also *Decker*, *supra*, 18 Cal.3d at p. 871 [granting new trial based on attorney misconduct]; *Love*, *supra*, 226 Cal.App.2d at p. 382 [same].)

Third, Monsanto's objections and the court's admonitions were ineffective in curbing the misconduct because Plaintiffs' counsel simply ignored the court's rulings. For example, before trial, the court prohibited Plaintiffs from eliciting testimony or arguing that glyphosate is present in food or any other source unrelated to Plaintiffs' alleged route of exposure. (6 AA 6468.) Plaintiffs' counsel violated this ruling in his opening statement (11 RT 1331:1-13) and again during the presentation of evidence (16 RT 2559:6-14). Although the trial court sustained a defense objection and struck the improper question that Plaintiffs' counsel posed at trial (16 RT 2559:15-20), counsel violated the same ruling again in closing argument (32 RT 5557:20-22). Similarly, after the trial court instructed Plaintiffs' counsel not to mention the *Johnson* or *Hardeman* cases by name (29 RT 4865:19-4866:21; see also 30 RT 5124:17-5127:4), counsel did so anyway (30 RT 5106:8). He claimed he did not understand the prior ruling, even though

that ruling was "very clear." (30 RT 5124:17-5127:4; see also 29 RT 4865:19-4866:21.)

Counsel's repeated violations of the trial court's rulings adversely impacted " 'the general atmosphere . . . of the trial,' " a fourth factor that also weighs in favor of a finding of prejudice. (*Garcia*, *supra*, 204 Cal.App.4th at p. 149; accord, *Martinez*, *supra*, 238 Cal.App.4th at p. 569.) Although the trial court concluded that counsel's misconduct was not prejudicial because she "issued curative instructions to the jury" (6 AA 8259), this court independently determines whether there was prejudice and those instructions, when given, obviously had no effect (see *Martinez*, at pp. 568, 569 [objections and admonitions were not effective where counsel "simply ignored the trial court's rulings and since there was no penalty for doing so, she was able to infect the case with extraneous matter"]; *Simmons*, *supra*, 62 Cal.App.3d at p. 356 [while an admonition may cure error that " 'is isolated and unemphasized, an attempt to rectify repeated and resounding misconduct by admonition is . . . like trying to unring a bell' " (emphasis omitted)]).

In sum, an independent review of the record makes clear that counsel's misconduct was prejudicial. The court should reverse and remand the case for a new trial on all issues.

VI. The punitive damages award should be stricken because there was no evidence, much less clear and convincing evidence, that Monsanto acted with malice or oppression.

Regulators in the United States and abroad have consistently agreed that exposure to glyphosate, one of the most studied substances in the world, does not pose a risk of cancer to humans. (See *ante*, pp. 21-23, 31-34.) Monsanto's reliance on that regulatory consensus in developing, marketing, and selling Roundup without a cancer warning was reasonable corporate conduct and does not come close to justifying an award of punitive damages, which is reserved for only the most egregious conduct. The trial court's reasons for upholding the punitive damages award are legally flawed, unsupported by the evidence presented at trial, and ignore the decision in *Echeverria*, *supra*, 37 Cal.App.5th 292. The punitive damages award should be stricken because there is no basis for that exceptional remedy in this case.

A. Selling a product without a cancer warning that regulators worldwide have concluded is not a human carcinogen does not support an award of punitive damages.

Punitive damages may be awarded only "where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice." (Civ. Code, § 3294, subd. (a).) The trial court concluded there was clear and convincing evidence of malice, which (as relevant here) means "despicable

conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others." (*Id.*, § 3294, subd. (c)(1).)

Both elements of malice—despicable conduct and conscious disregard—present high hurdles. "Despicable conduct" is conduct that is "so vile, base, contemptible, miserable, wretched or loathsome that it would be looked down upon and despised by ordinary decent people"—conduct that generates the type of "outrage frequently associated with crime." (*Echeverria*, *supra*, 37 Cal.App.5th at pp. 332-333, internal quotation marks omitted.) Conscious disregard, in turn, may be found "where the defendant is aware of the probable dangerous consequences of his or her conduct and he or she willfully fails to avoid such consequences." (*Id.* at p. 332, internal quotation marks omitted.) "Put another way, the defendant must 'have *actual* knowledge of the risk of harm it is creating and, in the face of that knowledge, fail to take steps it knows will reduce or eliminate the risk of harm.' " (*Butte Fire Cases* (2018) 24 Cal.App.5th 1150, 1159.)

