Nos. 19-16636, 19-16708

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

EDWIN HARDEMAN,
Plaintiff-Appellee/Cross-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellant/Cross-Appellee.

On Appeal from the United States District Court
for the Northern District of California,
Nos. 16-cv-00525 & 16-md-02741 (Chhabria, J.)

FIRST STEP BRIEF FOR MONSANTO COMPANY

BRIAN L. STEKLOFF
RAKESH KILARU
WILKINSON WALSH AND ESKOVITZ LLP
2001 M Street, NW
10th Floor
Washington, DC 20036

PHILIP J. PERRY
RICHARD P. BRESS
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004

SETH P. WAXMAN
PAUL R.Q. WOLFSON
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000
seth.waxman@wilmerhale.com

THOMAS G. SPRANKLING
WILMER CUTLER PICKERING HALE AND DORR LLP
950 Page Mill Road
Palo Alto, CA 94304

December 13, 2019

ADDITIONAL COUNSEL LISTED ON INSIDE COVER

MICHAEL X. IMBROSCIO
DAVID M. ZIONTS
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001

LEE MARSHALL
BRYAN CAVE LEIGHTON
PAISNER LLP
Three Embarcadero Center
7th Floor
San Francisco, CA 94111

LEON T. KENWORTHY
CLAIRE H. CHUNG
JAMES BARTON
RAFAEL J. GALLARDO HEVIA
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006

HENRY J. BECKER
WILMER CUTLER PICKERING
HALE AND DORR LLP
950 Page Mill Road
Palo Alto, CA 94304

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendant-Appellant/Cross-Appellee Monsanto Company certifies that it is an indirect, wholly owned subsidiary of Bayer AG and that Bayer AG is a publicly held corporation. No other publicly held corporation owns 10% or more of Monsanto Company's stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

Page(s)

DOCKETED CASES

CONSTITUTIONS, STATUTES, RULES, AND REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

This is the first federal appeal involving a challenge to the label for Roundup products, an herbicide manufactured by Monsanto. About 5,000 cases have been filed in federal court alleging that Monsanto failed to warn of the risk that Roundup causes non-Hodgkin's lymphoma, a cancer that affects white blood cells. This appeal has the potential to shape how every subsequent Roundup case is litigated.

The key ingredient in Roundup is glyphosate. Glyphosate "more closely approximates to a perfect herbicide than any other" because it is highly effective and "environmentally benign." ER1835-1836. Glyphosate is "a precious herbicide resource for world agriculture" and "the most important herbicide of th[e] [postwar] period." ER1835.

Glyphosate has been repeatedly approved for sale by the Environmental Protection Agency ("EPA"), which—along with other regulatory agencies worldwide—has consistently concluded that glyphosate does not cause cancer in humans. Indeed, earlier this year, EPA announced that including a cancer warning on a glyphosate-based product would constitute *misbranding* in violation of federal law. Against this consensus, a working group at the International Agency for Research on Cancer ("IARC") in 2015 classified glyphosate as "probably carcinogenic to humans." IARC did not identify either the circumstances under

which glyphosate might cause cancer or the amount of exposure required. Many regulatory agencies, including EPA, reviewed and rejected its conclusion. Still, based on that slender reed, thousands of litigants filed suit asserting that Monsanto had failed to warn them about the cancer risks of using Roundup.

Plaintiff Edwin Hardeman alleges that Monsanto is liable for failing to warn that exposure to Roundup could cause non-Hodgkin's lymphoma. Notwithstanding that federal law prohibited Monsanto from warning that Roundup is carcinogenic, the district court allowed Hardeman to present his failure-to-warn claims to a jury. The court then made a series of critical evidentiary errors, beginning with its failure to exclude expert testimony on causation, despite recognizing that the evidence was feeble and likely inadmissible in other Circuits. The court then exacerbated that error by allowing Hardeman to emphasize IARC's conclusion without allowing Monsanto to show the jury that regulatory agencies worldwide have rejected it, and then by instructing the jury on a causation theory that California courts would not have allowed and that even Hardeman repudiated. As a consequence of those errors, the jury returned a massive verdict against Monsanto, including (even after reduction) quadruple punitive damages.

That verdict defies both expert regulatory judgment and sound science. This Court should reverse, and make clear that a manufacturer cannot be forced by state law to add a warning to its products that federal law would deem illegal; that

expert testimony dependent on fundamental methodological flaws cannot be sufficient to take such a speculative case to a jury; and that a manufacturer cannot be punished for doing something that was perfectly legal both at the time and now—marketing without a cancer warning a product that regulators and reliable scientific studies have deemed non-carcinogenic.

JURISDICTION

The district court had jurisdiction under 28 U.S.C. §1332 because Monsanto and Hardeman are residents of different states and the amount in controversy exceeds $75,000. ER2280. The district court entered final judgment on July 17, 2019, and Monsanto filed a timely notice of appeal on August 15, 2019. ER1-2, 125-126. This Court has jurisdiction under 28 U.S.C. §1291.

ISSUES ON APPEAL

1. Whether Hardeman's claims are preempted under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §136 *et seq*.

2. Whether the district court misinterpreted the *Daubert* standard, which caused it to admit unreliable expert testimony purporting to link glyphosate to Hardeman's non-Hodgkin's lymphoma.

3. Whether the district court erred by admitting IARC's conclusion about the carcinogenicity of glyphosate and excluding evidence that numerous regulatory bodies have rejected IARC's conclusion.

4. Whether the district court erred by instructing the jury that it could find for Hardeman if it believed that Hardeman's cancer was independently caused by *both* Roundup *and* by another factor, even though Hardeman argued that Roundup was the *sole* factor.

5. Whether the district court should have granted judgment as a matter of law, because the alleged carcinogenic risk of glyphosate was not known or knowable under the generally recognized and prevailing best scientific and medical knowledge at the time of Hardeman's exposure.

6. Whether the jury's award of punitive damages violates California Civil Code §3294 or the Due Process Clause of the Fourteenth Amendment.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Relevant provisions of the U.S. Constitution, FIFRA, and California Civil Code §3294 are in the addendum.

STATEMENT

A. Glyphosate's Longstanding Record Of Regulatory Approvals And Findings Of Non-Carcinogenicity

1. EPA approves glyphosate for sale and determines that it is not carcinogenic[1]

a. The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") requires EPA to regulate "the use, sale[,] … and labeling of pesticides." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 437 (2005); *see* 7 U.S.C. §136 *et seq.* FIFRA is a "comprehensive regulatory statute." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). For EPA to register a pesticide for sale in the United States, EPA must "determine that the pesticide will not cause 'unreasonable adverse effects on the environment,'" *id.* at 992 (quoting 7 U.S.C. §136a(c)(5)(C)), which is defined to include an unreasonable adverse effect on human health, 7 U.S.C. §136(bb). EPA makes registration determinations only after considering voluminous scientific data, 7 U.S.C. §§136a(c)(1)(F), (c)(2(A); 40 C.F.R. §158.500, and FIFRA requires EPA to re-review a pesticide's registration, including its effects on human health, every fifteen years, 7 U.S.C. §136a(g). As

[1] Because glyphosate is Roundup's active ingredient, this brief treats the terms "Roundup" and "glyphosate" as synonymous. Although Hardeman briefly suggested at trial that there was a meaningful difference between the two substances, the district court found that the evidence supporting this position was "exceedingly thin." ER128. Accordingly, nothing in this brief turns on that distinction.

part of the registration process, EPA must approve a pesticide's label, which the manufacturer then must use without modification. *Id.* §136j(a)(1)(E). A state may "not impose or continue in effect any requirements for labeling or packaging in addition to or different from those" required by EPA. *Id.* §136v(b).

b. Starting in 1974, EPA has registered pesticides containing glyphosate, reflecting the agency's conclusion that glyphosate did not have an unreasonable adverse effect on human health. *See* EPA, *Glyphosate: Proposed Interim Registration Review Decision* 4 (Apr. 2019), https://tinyurl.com/y6h2u8w6 ("PID").[2] Since then, EPA has repeatedly approved the use of glyphosate as a pesticide, each time concluding that it is not likely to be carcinogenic to humans.

EPA has evaluated whether glyphosate is carcinogenic on multiple occasions. *See* EPA, Revised Glyphosate Issue Paper (Dec. 12, 2017), excerpts at ER1852-1861 (full document at https://tinyurl.com/eparevdglyphosate). In the early 1990s, EPA conducted a robust re-evaluation of glyphosate's effects on human health as part of its regular review of glyphosate's registration. *See* ER1844. EPA considered numerous carcinogenicity studies in rats and mice, none of which showed "convincing evidence" that glyphosate was a carcinogen. ER1845. On that basis, the agency "classified glyphosate as a Group E

[2] FIFRA treats herbicides, which target unwanted vegetation, as pesticides that must be registered with the EPA. 7 U.S.C. §136(t), (u); 40 C.F.R. §152.15.

carcinogen"—signifying "evidence of non-carcinogenicity in humans." ER1844. Over the subsequent years, EPA repeatedly reaffirmed its conclusion that glyphosate is not carcinogenic. *See, e.g.*, ER1848 ("Data indicate that glyphosate is a group E carcinogen ([*i.e.*,] evidence of noncarcinogenicity for studies in humans …)"), ER1851 ("Glyphosate has no carcinogenic potential."); *see also* Monsanto Mot. for Summ. J., No. 3:16-md-02741, Dkt. 2419 at 12-13 (identifying numerous instances where EPA has taken the position that glyphosate is non-carcinogenic).

2. IARC's incomplete finding

In 2015, a working group at IARC, an agency of the World Health Organization, issued a report classifying glyphosate as a "Group 2A" agent, meaning it is "probably carcinogenic to humans," based on glyphosate's "limited" evidence of cancer in humans and "sufficient" evidence of cancer in experimental animals. ER1819 (emphasis omitted). IARC classifies 82 agents under group 2A, including very hot beverages, shift work, and red meat. *See* Monsanto Mot. to Dismiss, No. 3:16-cv-00525, Dkt. 18 at 4-5 (collecting IARC reports).

IARC's classification is only a "hazard identification," which is merely the first step of an overall public health assessment designed to "identify cancer hazards even when risks are very low at current exposure levels." ER58. That hazard determination asks whether glyphosate "is capable of causing cancer under

some circumstances," but a public health assessment requires a second necessary step—an actual "risk assessment" which gauges the carcinogenic effects from real-world human exposure. *Id.* (emphasis added). IARC left that critical risk assessment step to "other public health entities." ER50.

3. EPA and other agencies reaffirm their conclusions that glyphosate is not carcinogenic

In response to IARC's report, EPA and other regulatory agencies re-analyzed available scientific data and affirmed their earlier conclusions of glyphosate's non-carcinogenicity.

a. EPA fully considered IARC's report and the studies on which it relied, as well as other studies, and then reaffirmed that glyphosate is not likely to cause cancer. When the IARC report was released, EPA was conducting its most recent registration review of glyphosate. *See* Revised Glyphosate Issue Paper 12-13; Monsanto Mot. for Summ. J., No. 3:16-md-02741, Dkt. 2419 at 13. As part of that process, EPA examined "63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies," ER1861—including all those taken into account by IARC and many more. The agency submitted its proposed conclusion—that glyphosate was "not likely to be carcinogenic to humans"—to an independent panel of experts. Revised Glyphosate Issue Paper 13. Although the panel did not reach a consensus about any connection between glyphosate and non-Hodgkin's lymphoma, no member of the panel believed that

glyphosate should be classified as a likely or known carcinogen. PID 7. EPA once again concluded in December 2017 that glyphosate is "not likely to be carcinogenic to humans." ER1861.

Virtually every other national and international agency charged with reviewing and approving pesticides reached a similar conclusion: Scientific evidence does not show that glyphosate causes cancer in humans. That group includes the European Union's European Chemicals Agency ("ECA") and European Food Safety Authority ("EFSA"),[3] and the national health authorities of Australia, Canada, Germany, and New Zealand.[4]

b. Based solely on IARC's classification, and despite the consensus among regulators to the contrary, California law automatically categorized glyphosate as a "chemical known to the state to cause cancer." That classification triggered a state-law requirement to attach a warning label to glyphosate products. *See* Cal. Health & Safety Code §§25249.6, 25249.8; Cal. Code Regs. tit. 27, §25306(l)(1).[5] Because of that state-law requirement, some glyphosate registrants

---

[3] ER1866-1867 (ECA), ER1739 (EFSA); *see also* ER1864 (European Commission Health & Consumer Protection Directorate-General).

[4] ER1739 (Australia), ER1732 (Canada), ER1869-1870 (New Zealand); *National Ass'n of Wheat Growers v. Zeise*, 309 F. Supp. 3d 842, 852 (E.D. Cal. 2018) (Germany).

[5] A district court enjoined the glyphosate warning mandate as a likely violation of the First Amendment, in part because the warning would be

asked EPA to approve a change in labeling to include a cancer warning, which requires agency approval. *See* 40 C.F.R. §152.44(a).

EPA refused to approve the requested change, emphasizing its conclusion that glyphosate does *not* cause cancer. In August 2019 (after the final judgment in this case), EPA issued a letter to all glyphosate registrants informing them of that decision. *See* Letter from Michael L. Goodis, EPA, Office of Pesticide Programs (Aug. 7, 2019), https://tinyurl.com/y552m94m ("August 7 Letter").[6] EPA unequivocally disagreed with IARC's assessment. It informed registrants 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. *See id.* (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 2.

"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." *National Ass'n of Wheat Growers*, 309 F. Supp. 3d at 851.

[6] This Court may consider the August 7 Letter in the preemption analysis, as it helps "establish[] the legal principles governing" this case. *Reid v. Johnson & Johnson*, 780 F.3d 952, 962 & n.4 (9th Cir. 2015); *see also Smith v. Los Angeles Unified Sch. Dist.*, 830 F.3d 843, 851 n.10 (9th Cir. 2016).

