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.)

EDWIN HARDEMAN'S PRINCIPAL AND RESPONSE BRIEF

Aimee H. Wagstaff, Esq.
David J. Wool, Esq.
Andrus Wagstaff, PC
7171 W. Alaska Dr.
Lakewood, CO 80226
(866) 795-9529
aimee.wagstaff@andruswagstaff.com
david.wool@andruswagstaff.com

Jennifer A. Moore, Esq.
Moore Law Group, PLLC
1473 South 4th St.
Louisville, KY 40208
(502) 717-4080
jennifer@moorelawgroup.com

Leslie A. Brueckner
Public Justice
475 14th St. Suite 610
Oakland, CA 94612
(510) 622-8205
lbrueckner@publicjustice.net

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES Page(s)

Statutes and Regulations

Other Authorities

INTRODUCTION

This appeal involves Roundup, a weed killer containing the active ingredient glyphosate. Roundup also contains a number of additional ingredients that make it far more carcinogenic than glyphosate alone.

Despite massive market share and millions of products sold, Monsanto has never attempted to determine whether Roundup causes cancer. As recently as 2009, Monsanto's chief glyphosate spokesperson bluntly stated, "[we] cannot say that Roundup does not cause cancer [because] we have not done carcinogenicity studies with 'Roundup'." PSER244.[1] And so Roundup remains on the market, despite overwhelming evidence that the product causes cancer in humans.

Starting in 2015, thousands of cancer victims sued Monsanto in state and federal courts, alleging that Roundup caused their cancer. The federal court cases were consolidated into a multidistrict litigation ("MDL") in the Northern District of California before Judge Vince Chhabria. ER2254-56.

This appeal arises out of the first and only bellwether trial in that MDL. Edwin Hardeman regularly sprayed Roundup for over 25 years on his properties. In early 2015 he was diagnosed with diffuse large B-cell lymphoma (DLBCL), a

[1] Citations to PSER are to Plaintiff's Supplementary Record Excerpts. Citations to ER are to Monsanto's Record Excerpts.

subtype of non-Hodgkin's lymphoma (NHL). He sued Monsanto in February 2016, alleging his cancer was caused by his long-term exposure to Roundup.

In March 2019, after a month-long trial, the jury returned a verdict in favor of Hardeman, awarding him roughly $5 million in compensatory damages and $75 million in punitive damages for Monsanto's decades of undermining the science, failing to test its own product, and recklessly endangering Hardeman. ER1680-81.

In ruling that punitive damages were appropriate, the district court held that "the evidence easily supported a conclusion that Monsanto was more concerned with tamping down safety inquiries and manipulating public opinion than it was with ensuring that its product was safe." ER7. As the court put it, "the evidence at trial painted the picture of a company focused on attacking or undermining people who raised concerns, to the exclusion of being an objective arbiter of Roundup's safety." ER8-9.

* * *

In this appeal, Monsanto ignores the jury's factual findings. Instead, it retells a narrative the jury already considered and rejected. Moreover, it flouts controlling Supreme Court precedent by claiming Hardeman's claims are expressly or impliedly preempted under FIFRA. This assertion of law rests on a two-page, post-verdict letter from EPA's Office of Pesticide Program (OPP) that tells registrants such as Monsanto that—contrary to EPA decisions from a few months

ago—they cannot change their product labels to warn of *glyphosate's* risks at this time. Monsanto presents precisely no evidence of the factual record OPP relied upon to issue its letter; cannot claim that the letter addresses the risks of *Roundup*, as opposed to *glyphosate*; and cannot seriously maintain that an informal letter of this nature carries the force of law.

The record below is the only one before this Court. And based on that record, there is substantial evidence to support the jury's verdict. The jury heard credible evidence that Roundup is carcinogenic and that it caused Plaintiff's cancer. It reviewed Monsanto's own admission that it has never "done carcinogenicity studies with Roundup." PSER244. On this record, the jury's judgment cannot be disturbed based on Monsanto's alternative version of the facts.

Nor can Monsanto escape liability by misstating the law. Monsanto's preemption argument is not only premised on a fallacy—that Roundup is "synonymous" with glyphosate (Monsanto Brief ("MB") 5 n.1)—it is also foreclosed by the U.S. Supreme Court's decision in *Bates v. Dow Agrosciences*, 544 U.S. 431 (2005), which held that FIFRA *preserves* state-law warning claims that parallel federal misbranding standards.

Monsanto's other main legal argument—that the district court erred by applying an incorrect standard for determining admissibility of expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)—is just

as flawed. The district court heard lengthy testimony from every expert, learned the science in minute detail, and issued well-reasoned decisions on both general and specific causation, applying *Daubert* with precision. There was no legal error, let alone an abuse of discretion, in admitting Hardeman's experts.

Monsanto's kitchen-sink arguments—including that the court erred in applying an incorrect jury instruction, by excluding certain regulatory classifications as cumulative, and by allowing the jury to award punitive damages—hardly bear mentioning at this juncture, except to say that the Court's determinations were as detailed, deliberate, and well-considered as its *Daubert* rulings. Monsanto's appeal should be rejected and the jury's verdict, including its punitive damages award, should stand.[2]

JURISDICTION

Plaintiff-Appellee/Cross-Appellant Edwin Hardeman agrees with Monsanto's statement of jurisdiction as to Monsanto's appeal. This Court has jurisdiction over Hardeman's cross appeal under 28 U.S.C. §1291.

[2] The district court's only error was in reducing the punitive damages award from $75 million to $20 million. That decision, which is the subject of Plaintiff's cross appeal, is addressed *infra* at VI(B).

COUNTERSTATEMENT OF ISSUES FOR MONSANTO'S APPEAL

1. Whether Hardeman's claims are preempted under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §136 *et seq.* (FIFRA), when his claims are substantively equivalent to FIFRA's misbranding requirements.

2. Whether the district court (a) applied the correct legal standard for determining admissibility of expert testimony; and (b) acted within its discretion by admitting the testimony of Hardeman's experts as both reliable and relevant.

3. Whether the district court acted within its discretion by allowing Hardeman to introduce evidence of IARC's classification that glyphosate is a probable carcinogen during the first phase of trial in order to mitigate the substantial prejudice Hardeman suffered from bifurcation of the trial, while at same time allowing Monsanto to admit three different regulatory agencies' opposition to IARC.

4. Whether the district court properly instructed the jury it could find for Hardeman if it found that Roundup caused Hardeman's cancer and that Monsanto cannot avoid responsibility even if it other independent factors may have been sufficient on their own to cause his cancer.

5. Whether the district court properly denied Monsanto's request for judgment as a matter of law on the ground that the risks of Roundup were "known or knowable" to Monsanto in light of the overwhelming scientific evidence that

Monsanto willfully refused to test Roundup and spent decades impeding, discouraging, and distorting the science regarding Roundup's risks.

6. Whether the jury's punitive damages award violated California Civil Code §3294 and the Due Process Clause of the Fourteenth Amendment where the jury heard overwhelming evidence that Monsanto misled regulators and the public about Roundup's dangers in order to protect its bottom line.