Both of these elements must be proved by clear and convincing evidence, which requires proof that " ' "leave[s] no substantial doubt [and is] sufficiently strong to command the unhesitating assent of every reasonable mind." ' " (*In re Angelia P.* (1981) 28 Cal.3d 908, 919, superseded by statute on another ground as stated in *In re Cody W.* (1994) 31 Cal.App.4th 221, 230.) A punitive damages award may be upheld only where "the record contains substantial evidence to support a determination by clear and convincing evidence." (*Echeverria*, *supra*, 37 Cal.App.5th at p.

333, internal quotation marks omitted.) The appropriate question on appeal should be " 'whether there is substantial evidence from which a reasonable trier of fact could make the necessary findings *based on the clear and convincing evidence standard.*' " (*T.J. v. Superior Court* (2018) 21 Cal.App.5th 1229, 1239 (*T.J.*).)[20]

There is no evidence that Monsanto had "actual knowledge" that cancer was a "probable consequence" of exposure to Roundup. Instead, Monsanto relied on a worldwide regulatory consensus that glyphosate is not a human carcinogen in developing, marketing, and selling Roundup without a cancer warning. (See *ante*, pp. 21-23, 31-34.) Moreover, even if there was some basis for the jury to disagree with the experts at EPA and many other respected agencies, the record cannot possibly support a finding of clear and convincing evidence that Monsanto acted with malice by developing and selling a product without a cancer warning that it and expert regulators then believed, and still believe, is not a human carcinogen.

The Court of Appeal's recent decision in *Echeverria* makes clear that punitive damages may not be awarded in a case like this one. There, the jury found that one of the defendants had failed to warn the plaintiff of the potential risk of cancer caused by the

[20] Some courts haves erroneously held that the clear and convincing evidence standard is irrelevant in determining whether there is substantial evidence to support a judgment. (See *T.J.*, *supra,* 21 Cal.App.5th at p. 1239.) The issue of which standard of review governs—substantial evidence or clear and convincing evidence—is now pending before the California Supreme Court. (See *Conservatorship of O.B.* (2019) 32 Cal.App.5th 626, 628, review granted May 1, 2019, S254938.)

company's talcum powder—a conclusion that rested in part on an IARC classification that the powder was "possibly carcinogenic." (*Echeverria*, *supra*, 37 Cal.App.5th at pp. 298, 320-324.) Although the appellate court upheld the failure-to-warn verdict, it ruled that punitive damages were not appropriate as a matter of law. (*Id*. at pp. 332-335.)

Echeverria's punitive damages ruling rested on factors that are also present in this case. First, the court noted that "the FDA has not concluded there is a causal link between talc and ovarian cancer" and concluded that "it [was] not universally accepted in the scientific or medical community that talc is even a significant risk factor for . . . cancer." (*Echeverria*, *supra*, 37 Cal.App.5th at pp. 333, 335.) And although the defendant had arguably "refused to draw a causal connection between . . . talc use and ovarian cancer before experts in the relevant fields have done so," that was not the kind of clear and convincing evidence of " 'despicable conduct' " required to impose punitive damages under state law. (*Id*. at p. 335.)

The same is true here. Monsanto met its regulatory obligations related to Roundup, repeatedly obtaining EPA's approval to market Roundup without a cancer warning. (See *ante*, pp. 21-23, 31-33.) And at the time of the Pilliods' relevant exposures to Roundup, before release of the IARC study (*ante*, pp. 36-37, fn. 6), not a single regulatory body worldwide had concluded that glyphosate exposure might cause cancer (*ante*, pp. 21-23, 31-34). As Plaintiffs' own expert testified, even at the time of trial, reasonable people could disagree about whether glyphosate should

be classified as a carcinogen. (25 RT 4072:20-4073:2.) Meanwhile, EPA, following consideration of a more extensive dataset than IARC, continues to take the view that glyphosate is not likely to be carcinogenic to humans and will not permit Monsanto to include a cancer warning. (See *ante*, pp. 31-33, 41, 44-51.)