B. Hardeman's Complaint And Allegations

Plaintiff Edwin Hardeman sued Monsanto, alleging that his use of glyphosate to treat weeds and other vegetation on his property—which spanned many years and ended in 2012—led to his diagnosis of non-Hodgkin's lymphoma in early 2015. ER2294.[7] Non-Hodgkin's lymphoma is a cancer that affects white blood cells in the immune system. Monsanto Mot. to Exclude on *Daubert* Grounds, No. 3:16-md-02741, Dkt. 2420 at 3. Approximately 70% or more of cases are idiopathic—*i.e.*, they develop for unknown reasons. *Id.* However, some causes of the cancer—such as hepatitis C—are well established. ER38 n.4. Hardeman had hepatitis C for 25 to 40 years before developing non-Hodgkin's lymphoma. *See* ER2322.[8]

At trial, Hardeman pursued a theory based on Monsanto's failure to warn him of the alleged carcinogenic potential of Roundup. ER2296-2305.[9] At the time

---

[7] Hardeman has the most common subtype of non-Hodgkin's lymphoma (Diffuse Large B-Cell Lymphoma (DLCBL)). Monsanto follows the district court's convention of using "non-Hodgkin's lymphoma" or "NHL" to describe Hardeman's illness.

[8] Hardeman's case is one of approximately 5,000 cases in federal court alleging that Roundup causes non-Hodgkin's lymphoma. The Judicial Panel on Multidistrict Litigation consolidated those cases for pretrial proceedings in the Northern District of California. *See* ER2254-2256. Thousands of similar actions have been filed against Monsanto in state courts across the country.

[9] The other claims in Hardeman's complaint were design defect and breach of warranty. Hardeman did not pursue his breach of warranty claim. The district

of Hardeman's exposure, no regulatory or public health body—including IARC—had concluded that glyphosate might cause cancer. Although Hardeman pointed to IARC's 2015 report as establishing that glyphosate is carcinogenic, ER2289-2290, he claimed that Monsanto had become aware of glyphosate's allegedly carcinogenic properties "[a]s early as the 1980's," ER2287.

C. Pretrial Proceedings

The district court issued several rulings that had major ramifications for the ultimate verdict.

1. Preemption

Monsanto moved to dismiss, arguing that Plaintiff's claims were preempted by FIFRA, given EPA's registration of glyphosate, approval of the Roundup label, and classification of glyphosate as non-carcinogenic. *See* Monsanto Mot. to Dismiss, No. 3:16-cv-00525, Dkt. 18 at 5-10. The district court denied Monsanto's motion. ER117-122. Monsanto raised preemption again in a motion for summary judgment, which the district court likewise denied. *See* Monsanto Mot. for Summ. J., No. 3:16-md-02741, Dkt. 2419 at 3-14.

---

court held that, in light of the evidence at trial, Hardeman's only viable defect theory was the absence of a warning. *See infra* pp. 25-26, n.10.

2. Expert testimony on causation

Hardeman's case depended on establishing that glyphosate caused his cancer. The parties disputed both general causation (whether glyphosate can cause non-Hodgkin's lymphoma at all) and specific causation (whether exposure to Roundup caused *Hardeman's* non-Hodgkin's lymphoma). Monsanto moved to exclude Hardeman's proffered experts on both issues, arguing their testimony did not meet the standards for scientific expert testimony under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

The district court first granted in part and denied in part Monsanto's motion to exclude Hardeman's general causation experts. The court cast doubt on the testimony of Hardeman's experts, finding it "too equivocal to support any firm conclusion that glyphosate causes" non-Hodgkin's lymphoma. *See, e.g.*, ER87-89, 99-102; *see also* ER49 (acknowledging that "significant problems with [Hardeman's] presentation" made it a "very close question" whether Hardeman had valid expert testimony on general causation). But the court interpreted Ninth Circuit case law on *Daubert* as requiring "slightly more room for deference to experts in close cases than might be appropriate in some other Circuits," ER57, and on that basis allowed general causation testimony by three primary experts, ER51. The court added that, "[g]iven how close the question is at the general causation

phase, [Hardeman] appear[s] to face a daunting challenge at the [specific causation] phase." ER51.

Nonetheless, the district court later denied Monsanto's motion to exclude Hardeman's specific causation experts. ER33-41. The court acknowledged that the experts' inability to differentiate Roundup users who developed non-Hodgkin's lymphoma because of their glyphosate exposure from those who would have developed it without such exposure would probably doom Hardeman's case "[u]nder a strict interpretation of *Daubert*." ER36. But the court concluded that Hardeman's "borderline" expert opinions were admissible because this Circuit supposedly affords experts "wide latitude in how they practice their art when offering causation opinions" and permits "a wider range of expert opinions (arguably much wider)" than other Circuits. ER37. The court denied Monsanto summary judgment based solely on the admission of Hardeman's experts' testimony. ER33.

3. Evidence about regulatory conclusions

Monsanto moved to exclude all evidence regarding IARC's report as irrelevant and likely to confuse and distract the jury. Monsanto Mot. in Limine, No. 3:16-md-02741, Dkt. 2610 at 1. But if IARC evidence was admitted, Monsanto argued, "basic principles of fairness and completeness would compel the admission of the worldwide regulatory consensus that glyphosate is safe." *Id.* The

court ultimately excluded IARC's *report*, recognizing that "the primary inquiry is what the scientific studies show, not what IARC concluded they show," but held that the *fact* of IARC's classification of glyphosate as probably carcinogenic could be admitted. ER42.

Hardeman moved to exclude EPA's post-IARC reports reaffirming glyphosate's classification as non-carcinogenic, as well as evidence that several foreign regulatory agencies had made the same determination. Hardeman Mots. in Limine, No. 3:16-md-02741, Dkts. 2594, 2596. Granting Hardeman's motions almost entirely, the court excluded from the causation phase of trial all EPA and foreign regulators' reports on glyphosate. *See infra* pp. 16-17. Instead, it allowed Monsanto to introduce only the *fact* that EPA had approved glyphosate and to impeach one of Hardeman's experts with evidence that two European regulators had not been persuaded by his attempts to cast doubt on their approval of glyphosate. ER46-47; *see also* ER31-32, 744-755. The court excluded evidence that other international regulators had reaffirmed that glyphosate is not carcinogenic after IARC's report was issued, thus obscuring from the jury the overwhelming regulatory consensus supporting the safety of glyphosate. ER42.

D. Trial

Because causation was the central issue at trial, the district court bifurcated the proceedings. The first phase lasted ten days and largely consisted of the

testimony of each side's experts, who focused on the scientific issues of general and specific causation. *See supra* pp. 13-14; *infra* pp. 40-41, 48-63. The second phase, which lasted three and a half days, concerned all other issues of liability and damages.

1. Phase one (causation)

Evidence about IARC and regulators. The evidence at the causation phase left the jury with a skewed impression of the relative importance of IARC's conclusion about the carcinogenicity of glyphosate as opposed to the consensus of regulators that glyphosate does not cause cancer. Although the district court's pretrial ruling had limited Hardeman to a very narrow reference to IARC, *see supra* pp. 14-15, Hardeman failed to adhere to that ruling at trial. During Hardeman's opening statement, his counsel suggested that the jury should defer to IARC's expertise about whether glyphosate can cause cancer, without mentioning that IARC had conducted only an initial "hazard identification" and had not done any new research. *See supra* pp. 7-8. Before even discussing any of the studies on which Hardeman's experts relied, she told the jury that the agency "we lovingly refer to as IARC"—"an arm of the World Health Organization"—had convened a working group consisting of "leading experts on cancer" who examined the existing data on glyphosate. ER991. And she stated—without elaboration—that "IARC [then] unanimously decided to list glyphosate as a Class 2[A] carcinogen,

which means that they unanimously decided after looking at the literature that it was a probable human carcinogen." ER992.

But despite Hardeman's heavy reliance on IARC's classification, the district court limited Monsanto's ability to respond by showing that regulators worldwide have rejected IARC's classification of glyphosate as a probable carcinogen. Although the court allowed Monsanto to introduce the basic fact that EPA has concluded that glyphosate is not carcinogenic, it refused to allow Monsanto to elicit EPA's full explanation for rejecting IARC's conclusion. ER322, 326. And, as noted above (*supra* p. 15), the court excluded evidence that other national and international regulators have also rejected IARC's conclusion.

Jury instructions on causation. The parties took directly opposing positions on the cause of Hardeman's non-Hodgkin's lymphoma. Plaintiff's experts testified that it was caused by his exposure to glyphosate. *See* ER187-188. Monsanto's experts testified that there is no scientific evidence that glyphosate can cause cancer in human beings, Transcript, No. 3:16-md-02741, Dkt. 3114 at 1409-1411, and that Hardeman's 25-to-40 years' exposure to active hepatitis C (and not Roundup) was the most likely cause of his cancer, ER191-223. Monsanto's experts also testified that it may not be possible to determine the cause of Hardeman's cancer, as is true of the vast majority of non-Hodgkin's lymphoma cases. ER192-194. Neither party presented evidence that Hardeman's cancer

could have been independently and concurrently caused by *both* Roundup and hepatitis C. ER262. To the contrary, Hardeman's experts testified that his cancer was *not* caused by hepatitis C. ER337-338.

Over both parties' objections, ER303-307, the district court delivered a "substantial factor" causation instruction that deviated from standard California instructions. The court first correctly charged the jury that to rule for Hardeman, it was required to find that exposure to glyphosate was a but-for cause of his cancer, but then—departing from the pattern instructions—the court told the jury it could find for Hardeman if it concluded that glyphosate was one of two or more factors that independently could have caused Hardeman's cancer. ER1721.

After five days of deliberation, the jury returned a verdict that Hardeman had proved that his exposure to Roundup was a substantial factor in causing his non-Hodgkin's lymphoma. ER167, 1710.

2. Phase two

After the second phase of trial, the jury deliberated for one day and returned a verdict in favor of Hardeman. It awarded $5,267,634.10 in compensatory damages and $75,000,000 in punitive damages. ER1680-1681.

E. Post-Trial Proceedings

In post-trial motions, Monsanto argued that the court had improperly excluded evidence of the "global regulatory consensus about glyphosate's safety,"

which deprived the jury of an accurate sense of the "volume and scope of evidence reinforcing Monsanto's view of the science." Monsanto Mot. for J. as Matter of Law, No. 3:16-md-02741, Dkt. 3976 at 23-24. The court rejected that argument, stating summarily that evidence about other foreign regulators would have been "cumulative under Rule 403." ER16 n.5. Finding the expert evidence sufficient to sustain the verdict, the district court denied Monsanto judgment as a matter of law. ER3-10.

The district court sustained Hardeman's compensatory damages award but reduced his punitive damages award to $20 million, "approximately four times the compensatory damages award." ER10. The court determined that amount was the maximum consistent with due process based on "the nature of Monsanto's conduct," *id.*, in view of "the repeated approvals of glyphosate by the EPA … and other worldwide regulatory agencies, [which] surely diminish … Monsanto's culpability," ER8. The district court justified awarding punitive damages at all largely based on its conclusion—without any citation to the record—that Monsanto "was more concerned with tamping down safety inquiries and manipulating public opinion than it was with ensuring its product is safe." ER7.

SUMMARY OF ARGUMENT

Even though expert regulatory agencies worldwide, including EPA, have concluded that glyphosate does not cause cancer, and even though no scientific

studies have yielded reliable evidence of such causation, the district court allowed the jury to return a massive verdict against Monsanto. That verdict depends on serious legal errors that warrant reversal and judgment for Monsanto.

I. Hardeman's state-law failure-to-warn case is both expressly and impliedly preempted by federal law. FIFRA gives EPA the authority to regulate pesticide labeling and prohibits states from imposing any labeling requirement "in addition to or different from" federal requirements. 7 U.S.C. §136v(b). Because EPA has consistently approved the sale of glyphosate without a cancer warning and has stated that including such a warning on the label would render the product misbranded, any state-imposed cancer warning would be in addition to or different from federal requirements, and is expressly preempted. Moreover, given EPA's repeated conclusion that glyphosate does not pose a risk of cancer in humans and its instruction that glyphosate manufacturers *may not* add the warning Hardeman seeks, the warning is impliedly preempted as well, for it would be impossible for Monsanto to comply with both state and federal law, and Monsanto could not have added the warning without EPA's approval, which will not be given.

II. The district court made several evidentiary and instructional errors relating to causation, the central issue in the case. Those errors were prejudicial and require reversal.

A. Under the mistaken belief that this Circuit applies a more lenient *Daubert* standard than other Circuits, the district court improperly admitted Hardeman's expert testimony on the purported link between Roundup and Hardeman's non-Hodgkin's lymphoma. Contrary to the district court's misimpression, *Daubert* does not allow expert testimony that is dependent on fundamental methodological flaws and contradicts reliable scientific evidence based on the notion that a doctor can testify based on "art" and "subjective judgment."

In this case, the district court's legal error led to the improper admission of unreliable testimony about both general and specific causation. As to general causation, the court allowed testimony that relied on flawed studies and deviated from basic statistical norms. As to specific causation, the court allowed Hardeman's experts to engage in a unsupported "always glyphosate" approach—deeming exposure to glyphosate above a certain number of days to be a cause of non-Hodgkin's lymphoma, even though more than 70% of such cases have no known etiology and even though Hardeman had lived with hepatitis C, a well established cause of the cancer, for decades.

B. The jury's causation inquiry was further warped by the court's erroneous admission of IARC's idiosyncratic classification of glyphosate as a probable cause of cancer. IARC's conclusion was admitted even though the jury

was not likely to understand the limited meaning of that classification and even though that conclusion added nothing to the underlying studies on which it was based except to lend them an inappropriate air of authority. The district court compounded the error by refusing to mitigate that prejudice by allowing Monsanto to admit evidence of the worldwide regulatory consensus rejecting IARC's conclusion—thus leaving the jury with the mistaken impression that IARC's and EPA's conclusions were equally valid and in equipoise.

C. The causation determination rests on yet another legal flaw: The district court erroneously instructed the jury on *both* a theory of "but-for causation" and a theory of "concurrent independent causes." The district court issued that instruction even though California courts, recognizing the theories are inherently contradictory, do not allow jurors to be instructed on the two theories in the same case, and even though Hardeman forswore reliance on the second theory. The inevitable result was prejudicial confusion.