STATEMENT OF ISSUE FOR HARDEMAN'S CROSS APPEAL

Whether the district court erred as a matter of law in holding that the jury's punitive damages award of $75 million—an amount less than 0.1% of Monsanto's net worth—was constitutionally excessive, and reducing that award to $20 million, in light of the extreme reprehensibility of Monsanto's decades of misconduct and the fact that its intentional deception continues to threaten the health of millions of consumers worldwide.

STATEMENT OF THE CASE

A. Statutory Background.

FIFRA requires pesticide manufacturers to register their products with the EPA. 7 U.S.C. § 136a(a). FIFRA states, however, that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." 7 U.S.C. §136a(f)(2). Rather, registration of a

pesticide is merely "*prima facie* evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter." *Id*.

EPA is entirely reliant on pesticide applicants to prove that their labels comply with FIFRA. *See Jeffers v. Wal-Mart Stores, Inc*., 171 F. Supp. 2d 617, 623 (S.D.W.Va. 2001) ("EPA does not independently test, study, or otherwise set particular composition standards for the pesticides."); *EPA Pesticide Registration Manual Ch. 1*, Overview of Requirements for Pesticide Registration ("An applicant who wishes to obtain a registration for its own pesticide product is responsible for submitting or citing to all of the information and data that are required to support the application.").[3]

EPA can bring various enforcement actions against the manufacturer of a registered pesticide if it determines that the product is "misbranded," including seeking civil and criminal penalties. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 439, 439 n.11 (2005) (citation omitted).

A duly registered pesticide is misbranded if, *inter alia*, the label "does not contain adequate instructions for use, or if its label omits necessary warnings or cautionary statements." *Bates*, 544 U.S. at 438 (citation omitted). And, "[b]ecause it is unlawful under the statute to sell a pesticide that is registered but nevertheless

[3] Available at https://tinyurl.com/u3slhsv.

misbranded, manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements." *Id*. at 438 (citations omitted). These obligations include a duty to seek approval to amend a label that does not contain all "necessary warnings or cautionary statements." *Id*.

EPA's decision to register a pesticide also does not render a manufacturer immune from regulation by the States; to the contrary, a State can regulate or even *ban* a federally registered pesticide, even if the EPA does not consider it misbranded under FIFRA. *Id.* at 446 (citation omitted).

FIFRA's only limitation on state authority is set forth in the Act's preemption clause: 7 U.S.C. §136v(b). As *Bates* explained, this provision is "narrow." 544 U.S. at 452. Although Section 136v(b) "reaches beyond positive enactments…to embrace common-law duties," *id.* at 443, it "prohibits only state-law labeling and packaging requirements that are '*in addition to or different from*' the labeling and packaging requirements under FIFRA." *Id.* at 447 (quoting 7 U.S.C. §136v(b); (emphasis in original).

B. Regulatory Background.

1. EPA Has Only Made Findings Regarding Glyphosate, Not Roundup.

Starting in 1974, EPA has registered various pesticide formulations containing glyphosate, the active ingredient in Roundup. *See* EPA, *Glyphosate: Proposed Interim Registration Review Decision* (Apr. 23, 2019), ("*2019 Interim Glyphosate*

Review").[4] A glyphosate-based formulation (GBF) is a product that contains glyphosate *plus* other ingredients that make the product more effective and/or longer lasting. PSER489[5]

Roundup is such a product: it contains glyphosate, water, and other ingredients (called "surfactants") that make it a potent weedkiller (and also, as the jury found, a particularly carcinogenic herbicide).

Over the past 40 years, EPA has only made findings regarding the carcinogenicity of glyphosate, not the formulated product Roundup. PSER489-93.

2. EPA's Mixed Conclusions Regarding Glyphosate.

Even EPA's conclusions about glyphosate have been mixed. EPA first reviewed the potential carcinogenic effects of glyphosate in 1985. In that year, an EPA review of a mouse study found that "glyphosate was oncogenic in male mice," causing rare tumors. PSER264. EPA classified glyphosate as a possible human carcinogen. PSER486.

[4] Available at https://tinyurl.com/y6h2u8w6.

[5] *See* EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, Office of Pesticide Programs (Dec. 12, 2017) at 137, available at https://tinyurl.com/eparevdglyphosate. ("*2017 Revised Issue Paper*").

In 1991, EPA changed its designation of glyphosate to non-carcinogenic based in part on new evidence submitted by Monsanto—evidence that turned out to have been falsified, as Plaintiff proved at trial. *See infra* pp. 27-28.

But even at the time, EPA's Scientific Advisory Panel (SAP) was internally divided on whether glyphosate causes cancer. PSER307. Several voted *not* to reverse the agency's initial designation of glyphosate as a possible human carcinogen. Although the dissenting scientists were overruled, EPA's divided SAP cautioned "that designation of an agent [as non-carcinogenic] is based on the available evidence…and *should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances*." PSER306 (emphasis added).

3. IARC's 2015 Finding that Glyphosate is Carcinogenic.

On the heels of these events, independent studies emerged in the 1990s and early 2000s showing that glyphosate and Roundup pose a cancer risk to humans. PSER379-80; PSER411-40 (discussing epidemiology). As Plaintiff proved at trial, Monsanto spent years suppressing and manipulating the science to convince the public that Roundup is safe. *See infra* at pp. 27-30.

But in 2015, a working group of 17 experts from 11 countries assembled for the International Agency for Research on Cancer (IARC), part of the World Health Organization, to thoroughly review data relating to glyphosate, and concluded that

the chemical is "probably carcinogenic to humans." PSER 509-10. Unlike EPA, which relied heavily on industry-generated studies and data from Monsanto that focused predominantly on glyphosate in isolation, IARC relied mostly on peer-reviewed scientific studies, including those that focused more on glyphosate formulations, like Roundup. PSER 506.

4. EPA's Registration Review for Glyphosate.

In 2015, the same year IARC found glyphosate a probable human carcinogen, EPA began its reexamination of the carcinogenic potential of glyphosate—a process FIFRA requires every 15 years after a pesticide's registration.

Just as in 1991, the scientists and external advisors disagreed as to the carcinogenicity of glyphosate. PSER498-502, 572-74. Some independent scientists on EPA's Scientific Advisory Panel, evaluating the carcinogenic potential of glyphosate, noted that EPA's "evaluation [did] not appear to follow EPA [guidelines]" and its "conclusion of 'not likely to be carcinogenic to humans'" should be rejected. PSER572-74. But in 2017, despite these conflicting views, EPA published a draft risk assessment that simply "concluded that glyphosate is classified as 'not likely to be carcinogenic to humans.'"[6]

[6] EPA, *Glyphosate: Draft Human Health Risk Assessment for Registration Review* (Dec. 12, 2017) at 3, available at https://tinyurl.com/uwmmhc7.

At the same time, however, EPA published another assessment—the *2017 Revised Issue Paper*—which admitted that EPA's advisors had "conflicting views on how to interpret the overall results for NHL." PSER487-88.[7]

Part of the difficulty, EPA explained, was that "uncertainties" exist in the data, partly because "farmers and other applicators apply *formulations, not the active ingredient alone*." PSER489 (emphasis added). The agency acknowledged a need for additional research "to determine whether formulation components, such as surfactants, increase the toxicity of glyphosate formulations." PSER491.