In other words, it is still "not universally accepted in the scientific or medical community that [glyphosate] is even a significant risk factor for . . . cancer." (*Echeverria*, *supra*, 37 Cal.App.5th at p. 333.)

Second, the *Echeverria* court observed that "[t]here was no evidence [defendant] had any information about the dangers or risks of . . . talc use that was unavailable to the scientific or medical community." (*Echeverria*, *supra*, 37 Cal.App.5th at p. 334.) Indeed, the defendant's belief that its product was non-carcinogenic was "largely consistent with third party entities' evaluations of the same studies, including . . . the FDA." (*Ibid.*)

The same is also true here. Although the trial court concluded (incorrectly, as discussed below), that Monsanto attempted to "impede, discourage, or distort scientific inquiry" (6 AA 8269), the court did not conclude—and Plaintiffs presented no evidence that—Monsanto had information about any "dangers or risks" of glyphosate that was "unavailable to the scientific or medical community" (*Echeverria*, *supra*, 27 Cal.App.5th at p. 334). Moreover, Monsanto's belief that Roundup is non-carcinogenic is "consistent with third party entities' evaluations of the same studies"—namely EPA, as well as numerous other worldwide

regulatory agencies. (*Ibid.*) Accordingly, the record cannot support a punitive damages award.

B. The trial court's reasons for denying JNOV on the punitive damages claim are unsupported by the record, legally flawed, and ignore *Echeverria*'s holding.

The trial court's sole basis for distinguishing *Echeverria* and concluding there is substantial evidence to support the punitive damages award in this case was that the defendant in *Echeverria* "mounted a policy debate" while Monsanto supposedly "made efforts to impede, discourage, or distort the underlying scientific inquiry." (6 AA 8270-8271.) Yet the trial court recognized "Monsanto presented evidence that it relied on the publicly known and generally accepted science about glyphosate" to support its conclusion that there is no causal link between glyphosate exposure and NHL. (6 AA 8271.) The court also recognized that "reasonable people can disagree on whether glyphosate causes NHL," as Dr. Nabhan acknowledged. (*Ibid.*) These facts alone should have doomed Plaintiffs' punitive damages claims. (See *Kendall Yacht Corp. v. United California Bank* (1975) 50 Cal.App.3d 949, 959 [reversing punitive damages award because it "remains purely speculative as to whether the [defendant] acted with such malice rather than out of a bona fide disagreement over" plaintiff's claims]; *Satcher v. Honda Motor Co.* (5th Cir. 1995) 52 F.3d 1311, 1316-1317 ["genuine dispute" over efficacy of motorcycle leg guards barred punitive damages as a matter of law];

Berroyer v. Hertz (3d Cir. 1982) 672 F.2d 334, 342 ["difference of medical opinion on the degree of the cancer risk" among experts is "insufficient support" for punitive damages].)

Nevertheless, as discussed above, the trial court reasoned that the jury could have simply disregarded the prevailing scientific view that glyphosate-based herbicides do not pose a real-world cancer risk and the conclusion of Plaintiffs' own expert that there is a "reasonable" scientific dispute because Monsanto's conduct was akin to spoliation of evidence described in CACI No. 204, an instruction the court never gave to the jury. (6 AA 8262, 8270-8271; see *ante*, pp. 58-60.) But the trial court cited no case to support the novel conclusion that, absent a spoliation instruction and evidence of destruction of evidence, a jury could ignore evidence of a prevailing scientific view that was consistent with Monsanto's view and an admitted "reasonable" scientific debate, and find that Monsanto willfully and despicably disregarded a known risk of harm to its customers.

Moreover, there is simply no evidence, much less clear and convincing evidence, to support the trial court's conclusion that Monsanto's conduct was anything akin to spoliation of evidence. As previously discussed, the claims of alleged "ghostwriting," so-called attempts to discredit Dr. Parry, and alleged improper reporting of mouse studies to EPA are not supported by the record, and in any event, cannot establish the type of malicious conduct that can support a claim of punitive damages. (See *ante*, pp. 60-62.) Moreover, while the trial court expressed its belief that EPA relied on science allegedly tainted by Monsanto (6 AA 8270-8273),

the court pointed to no evidence supporting the conclusion that EPA and other worldwide regulatory agencies were either influenced by any information that was tainted by Monsanto or that Monsanto deprived regulatory agencies of access to any relevant scientific information. The evidence, at best, showed that Monsanto participated in a complex and evolving scientific debate and exercised its right to lobby EPA.