III. In any event, the jury had no basis to conclude that Monsanto violated a duty to warn Hardeman. A duty to warn of a particular risk arises under California law only if the risk was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge at the relevant time. The evidence at trial established the opposite point—that, under the

prevailing knowledge at the time of Hardeman's exposure (and now), glyphosate does not cause cancer.

IV. Finally, the district court erroneously concluded that Monsanto was eligible for punitive damages. A defendant that markets without a cancer warning a product that the vast majority of regulators and scientists have concluded is non-carcinogenic does not engage in the kind of egregious behavior that warrants punishment akin to a criminal fine. And in any event, quadruple punitive damages are unwarranted, given the strong evidence of Monsanto's good faith and the substantial compensatory damages awarded.

STANDARD OF REVIEW

This Court reviews de novo whether a state tort claim is preempted. *Nathan v. Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1203 (9th Cir. 2002).

This Court reviews de novo the district court's "'construction or interpretation of ... the Federal Rules of Evidence, including whether particular evidence falls within the scope of a given rule,'" and the ultimate ruling on the admissibility of expert testimony for abuse of discretion. *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 462 (9th Cir. 2014) (en banc). Rulings pursuant to Federal Rule of Evidence 403 are similarly reviewed for abuse of discretion. *Old Chief v. United States*, 519 U.S. 172, 174 n.1 (1997).

This Court reviews de novo whether a jury instruction states the law correctly. *Peralta v. Dillard*, 744 F.3d 1076, 1082 (9th Cir. 2014) (en banc).

This Court reviews de novo whether Monsanto should have received judgment as a matter of law. *Lakeside-Scott v. Multnomah Cty.*, 556 F.3d 797, 802 (9th Cir. 2009)

This Court reviews de novo whether a punitive damages award violates the Due Process Clause, *Arizona v. ASARCO LLC*, 773 F.3d 1050, 1054 (9th Cir. 2014) (en banc), and reviews the jury's decision to award punitive damages for substantial evidence, *Kaffaga v. Estate of Steinbeck*, 938 F.3d 1006, 1013 (9th Cir. 2019).

ARGUMENT

I. HARDEMAN'S CLAIMS ARE PREEMPTED BY FEDERAL LAW

The Supremacy Clause provides that federal law "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. Where state and federal law "directly conflict," state law—including state common law tort claims—must give way. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011). As relevant here, state law is preempted when Congress enacts a statute "containing an express preemption provision" that bars the state rule at issue, *Arizona v. United States*, 567 U.S. 387,

399 (2012), or when it would be "impossible for a private party to comply with both state and federal requirements," *PLIVA*, 564 U.S. at 618.

Both express preemption and impossibility preemption principles bar this suit. National uniformity of pesticide labeling is a bedrock principle of FIFRA. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 n.26 (2005). An applicant intending to register a pesticide for sale must submit for EPA approval any labeling that will accompany the pesticide. 7 U.S.C. §136a(c)(1)(C). Once that labeling is approved, the manufacturer generally may not change it without prior EPA approval. 40 C.F.R. §§152.44, 152.46. FIFRA expressly prohibits states from "impos[ing]" any labeling requirement "in addition to or different from" federal requirements. 7 U.S.C. §136v(b). And a pesticide that is sold with any labeling that is "false or misleading in any particular" is misbranded in violation of federal law. *Id.* §§136(q)(1), 136j(a)(1)(E); *see id.* §136*l* (penalties for selling misbranded pesticides).

Those provisions make clear that Hardeman's claims are preempted by FIFRA.[10] Hardeman contends that Monsanto was required to change its pesticide

[10] Hardeman brought negligence and strict-liability failure-to-warn claims expressly premised on Monsanto's alleged breach of a state-law duty to warn. *See* ER1695-1696. The jury also found Monsanto liable on a design-defect claim. ER1680. But as the district court explained, Hardeman did not genuinely press any design-defect claim separate and apart from "the absence of a warning," and so the jury's verdict necessarily rested entirely on an alleged failure to warn. ER15. To the extent Hardeman intended to rely on any design-defect theory *other* than the

labeling to warn consumers about the supposed danger of cancer from exposure to glyphosate. But having determined that glyphosate does not pose a cancer risk to humans, EPA has long approved Roundup's labeling *without* such a warning, and so any state-imposed duty to include such a warning would be a labeling requirement "in addition to or different from" FIFRA's requirements. Moreover, EPA's recent letter—issued after a comprehensive review of the science regarding glyphosate—confirms what has been evident for decades: Manufacturers *may not* add the warning that Hardeman seeks. *See supra* pp. 9-10. Under federal law, Roundup would be *misbranded* if it were sold with that warning.

Whether analyzed as a matter of express or impossibility preemption, the conclusion is the same. EPA has long concluded that a label warning that glyphosate is carcinogenic is not appropriate under FIFRA. Monsanto therefore cannot be compelled by state law to add such a warning.

A. FIFRA Requires Uniform Labeling Of Pesticides And Forbids States From Adding Labeling Requirements

FIFRA charges EPA with "safeguarding the public interest" by ensuring that pesticides are safe for human beings. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). No pesticide may be sold in the United States unless and until EPA has "registered" the pesticide—that is, approved it for sale after an extensive

---

absence of a warning, the district court expressly held that "judgment as a matter of law would be entered for Monsanto" on that claim. *Id.*

scientific review and a determination that the pesticide will not pose an unreasonable risk to human health. *See supra* pp. 5-7 (explaining EPA review requirements); 7 U.S.C. §§136(bb), 136a(a), (c)(1)(F), (c)(2)(A); 40 C.F.R. §§152.20, 158.200.

As part of its registration decision, EPA exercises comprehensive control over the labeling of federally registered pesticides. Applicants must submit to EPA a "complete copy" of the proposed "labeling of the pesticide." 7 U.S.C. §136a(c)(1)(C). The proposed labeling must comply with EPA's extensive regulations governing the contents of pesticide labeling. *See* 40 C.F.R. §156.10. Chief among these, proposed labeling must include detailed "[h]azard and precautionary statements" about the pesticide's impact on human health. *Id.* §§156.10(a)(1)(vii), 156.60. EPA will not register a pesticide unless it determines that its labeling "compl[ies] with" FIFRA's "requirements." 7 U.S.C. §136a(c)(5)(B). And once labeling is approved by EPA, virtually all substantive changes to the labeling must likewise be approved by EPA. 40 C.F.R. §§152.44, 152.46; *see also* 7 U.S.C. §136a(c)(9)(C).

Compliance with EPA's labeling requirements is essential for pesticide manufacturers. FIFRA makes it illegal to sell a pesticide with labeling that reflects "claims" not approved by EPA, 7 U.S.C. §136j(a)(1)(B), and likewise makes it illegal to make a pesticide that has been "misbranded," *id.* §136j(a)(1)(E)—that is,

a pesticide with labeling containing a "false or misleading" statement, *id.* §136(q)(1)(A). Such conduct exposes the violator to a wide range of enforcement actions, including an order that the violator stop selling the product, a civil penalty, and imprisonment. *Id.* §§136k, 136*l*.

Finally, FIFRA specifically delineates the "[a]uthority of states" in pesticide regulation. 7 U.S.C. §136v. Although states may generally "regulate the use or sale" of a federally registered pesticide, states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those" required by FIFRA. *Id.* §136v(b). As the Supreme Court explained in *Bates*, this limitation on state authority ensures "uniformity" in the labeling of federally registered pesticides. *See* 544 U.S. at 452 n.26. Absent such a limitation, pesticide manufacturers might face "50 different labeling regimes," *id.* at 452, fracturing interstate commerce in pesticides and making it impractical for manufacturers to sell their products nationally.

B. Hardeman's Claims Are Expressly Preempted By FIFRA

Hardeman's claims all rest on the premise that Monsanto violated a state-law duty to warn consumers that glyphosate may cause cancer, and seek to impose liability for Monsanto's failure to include a warning on Roundup labeling that the product may be a carcinogen. But federal law imposes a different requirement: Monsanto *cannot* include such a warning on Roundup labeling. The purported

state-law duty to warn on which the verdict rests thus imposes a "requirement[] for labeling or packaging" that is "in addition to or different from" that required by EPA under FIFRA, 7 U.S.C. §136v(b), and so is preempted by FIFRA.

The Supreme Court's decision in *Bates* established a two-part test to determine whether a state law claim is expressly preempted by § 136v(b). First, the state law must impose a "requirement for labeling and packaging"; and second, that requirement must be "in addition to or different from" a requirement imposed under FIFRA. 544 U.S. at 444 (quotation marks and emphasis omitted).

Hardeman's claims satisfy both parts of this test. First, there can be no dispute that the state-law duty to warn that Hardeman has invoked would impose a state-law "requirement[] for labeling or packaging"; indeed, the Supreme Court held as much in *Bates*. *See* 544 U.S. at 446. Second, that requirement is "in addition to or different from" those requirements imposed by EPA under FIFRA. On the basis of its recurring determinations that glyphosate is not carcinogenic, EPA repeatedly registered Roundup for sale and determined that no cancer warning was necessary or appropriate on its labeling. Indeed, EPA recently confirmed what has long been apparent from the agency's approvals and scientific determinations: A cancer warning would be "false and misleading" and would make the product "misbranded pursuant to" 7 U.S.C. §136j(a)(1)(E). August 7

Letter at 1. Any divergent state-law labeling requirement is accordingly preempted by FIFRA.

That conclusion is fully consistent with *Bates*. In *Bates*, a group of farmers brought a state-law suit against a pesticide manufacturer for failing to warn them that the pesticide would stunt their crops. 544 U.S. at 435. The manufacturer argued that the suit was barred by §136v(b), because the verdict would require a change to the pesticide's labeling, regulation of which was entrusted to EPA. *Id.* at 448. The Court concluded that some tort suits—suits that *parallel* federal law, rather than seek to surpass it—could be brought notwithstanding §136v(b). *Id.* at 447. *Bates*, the Court explained, might be such a case: 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, *id.* at 440, and it was not clear whether the plaintiffs' state-law claims effectively sought to enforce FIFRA or to impose requirements that went beyond it, *id.* at 453.

This case presents a very different situation—a suit in which the warning imposed by state law has not only been considered by the agency, but has also been repeatedly rejected by it. As the *Bates* Court explained, where EPA determines that a pesticide should be accompanied by one warning (such as "CAUTION") but a jury concludes under state law that the label should include a more aggressive one (such as "DANGER"), then the state-law rule on which the

verdict rests "would be pre-empted" by §136v(b). 544 U.S. at 453. That is so because, by selecting a less aggressive warning, EPA necessarily rejected the more aggressive warning.

The same principle applies here. EPA cannot register a pesticide for sale in the United States without determining that it does not pose an unreasonable risk to human health, and in doing so it determines exactly what warnings are required on the pesticide's labeling—and what warnings are *not* warranted. *See supra* pp. 5-6, 26-28. EPA has for decades exercised that authority by registering glyphosate without the warning Hardeman seeks, having fully considered the question whether it causes cancer and having analyzed all of the evidence on which Hardeman relied. EPA has thus concluded that glyphosate's labeling should *not* contain the warning that state law here purportedly requires, making clear that that state-law requirement is preempted under §136v(b).

This case is analogous to *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), in which the Supreme Court, applying a similarly worded preemption provision, held that FDA's premarket approval of a medical device—a process that included safety and labeling review—preempted a state tort suit alleging defects in that device. As the Court explained in *Riegel*, "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the

approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323. Much the same is true here. When EPA approves pesticide labeling, it determines that *that labeling*, not labeling more aggressive or subdued, provides appropriate warnings, and a manufacturer may not change the labeling without prior EPA approval.

The Court in *Riegel* distinguished its decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), where it had concluded that a state-tort suit was not preempted because the agency had *not* reviewed the device for effectiveness and safety (but had instead approved it via an alternative pathway). *Id.* at 493. *Lohr*, therefore, is analogous to *Bates*, in which EPA *had not* reviewed the pesticide or its labeling for any claims of efficacy. Here, by contrast, EPA *has* frequently examined glyphosate's effects on human health and has determined that no cancer warning is appropriate. As in *Riegel*, Hardeman's claims are thus preempted because they seek to impose a different and incompatible state-law requirement.

C. Hardeman's Claims Are Also Impliedly Preempted By FIFRA

Hardeman's state-law claims are also preempted because it would be "impossible" for Monsanto to comply with both federal law and the state-law duty to warn on which the verdict rests. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009); *PLIVA*, 564 U.S. at 618. That is so for two reasons. First, EPA's repeated determinations that glyphosate does not cause cancer—and its express affirmation

that including a cancer warning on glyphosate-based products would violate FIFRA—establish that Monsanto could not have added such a warning to Roundup's labeling. Second, even absent EPA's prior conclusion, Monsanto lacked the authority to change Roundup's label without EPA's prior approval.

1. There is no doubt that EPA would refuse to allow Monsanto to make the labeling change that state law here purportedly requires. Indeed, EPA has made clear that adding a cancer warning would render glyphosate "misbranded" in violation of federal law. *See supra* p. 10. That agency determination conclusively establishes that it is impossible for Monsanto to comply with both state and federal law.

The Supreme Court's decisions in *Wyeth v. Levine* and *Merck Sharp & Dohme v. Albrecht*, 139 S. Ct. 1668 (2019), establish that Hardeman's claims are preempted because there is "clear evidence" that EPA, being fully informed, would refuse to allow Monsanto to make the labeling change that state law here purportedly requires. In *Wyeth*, the Court considered whether it was impossible for the manufacturer of a brand-name drug to comply with both a state duty to warn of adverse health effects and federal labeling law. 555 U.S. at 563. The Court concluded that, because federal law allowed the manufacturer to make some changes to the drug label without the agency's prior approval—and because the manufacturer had not provided "clear evidence" that the agency would have

rejected the proposed warning had the manufacturer tried to add it—the plaintiff's claim was not preempted. *Id.* at 571.

Merck elaborated on *Wyeth*'s "clear evidence" standard. The Court explained in *Merck* that a manufacturer can establish "impossibility pre-emption" under *Wyeth* if (1) the agency was "fully informed" of "the justifications for the warning" the plaintiff demands, (2) the agency has "informed the … manufacturer that [it] would not approve changing the … label to include that warning," and (3) the agency's action "carr[ies] the force of law." 139 S. Ct. at 1678-1679.