In April 2019—shortly after the jury verdict in this case—EPA published its *2019 Interim Glyphosate Review*, *supra* at 9.[8] In that "interim" document, EPA noted that many commenters "expressed concerns that glyphosate formulations are more toxic than glyphosate alone..." *Id*. at 10.

In response, EPA again acknowledged that, "there are few research projects that have attempted to directly compare technical grade glyphosate to the formulations under the same experimental design." *Id.* at 11. EPA stated that "If at any time, information becomes available that indicates adverse human health effects of concern for exposure to glyphosate *or its formulations*, the EPA intends

[7] Available at https://tinyurl.com/eparevdglyphosate at 67; *see also id*. at 133.

[8] Available at https://tinyurl.com/y6h2u8w6.

to review it and determine the appropriate regulatory action." *Id.* (emphasis added).

On January 22, 2020, EPA issued its *Interim Registration Review Decision.*[9] EPA did not exclude the possibility that glyphosate-containing formulations (such as Roundup) can be harmful to humans. Instead, it merely reiterated that, "glyphosate is not likely to be carcinogenic to humans." *Id*. at 10. EPA stated, however, that it "will continue to monitor the open literature for studies that use scientifically sound and appropriate methodology and relevant routes of exposure that have the potential to impact the risk evaluation of glyphosate." *Id* at 7.

5. The Office of Pesticide Program's August 2019 Letter to California.

Meanwhile, in August 2019—five months after the jury verdict in this case—EPA's OPP issued a press release announcing that it had sent a two-page letter to "Registrants" of glyphosate-containing products.[10]

The OPP Letter, which was not the product of any formal proceedings, was not published in the Federal Register, does not cite any new scientific findings, and takes no position on whether Roundup causes cancer.

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[9] EPA, *Glyphosate: Interim Registration Review Decision* (Jan. 22, 2020) https://tinyurl.com/wnklu3d.

[10] Available at https://tinyurl.com/u656c3x.

Instead, it challenges California's inclusion of glyphosate on Proposition 65 as contrary to the "EPA's determination that *glyphosate* is 'not likely to be carcinogenic.'" *Id*. at 1 (emphasis added). Given this determination, said OPP, EPA "considers the Proposition 65 warning language based on the chemical glyphosate to constitute a false and misleading statement" under FIFRA. *Id.*

6. EPA Has Approved Proposition 65 Warnings for Glyphosate-Containing Pesticides.

As the OPP Letter makes clear, EPA *has* previously approved cancer warnings on glyphosate-containing products. *See id*. at 2 (stating that EPA "will no longer approve [such warnings]" and ordering registrants "[to propose] amended labeling that removes such language…"). The United States admits that, in the wake of California's listing of glyphosate as a probable carcinogen, "some" manufacturers that had been "registered to use glyphosate…specifically sought EPA's approval to amend their product labels to satisfy Proposition 65"—and EPA initially said yes. U.S. Br. at 10.[11]

C. This Lawsuit.

7. Background.

[11] The United States nonetheless insists, without any factual support, that "these label-change approvals were erroneous because the proposed edits warned of a cancer risk that, according to EPA's assessment, does not exist." *Id.*

Edwin Hardeman began using Roundup in the 1980s to control poison oak and weeds on his property. He purchased Roundup concentrate and mixed the Roundup himself, frequently getting it on his skin. PSER107. He read the label and followed all instructions when he sprayed. PSER21. Following over 25 years of Roundup exposure, ending in 2012, Hardeman was diagnosed with NHL in 2015. He sued Monsanto in 2016, alleging that Roundup is defective, dangerous to human health, and lacked proper warnings. ER2279.

From the outset, the distinction between Roundup and glyphosate was central to Plaintiff's theory of the case. Hardeman alleged in his complaint that "[Monsanto] knew or should have known that Roundup is more toxic than glyphosate alone and that safety studies on Roundup…were necessary to protect Plaintiff from Roundup," and that "[Monsanto] knew or should have known that tests limited to Roundup's active ingredient glyphosate were insufficient to prove the safety of Roundup." ER2289.

Hardeman further alleged that despite knowing "that Roundup was considerably more dangerous than glyphosate alone, [Monsanto] continued to promote Roundup as safe." ER2289.

8. Pre-Trial Proceedings Related to Causation.

a. General-Causation Background.

At Monsanto's request, the district court bifurcated discovery at the outset of the MDL, allowing discovery ***solely*** on the issue of whether Roundup can cause NHL in human beings ("general-causation"). PSER9. The district court ultimately rejected Monsanto's contention that Hardeman could not produce relevant and reliable expert testimony on general-causation sufficient to meet Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

b. Plaintiff's General Causation Experts.

To satisfy his general causation burden, Hardeman proffered three experts whose opinions are subject to this appeal. ER82-111.

Each expert examined all three pillars of scientific evidence: epidemiology, toxicology (animal studies), and genotoxicology (evidence of the mechanism by which Roundup causes NHL, referred to here as "cell studies"). ER61-77; 77-81; 81-82.[12]

The experts all applied the generally accepted Bradford Hill criteria. ER61-62; ER83 (explaining that the Hill criteria are "a reliable method for determining

[12] A "genotoxin" is a chemical or other agent that damages DNA, which can result in mutations leading to cancer. ER1660.

causation as a general matter" and citing *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1235 n.4 (9th Cir. 2017)).

Step one required Hardeman's experts to determine whether there was an association between Roundup and NHL within the epidemiological literature. ER83. Each expert found such an association. The experts individually relied on a series of case-control[13] epidemiological studies that showed elevated odds ratios[14] in individuals exposed to Roundup.

The experts supported their opinions with several meta-analyses, which combined and analyzed the results of multiple case-control studies together to create greater statistical power. ER68-69. The meta-analyses, including one sponsored by Monsanto, also observed elevated odds ratios. *Id.*

Step two required Hardeman's experts to survey "all the available evidence that might support or disprove causation" to determine whether the observed association is causal. ER83. "All evidence" means just that—the epidemiology,

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[13] A case-control study "starts with a group of people who have the disease of interest (the 'cases'), selects a similar population of people without the disease (the 'controls'), and then compares the groups on the basis of past exposure to the chemical the investigators are studying." ER62.

[14] An odds ratio "is the ratio of the odds that a case (one with the disease) was exposed to the odds that a control (one without the disease) was exposed." ER62 (quoting Michael D. Green et al., *Reference Guide on Epidemiology*, *in* Reference Manual on Scientific Evidence 551, 568 (3d ed. 2011)). "An odds ratio greater than 1.0 indicates an association..." ER63.

the animal and cell studies related to glyphosate and GBFs such as Roundup. *Id*. Thus, "none of [Hardeman's] experts base[d] their opinions exclusively on the epidemiology." ER61. Rather, each expert weighed all the scientific evidence and found that the distinct lines of evidence, including the animal and cell studies, corroborated and strengthened each other. ER84. On that basis, Hardeman's experts opined that the weight of the scientific evidence supported their conclusion that Roundup can cause NHL.

c. Monsanto's General Causation Experts.