When confronted with this evidentiary void, the trial court quickly changed course, wrongly insisting that whether Monsanto succeeded in influencing EPA's decision is "not relevant to whether the efforts were reprehensible." (6 AA 8273.) But the trial court is wrong. The law is clear that "[p]unitive damages are not simply recoverable in the abstract. They must be tied to oppression, fraud or malice *in the conduct which gave rise to liability in the case*." (*Medo v. Superior Court* (1988) 205 Cal.App.3d 64, 68 (*Medo*).) Thus, even if Monsanto's conduct rose to the level of "despicable" conduct—it did not—that conduct cannot support the punitive damages award absent any evidence such conduct unduly influenced the scientific debate and the conclusions of worldwide regulatory agencies. Plaintiffs offered no such evidence. Even after Plaintiffs' experts and attorneys have raised multiple allegations of Monsanto's "undue influence", regulators still conclude to this day that glyphosate "is not likely to be carcinogenic to humans." (EPA, Glyphosate Proposed Interim Registration Review Decision, *supra*, p. 19.)

The trial court also based its conclusion of alleged interference on a finding that "Monsanto made an aggressive

attempt to discredit the IARC decision," but that finding is likewise unsupported by the record. (6 AA 8244.) Monsanto's response to IARC's classification was not improper and entailed no wrongdoing. (See 6 AA 6709-6711.) Instead, Monsanto's conduct in anticipating the IARC decision was consistent with a company that truly believes its product to be safe, as confirmed by the conclusions of worldwide regulatory agencies both before and *after* IARC published its Monograph.

Indeed, such actions and communications in response to IARC's findings amount to protected speech under the First Amendment. (See, e.g., *ONY, Inc. v. Cornerstone Therapeutics, Inc.* (2d Cir. 2013) 720 F.3d 490, 497; *Underwager v. Salter* (7th Cir. 1994) 22 F.3d 730, 736; see also *Ludwig v. Superior Court* (1995) 37 Cal.App.4th 8, 21 & fn. 17.) The trial court recognized as much, noting that "a defendant's efforts to influence or persuade agencies regarding policy decisions cannot support punitive damages. A defendant has a right to petition the government and government agencies regarding policy choices." (6 AA 8243.) Despite that recognition, the court nonetheless pointed to just such conduct in attempting to justify the punitive damages award. (6 AA 8243-8247.) Finally, because the IARC Monograph was published *after* Plaintiffs' relevant exposures to Roundup already occurred, Monsanto's response to IARC's glyphosate classification cannot support the punitive damages award. (See *Medo*, *supra*, 205 Cal.App.3d at p. 68.)

In sum, while the trial court concluded that Monsanto's alleged "interference" with the science could justify an award of

punitive damages, the record provides no evidence, let alone clear and convincing evidence, to support that conclusion. Accordingly, there is no meaningful distinction between this case and *Echeverria*. As in *Echeverria*, the relevant regulatory body—here, EPA—"has not concluded that there is a causal link between [glyphosate exposure] and . . . cancer." (*Echeverria*, *supra*, 37 Cal.App.5th at p. 335.) As in *Echeverria*, "it is not universally accepted in the scientific or medical community that [glyphosate] is even a significant risk factor for . . . cancer." (*Id.* at p. 333.) And as in *Echeverria*, Monsanto's "refus[al] to draw a causal connection between" glyphosate exposure and NHL "before experts in the relevant fields have done so" is not a basis for an award of punitive damages. (*Id.* at p. 335.) For these reasons, this court should reverse the trial court's denial of JNOV and strike the entirety of the punitive damages award.

VII. The court should grant a new trial or reduce the punitive damages award because that award is constitutionally excessive and violates due process.