Each of the *Merck* conditions is met here. First, EPA was "fully informed" regarding "the justifications for the warning required by state law"—*i.e.*, the evidence that glyphosate is allegedly carcinogenic—when it determined that no cancer warning was warranted. 139 S. Ct. at 1678. As described above, the agency has repeatedly undertaken in-depth scientific reviews of the evidence on glyphosate's safety, and has concluded that it is not carcinogenic. *See supra* pp. 6-10. Each time, EPA's determination was based on an extensive review of scientific evidence, and the most recent determination (which followed a lengthy opportunity for public comment) was made after all of the evidence of glyphosate's alleged carcinogenicity cited in the complaint became public. Indeed, as part of EPA's registration review process, the agency evaluated every study on which Hardeman's experts relied, and more. *See supra* pp. 8-9.

Second, EPA has repeatedly indicated that it "would not approve changing" Roundup's labeling to include a cancer warning. *Merck*, 139 S. Ct. at 1678. EPA has done so through its consistent findings that glyphosate is not carcinogenic and its consequent determinations in the course of registration decisions that no cancer warning is warranted. EPA's recent letter informing glyphosate registrants that it would not approve the addition of a cancer warning to product labels underscores what has been true for decades: EPA does not believe glyphosate is a carcinogen, EPA views a cancer warning in these circumstances as false and misleading, and EPA "would not approve changing the [product's] label to include" such a warning. *Id.*

Finally, EPA's decision to register a pesticide and approve its labeling "carr[ies] the force of law." *Merck*, 139 S. Ct. at 1679. EPA's exercise of its authority to interpret FIFRA's misbranding provision when reviewing labeling in the course of registration decisions "has practical and significant legal effects." *Reckitt Benckiser, Inc. v. EPA*, 613 F.3d 1131, 1138 (D.C. Cir. 2010); *see* 7 U.S.C. §136a(c)(5). The August 7 Letter confirms as much: By telling registrants of glyphosate-based pesticides, including Monsanto, that EPA "will no longer approve labeling that includes" a warning statement that would satisfy state law, *see* August 7 Letter at 2, the agency specifically invoked the authority delegated to

it by FIFRA to determine what does and does not qualify as misbranding under the statute.

In short, Monsanto has done exactly what the Supreme Court described in *Wyeth* and *Merck*. It has proffered clear evidence that, had it sought EPA approval to change Roundup's labeling to accommodate state law, the agency would have rejected its request. It is thus impossible for Monsanto to comply with both federal and state law, and under the Supremacy Clause, state law must give way.

2. Hardeman's claims are impliedly preempted for another reason: Under FIFRA, Monsanto lacked the authority to make a unilateral change to Roundup's label.

PLIVA held that a state-law failure-to-warn claim is preempted where federal law does not permit a manufacturer to make a unilateral decision (*i.e.*, without prior agency approval) to enact the labeling change state law requires. 564 U.S. at 617-618. In that case, manufacturers of generic drugs argued that 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 label approved by the FDA for the equivalent brand-name drug. *Id.* at 617. The Court agreed and held that, even assuming the manufacturer could ultimately have persuaded the FDA to adopt state-law compliant labeling, it was nonetheless "impossible for [the manufacturers] to comply with both state and federal requirements." *Id.* at 618.

The same is true here. Like the generic drug manufacturers in *PLIVA*, a pesticide manufacturer may not change substantive aspects of its product's labeling without the agency's prior approval.[11] To change its labeling, a pesticide manufacturer must submit an amended registration application—that is, a request that the agency re-register the pesticide in full, including the submission of all data relevant to the change—and that change must be approved by EPA before the new labeling may be used. 40 C.F.R. §§152.44(a), 152.50. Monsanto is thus in the same position as the manufacturers in *PLIVA*: "[S]tate law impose[s] a duty on [it] to take a certain action"—*i.e.*, unilaterally change its label to add a warning—but "federal law bar[s] [it] from taking that action." 564 U.S. at 624.[12]

3. The district court gave several reasons for rejecting Monsanto's impossibility-preemption arguments, all of which are erroneous. ER27-29. First,

---

[11] Although a pesticide manufacturer may make certain changes to the label via "notification" (or, in rare instances, without any notification at all), *see* 40 C.F.R. §152.46; EPA, Office of Pesticide Programs, *Pesticide Registration Notice 98-10*, at 2-14 (Oct. 22, 1998), https://tinyurl.com/yejwzhkt, that streamlined process is limited to "minor modifications," such as the change of a pesticide's brand name or the addition of bilingual labeling, *id.* at 2, 13. Adding a warning about cancer would hardly qualify as a "minor modification."

[12] *Bates* is not to the contrary. That case concerned an efficacy warning, not a safety warning, and the Court emphasized that EPA had since 1978 waived manufacturers' obligation to confirm claims about their pesticides' efficacy. *See* 544 U.S. at 440. Therefore, unlike Monsanto here, the manufacturer in *Bates* could have changed efficacy claims on its labeling without prior approval of the agency.

the court suggested that the Supreme Court's reasoning in *Bates*, which focused on and rejected the manufacturer's express preemption arguments, implicitly cast doubt on whether implied preemption is even possible under FIFRA. ER27-28. That is incorrect. The Supreme Court has long held that "the existence of an 'express preemption provisio[n] does not bar the ordinary working of conflict preemption principles.'" *Arizona*, 567 U.S. at 406; *see also Geier v. American Honda Motor Co.*, 529 U.S. 861, 869-872 (2000). Thus, even though FIFRA contains an express preemption provision, impossibility-preemption principles are fully applicable as well.

The district court also concluded that *Bates* "necessarily rejected the possibility of implied preemption" because, in the court's view, although *Bates* "centered on the scope of FIFRA's express preemption provision, the implied preemption question was also before the court." ER27-28. But the scope of FIFRA's express preemption provision was the only question resolved by the Supreme Court, which did not cite or rely on principles of implied preemption. *See* 544 U.S. at 440-441.

Second, the district court reasoned that, because FIFRA allows states to *ban* federally registered pesticides, California must "surely" be able to "impose state-law duties that might require Monsanto to seek EPA approval" before continuing to sell Roundup in the state. ER28-29. That conclusion is wrong as well. That a

state may regulate the *uses* of a federally registered pesticide pursuant to §136v(a) does not mean that it must also have the authority to impose labeling requirements. Such an outcome would run directly counter to §136v(b), which prohibits a state from imposing such labeling requirements where they conflict with the federal label. *See Bates*, 544 U.S. at 452 n.26 (citing "the industry's need for uniformity" in labeling pesticides in a nationwide market as impetus for this provision).

In any event, the Supreme Court has rejected the theory that a manufacturer could comply with conflicting state and federal laws simply by "ceas[ing] to act" at all (such as by ceasing to sell its products within a state). *See Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013). Such a theory, the Court explained, is "incoheren[t] … when viewed through the lens of" the Court's impossibility decisions, because "[i]n *every* instance in which the Court has found impossibility pre-emption, the 'direct conflict' between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting." *Id.* If that option defeated a claim of impossibility preemption, the Court explained, "the vast majority—if not all—of the cases in which the Court ha[d] found impossibility pre-emption[] were wrongly decided." *Id.* at 489. The fact that Monsanto could simply stop selling Roundup in California, consistent with FIFRA, thus "is irrelevant" to the analysis. *Id.* at 490.

II. THE DISTRICT COURT MISINTERPRETED THE *DAUBERT* STANDARD IN ADMITTING THE CAUSATION OPINIONS OF HARDEMAN'S EXPERTS

Hardeman's suit should never have gone to the jury because his expert opinions on the central issue in the case—whether glyphosate caused Hardeman's illness—should not have been admitted. The district court admitted that flawed testimony only because it misread this Circuit's *Daubert* decisions and failed to exercise its gatekeeping responsibilities properly.

Hardeman had the burden to prove that exposure to glyphosate caused his non-Hodgkin's lymphoma. This required Hardeman to establish that (1) glyphosate, more likely than not, can cause non-Hodgkin's lymphoma in humans (general causation); and (2) glyphosate, more likely than not, caused *his* cancer (specific causation).

Hardeman's experts, however, could not provide a reliable methodology at either step. As to general causation, they dismissed "the most powerful" evidence, a highly regarded study examining farmers' exposure to pesticides, *see* ER72-74, 77 (discussing the Agricultural Health Study), and relied instead on cherry-picked data from flawed studies to support their conclusions. As to specific causation, they did not appropriately address either the fact that more than 70% of non-Hodgkin's lymphoma cases, including for Hardeman's subtype, ER193-194, are idiopathic (*i.e.*, they develop for unknown reasons), or that Hardeman had lived with hepatitis C, a known cause of non-Hodgkin's lymphoma, for decades. Given

these facts, the experts needed some basis for attributing *Hardeman's* cancer to glyphosate, but they offered nothing beyond guesswork.

The district court rightly expressed its "skeptic[ism]" about the methodologies Hardeman's experts applied at both steps of the inquiry. *E.g.*, ER33, 38. It said the experts' opinions were "borderline" and "sometimes cross[ed] into the realm of junk science," recognizing that they would be inadmissible under the interpretation of *Daubert* applied by other Circuits. *See* ER36-39; *see also* ER50 (underlying scientific evidence was "rather weak" and "too equivocal"). Nonetheless, the district court admitted the experts' opinions under the theory that "district courts in the Ninth Circuit must be more tolerant of borderline expert opinions than in other circuits." ER37.

Admitting this flawed testimony was error. This Court does not employ a lower *Daubert* standard than other Circuits. Because Hardeman had no other evidence sufficient to prove causation, Monsanto was entitled to judgment as a matter of law on all of Hardeman's claims. *See Weisgram v. Marley Co.*, 528 U.S. 440, 454-456 (2000).

A. The District Court Misinterpreted This Court's *Daubert* Standard

Daubert requires district courts to perform a "gatekeeping" role to scrutinize "whether the reasoning or methodology underlying [an expert's] testimony is scientifically valid and … whether that reasoning or methodology properly can be

applied to the facts in issue." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592-593 (1993). In other words, the district court must probe "whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1316-1317 (9th Cir. 1995) ("*Daubert II*"). In particular, when an expert presents scientific data in support of her conclusion, the court must explore whether "there is simply too great an analytical gap between the data and the opinion proffered," such that the conclusion is "connected to existing data only by the *ipse dixit* of the expert." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *see also Daubert*, 509 U.S. at 597 ("Conjectures that are probably wrong are of little use … in the project of reaching a quick, final, and binding legal judgment[.]"). This Court has recently reiterated this point, recognizing that an expert's opinion must be based on "'reasonable extrapolations'" from the underlying data. *Murray v. Southern Route Mar. SA*, 870 F.3d 915, 923 (9th Cir. 2017).

The district court interpreted this Court's *Daubert* decisions to be significantly more forgiving of experts' "extrapolations" than cases like *General Electric* and *Murray*, as well as *Daubert* case law in other Circuits, allow.[13] Citing

[13] Not only is the *Daubert* standard applied by the district court wrong under this Court's precedent, it is also inconsistent with the tests in other Circuits. *See* ER56-57 (citing *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858

Wendell v. GlaxoSmithKline LLC, 858 F.3d 1227 (9th Cir. 2017), and *Messick v. Novartis Pharmaceuticals Corp.*, 747 F.3d 1193 (9th Cir. 2014), the district court believed there was "slightly more room for deference to experts" that "could matter" in "close" cases, ER56-57 (general causation), and that it was required to admit "borderline expert opinions" that may not pass muster under a more rigorous approach to *Daubert*, ER36-37 (specific causation).

The district court also suggested that this Court allows "'art'" as a separate category of admissible expert testimony. ER36-38 (quoting *Wendell*, 858 F.3d at 1237). "Art," the district court indicated, exists on a spectrum between junk science and science, and encompasses experts' judgment based on "'clinical experience'" (even if unsupported by scientific literature). ER37. The district court believed that "the Ninth Circuit's recent decisions reflect a view that district courts should typically admit" even those opinions "that lean strongly toward the 'art' side of the spectrum." ER37.

As explained in further detail below, the district court relied on this misreading of *Wendell* and *Messick* to allow Hardeman's experts to fill the gaps in

---

F.3d 787, 800 (3d Cir. 2017), and *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1244-1245 (11th Cir. 2005)), ER36-38 (citing *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 677-678 (6th Cir. 2010), and *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 892 F.3d 624, 643-645 (4th Cir. 2018)). None of the cases on which the district court relied suggests that this Court applies a more lenient *Daubert* standard than other Circuits.

the data with conclusions based on their subjective judgments. *See infra* pp. 40-63. On general causation, the district court allowed Hardeman's experts to rely on findings that were demonstrably flawed—reflecting an analytical gap between the data and the experts' testimony. ER49, 51. The court warned that Hardeman "appear[s] to face a daunting challenge at" specific causation. ER51. But it again deferred to the experts' subjective opinions on specific causation, ER33, 37, allowing the experts to testify based on "background education in medicine," "clinical practice," and "subjective decision," without scientific support. ER1131, 1143 (Shustov), ER1115-1116 (Nabhan), ER1095, 1105-1106 (Weisenburger).

The district court fundamentally misread *Wendell* and *Messick* for two reasons. *First*, to the extent this Court permitted the experts in *Wendell* and *Messick* to supplement reliable science with "art," it did so because of exceptional circumstances that are not present in Hardeman's case. For example, in *Wendell*, the plaintiff's experts addressed the cause of an "exceedingly rare" subtype of non-Hodgkin's lymphoma that had only about 200 worldwide reported cases. 858 F.3d at 1236; *see* Wendell Br. 11, No. 14-16321 (9th Cir.), Dkt. 11.[14] Although it was thus impossible to collect the large amount of data necessary to conduct a systematic epidemiological study, the experts explained based on other scientific

[14] Two of the experts in *Wendell*—Shustov and Weisenburger—also testified in this case.

literature that the asserted causal association and mechanism (involving exposure to certain drugs) was "'well known'" (unlike here) and accepted by "'the entire medical community'" in the rare instances where that disease did occur (also unlike here). Wendell Br. 13, 16; *see also Wendell*, 858 F.3d at 1234 (chance of developing cancer without taking the drugs at issue was "one in six million"). Moreover, one expert had the particularly relevant clinical experience of having treated seven patients with the cancer, two of whom were known to have taken the drugs in question. 858 F.3dat 1233-1234.