In sharp contrast, Monsanto's experts performed a siloed inquiry, examining each line of evidence without reference to the other evidence. In other words, Monsanto's epidemiologists did not review the animal studies, and Monsanto's toxicologists did not review the epidemiology. Monsanto's expert on cell studies did not review the epidemiology or animal studies. None of these experts offered an opinion as to what the whole of the evidence indicated on whether Roundup exposure causes NHL. Predictably, all of Monsanto's experts offered opinions that the specific, single line of evidence they examined did not support an opinion that Roundup can cause NHL. PSER542-67.

d. General-Causation Hearings and Opinion.

The district court conducted a solid week of hearings on the general-causation experts, which were videotaped so they could be used by judges in other

cases against Monsanto involving Roundup. ER54.[15] Each of Hardeman's experts authored at least two reports and sat for two depositions on general causation alone. The court ordered two separate rounds of *Daubert* briefing, the latter round limited exclusively to one study. PSER6-7. After oral argument, the court ordered that Drs. Portier and Ritz return for another round of live testimony. PSER5.

In July 2018, the court issued a comprehensive, 67-page opinion on general causation. ER49-116. The court examined each discrete line of evidence in painstaking detail, and individually evaluated the strengths and weaknesses of every epidemiological study. The court excluded certain experts in their entirety (ER104-07; ER109-11), and excluded portions of certain other experts' testimony. ER107-09. The court concluded that Drs. Portier, Ritz, and Weisenburger's opinions were both relevant and reliable, satisfying *Daubert*. ER115. Based on this decision, the court held that "the plaintiffs have presented evidence from which a reasonable jury could conclude that glyphosate can cause NHL at human-relevant doses" and denied Monsanto's motion for summary judgment on general causation. ER116.

e. Specific-Causation Daubert Ruling.

[15] Available at https://tinyurl.com/wpwuel4.

After defeating summary judgment at the general-causation stage, Plaintiff's efforts shifted to specific causation—whether Roundup caused *his* NHL.

Hardeman's experts performed a differential diagnosis, a methodology by which a physician "rules in" all potential causes of a disease, "rules out" those for "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. Apart from his Roundup exposure, Hardeman's experts considered other risk factors that could explain his disease, including age, race, obesity, hepatitis B (HBV), and hepatitis C (HCV), as well as the possibility that Hardeman's NHL was idiopathic in origin—i.e., had no known cause.

They concluded that Roundup did cause Hardeman's NHL and ruled out Monsanto's theory that HCV could have caused damage to Hardeman's cells that later developed into NHL. PSER141-33; PSER150-51; PSER157-64. Plaintiff's experts also rebutted Monsanto's argument that Hardeman's NHL could have been idiopathic. ER38-39.

Monsanto again moved for summary judgment, arguing that Hardeman's specific-causation experts' opinions did not satisfy *Daubert*. *See* Monsanto Mot. to Exclude on *Daubert* Grounds, No. 3:16-md-02741, Dkt. 2420. In response the court again held *Daubert* hearings with live testimony from three specific-

causation experts.[16] Based on the evidence presented, including their expert reports, the district court denied Monsanto's motion for summary judgment. ER33-41.

The court first determined that Hardeman's experts reliably ruled in Roundup as a potential cause of Hardeman's NHL on the basis of the general-causation experts' opinions. ER38. As to idiopathy, the court relied upon this Circuit's holdings in *Messick* and *Wendell* to support its view that "[i]t is sufficient for a qualified expert, in reliance on his clinical experience, review of a plaintiffs' medical records, and evaluation of the general-causation evidence, to conclude that an 'obvious and known risk factor[]' is the cause of that plaintiff's disease." ER37 (quoting *Wendell*, 858 F.3d at 1235).

The court concluded that the experts' core opinion—that Roundup was a "substantial factor in causing [Hardeman's] NHL"—was admissible. ER38.

f. Bifurcation and *In Limine* Rulings.

Approximately two months before trial, Monsanto requested that the trial be bifurcated, with the first phase addressing only whether Roundup caused Hardeman's cancer (without reference to any regulatory decisions regarding glyphosate or Roundup) and the second phase limited to liability and damages

[16] Available at https://www.uscourts.gov/cameras-courts/re-roundup-products-liability-litigation

(where the jury could at least see some of that evidence). Monsanto Mot. To Reverse Bifurcation, No. 3:16-md-02741, Dkt. 2282 at 1.

Monsanto argued that bifurcation would "avoid potential confusion or distraction created by the assessments of…evidence [regarding] regulators and IARC, and by arguments about the methods and motives of those bodies." Monsanto Mot. To Reverse Bifurcation, No. 3:16-md-02741, Dkt. 2282 at 2.

Plaintiff objected that "[t]he type of reverse bifurcation proposed by Monsanto—where the defendant is permitted to have a trial on its favored defense [causation] before reaching any other issue—is unheard of in the modern MDL bellwether process." Plaintiffs' Opp. to Issue Bifurcation, No. 3:16-md-02741, Dkt. 2302 at 1. Plaintiff argued that bifurcation would "create structural and substantive prejudice" against Hardeman, in part because "the jury will be left with a nagging question—if [Roundup] can cause cancer, why has it been on the market for over forty years with no warning?" *Id.* at 1, 10.

Despite these objections, the district court sided with Monsanto and bifurcated the trial, which meant that the first phase would focus solely on causation, without reference to any of Monsanto's decades-long manipulation of the science and attempts to influence regulators. PSER3-4.

In so ruling, the district court acknowledged the structural prejudice its unusual order created. PSER3-4. But the court held that this prejudice would be

mitigated by the jury receiving receive "some limited information about the IARC classification" to counterbalance the fact that EPA allows Monsanto to sell Roundup without a cancer warning. PSER4. The court also stated that any remaining damage to Plaintiff from bifurcation would be cured by a jury instruction that "they must not defer to regulatory agencies, and must instead reach their own judgment based on the evidence presented at trial." PSER3.

Despite this ruling, shortly before trial Monsanto asked that Hardeman be barred from introducing *any* evidence about IARC during Phase One. Monsanto Mot. in Limine, No. 3:16-md-02741, Dkt. 2610-1 at 1. The court granted Monsanto's motion in part, but allowed Hardeman to present only the "fact of [IARC's] classification" during the first phase. ER42. The court also permitted Monsanto to introduce the bottom-line classification of EPA and two European regulatory agencies disagreeing with IARC during Phase One. ER47.

At the same time, the court precluded Hardeman from introducing evidence of California's own regulatory decisions during *either* phase of the trial. ER44.

Monsanto also moved to preclude Hardeman from introducing any evidence pertaining to Monsanto's lobbying efforts of regulatory bodies and *any* of Monsanto's conduct occurring after 2012 (the last year of Hardeman's exposure to Roundup), including Monsanto's post-2012 ghostwriting and attempts to influence

regulators, during *either* phase of the trial. ER44. The court granted this request as well. ER44.