Beyond the legally erroneous decision to allow any award of punitive damages, the trial court's decision to permit plaintiffs to recover nearly $70 million in punitive damages—four times the amount of compensatory damages following remittitur—violated the Fourteenth Amendment. The punitive damages award also violated due process by punishing Monsanto multiple times for the same conduct. Accordingly, if the court does not strike the punitive damages award in its entirety, at a minimum, the court should

reduce the punitive damages award to an amount equivalent to the Pilliods' compensatory damages award—i.e., a 1:1 ratio between punitive and compensatory damages.

A. The evidence did not support a 4:1 ratio between punitive and compensatory damages.

Courts use three guideposts to assess whether a punitive damages award is unconstitutionally excessive: (1) the degree of reprehensibility; (2) the ratio of punitive damages to compensatory damages; and (3) the type of civil or criminal penalties that could be imposed for comparable misconduct or that are imposed in comparable cases. (*State Farm Mut. Automobile Ins. Co. v. Campbell* (2003) 538 U.S. 408, 419-428 [123 S.Ct. 1513, 155 L.Ed.2d 585] (*State Farm*); *Roby v. McKesson Corp.* (2009) 47 Cal.4th 686, 712-719 (*Roby*).) These three guideposts highlight that the punitive damages award the trial court left in place was "grossly excessive" and therefore violated the Due Process Clause. (*State Farm*, at p. 416.)

First, Monsanto's conduct was not reprehensible. Monsanto acted in good faith and consistent with the existing worldwide scientific and regulatory consensus, recently reaffirmed by EPA, that glyphosate is not carcinogenic to humans and that a warning to that effect is not required or even permissible as a matter of federal law. (See *ante*, pp. 21-28, 31-34, 41-51.) As *Echeverria* makes clear, to the extent Monsanto failed to anticipate a change in a complex area of science, that conduct cannot support an award of punitive damages and precludes a finding of reprehensibility.

Second, the 4:1 ratio of punitive to compensatory damages the trial court permitted violated due process. Following remittitur, Mr. Pilliod was awarded $6.1 million in compensatory and almost $25 million in punitive damages, while Mrs. Pilliod was awarded $11.25 million in compensatory and nearly $45 million in punitive damages. (6 AA 8277-8278.) Mr. Pilliod's $6.1 million in noneconomic damages comprised more than 99 percent of his compensatory award while Mrs. Pilliod's $11 million in noneconomic damages was approximately 98 percent of her total compensatory award. (See *ibid.*) Such high percentages likely reflect "the jury's indignation at [defendant's] conduct, thus including a punitive component," and require reduction of punitive damages to a ratio of 1:1. (*Roby*, *supra*, 47 Cal.4th at p. 718.) Here, because "compensatory damages are substantial" and already include a punitive component, due process limited Plaintiffs to punitive damages that equaled, but did not exceed, their compensatory awards. (*State Farm*, *supra*, 538 U.S. at pp. 425-426; see also *Roby*, at pp. 718-720 [same].)

Finally, because it is not misconduct to sell Roundup without a warning when manufacturers, scientists, and regulators all agree it is safe for public use and does not require a warning, it is impossible to compare the punitive damages award to civil or criminal penalties. This is especially so here where EPA has always taken the view that a warning is not necessary and recently reaffirmed that adding a cancer warning would amount to misbranding. Even more, Plaintiffs admitted that the third guidepost is not applicable (6 AA 8162), and California courts have

likewise recognized that it "is less useful in a case like this one, where plaintiff prevailed only on a cause of action involving 'common law tort duties that do not lend themselves to a comparison with statutory penalties' " (*Simon v. San Paolo U.S. Holding Co., Inc.* (2005) 35 Cal.4th 1159, 1183-1184). The absence of a relevant benchmark for civil or criminal penalties highlights that punitive damages are not appropriate and should not have been awarded at all.

B. The punitive damages award violates due process by punishing Monsanto multiple times for the same conduct.

The nearly $70 million punitive damages award violates due process because it is the third such award levied against Monsanto for the same alleged conduct. In considering the quantum of appropriate punitive damages, if any, the court should consider whether "there is the likelihood of several jury-imposed punitive damage awards, each of which is sufficient to punish in the entirety for the misconduct involved." (*Delos v. Farmers Insurance Group* (1979) 93 Cal.App.3d 642, 667.) As the Court of Appeal has observed, "[p]unitive damages previously imposed for the same conduct are relevant in determining the amount of punitive damages required to sufficiently punish and deter." (*Stevens v.*