In *Messick*, this Court similarly held that an expert had offered a "scientific basis" for his causation opinion when he relied on "his own extensive clinical experience" as the basis for specific causation, *as well as* his examination of medical literature and Messick's records. 747 F.3d at 1198. The expert noted that in his decades of experience as a clinician, "'th[e] scenario'" that someone could develop the condition at issue without the drugs in dispute "'just doesn't exist,'" Messick Br. 22-23, No. 13-15433 (9th Cir.), Dkt. 19-1, and thus Messick's use of the drugs leading to her condition was like "oxygen necessary to start a fire," 747 F.3d at 1197.

This case bears no resemblance to *Wendell* or *Messick*. Far from being an "exceedingly rare" cancer, Hardeman's subtype of non-Hodgkin's lymphoma is all

too common, with more than 18,000 new cases each year.[15] And it has been extensively studied; there are numerous epidemiological studies on the association between glyphosate and Hardeman's subtype of non-Hodgkin's lymphoma that obviated the need for any reliance on "art." *See infra* pp. 52-53. Moreover, far from glyphosate being the "oxygen necessary to start [the] fire" that is non-Hodgkin's lymphoma, the district court found that evidence of a positive association between glyphosate and non-Hodgkin's lymphoma was "rather weak" and "too equivocal." ER50, 88-89. Even Hardeman's experts acknowledged that he could have developed his cancer *without* exposure to glyphosate. *See* ER2393-2394 (Weisenburger), ER2318 (Shustov), ER2311 (Nabhan). And his principal trial expert admitted that (1) he could not "identify any peer-reviewed published article stating it is generally accepted that" glyphosate causes Hardeman's subtype of non-Hodgkin's lymphoma, and (2) the amount of exposure to glyphosate sufficient to make it the cause of Hardeman's cancer is a "subjective decision," untethered to scientific literature. ER1095, 1099 (Weisenburger). Although Hardeman's specific causation experts had experience treating patients with Hardeman's subtype of non-Hodgkin's lymphoma, none of them had ever before

[15] Lymphoma Research Foundation, About Lymphoma, Diffuse Large B-Cell Lymphoma, https://tinyurl.com/uos6u7p (last visited Dec. 13, 2019).

identified glyphosate as the cause of a patient's cancer. ER1138 (Shustov), 1111 (Nabhan), 2395 (Weisenburger).

Second, *Wendell* and *Messick* do not allow an expert's opinion to substitute "art" or "clinical experience" for reliable scientific evidence; they merely state that experience can supplement reliable scientific studies and medical literature. In fact, this Court emphasized in *Wendell* that the experts added "their own wealth of experience" to the established medical literature. 858 F.3d at 1236. The same was true in *Messick*, where this Court reiterated that an expert's opinion "'must be founded on more than subjective beliefs or unsupported speculation.'" 747 F.3d at 1198.

Accordingly, *Wendell* and *Messick* provided no basis for the district court to depart from the rigorous scrutiny required by *Daubert*. "Art" "doesn't become 'scientific knowledge' just because it's uttered by a scientist." *Daubert II*, 43 F.3d at 1315-1316. In overreading those cases, the district court abdicated its "'special obligation' to determine the … reliability of an expert's testimony," a role that "is vital to ensure accurate and unbiased decision-making by the trier of fact." *Elsayed Mukhtar v. California State Univ., Hayward*, 299 F.3d 1053, 1063-1064 (9th Cir. 2002), *overruled on other grounds by Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 467 (9th Cir. 2014) (en banc).

B. Under A Proper Application Of *Daubert*, Hardeman's Experts Should Have Been Excluded

Had the district court properly exercised its gatekeeping obligations under *Daubert*, the methodology of Hardeman's experts could not have survived the general causation inquiry, which the court viewed as a "very close question." ER49. Moreover, the methodology would not have "barely inched over the line" of reliability at the specific causation stage. ER33.

Hardeman's primary experts for general causation were Drs. Portier, Ritz, and Weisenburger, all of whom testified at trial. For specific causation, Hardeman offered Drs. Shustov, Nabhan, and Weisenburger at the *Daubert* stage, but called only Weisenburger as his specific causation expert at trial.

1. On general causation, Hardeman's experts' methodology was flawed because they cherry-picked unreliable epidemiological studies that could not support their opinions

To establish general causation, Hardeman had to prove that glyphosate more likely than not can cause non-Hodgkin's lymphoma in humans. ER50, 60. Hardeman's three general causation experts—Portier, Ritz, and Weisenburger—

stated that it can, relying on three kinds of studies: epidemiological,[16] animal,[17] and cellular.[18]

To survive scrutiny under *Daubert*, however, Hardeman had to produce scientifically valid and reliable epidemiological opinions that glyphosate can cause non-Hodgkin's lymphoma. As the district court recognized, animal studies and cell studies are relevant only if there is a sound basis for extrapolating conclusions from those studies to humans in real-world conditions. ER78, 81; *see also Domingo ex rel. Domingo v. T.K.*, 289 F.3d 600, 606 (9th Cir. 2002). For that reason, such studies are generally limited to "supplement[ing]" reliable epidemiological data, ER81, and are not admissible "where contrary epidemiological evidence in humans exists," ER78. Thus, without sound conclusions from reliable epidemiological studies, the animal and cell studies alone were insufficient to satisfy Hardeman's burden to establish causation. *See, e.g.*, *Domingo*, 289 F.3d at 606 ("[T]he district court retains its gatekeeper function in requiring analytical support for the extrapolation from animals to humans.").

---

[16] Epidemiology is "'the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations.'" ER61.

[17] The experts relied on studies investigating cancer in rodents. ER77.

[18] The experts relied on studies investigating the cellular mechanism by which glyphosate could cause cancer. ER81.

Here, the manner in which the experts used the epidemiological evidence to show an association between glyphosate and non-Hodgkin's lymphoma in humans was not reliable. In fact, the experts' treatment of that evidence demonstrated a persistent result-oriented approach, as they systematically favored studies with serious methodological flaws over a gold-standard study that refuted their opinions. As the district court seemed to recognize, the studies on which Hardeman's experts relied could *at most* support a conclusion that "glyphosate exposure is cause for concern," not that glyphosate can cause non-Hodgkin's lymphoma. ER50, 88-89. Had the court applied the proper *Daubert* test, it would not have allowed the general causation question to reach the jury.

a. To support their desired conclusion, Hardeman's experts had to ignore basic principles governing the use of statistics in public health studies, leading them to reach conclusions that were not supported by the underlying evidence. Four important principles are implicated here.

First, reliable epidemiology considers the latency period of the disease (*i.e.*, the expected period between exposure to a substance and the diagnosis of the disease allegedly caused by it). ER70. The minimum latency period for non-Hodgkin's lymphoma is (by a conservative estimate) five to ten years. *Id.* As a result, studies can reliably report on the association between glyphosate and non-

Hodgkin's lymphoma only if they involve individuals exposed to glyphosate more than at least five to ten years before they contract the disease. *Id.*

Second, reliability requires adjusting for confounding variables—other factors that could partially or wholly explain an observed association between the substance and the disease. A common confounder in glyphosate studies, which focus on farmer populations, is exposure to other pesticides used in farming. ER53, 63-64. Failure to adjust for such confounders can result in a false positive result (*i.e.*, an apparent association that is actually due to the confounding variable and not the substance under study).

Third, a study's reliability depends on its structure. As relevant here, cohort studies tend to be more reliable than case-control studies, because cohort studies are prospective—they select a population without the disease of interest, sort the population into exposed and unexposed groups, and follow those groups for a period of time to determine how often the disease occurs. ER72-73. By contrast, case-control studies are retrospective—they select people with and without the disease and compare them based on their past exposure to various environmental factors. ER62. Case-control studies are prone to recall bias (*i.e.*, people with the disease tend to remember greater exposure than those without it). ER72-73. They also tend to be smaller in size. ER1517-1518.

Finally, conclusions from a study are less reliable if the results are not statistically significant. Both cohort and case-control studies use odds, or risk, ratios to measure the association between the substance and condition in question. ER62-63, 73-74. An odds ratio exceeding 2.0 can provide evidence that an individual contracted the disease "'more likely than not'" because of the substance. ER39 (quoting *Cooper v. Takeda Pharm. Am., Inc.*, 191 Cal. Rptr. 3d 67, 98 (Ct. App. 2015)). But this information is statistically significant only if there is a high probability (95%) that a reported odds ratio indicates a true association rather than a sampling error. ER63. Scientists generally disfavor reliance on results that are not statistically significant because of the risk that the association may be due to chance. *Id.*

b. Hardeman's experts offered inadmissible testimony because they systematically focused on isolated findings from studies that suffered from serious flaws, while disregarding the most reliable epidemiological data that contradicted their conclusions.

As the district court acknowledged, "the most powerful evidence regarding the relationship between glyphosate" and non-Hodgkin's lymphoma" was the Agricultural Health Study (AHS), a cohort study conducted by the National Cancer Institute at the National Institutes of Health. ER72-74, 77. That study considered the largest number of non-Hodgkin's lymphoma cases across a broad range of

exposures for the longest time and found "no statistically significant association between glyphosate use and NHL." ER73. AHS also showed no dose-response relationship—*i.e.*, "no evidence of higher rates of [non-Hodgkin's lymphoma] with more days of exposure." *Id*. Despite these important and reliable findings, Hardeman's experts gave the AHS study essentially no weight.[19]

Instead, the experts focused on three case-control studies: De Roos (2003),[20] McDuffie (2001),[21] and Eriksson (2008).[22] Not only were these studies less reliable than AHS because of the flaws inherent to case-control studies, but each contained additional serious flaws.

First, the De Roos study—which analyzed data collected between 1979 and 1986—did not properly account for non-Hodgkin's lymphoma's latency period.

---

[19] The experts' criticisms of AHS only highlight the results-oriented nature of their opinions (and the reasons why they should have been excluded under *Daubert*). For example, although Ritz testified at length about purported methodological failures with the study, she had previously taught the study to her students at UCLA, praising it as a "wonderful study." ER1522; *see Daubert II*, 43 F.3d at 1317 (whether expert "developed their opinions expressly for purposes of testifying" affects reliability of methodology). And while Weisenburger (erroneously) criticized AHS for insufficiently accounting for the latency period of non-Hodgkin's lymphoma, he repeatedly lauded another study that was—if anything—*more* susceptible to the same criticism. *See infra* pp. 53-54 (discussing De Roos study); ER102.

[20] ER1889-1899.

[21] ER1900-1910.

[22] ER1881-1888.

ER65. Non-Hodgkin's lymphoma takes *at least* five to ten years to develop, which means too much of the data were collected too soon after Roundup was introduced to the market in 1974 to render the results of the study reliable. Even Hardeman's experts "implicitly acknowledge[d] that latency could be an issue with" De Roos' results. ER70.

Second, the McDuffie and Eriksson studies failed adequately to consider the effect of other pesticides on an individual's likelihood of developing non-Hodgkin's lymphoma. Specifically, McDuffie did not account for the effect of exposure to pesticides beyond glyphosate *at all*. ER1902. And while Eriksson did provide some results adjusted for the effect of other pesticides, the adjusted results did not show a statistically significant link between glyphosate and non-Hodgkin's lymphoma. ER67. That failure was especially problematic because, as the district court found, farmers who are exposed to pesticides "have long had an elevated risk of NHL, even before glyphosate went on the market." ER53, 65-67. Indeed, the district court noted that the experts' exclusive reliance on those numbers "would be disqualifying." ER98.

The experts' approach—emphasizing studies with serious methodological flaws because the result suited their opinions, while dismissing out of hand a highly regarded study without these same flaws because its conclusions were inconvenient—could not satisfy the *Daubert* standard for reliability. The district

court nonetheless allowed the experts' opinions—based "only [on] the *ipse dixit* of the expert," *General Elec.*, 522 U.S. at 146—because of its mistaken understanding that this Court extends more deference to experts. ER56-57; *see supra* pp. 40-47. The result was that Hardeman's experts presented their causation theories to the jury without reliable epidemiological support, even though Hardeman acknowledged that epidemiology was key to clearing the *Daubert* hurdle. *E.g.*, ER61. Had the district court conducted a proper *Daubert* inquiry, the court would have excluded the experts' opinions and Monsanto would have received judgment as a matter of law.

2. On specific causation, Hardeman's experts' differential diagnosis methodology was fundamentally unreliable because it ruled out likely causes based solely on subjective judgment

When the district court permitted Hardeman's experts to testify on general causation, it observed that "[g]iven how close the question is at the general causation phase," Hardeman "appear[s] to face a daunting challenge at" specific causation. ER51. But rather than subject Hardeman's specific causation experts to rigorous review, the district court admitted their testimony after a cursory analysis, again based on its mistaken reading of *Wendell* and *Messick*. *See* ER36-38; *see supra* pp. 40-47.

To establish that *Hardeman's* cancer was caused by glyphosate rather than some other factor, his experts had to "differentiate Roundup users who developed

NHL because they used the product from Roundup users who would have developed NHL regardless." ER36. Hardeman's experts—Weisenburger, Shustov, and Nabhan—purported to do so based on "differential diagnosis," a technique that starts with "all potential causes, then rules out the ones as to which there is no plausible evidence of causation, and then determines the most likely cause among those that cannot be excluded." *Wendell*, 858 F.3d at 1234; *see also Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1057 (9th Cir. 2003).