To counterbalance the prejudicial impact of this ruling on Plaintiff, the district court limited Monsanto, in Phase Two, to "only introduc[ing] evidence of [foreign] regulatory decisions that were in effect at the time the plaintiff[ ] [was] using Roundup." ER47.

g. The Trial.

As Monsanto had requested, Phase One was limited to causation. Phase Two concerned all other issues of liability and damages, including Monsanto's pre-2012 conduct relevant to punitive damages.

9. Evidence that Roundup is More Toxic than Glyphosate.

The jury heard testimony showing that Roundup is far more toxic than glyphosate.[17]

In Phase One, for example, Dr. Weisenburger highlighted studies showing that Roundup is ten to 100 times more genotoxic than glyphosate. ER573-77. As

[17] Monsanto's contention that Plaintiff failed to prove a "meaningful difference" between the two substances (MB5 n.1) is contrary to the expert testimony at trial, described below, and to Monsanto's internal documents, introduced at trial, admitting, *inter alia*, that "the terms glyphosate and Roundup cannot be used interchangeably" (PSER257) and that "Glyphosate is OK but the formulated product (and thus the surfactant) does the damage." PSER283. *See also* PSER272 (email from Monsanto toxicologist explaining, "if somebody came

he stated, "Roundup is much more genotoxic in human lymphocytes than glyphosate is." ER574. Studies on human lymphocytes are particularly important because "those are the cells that eventually would become non-Hodgkin's lymphoma." ER577. Summarizing the cell studies, Dr. Weisenburger stated: "So when you do studies of just glyphosate, you might not find much in the way of effects. But if you do the studies on Roundup, you are much more likely to find genotoxic effects." ER576.

The difference is due to the fact that Roundup contains "surfactants" that "help[ ] the glyphosate penetrate through the walls of the plants into the actual plant cells." ER521. As Dr. Weisenburger explained, "when you get Roundup on your skin, just like the Roundup will penetrate the plant cells, it will penetrate the cells of the skin and it will get into the tissues and it will then get into the lymph system and into the blood…" ER524.

10. Evidence that Monsanto Knew that Roundup and Glyphosate Are Not the Same.

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to me and said they wanted to test Roundup I know how I would react—with serious concern. We have to really think about [testing] formulations even if they are not on the market..."). This Court must "[v]iew th[is] evidence in the light most favorable to the party in whose favor the jury returned a verdict and draw all reasonable inferences in [his] favor." *Lakeside-Scott v. Multnomah County*, 556 F.3d 797, 802, n.2 (9th Cir. 2009).

The jury also heard evidence that Monsanto was well aware that, as Monsanto toxicologist Dr. Donna Farmer put it, "the terms glyphosate and Roundup cannot be used interchangeably." PSER257. In 2002, an email from Dr. William Heydens, Monsanto's head of "product safety strategy," to Dr. Farmer stated, with regard to endocrine-disruption studies, that "*we are in pretty good shape with glyphosate but vulnerable with surfactants*." PSER283 (emphasis added). Dr. Heydens added: "this continues to be the case with these studies—*Glyphosate is OK but the formulated product (and thus the surfactant) does the damage*." PSER283 (emphasis added). He said "Let's you and I sit down with all the new 'free studies' tomorrow. I want to see what they all say, and see if there's anything more we can do besides the usual '*pay no attention to the man behind the curtain*'." PSER284 (emphasis added).

11. Evidence that Monsanto Manipulated the Science to Hide the Risks of Roundup.

The jury also learned that Monsanto has manipulated the science since at least the early 1980s to block regulators and the public from knowing the risks of Roundup. Monsanto's initial approval of glyphosate by EPA was predicated on studies conducted on Monsanto's behalf from a laboratory embroiled in scientific fraud. PSER312-15; PSER445-46. In fact, from the time it came to market in

1974 until 1983, glyphosate's safety was unsupported by any valid carcinogenicity studies. PSER445-47.

When Monsanto conducted its first valid mouse study in 1983, to determine whether glyphosate was carcinogenic in rodents (and therefore a likely human carcinogen), the study reported rare tumors in mice as exposures to glyphosate increased—powerful evidence that glyphosate causes cancer in mammals. PSER269-270. This study caused EPA to designate glyphosate as possibly carcinogenic to humans in 1985. PSER486.

Monsanto hired a pathologist to undermine EPA's conclusions by reviewing the pathology and "discovering" a tumor in the control group. PSER466-71; PSER298-99. Prior to that "discovery," Monsanto wrote internally that the only way to get EPA to change its classification was to find a tumor in the control group—a result pre-determined by Monsanto—which is exactly what the retained pathologist ended up finding. PSER463-71; PSER295-96. EPA ultimately sided with Monsanto, even after the agency's own scientific advisory panel ("SAP") recommended that the studies needed repeating—which Monsanto refused to do. PSER301; PSER481-83.

The jury heard evidence that, beginning in the 1990s, numerous studies found an association between Roundup and NHL. PSER379-80; PSER411-40. In hope of countering some of the negative studies (referred to by Monsanto as the

"tip of the iceberg," PSER286), Monsanto hired Dr. James Parry, a world-renowned genotoxicologist, to rebut a number cell studies showing that Roundup is genotoxic. PSER209; 211.

This tactic backfired: Dr. Parry's report found strong evidence that glyphosate may be genotoxic. PSER220. He noted that one study demonstrated that Roundup was *ten times* more genotoxic than glyphosate alone. PSER215. *See also* PSER232 (nothing that "Glyphosate mixture but not Glyphosate produced an increase in uncharacterised DNA adducts *in vivo* in the liver and kidneys of mice.").

After reading Dr. Parry's final report, which urged Monsanto to conduct specific tests of Roundup's genotoxicity (including a study that "incorporates glyphosate formulations to clarify the validity of reports of differences in activity [between glyphosate alone and GBFs]" (PSER235)), Monsanto asked "has he ever worked with industry before?" and complained that "[w]e may have to help him write all this." PSER234-37; PSER222. Monsanto's Director of Toxicology said "[w]e want to find/develop someone who…can be influential with regulators and Scientific Outreach operations when genotox issues arise. My read is that Parry is not currently such a person, and it would take quite some time and $$$/studies to get him there. *We simply aren't going to do the studies Parry suggests*." PSER239 (emphasis added). Dr. Heydens added "Even if we think we can eventually bring

Parry around closer to where we need him, we should currently be looking for a second/back-up genotox supporter. We have not made much progress and are *currently very vulnerable in this area.*" PSER239 (emphasis added).

Monsanto never conducted all the tests Dr. Parry asked it to perform. PSER239; PSER373-74. Dr. Parry even offered to conduct the tests himself, but Monsanto refused. PSER400. And Monsanto never submitted Dr. Parry's reports to EPA, in violation of FIFRA. *See* 40 C.F.R. §§159.152. In fact, they were hidden from the public until this litigation. PSER405.

The jury also heard evidence that Monsanto refused to perform these tests because it *knew* they might prove that Roundup is genotoxic. A Monsanto toxicologist explained, "if somebody came to me and said they wanted to test Roundup I know how I would react—with serious concern. We have to really think about [testing] formulations even if they are not on the market..." PSER272.