Owens-Corning Fiberglas Corp. (1996) 49 Cal.App.4th 1645, 1661 (*Stevens*).)[21]

To date, Monsanto has already been ordered to pay almost $60 million in punitive damages in the *Johnson* and *Hardeman* cases. But punitive damages in all three cases were based on the same underlying conduct. (See 6 AA 8249-8250.) The conduct the trial court relied upon to justify the punitive damages award in this case—Monsanto's allegedly interfering with science, seeking to discredit a scientist, and ghostwriting articles all while continuing to sell Roundup—is not unique to or otherwise tethered to Plaintiffs or their claims in any way. Rather, this is the same conduct that invariably will be raised in every one of the thousands

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[21] *Stevens* erroneously held that evidence of punitive damages awarded in other cases must first be presented to the jury. (*Stevens*, *supra*, 49 Cal.App.4th at p. 1661.) As with other due process challenges to punitive damages awards, the question whether punitive damages violate due process by punishing a defendant multiple times for the same conduct may be resolved by an appellate court in the first instance. (See *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.* (2001) 532 U.S. 424, 437 [121 S.Ct. 1678, 149 L.Ed.2d 674] [" 'Unlike the measure of actual damages suffered, which presents a question of historical or predictive fact, . . . the level of punitive damages is not really a "fact" "tried" by the jury' " (citation omitted)]; *Nickerson v. Stonebridge Life Ins. Co.* (2016) 63 Cal.4th 363, 368 [in determining whether punitive damages violate due process, fees under *Brandt v. Superior Court* (1985) 37 Cal.3d 813 may be included when calculating the ratio of punitive to compensatory damages, even if the fees were awarded by the court after a jury awarded punitive damages].) Monsanto is presenting this court with the evidence it needs to make this determination—i.e., the judgments and related documents in *Johnson* and *Hardeman*—in its concurrently filed motion for judicial notice. (See Motion for Judicial Notice, Bochner Decl., exhs. D, E, F, G, H.)

of lawsuits that remain pending against Monsanto but that have yet to be tried. Due process does not permit imposition of this type of serial punishment on Monsanto. (See *Johnson v. Ford Motor Co.* (2005) 35 Cal.4th 1191, 1209 [rejecting punitive damages award due to multiple punishment problem].) At the very least, the multiple punitive damage awards already assessed against Monsanto for the same conduct reinforces that the trial court's decision to permit a punitive damages award four times the size of compensatory damages violated due process and must be stricken.

CONCLUSION

The court should reverse with directions to enter judgment for Monsanto because all of Plaintiffs' theories of liability are preempted by federal law and because there is no substantial evidence to support any liability theory or causation. Alternatively, the court should reverse and remand for a new trial on all issues because the trial court abused its discretion by denying severance, by admitting irrelevant and prejudicial evidence, and because Plaintiffs' counsel engaged in pervasive and prejudicial misconduct throughout trial. Finally, the court should strike the punitive damages award because there is no evidence to support the jury's finding of malice or oppression and because Monsanto has already been punished multiple times for the same alleged misconduct. Alternatively, the court should grant a new trial or reduce the punitive damages award to an amount

equivalent to the compensatory damages award, which must be the constitutional maximum.

February 7, 2020

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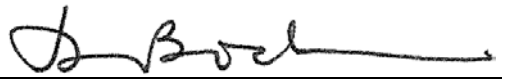

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PROOF OF SERVICE

Pilliod et al. v. Monsanto Company
Case No. A158228

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

At the time of service, I was over 18 years of age and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is 3601 West Olive Avenue, 8th Floor, Burbank, CA 91505-4681.

On February 7, 2020, I served true copies of the following document(s) described as **APPELLANT'S OPENING BRIEF** on the interested parties in this action as follows:

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BY MAIL: I enclosed the document(s) in a sealed envelope or package addressed to the persons at the addresses listed in the Service List and placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with Horvitz & Levy LLP's practice for collecting and processing correspondence for mailing. On the same day that correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

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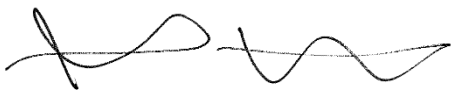
I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on February 7, 2020, at Burbank, California.



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