Hardeman's experts did not apply differential diagnosis in a credible way. They failed to reliably rule out alternative causes of Hardeman's cancer, including (1) an unknown cause in light of the fact that 70% or more of all cases of non-Hodgkin's lymphoma, including for Hardeman's subtype, are idiopathic and (2) Hardeman's hepatitis C. Instead, they concluded that glyphosate must have caused Hardeman's cancer because he was exposed to too much of it. What qualified as too much exposure, however, was based solely on their speculation. This methodology, which boiled down to *ipse dixit*, could not have survived proper application of *Daubert*.

a. *The experts' approach failed to adequately rule out idiopathy*

A critical problem in Hardeman's methodology was that 70% or more of cases of non-Hodgkin's lymphoma are idiopathic—*i.e.*, have unknown causes. Although differential diagnosis does not require an expert to "completely rule out

the possibility that [an illness] was idiopathic," *Wendell*, 858 F.3d at 1237, an expert cannot ignore idiopathy altogether, *Hall v. Conoco Inc.*, 886 F.3d 1308, 1314 (10th Cir. 2018). Thus, when there is an acknowledged high rate of idiopathy for a particular disease (*i.e.*, most cases arise from *unknown* causes), it is not sufficient for an expert to simply rule out all *known* causes for the disease until only one "plausible" *known* cause remains. *E.g.*, *Hall*, 886 F.3d at 1314-1315; *see also Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 476 (1st Cir. 2016) ("the extraordinary number of idiopathic … cases, coupled with the lack of a reliable means to rule out an idiopathic diagnosis here muted" the reliability of differential diagnosis).[23] Rather, the expert must point to a reason to rule out idiopathy (such as a strong association between the disease and a known risk factor) before she can reliably conclude that the known factor is a substantial cause. *E.g.*, *Wendell*, 858 F.3d at 1235, 1237 (expert could find a "known risk factor" was substantial

[23] Courts routinely require experts applying a differential diagnosis to adequately address idiopathy. *See Tamraz*, 620 F.3d at 671, 675 (reversing admission of differential diagnosis because "unknown (idiopathic) causation … currently accounts for the vast majority of Parkinson's Disease cases, making it impossible to ignore and difficult to rule out"); *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1343 (11th Cir. 2010) (an expert's application of differential diagnosis was unreliable because he could not explain "why potentially unknown, or idiopathic alternative causes were not ruled out"); *Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008) ("Where the cause of the condition is unknown in the majority of cases, Dr. Sprince cannot properly conclude, based upon a differential diagnosis, Bland's exposure to freon was 'the most probable cause' of Bland's exercise-induced asthma.")

cause—despite the fact he "was not entirely able to rule" out the possibility of idiopathy—in light of "literature show[ing] that patients exposed to" the drugs in question were "at an increased risk for" the disease).

Hardeman's experts did not satisfy this requirement. They acknowledged that they could not differentiate Hardeman's non-Hodgkin's lymphoma from idiopathic non-Hodgkin's lymphoma. ER36, 2395 (Weisenburger). Although the district court observed that this deficiency "perhaps … would be the end of the line" for Hardeman in other Circuits, it concluded the experts' approach passed muster under its misreading of *Wendell* and *Messick*. ER36-38.

Given the lack of a strong (and reliable) association between glyphosate and non-Hodgkin's lymphoma, the experts accordingly proceeded with a theory that Hardeman's glyphosate exposure was so high that it *must* have been the cause of his non-Hodgkin's lymphoma. *See, e.g.*, ER39 (district court describing experts' approach). The only substantive basis for the "high exposure" theory were two studies discussed above: McDuffie and Eriksson. *Supra* p. 54. Those studies concluded that for individuals who—like Hardeman—had used glyphosate *more than* two days per year or ten lifetime days, the odds ratio of developing non-Hodgkin's lymphoma was above 2.0. ER40-41; *see also* ER2324 (Weisenburger). The experts, however, could not have reasonably relied on those studies for two reasons.

First, the odds ratios in McDuffie and Eriksson are unreliable because they were not adequately adjusted for the effect of other pesticides. *See supra* p. 54; ER40, 66-67. Thus, Hardeman's experts could not extrapolate Hardeman's risk of cancer attributable to *glyphosate* (as opposed to some other factor, or no discernible factor) from McDuffie and Eriksson, nor could they conclude that glyphosate was more likely than not a substantial cause. The district court agreed, explaining that "it is not scientifically sound" to assign a particular risk to Hardeman based on "the unadjusted numbers from McDuffie and Eriksson." ER39-40.

Second, Hardeman's experts fundamentally misconstrued McDuffie and Eriksson, arguing at the *Daubert* hearing that because Hardeman's exposure was "much higher than [the] floor limits" in McDuffie and Eriksson (*i.e.*, two days per year or ten lifetime days of exposure), his risk ratio must have exceeded 2.0 *even if* other pesticides were taken into account. ER1090-1092 (Weisenburger).[24] As the

[24] This was a late shift in methodology. Initially, all three experts testified that two days per year or ten lifetime days of exposure was enough to establish that glyphosate was a substantial risk factor. ER1139 (Shustov), ER1112-1114 (Nabhan), 1093 (Weisenburger). But after the district court expressed skepticism about this theory during Shustov's and Nabhan's testimony at the *Daubert* hearing, Weisenburger changed his opinion. ER1140 (Shustov), ER1121-1123 (Nabhan), 1093-1096 (Weisenburger). That shift in position was itself a telltale sign that the testimony was questionable under *Daubert*. *See Daubert II*, 43 F.3d at 1322 ("[T]ailoring of the experts' conclusions would, at this stage of the proceedings,

district court explained, however, that view is based on a misreading of the two studies, which reported unadjusted odds ratios based on a sample of individuals who used glyphosate for "*more than*" two days per year or ten lifetime days. ER40-41. In other words, the studies themselves *already* considered "the kind of exposure that Mr. Hardeman had or [even] more." ER1107 (district court questioning Weisenburger).

Accordingly, Hardeman could not have had "higher" exposure than the parameters used in McDuffie and Eriksson. Indeed, the district court found that it would be "junk science" to say that Hardeman's "risk of developing NHL *more than doubled* because he used Roundup *far more than the threshold* of ten lifetime days set by the Eriksson and McDuffie studies." ER39-40 (emphases added). But that was precisely the methodology that Weisenburger offered.

What remained of the experts' reasoning was their "clinical" and "subjective" judgments about the link between glyphosate and Hardeman's illness. ER1095 (Weisenburger), ER1124-1125 (Nabhan), ER1143 (Shustov). Weisenburger attempted to save his opinion by speculating that, "in terms of the way … carcinogenic chemicals work, the more exposure you have, the higher your risk." ER1108 (Weisenburger). That generality flies in the face of all the *adjusted*

---

fatally undermine any attempt to show that these findings were 'derived by the scientific method.'").

epidemiological data cited before the district court, which found no statistically significant dose response between glyphosate and non-Hodgkin's lymphoma. ER65-77; *see also supra* pp. 52-55. Regardless, without any concrete numbers, Weisenburger could not support his specific conclusion that Hardeman was exposed to "enough glyphosate" or that his exposure was "so significant" that his cancer was not idiopathic or due to his decades of exposure to hepatitis C. ER38-39.

In sum, Hardeman's experts engaged in unreliable differential diagnosis because they purportedly ruled out idiopathy based on two flawed studies and their own subjective judgment. Had the district court applied the proper *Daubert* standard, this methodology would never have gone before the jury.

b. *The experts' approach to hepatitis C confirms that they employed a results-oriented methodology*

Because Hardeman's experts wanted to testify that glyphosate must have been a substantial cause of Hardeman's cancer, they barely addressed his hepatitis C.[25] This failure was an independent flaw that rendered their opinions unreliable.

Hepatitis C is an established cause of non-Hodgkin's lymphoma. *See, e.g.*, ER38 n.4 (Hardeman's hepatitis C is a "significant risk factor" for him). Although

[25] *See* ER2324 (Weisenburger report ruling out hepatitis C in a single, conclusory sentence), ER2401 (Nabhan report ruling out hepatitis C in four bullet points), ER2413 (Shustov report ruling out hepatitis C in a single paragraph).

Hardeman carried the hepatitis C virus for 25 to 40 years, his experts dismissed it as a cause of his cancer because of his treatment in 2005-2006. *See* ER2324, ER632-633 (Weisenburger); *see also* ER2401 (Nabhan), ER2413 (Shustov). But the latency period for non-Hodgkin's lymphoma after exposure to hepatitis C ranges from 5 to 35 years (with a median of 15 years). *See* ER1097-1098, 1100-1101 (Weisenburger); *see also* Transcript, No. 3:16-md-02741, Dkt. 2672 at 296 (Nabhan); ER1141-1142 (Shustov). As a result, even if the active virus in his body was successfully eliminated in 2005, he remained vulnerable to cellular damage caused by the virus for many years, including, eventually, non-Hodgkin's lymphoma.

The experts had no real response to the latency problem. Although Weisenburger testified that hepatitis C is unlikely to have caused Hardeman's non-Hodgkin's lymphoma because the treatment "get[s] rid of the virus" and "all the virally infected cells" that pose a risk of cancer, he also acknowledged that hepatitis C can damage cells that eventually turn to cancer regardless of whether the virus remains active. ER1102-1103. Further, as Weisenburger noted, scientific studies showed that treatment only reduces the risk of non-Hodgkin's lymphoma if it starts *shortly after* exposure to hepatitis C. ER456-457, 2392. Here, Hardeman first received treatment for non-Hodgkin's lymphoma *decades* after his exposure to hepatitis C. *See supra* p. 11; ER2391-2392. Thus, Hardeman's experts offered no

reliable testimony to rule out his hepatitis C as the likely cause of his non-Hodgkin's lymphoma.[26]

* * *

Hardeman's experts may be "'distinguished doctor[s],' and '[their] conjecture' about causation may be 'worthy of careful attention' …. But the courtroom is not the place for scientific guesswork, even of the inspired sort." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 672 (6th Cir. 2010). Even if "clinical experience" may supplement reliable science in unique circumstances like in *Wendell* and *Messick*, all that Hardeman's experts brought to the table was their subjective judgment. That does not satisfy *Daubert*, and their testimony should have been excluded.

III. THE DISTRICT COURT ERRED BY ADMITTING EVIDENCE ABOUT THE IARC DETERMINATION WHILE EXCLUDING EVIDENCE OF THE REGULATORY CONSENSUS THAT GLYPHOSATE DOES NOT CAUSE CANCER

The jury's verdict cannot stand for another reason: The district court improperly permitted Plaintiff's experts to buttress their deficient testimony on

[26] Shustov and Nabhan (neither of whom testified at trial) stated that hepatitis C could not have initiated Hardeman's non-Hodgkin's lymphoma after his successful treatment in 2005-2006. ER1126-1129 (Nabhan), 1594-1599 (Shustov). But they ignored the possibility that hepatitis C caused Hardeman to develop cancer *before* his treatment for hepatitis C and that the illness remained undiagnosed until 2015. As even Weisenburger admitted, there is "a period of time before [diagnosis] where [non-Hodgkin's lymphoma] probably is not detectable" that could span decades. ER1097.

causation with misleading appeals to the authority of IARC's hazard classification, and compounded that error by excluding evidence regarding regulators' rejections of IARC's conclusions, which were based on assessments of the same underlying studies.

"[T]he overwhelming majority of" national and international health authorities charged with approving pesticides "have determined [glyphosate] is not a cancer risk." *National Ass'n of Wheat Growers v. Zeise*, 2018 WL 3000488, at *2 (E.D. Cal. June 12, 2018); *supra* pp. 8-9. Against that consensus, a single working group at IARC classified glyphosate as a "probable carcinogen" in 2015. Admission of IARC's conclusion was error by itself, because the minimal probative value of IARC's conclusion was far outweighed by the unfair prejudice and juror confusion it caused. *See* Fed. R. Evid. 403. And the district court rendered that error even more prejudicial by excluding evidence of the regulatory consensus that glyphosate does not cause cancer, which left the jury with a false sense of the importance of IARC's conclusion.

1. IARC's conclusion had minimal probative value on causation. *First*, because IARC conducted none of its own research, *supra* pp. 14-15; ER42, 58, its "broad conclusory language" regarding glyphosate warranted little, if any, weight, *see City of New York v. Pullman Inc.*, 662 F.2d 910, 914-915 (2d Cir. 1981). And because Plaintiff's experts discussed the studies on which IARC relied in great

detail, Plaintiff had a full and fair opportunity to present anything of probative value from those studies to the jury. *See Huskey v. Ethicon, Inc.*, 848 F.3d 151, 161 (4th Cir. 2017) (upholding exclusion of FDA analysis that "simply opined on the work others had done").

Second, IARC's identification of glyphosate as a "probable carcinogen" does not amount to a conclusion that glyphosate actually poses a risk of cancer in human beings. Rather, IARC's classification—*i.e.*, its "hazard identification"—is merely the "first step" of an overall public health assessment and is designed only to "identify cancer hazards even when risks are very low at current exposure levels." ER58. Such a determination does not involve the second necessary step—an actual "risk assessment," which gauges the carcinogenic effects from actual human exposure—which IARC left to "other public health entities." ER50. In other words, IARC's conclusion does not address whether Roundup causes cancer in the real world, much less whether it actually caused *Plaintiff's* cancer. Indeed, the court recognized that IARC's classification was not the sort of inquiry "the jury need[ed] to conduct when deciding whether glyphosate actually causes NHL in people at past or current exposure levels." ER60.

On the other side of the Federal Rule of Evidence 403 balancing, evidence about IARC's determination was highly prejudicial and likely misled the jury. In particular, extensive discussion about IARC's status as an official body of the

World Health Organization, *supra* pp. 16-17, unjustifiably lent Plaintiff's causation evidence "an aura of special reliability and trustworthiness which [was] not … commensurate with its actual reliability." *Pullman*, 662 F.2d at 915 (internal quotation marks omitted); *see also Curtis v. M&S Petroleum, Inc.*, 174 F.3d 661, 673 (5th Cir. 1999) (state environmental agency report "would have been unduly prejudicial due to its apparent official nature"). Admitting the IARC classification created the danger that jurors would "defer to findings and determinations relevant to credibility made by an authoritative, professional factfinder rather than determine those issues for themselves." *United States v. Vasquez*, 540 F. App'x 623, 626-627 (9th Cir. 2013) (citation omitted).