Likewise, in 2003, Monsanto toxicologist and chief glyphosate spokesperson Donna Farmer stated, "you cannot say that Roundup is not a carcinogen…we have not done the necessary testing on the formulation to make that statement. PSER257-58. In 2009, she likewise admitted "you cannot say that Roundup does not cause cancer…we have not done carcinogenicity studies with 'Roundup'." PSER244.

12. Evidence that Monsanto Ghostwrote Scientific Articles to

Misrepresent that Roundup is Safe.

In parallel with Dr. Parry's review, Monsanto retained another expert, Dr. Gary Williams, to put his name on a glyphosate review article. The article, which listed Dr. Williams as the principle author, concluded that, contrary to Dr. Parry's assessment of largely the same body of evidence, "under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans." PSER540. But neither Dr. Williams nor any other listed author wrote that article; it was ghostwritten by Monsanto. PSER289.

The ghostwritten Williams article was widely cited in subsequent scientific literature and regulatory evaluations, giving Monsanto the cover it needed to prevent regulators and the public from learning the true risks of Roundup. Monsanto described the Williams article as an "invaluable asset" for "responses to agencies" and "regulator[y] reviews" and said that the article has "served us well in toxicology over the last decade." PSER252, 255. This was just one of several scientific articles ghostwritten by Monsanto to manipulate the scientific debate about Roundup. PSER360-69; PSER292-93.

13. The Verdict.

After Phase One, the jury found that "Mr. Hardeman prove[d] by a preponderance of the evidence that his exposure to Roundup was a substantial factor in causing his non-Hodgkin's lymphoma." ER1710.

After Phase Two, the jury found that Monsanto failed to warn of Roundup's risks, that "Monsanto was negligent by not using reasonable care to warn about Roundup's [non-Hodgkin's lymphoma] risk," that Roundup was defectively designed, and that Mr. Hardeman proved by "clear and convincing evidence that he is entitled to punitive damages." ER1680-81.

The jury awarded Hardeman roughly $5 million in compensatory damages and $75 million in punitive damages. ER1680-81.

14. Post Trial Proceedings.

The district court denied Monsanto's motion to overturn the verdict. ER11-20. But the district court reduced the jury's punitive damages award of $75 million to $20 million, bringing the total award to $25,267,634.10. ER3.

STANDARD OF REVIEW

The district court's preemption rulings are reviewed *de novo*. *Galvez v. Kuhn*, 933 F.2d 773, 776 (9th Cir. 1991).

The court's rulings on admissibility of expert testimony are reviewed for abuse of discretion. *Messick v. Novartis Pharm. Corp*., 747 F.3d 1193, 1196 (9th Cir. 2014). Whether the court applied the correct standard under *Daubert* is reviewed de novo. *Id*.

The district court's evidentiary rulings relating to regulatory decisions "should not be reversed absent clear abuse of discretion and some prejudice."

Estate of Barabin v. AstenJohnson, Inc., 740 F.3d 457, 462 (9th Cir. 2014) (citation omitted).

This Court "will not reverse a judgment because of a mistake in jury instructions if the instructions fairly and adequately cover the issues presented." *Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1337 (9th Cir. 1985) (citation omitted).

This Court reviews de novo whether Monsanto should have received judgment as a matter of law, "view[ing] the evidence in the light most favorable to the party in whose favor the jury returned a verdict and draw[ing] all reasonable inferences in her favor." *Lakeside-Scott*, 556 F.3d at 802.

The district court's determination that a jury award of punitive damages is permitted under California law is reviewed for an abuse of discretion. *Pavon v. Swift Transp. Co.*, 192 F.3d 902, 909 (9th Cir. 1999). A decision as to the constitutionality of such an award is reviewed *de novo*. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418 (2003) (citation omitted).

SUMMARY OF ARGUMENT

Monsanto received a fair trial in this case before a meticulous judge and an impartial jury. In fact, at Monsanto's request, the district court bifurcated the trial for Monsanto's benefit. Monsanto nonetheless contends that the jury's decision

was flawed and that the verdict was infected with serious legal errors that warrant reversal. Monsanto is incorrect.

I. Plaintiff's claims are not preempted by federal law. There is no express preemption because Plaintiff's claims are substantively equivalent to FIFRA's misbranding requirements, which provide that a duly registered pesticide can be found misbranded if its label omits necessary warnings—and Roundup's label did just that.

Implied preemption is inapplicable in the context of FIFRA. But even if implied preemption were applicable here, there is no implied preemption because EPA has only made findings regarding glyphosate, not Roundup. The post-verdict letter from EPA's Office of Pesticide Programs does not address the risks of Roundup and, in any event, is not the type of formal agency action that can preempt state law. And the mere fact that EPA has pre-approval authority over changes to pesticide labels does not create any basis for impossibility preemption in light of the fact that under FIFRA (and unlike in the pharmaceutical context), states can entirely *ban* pesticides that have been registered with EPA.

II. None of the district court's rulings on causation warrant reversal. The court undoubtedly applied the correct legal standard for determining admissibility of expert testimony: whether the testimony is both relevant and reliable. And rather than disallowing testimony it viewed as "borderline," the court allowed the

jury to weigh the experts' conclusions, just as *Daubert* requires. That the jury came to a conclusion that Monsanto does not like is no reason to find the court abused its discretion in allowing them to do their job.

III. Monsanto's argument that the district court abused its discretion in admitting evidence about IARC during Phase One is just as flawed. The court gave Monsanto an enormous advantage when it bifurcated the trial, thereby preventing the jury from learning about Monsanto's attempts to manipulate the same science undergirding the question of causation. That the court allowed the jury to know about IARC's classification that glyphosate is a probable carcinogenic—a fact counterweighed by evidence from EPA and two foreign regulators that disagreed with IARC—was the least it could do to mitigate the prejudice Hardeman suffered from that decision. It is simply false to claim that the jury did not hear about contrary regulatory conclusions in Phase 1.

IV. Monsanto's complaint about the jury instruction on causation fares no better. The instruction comports with California law, and was properly designed to ensure that the jury would not exonerate Monsanto in the event it found that Roundup caused his NHL, even if the jury also thought that Hardeman might eventually develop cancer from some other independent reason.

V. Monsanto's argument that the jury verdict violated California law on failure to warn because the risks of Roundup were not "known or knowable" at the

time of Plaintiff's exposure ignores the veritable mountain of evidence to the contrary. Monsanto has known the potential risks of Roundup since at least the 1980s, when it falsified evidence to get EPA to change its classification of glyphosate as a possible carcinogen. That Monsanto has refused to study the *full* risks of Roundup in order to protect its own bottom line does not mean that those risks are not knowable.

VI. Monsanto's challenge to the punitive damages award as contrary to California law and federal due process is predicated on the specious argument that Monsanto was not aware of the risks of its product. Monsanto has spent decades manipulating the science to *hide* the risks of Roundup. The company's strategy for concealing its misconduct was to tell regulators to "pay no attention to the man behind the curtain." PSER284. But the jury *saw* the man behind the curtain: it was Monsanto. The jury's decision to award $75 million in punitive damages—less than 0.1 percent of Monsanto's net worth—was restrained. It should not have been disturbed.