IARC's confusing and broadly worded classification also likely misled the jury into believing that IARC had actually established a strong causal link between cancer and real-world exposure to glyphosate. Although it suggests that IARC established that glyphosate "more likely than not" causes cancer, IARC's use of the term "probable" to designate the cancer threat posed by glyphosate actually has "no quantitative significance." ER60. A layperson cannot reasonably be expected to understand that IARC designations like "probable carcinogen" have a specific, idiosyncratic meaning that does not correspond to actual real-world cancer risk. *See CTIA–The Wireless Ass'n v. City & Cty. of San Francisco*, 827 F. Supp. 2d 1054, 1063 (N.D. Cal. 2011) ("The uninitiated will tend to misunderstand [an

IARC classification of carcinogenicity] as more dangerous than it really is."), *aff'd*, 494 F. App'x 752 (9th Cir. 2012); *see also Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996) (IARC's "threshold of proof" for "assess[ing] the carcinogenicity of various substances" "is reasonably lower than that appropriate in tort law").

2. None of the district court's efforts to minimize that prejudice redeemed its error. Indeed, those efforts compounded the misleading and prejudicial nature of the IARC evidence, resulting in further prejudice.

The court purported to balance admission of IARC's conclusion by allowing the jury to hear (1) EPA's conclusion that glyphosate is likely not a human carcinogen and (2) fleeting impeachment evidence about two European agencies' responses to one of Plaintiff's expert's criticisms. *See supra* pp. 14-17. But that suggested at most that the conflicting views of IARC and EPA were equally supported and in equipoise. The district court excluded the critical information that IARC's classification was an outlier because virtually every regulatory agency that studied the issue—including not just EPA and two European Union agencies but the national regulatory authorities of Australia, Canada, Germany, Japan, and New Zealand—had *expressly rejected* IARC's determination. *See supra* p. 9. The district court's "rulings, in combination"—both admitting IARC's classification and withholding that vital context—"assured that the jury would be provided with

a one-sided picture of" scientific views on glyphosate's carcinogenicity, which was misleading. *United States v. Waters*, 627 F.3d 345, 357 (9th Cir. 2010).

The court offered no justification for that exclusion apart from a conclusory footnote stating that such evidence would have been "cumulative." ER16 n.5; *see also* ER46-47 (excluding foreign regulators' evidence before causation phase without explanation). But those agencies' findings were far from "*needless[ly]* … cumulative," Fed. R. Evid. 403 (emphasis added)—a category limited to evidence that "adds very little to the probative force of the other evidence in the case, so that if it were admitted its contribution to the determination of truth would be outweighed by its contribution to the length of the trial," *United States v. Williams*, 81 F.3d 1434, 1443 (7th Cir. 1996). Rather, the fact that regulatory reaffirmations of glyphosate's safety had "accumulated" in response to IARC was precisely what rendered that evidence crucial, because only the full regulatory picture would show the jury that IARC's conclusion stood alone and so was entitled to little weight. *See United States v. Kizeart*, 102 F.3d 320, 325 (7th Cir. 1996) (testimony of third government witness on same subject was "far from needless" because it further strengthened impeachment of defense witness). And the court's error was particularly grave given its recognition that IARC's classification was only a preliminary hazard identification, whereas the "other public health entities" whose findings the court excluded had conducted the more relevant risk assessment

necessary to provide a complete public health assessment of glyphosate's carcinogenicity. ER50.

3. The district court's erroneous admission of IARC evidence cannot be saved by its boilerplate instruction that the jury "should not defer" to the conclusions of IARC, EPA, or foreign regulators. ER1722. That instruction was "neither as forceful nor as comprehensive as warranted under the circumstances." *B.K.B. v. Maui Police Dep't*, 276 F.3d 1091, 1105 (9th Cir. 2002). It could not mitigate Plaintiff's reliance on IARC as a crutch to convince the jury that its theory of causation had the imprimatur of the worldwide scientific community. *See* ER189, 991-992 (Plaintiff's opening and closing statements).

Nor was the court's error harmless. The erroneous admission of evidence is harmless only if it is "'more probable than not that the erroneous admission of the evidence did not affect the jury's verdict.'" *United States v. Ramirez-Robles*, 386 F.3d 1234, 1244 (9th Cir. 2004). Here, the unfair benefit Hardeman gained by presenting his causation evidence as supported by the finding of an international body of cancer experts was surely enough to push the jury over the line. IARC's classification endowed Hardeman's "borderline" expert evidence with an air of authority that encouraged the jury to credit that testimony despite his experts' disregard for the most reliable epidemiological study (AHS) in favor of less

rigorous studies and failure to rule out idiopathy and other potential causes of his disease. *See supra* pp. 48-63.

IV. THE DISTRICT COURT'S CAUSATION INSTRUCTION MISSTATED THE LAW AND CONFUSED THE JURY

For five days, the jury deliberated on whether Hardeman had proven that Roundup caused his non-Hodgkin's lymphoma. The jury's work was made substantially more difficult by the district court's decision to provide a causation instruction that both contravened California law and permitted Hardeman to prevail on a theory of liability that he had expressly disclaimed. Specifically, even though Hardeman's experts told the jury that they had definitively ruled out all non-Roundup causes for Hardeman's cancer, *see supra* pp. 17-18, 55-63, the court instructed the jury to find for Hardeman even if it concluded that Roundup *and* some other factor could each, entirely independently, have caused his non-Hodgkin's lymphoma:

> To prevail on the question of medical causation, Mr. Hardeman must prove by a preponderance of the evidence that Roundup was a substantial factor in causing his non-Hodgkin's lymphoma. A substantial factor is a factor that a reasonable person would consider to have contributed to the harm. It must be more than a remote or trivial factor. It does not have to be the only cause of the harm. *Subject to the additional instructions below*, conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct.
>
> *The following additional instructions apply if you believe that two or more NHL-causing factors operated independently on Mr. Hardeman:*

> If you conclude that Mr. Hardeman has proven that his exposure to Roundup was sufficient on its own to cause his NHL, then you must find for Mr. Hardeman *even if you believe that other factors were also sufficient on their own to cause his NHL*. On the other hand, if you conclude that Mr. Hardeman has not proven that his exposure to Roundup was sufficient on its own to cause his NHL, then you must find for Monsanto.

ER1721 (emphasis added); *see* ER172-173 (oral instruction). Those instructions—which prompted objections from both parties—were legally erroneous, confusing, and prejudicial to Monsanto.

First, as a matter of law, the district court should not have included the second and third paragraphs at all. Under California law, a plaintiff must prove that a defendant's negligence was "a substantial factor in bringing about the injury." *Rutherford v. Owens-Ill., Inc.*, 941 P.2d 1203, 1214 (Cal. 1997); *see also* Cal. Civ. Jury Instruction ("CACI") 430 (California pattern substantial-factor instruction). This "substantial factor" test requires the plaintiff to prove that *but for* the defendant's conduct, the harm would not have occurred. *See Viner v. Sweet*, 70 P.3d 1046, 1051 (Cal. 2003). It applies in all cases except the "exceptional situation" where the injury may have resulted from concurrent independent causes. *See Major v. R.J. Reynolds Tobacco Co.*, 222 Cal. Rptr. 3d 563, 579 (Ct. App. 2017); *Xavier v. Philip Morris USA Inc.*, 787 F. Supp. 2d 1075, 1080 (N.D. Cal. 2011). "Concurrent independent causes" are "multiple forces

operating at the same time and independently, each of which would have been sufficient by itself to bring about the harm." *Viner*, 70 P.3d at 1051.

Because of the tension between these two tests—one requiring that an injury be traced to a single source and the other contemplating that an injury could be caused by multiple sources operating independently—the Judicial Council of California has warned judges *not* to instruct a single jury on both theories. *See* CACI 430, Directions for Use (May 2018) ("[D]o not include the [but-for test] in a case involving concurrent independent causes."). The district court ignored that guidance. Instead, the court first told the jury that if it concluded Hardeman would have developed non-Hodgkin's lymphoma regardless of Monsanto's actions, it could not find Monsanto liable—and then, two sentences later, told it just the opposite. As even Hardeman's counsel pointed out in objecting to this instruction, the language was "internally inconsistent," "likely [to] confuse the jury," and would not be able to "withstand appellate scrutiny." ER1730.

Moreover, neither party pursued the "concurrent independent cause" theory of liability at trial; in fact, Hardeman actively lobbied the jury to reject it. As discussed above, Hardeman's experts used differential diagnosis to "rule out" any cause of Hardeman's non-Hodgkin's lymphoma other than Roundup. *See supra* pp. 55-63. Hardeman never presented evidence suggesting that multiple factors independently could have caused his cancer, and indeed, the district court

prohibited him from making that argument because it was not supported by the evidence at trial. ER236, 307; *see also* ER262. Nevertheless, the court instructed the jury to find Monsanto liable if it was persuaded by that very theory, an opening Hardeman's counsel seized on in her closing statement. ER182-183. Put another way, Hardeman spent two weeks trying to convince the jury that Roundup alone caused his non-Hodgkin's lymphoma, but the court instructed the jury to find in Hardeman's favor even if it found that Roundup was just one potential cause of his cancer.

The district court's erroneous and confusing instruction effectively lessened Hardeman's burden of proof by permitting him to prevail on a theory of liability that he had expressly disclaimed. And it was prejudicial to Monsanto, for it was "reasonably probable that a result more favorable to the appealing party would have been reached in the absence of error." *Mitchell v. Gonzales*, 819 P.2d 872, 880 (Cal. 1991); *see Soule v. General Motors Corp.*, 882 P.2d 298, 317 (Cal. 1994). The issue of causation was the only question presented to the jury in Phase One of the bifurcated proceedings. Nevertheless, the jury deliberated for *five days*, suggesting a very real struggle over how it should apply the law to the facts of this case—a task made more confusing by the court's misguided and contradictory instructions.

V. HARDEMAN'S FAILURE-TO-WARN CLAIMS FAIL AS A MATTER OF LAW

To prevail on his failure-to-warn case, Hardeman was required to prove that the purported link between Roundup and cancer 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." *Anderson v. Owens–Corning Fiberglas Corp.*, 810 P.2d 549, 558 (Cal. 1991). The evidence Hardeman presented at trial did not satisfy that burden. At the time Hardeman stopped using Roundup in 2012, Transcript, No. 3:16-md-02741, Dkt. 3112 at 1036, and when he was diagnosed with non-Hodgkin's lymphoma in February 2015, ER2294, the prevailing scientific view was that glyphosate was *not* likely to cause cancer, *supra* pp. 5-10.

The district court recognized that there was no evidence that Monsanto "was in fact aware that glyphosate caused cancer" at the time of Hardeman's exposure. ER8. Nor was such a link reasonably "knowable" at the relevant time. Before IARC's report issued in March 2015, every regulatory agency to review the scientific evidence had concluded that glyphosate was likely not carcinogenic, and EPA's 2016 examination of 63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies reaffirmed that finding. ER1861. Moreover, what the district court acknowledged was the "most powerful evidence" regarding glyphosate's carcinogenicity—AHS and published studies that relied on

its data—found no association between glyphosate and non-Hodgkin's lymphoma. ER74, 77.

Hardeman produced no evidence to the contrary. IARC's conclusions were announced in March 2015 and published in July 2015, long after Hardeman's alleged exposure and diagnosis. Such a publication cannot constitute evidence of "'generally recognized and prevailing best scientific and medical knowledge'" at the time relevant to Hardeman's failure-to-warn claims. *See Rosa v. Taser Int'l, Inc.*, 684 F.3d 941, 946, 948 (9th Cir. 2012). Even today, IARC remains an outlier among "the overwhelming majority of" national and international health authorities that have reaffirmed since 2015 that glyphosate is not a cancer risk. *National Ass'n of Wheat Growers*, 2018 WL 3000488, at *2. And Hardeman's own expert could not identify "any peer-reviewed published article stating" that the alleged causal link between glyphosate and non-Hodgkin's lymphoma was "generally accepted" in the scientific community at any time, past or present. ER1099 (Weisenburger).

Aside from the IARC report, Hardeman cited only a handful of studies that were seriously flawed, for the reasons discussed above (*supra* pp. 53-55), and, in any event, were a far cry from establishing a generally accepted scientific consensus that Roundup warranted a warning label. This is because a "manufacturer is not under a duty to warn of 'every report of a possible risk, no

matter how speculative, conjectural, or tentative,'" and "reports of isolated or speculative injuries do not constitute generally accepted [scientific] knowledge." *Rosa*, 684 F.3d at 946-947 (quoting *Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1153 (Cal. 1984)); *see also* CACI No. 1205, Directions for Use (Dec. 2011) (duty to warn arises only where the risk is recognized as "prevailing in the relevant scientific community" and "represents the best scholarship available"; a "minority view," even if "advanced by one body of scientific thought and experiment," is not "prevailing"). This Court should therefore direct judgment for Monsanto as a matter of law on Hardeman's failure-to-warn claims.[27]

VI. HARDEMAN WAS NOT ENTITLED TO ANY PUNITIVE DAMAGES AND CERTAINLY NOT QUADRUPLE PUNITIVE DAMAGES

Under both California law and the U.S. Constitution, eligibility for a punitive damages award requires a showing that the defendant engaged in despicable or reprehensible conduct. Hardeman failed to present such evidence and thus should not have received punitive damages. At a minimum, the $20

[27] The jury found Monsanto liable for its failure to warn about glyphosate's supposed risks under both a strict liability theory and a negligence theory. Because these two claims were premised on the same set of facts, setting aside the jury's verdict on the strict liability theory—which encompasses a broader range of potentially tortious activity—should also result in a reversal of the jury's verdict on the narrower negligence theory. *See, e.g.*, *Trejo v. Johnson & Johnson*, 220 Cal. Rptr. 3d 127, 146-147 (Ct. App. 2017); *Mathis v. Milgard Mfg., Inc.*, 2018 WL 2095757, at *2 (S.D. Cal. May 7, 2018).

million award—four times the amount of the already significant compensatory damages award—was excessive.