ARGUMENT

I. PLAINTIFF'S CLAIMS ARE NEITHER EXPRESSLY NOR IMPLIEDLY PREEMPTED.

A. Plaintiff's Claims Are Not Expressly Preempted.

Monsanto argues that Plaintiff's claims are expressly preempted because they seek to impose state-law "requirements" for labeling "in addition to or different

from those required under [FIFRA]." 7 U.S.C. §136v(b). This argument fails because Plaintiff's claims are entirely consistent with, and affirmatively reinforce, FIFRA's misbranding standards.[18]

1. Plaintiff's Claims Are Not Expressly Preempted Because they Mirror Federal Misbranding Standards.

Though state common-law duties are "requirements" under FIFRA, those requirements are not preempted if they are "equivalent to, and fully consistent with FIFRA's misbranding provisions." *Bates*, 544 U.S. at 447.[19]

[18] Even if Plaintiff's failure-to-warn claim is preempted, which it is not, his design-defect claim should survive. *See Bates*, 544 U.S. at 444 (holding that common-law rules that "require manufacturers to design reasonably safe products" are not preempted by FIFRA). Monsanto tries to avoid this outcome by arguing that "the district court held that, in light of the evidence at trial, Hardeman's only viable defect theory was the absence of a warning." MB 11-12 n.9. Such dicta is incorrect. Hardeman's design defect theory encompassed more than lack of warning. ER1694. Regardless, there was no reason for Plaintiff to appeal this point because he prevailed on the claim below. *See* ER13-15. If this Court finds that Plaintiff's design defect claim is preempted, the case should be remanded to allow Plaintiff to address this issue with the district court.

[19] *Bates* rejected the United States' "particularly dubious" position that FIFRA expressly preempts "*all* state requirements concerning labeling," noting that the United States had taken a contrary position "just five years ago" in an *amicus* brief filed with the California Supreme Court in *Etcheverry v. Tri-Ag Service, Inc., et al.*, S:072524. 544 U.S. at 449 & n.24; *see also* https://www.citizen.org/wp-content/uploads/usetcheverrybrief.pdf (copy of U.S.'s brief in *Etcheverry*). The United States advances that "particularly dubious" position again in this case.

As the lower court twice held, Plaintiff's claims readily pass this test. *See* ER27-29; 117-20. The analysis under *Bates* is straightforward: state law and FIFRA are "equivalent" when a violation of state law would violate FIFRA's misbranding provisions. 544 U.S. at 447.

FIFRA, in turn, provides that even a duly registered pesticide can be found misbranded if its label "does not contain adequate instructions for use, or if its label omits necessary warnings or cautionary statements." *Id*. at 438 (citing 7 U.S.C. §§136(q)(1)(F), (G)).

California law, similarly, requires a manufacturer to warn either of any risk that is known or knowable (in strict liability) or at least those risks "a reasonably prudent manufacturer would have known and warned about" in negligence. *Conte v. Wyeth, Inc.*, 85 Cal.Rptr.3d 299, 310 (Ct. App. 2008).

As the district court observed, "[i]f anything, a manufacturer's duty under California law is slightly narrower than its duty under FIFRA," because California negligence law "allows a manufacturer to establish liability where a warning would be unreasonable," whereas FIFRA "seems always to require a warning that is 'necessary' and 'adequate' to protect human health—whether or not such a warning is otherwise unreasonable." ER118; *see* 7 U.S.C. §§136(q)(1)(F), (G).

Given that Plaintiff seeks to enforce a duty under California law that is actually *narrower* than FIFRA's misbranding standard, FIFRA's express

preemption clause is facially inapplicable. *See Bates*, 544 U.S. at 447 n.23; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) ("While…a narrower [state-law] requirement might be 'different from' the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule.").

2. EPA's Approval of Roundup Without a Cancer Warning and Its Findings Regarding Glyphosate Do Not Trigger Express Preemption.

Monsanto contends that Plaintiff's claims are expressly preempted because EPA has "recently confirmed" that "[a] cancer warning [on Roundup] would be 'false and misleading' and would make the product misbranded…" MB29. This argument fails as a matter of law and fact.

a. Monsanto's Attempt to Distinguish *Bates* Fails as a Matter of Law.

As a legal matter, Monsanto wrongly assumes that the Supreme Court would have decided *Bates* differently if the EPA had said that the warning advocated by plaintiffs would render the product misbranded. *See* MB30 (emphasizing that, in *Bates*, "[t]he agency had taken no position on whether the warning sought by the plaintiffs was warranted…").

But *Bates* suggests no such thing. There, Dow argued that the Court's "parallel requirements" reading of § 136v(b) *must* be wrong because it would "establish a crazy-quilt of anti-misbranding requirements different from the one

defined by FIFRA itself and intended by Congress to be interpreted authoritatively by EPA." 544 U.S. at 448 (citations omitted). The Court rejected this argument, stating that "the clear text of § 136v(b)…cannot be so easily avoided," particularly given the Court's "duty to accept the reading that disfavors preemption." *Id*. at 448-49.

Thus, *Bates* made clear that even a "crazy-quilt" of different "anti-misbranding" requirements would not trigger express preemption under FIFRA, so long as the state law underlying a particular plaintiff's warning claim is substantively equivalent to FIFRA's general misbranding requirements (and here, as the district court found, it is). ER118.

Monsanto counters by pointing to *Bates*' statement that "a failure-to-warn claim alleging that a pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted because it is inconsistent with 40 CFR § 156.64 (2004), which specifically assigns these warnings to particular classes of pesticides based on their toxicity." MB30-31 (citing *Bates*, 544 U.S. at 453). So here too, says Monsanto, this lawsuit is preempted because it is inconsistent with EPA's approval of Roundup without a cancer warning. *Id.* at 31.

This argument fails because the quoted language merely establishes that where a failure-to-warn claim is—to use *Bates*' words—inconsistent with a

"relevant EPA *regulation* that gives content to EPA's misbranding standards," the state claim is preempted by FIFRA. 544 U.S. at 453 (emphasis added).

That is quite true, but it has nothing to do with this case, for two reasons.

First, Plaintiff's claims are not inconsistent with any EPA misbranding regulations, as *Bates* itself confirms. *See* 544 U.S. at 453 n.28 (EPA has promulgated "relatively few regulations that refine or elaborate upon FIFRA's broadly phrased misbranding standards.").

Second, as the lower court found, "there's no indication that the EPA's approval of Roundup's label had the force of law." ER 119 (citing *United States v. Mead Corp.*, 533 U.S. 218, 227-34 (2001)). That ruling *has* to be correct, because if the mere approval of a label by EPA had sufficient force of law to trigger express preemption under FIFRA, then the statute would wipe out *all* state-law warning claims involving federally registered products—a result so obviously contrary to *Bates* that not even Monsanto dares overtly to suggest it.