A. The Punitive Damages Award Cannot Be Justified Under California Law

Under California law, 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." Cal. Civ. Code §3294(a). The district court concluded Monsanto had exhibited "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(c)(1); *see also* ER7.[28]

"Despicable conduct" is behavior that is "so vile, base, contemptible, miserable, wretched or loathsome that it would be looked down upon and despised by most ordinary people"—conduct that generates the type of "outrage frequently associated with crime." *Pacific Gas & Electric Co. v. Superior Court*, 235 Cal. Rptr. 3d 228, 236 (Ct. App. 2018). Conscious disregard, in turn, requires the plaintiff to establish that there was "actual knowledge" of a risk of harm and that

[28] Although the jury was instructed that it could award punitive damages for "malice or oppression," oppression requires a showing that defendant subjected the plaintiff "to cruel and unjust hardship in knowing disregard of his rights." ER132. As the court found that there was no evidence that Monsanto knew Roundup causes cancer, *see* ER8, the jury could not have found Monsanto's conduct to be oppressive.

"in the face of that knowledge, [the defendant] fail[ed] to take steps it kn[ew would] reduce or eliminate the risk of harm." *Erhardt v. Brunswick, Inc.*, 231 Cal. Rptr. 60, 65 (Ct. App. 1986).

Johnson & Johnson Talcum Power Cases (Echeverria), 249 Cal. Rptr. 3d 642 (Ct. App. 2019), 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 company's talcum powder—a conclusion that rested in part on an IARC classification that the powder was "possibl[y]" carcinogenic. *Id.* at 649-650, 667-670. 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 678-679.

The *Echeverria* court's punitive damages ruling rested on several factors also present in this case. *First*, it stressed that "[t]he FDA has not concluded there is a causal link between talc and ovarian cancer," noting that "it was not universally accepted in the scientific or medical community that talc is even a significant risk factor for … cancer." 249 Cal. Rptr. 3d at 677-678. And although the defendant had "refused to draw a causal connection between … talc use and ovarian cancer before experts in the relevant fields have done so," that was at most "unreasonable and negligent" behavior—not the kind of clear and convincing evidence of "despicable conduct" required under state law. *Id.* at 678.

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 supra* pp. 5-10. And at the time of Hardeman's exposure, before the release of the IARC study, not a single regulatory body worldwide had concluded that glyphosate exposure might cause cancer. *See supra* pp. 6-10; ER8 (district court finding that "scientific landscape was even more favorable to Monsanto during the time Mr. Hardeman was using Roundup" than it is at present day). As the district court recognized, "the repeated approvals of glyphosate by the EPA, the European Chemicals Agency, Health Canada, and other worldwide regulatory agencies, surely diminish" any culpability Monsanto might be thought to have. *Id.*

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." 249 Cal. Rptr. 3d at 677. 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." *Id.*

Here, the district court found that Monsanto did not have access to any evidence about the dangers of glyphosate beyond what was available to the

scientific community. It found that there was no evidence that Monsanto was "in fact aware that glyphosate caused cancer." ER8; *see also* ER129.

Third, the *Echeverria* court stated that when a "'record … presents a close case'" regarding a failure to warn claim, "'the sufficiency of the evidence [for that claim] will inevitably provide a tenuous basis for supporting an award of punitive damages.'" 249 Cal. Rptr. 3d at 678. Thus, even though the plaintiff in that case presented sufficient evidence to sustain the verdict, that same evidence could not *also* "support a finding, by clear and convincing evidence, of despicable conduct." *Id.* at 679.

Here, at best for Hardeman, this was a very close case—particularly on the issue of causation. As detailed above, the district court noted that Hardeman's expert testimony was "rather weak," "questionable," and even perhaps inadmissible under "a strict interpretation of *Daubert*." *See supra* pp. 40-47. The jury took five days to decide that glyphosate caused Hardeman's non-Hodgkin's lymphoma. *See supra* p. 18. In light of the weakness of the causation evidence—and Monsanto's lack of knowledge that glyphosate was carcinogenic—the record cannot support a punitive damages award.

B. The Punitive Damages Award Violates The Federal Due Process Clause

1. The imposition of punitive damages also violated the Fourteenth Amendment. Due process forbids states from levying a "grossly excessive" or

"arbitrary punishment[] on a tortfeasor." *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003). Because "punitive damages pose an acute danger of arbitrary deprivation of property," *id.* at 409, the Supreme Court has imposed significant limits on a jury's authority to award them. In particular, the Court has emphasized that "the most important indicium" of a punitive damages award is evidence of reprehensible conduct. *BMW of N. Am. v. Gore*, 517 U.S. 559, 575 (1996). That limitation, which is enforced with "[e]xacting appellate review," *State Farm*, 538 U.S. at 418, 429, ensures that punitive damages are tailored to serve their function of deterring outrageous conduct.

Here, for the reasons just stated, Monsanto's behavior was not reprehensible. *See supra* pp. 77-80. Punishing a company when it had no knowledge that its conduct was unlawful and when that conduct complied with regulatory standards raises the same "fundamental due process concerns" present in other cases where the Supreme Court disapproved punitive damages awards—"risks of arbitrariness, uncertainty, and lack of notice." *Philip Morris USA v. Williams*, 549 U.S. 346, 354 (2007).

Indeed, a crucial factor for determining whether punitive damages are appropriate is that the "misconduct" supporting such damages "could be" subject to "civil or criminal penalties" under a statutory provision. *BMW*, 517 U.S. at 583. Conduct that was permissible under existing law cannot merit punitive damages,

for it would be arbitrary to punish a defendant for conduct that was lawful at the time. *See Landsgraf v. USI Film Prods.*, 511 U.S. 244, 266, 281 (1994) (noting that "[t]he Due Process Clause … protects the interests in fair notice and repose that may be compromised by retroactive" changes to the law and noting that "[r]etroactive imposition of punitive damages would raise a serious constitutional question"); *see also United States v. Carlton*, 512 U.S. 26, 30 (1994) ("retroactive application" of law violates due process when the result is "'harsh and oppressive'"). Thus, the *BMW* Court noted that, in at least some circumstances, a corporation can "reasonably rely" on existing law "for guidance" in determining whether conduct is appropriate. *See* 517 U.S. at 579.

Moreover, the Supreme Court has repeatedly emphasized that the purposes of punitive damages are deterrence and punishment. *See, e.g.*, *BMW*, 517 U.S. at 574; *State Farm*, 538 U.S. at 416. Awarding punitive damages is irrational when a company has consistently satisfied regulatory requirements and marketed a product that both the company and the vast majority of scientists and regulators concluded was non-carcinogenic.

2. At a minimum, the evidence in this case cannot support a 4:1 punitive damages ratio. The Supreme Court has established three guideposts for assessing 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. *See BMW*, 517 U.S. at 575-582; *see also State Farm*, 538 U.S. at 419-428. Here, all of those factors suggest that a $20 million punitive damages award was far too high.

First, as discussed above, Monsanto's conduct was not reprehensible. Monsanto sold Roundup without a cancer warning in good faith and in accordance with the scientific and regulatory consensus regarding glyphosate. *See supra* pp. 6-10, 77-80.

Second, the punitive damages award did not bear "'a reasonable relationship' to [the] compensatory damages" awarded. *BMW*, 517 U.S. at 581. The jury awarded a significant amount of compensatory damages in this case—roughly $5 million dollars—and the court permitted an additional $20 million in punitive damages, a ratio of 4:1. The Supreme Court has explained that in this situation, "[w]hen compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of due process." *State Farm*, 538 U.S. at 425-426; *see also Roby v. McKesson Corp.*, 219 P.3d 749, 770, 880 (Cal. 2009) ("one-to-one ratio" was constitutionally required where defendant had "a relatively low degree of reprehensibility" and there was a "substantial compensatory damages verdict").

Finally, it is impossible to compare "the punitive damages award to civil or criminal penalties that could be imposed for comparable misconduct," *see BMW*, 517 U.S. at 582, because selling without a warning a product that manufacturers, scientists, and regulators alike agree is safe for public use and needs no warning is not "misconduct" under any reasonable understanding of the word. Just as "[t]he existence of a criminal penalty [has] bearing on the seriousness with which a State views [a] wrongful action," *see State Farm*, 538 U.S. at 428, the *non-existence* of such a penalty is logically a telling indicator that punitive damages are inappropriate.

C. The District Court's Reasons For Upholding Quadruple Punitive Damages Are Insufficient

The district court identified three flawed reasons to support its $20 million punitive damages award. ER6-10.

First, the court stated, without any citation to the record, that Monsanto "was more concerned with tamping down safety inquiries and manipulating public opinion than it was with ensuring its product is safe." ER7. But as *Echeverria* makes clear, punitive damages are not appropriate merely because a manufacturer defends the safety of its product. In *Echevarria*, the defendant, faced with studies that talcum powder could cause ovarian cancer, responded by "mount[ing] a defense against" the studies. 249 Cal. Rptr. 3d at 677. Indeed, the *Echeverria* court concluded that "[t]he jury could reasonably infer that, faced with the

possibility that talc might be shown to cause ovarian cancer, [defendant's] response was focused solely on avoiding such a conclusion." *Id.* Nonetheless, the court concluded that the defendant's behavior could not sustain a punitive damages award.

Second, the district court faulted Monsanto for failing to affirmatively introduce into evidence "email[s] suggesting that Monsanto officials were actively committed to conducting an objective assessment of its product." ER9. But that approach improperly shifted the burden of proof—it was Hardeman's burden to produce clear and convincing evidence proving despicable conduct, *see* Cal. Civ. Code §3294(a); *see also supra* p. 77. And a company's decision to "mount a defense" of a product that it reasonably believes to be safe and to "refuse to draw a causal connection between" that product and cancer absent reliable scientific evidence does not warrant the imposition of punitive damages. *Echeverria*, 249 Cal. Rptr. 3d at 678. The test for punitive damages under both federal and state law is whether the defendant behaved in a sufficiently egregious manner to merit the equivalent of a criminal punishment, *see supra* pp. 76-82, not whether the judge views the defendant as a model corporate citizen.

Finally, the district court noted that "the jury was aware that Monsanto has repeatedly sold—and continues to sell—Roundup without any form of [a cancer] warning label." ER9. But this can hardly be considered reprehensible or

despicable standing alone, especially given the broad consensus that glyphosate is not carcinogenic.

* * *

The district court upheld a massive verdict sanctioning Monsanto for selling glyphosate without a cancer warning even though (a) regulatory agencies worldwide, including EPA, have repeatedly concluded that glyphosate does not cause cancer, (b) EPA has concluded that such a cancer warning would be unlawful under federal law, and (c) reliable scientific studies have found no association between glyphosate and non-Hodgkin's lymphoma. That result was only possible because of the district court's serious legal errors—especially its misunderstanding of the relationship between federal and state law governing pesticide labels and its failure to exercise its proper authority to ensure that expert testimony is based on reliable scientific methodologies rather than speculation and conclusory assertions. If the judgment is allowed to stand, those errors will spread to thousands of other Roundup cases. This Court should reverse and direct judgment for Monsanto.

CONCLUSION

The district court's judgment should be reversed.

December 13, 2019

Respectfully submitted,

s/ Seth P. Waxman

SETH P. WAXMAN
PAUL R.Q. WOLFSON
LEON T. KENWORTHY
CLAIRE H. CHUNG
JAMES BARTON
RAFAEL J. GALLARDO HEVIA
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave, NW
Washington, DC 20006
(202) 663-6000
seth.waxman@wilmerhale.com

THOMAS G. SPRANKLING
HENRY J. BECKER
WILMER CUTLER PICKERING
HALE AND DORR LLP
950 Page Mill Road
Palo Alto, CA 94304

BRIAN L. STEKLOFF
RAKESH KILARU
WILKINSON WALSH AND
ESKOVITZ LLP
2001 M Street, NW
10th Floor
Washington, DC 20036

PHILIP J. PERRY
RICHARD P. BRESS
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004

MICHAEL X. IMBROSCIO
DAVID M. ZIONTS
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001

LEE MARSHALL
BRYAN CAVE LEIGHTON
PAISNER LLP
Three Embarcadero Center
7th Floor
San Francisco, CA 94111

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form08instructions.pdf

9th Cir. Case Number(s) 19-16636, 19-16708

I am the attorney or self-represented party.

This brief contains 19,271 **words**, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

I certify that this brief *(select only one)*:

- ○ complies with the word limit of Cir. R. 32-1.
- ○ is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.
- ○ is an **amicus** brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).
- ○ is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.
- ○ complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one):*
  - ○ it is a joint brief submitted by separately represented parties;
  - ○ a party or parties are filing a single brief in response to multiple briefs; or
  - ○ a party or parties are filing a single brief in response to a longer joint brief.
- ○ complies with the length limit designated by court order dated _____.
- ◉ is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature s/Seth P. Waxman **Date** Dec 13, 2019

(use "s/[typed name]" to sign electronically-filed documents)

Feedback or questions about this form? Email us at forms@ca9.uscourts.gov

ADDENDUM

ADDENDUM
TABLE OF CONTENTS

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

U.S. Const. art. VI cl. 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. amend. XIV, § 1

All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

7 U.S.C. § 136v(a)-(b)

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

Cal. Civ. Code § 3294(a)-(c)

(a) In an action for the breach of an obligation not arising from contract, where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice, the plaintiff, in addition to the actual damages, may recover damages for the sake of example and by way of punishing the defendant.

(b) An employer shall not be liable for damages pursuant to subdivision (a), based upon acts of an employee of the employer, unless the employer had advance knowledge of the unfitness of the employee and employed him or her with a conscious disregard of the rights or safety of others or authorized or ratified the wrongful conduct for which the damages are awarded or was personally guilty of oppression, fraud, or malice. With respect to a corporate employer, the advance knowledge and conscious disregard, authorization, ratification or act of oppression, fraud, or malice must be on the part of an officer, director, or managing agent of the corporation.

(c) As used in this section, the following definitions shall apply:

(1) “Malice” means conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others.

(2) “Oppression” means despicable conduct that subjects a person to cruel and unjust hardship in conscious disregard of that person's rights.

(3) “Fraud” means an intentional misrepresentation, deceit, or concealment of a material fact known to the defendant with the intention on the part of the defendant of thereby depriving a person of property or legal rights or otherwise causing injury.

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of December 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Seth P. Waxman
SETH P. WAXMAN