Monsanto fares no better in analogizing this case to *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which found federal preemption of a state-law claim under "a similarly worded" statute: the Medical Device Amendments (MDA) to the Food Drug and Cosmetic Act (FDCA). *See* MB31-32.

First, *Riegel* actually confirms that state-law claims that parallel federal requirements are *not* preempted by federal law. 522 U.S. at 330 (holding that state

tort claims "are pre-empted under the MDA *only* to the extent that they are 'different from or in addition to,' the requirements imposed by federal law…") (emphasis added; citation omitted). *Bates* said exactly the same thing. *See* 544 U.S. at 447 ("[A] state-law labeling requirement is not pre-empted…if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions.") (citation omitted).

There is no daylight between *Bates* and *Riegel* on this key point. The only difference between the cases is that the *Riegel* plaintiffs could not pursue this argument because it was waived (544 U.S. at 330), whereas Hardeman has steadfastly contended throughout this litigation that his claims are not preempted precisely *because* they parallel federal misbranding standards.

Second, Monsanto ignores that FIFRA—unlike the MDA—expressly provides that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." 7 U.S.C. § 136a(f)(2). As a result, EPA's approval of a pesticide's label does not mean that the label complies with FIFRA. That alone defeats Monsanto's reliance on *Riegel* as dispositive in the FIFRA context.

b. Monsanto's Attempt to Circumnavigate *Bates* Fails as a Matter of Fact.

Monsanto's attempt to distinguish *Bates* on its facts falls just as flat. Monsanto says that *Bates* has no bearing here because EPA has "repeatedly rejected" a cancer warning for Roundup. MB30. This is simply untrue. Monsanto has never asked for a cancer warning on Roundup. Unsurprisingly, EPA has never rejected one.

In reality, EPA has only made findings as to the carcinogenicity of *glyphosate*, which is far less toxic than Roundup. And the agency has repeatedly acknowledged a need "to evaluate the role of glyphosate in product formulations [e.g., Roundup] *and* the differences in formulation toxicity." PSER491-92; *see also 2019 Interim Glyphosate Review* at 11.

Even the OPP Letter, which Monsanto repeatedly cites as proof that a cancer warning on Roundup would "make the product misbranded" in EPA's judgment (MB29-30), disproves Monsanto's point. There, OPP admits that it *has* previously approved cancer warnings on glyphosate-containing products. OPP then says that it will no longer approve label changes "where the *only basis* for the [cancer warning] is [that the product contains] glyphosate..." OPP Letter at 2 (emphasis added). But this lawsuit has never contended that the mere presence of glyphosate in Roundup caused Hardeman's cancer—or rendered the product's label inadequate. To the contrary, Hardeman has alleged, and proved at trial, that Roundup is more carcinogenic than glyphosate alone. *See* pp. 15-16, 25-27.

Thus, even if a disagreement between EPA and a state jury verdict as to the adequacy of a warning on a particular product could trigger express preemption under FIFRA—and, under *Bates*, it does not—there is no such disagreement here because EPA has never rejected a cancer warning for Roundup.

B. Plaintiff's Claims Are Not Impliedly Preempted.

Monsanto's implied preemption arguments are equally flawed. Despite the United States' concession that EPA actually "approved glyphosate cancer warnings on at least two prior occasions" (U.S. Br. at 18-19 n.14)—a concession that causes the United States to abandon implied preemption entirely (*see id.*)—Monsanto argues that it would be "impossible" for Monsanto to comply with both federal law and the state-law duty to warn on which the verdict rests. MB32. Not so.

1. Any Inquiry Into Implied Preemption Foreclosed by *Bates*.

As a threshold matter, this Court should not even reach these arguments because any finding of implied preemption is foreclosed by *Bates*, which declined to address impossibility preemption even though that issue was extensively briefed by both parties and their amici. *See* 544 U.S. at 459 (noting that the majority's decision "comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption.") (Thomas, J., concurring in judgment and dissenting in part); *see also Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270, 1281-82 (D. Haw. 2015) (citing *Bates*

briefs and finding that *Bates* necessarily rejected implied preemption *sub silentio*).

As *Ansagay* explained, *Bates* "*had* to consider any arguments that, if successful, would have affirmed the lower court decision finding preemption." *Id.* at 1281 (emphasis added; citation omitted). Therefore "it makes no sense" to think that *Bates* did not foreclose implied preemption under FIFRA. *Id*.

2. Monsanto's Implied Preemption Argument Fails on the Merits.

But even if *Bates* did not entirely foreclose any inquiry into implied preemption, there is no such preemption here. Monsanto offers two grounds for this argument: (1) that there is "clear-evidence" that EPA would not approve a cancer warning on Roundup; and (2) that EPA's right to veto label changes proposed by registrants preempts any warning claim. Each argument fails.

a. Monsanto Has Not Shown "Clear-Evidence" of Impossibility Under *Merck*.

First, the burden of providing impossibility preemption under the clear-evidence standard lies with Monsanto—and that burden is a heavy one. As the Supreme Court has said, "[i]mpossibility pre-emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). For a state law to be invalidated, it must "*require* a private party to violate federal law," *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 475 (2013) (emphasis added). The mere "possibility of impossibility is not enough." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019) (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 625 n.8

(2011)). Rather, a court must find that the relevant federal and state laws "irreconcilably conflic[t]." *Id*. at 1679 (quoting *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)).

To demonstrate an "irreconcilable conflict," a manufacturer must present "clear evidence" (1) that the manufacturer fully informed the agency of the justifications for the warning that would be required by state law; (2) that the agency, in turn, informed the drug manufacturer that the FDA would not approve the change; and (3) that the agency action at issue "carr[ies]the force of law." *Id*. at 1679. Monsanto has not carried its burden for any of these factors.

i. "Clear Evidence" of Impossibility Must Exist at the Time of Plaintiff's Injuries.

As a threshold matter, when evaluating "clear-evidence" under *Merck*, a court is limited to considering events at the time of the plaintiff's injury. *See In re Avandia Marketing, Sales & Products Liability Litig.*, 945 F.3d 749, 757 (3d Cir. 2019). In *Avandia*, for example, the court rejected an impossibility defense predicted on FDA's conclusion "that a link between Avandia use and increased cardiovascular risk does not exist" based on post-injury data. *Id*. at 756–57; *see also Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 255 (3d Cir. 2008) (holding that "informal policy opinion[s]" made "only after [plaintiff's] injuries" have no preemptive effect).

In this case, Hardeman's exposure ended in 2012—years before EPA took any of the recent actions that lie at the heart of Monsanto's preemption arguments. At that time, EPA had not made any registration decisions about glyphosate since 1991, when it cautioned that its designation of glyphosate as non-carcinogenic "is based on the available evidence at the time of evaluation and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances." PSER306.

But even if EPA's post-exposure actions regarding glyphosate were relevant to the analysis, Monsanto has still not shown clear evidence of impossibility.

ii. Monsanto Never "Fully Informed" EPA of the Justification for a Cancer Warning on Roundup.

The first clear-evidence factor—that the manufacturer must show it "fully informed" the agency of the justification for a warning—makes little sense in the context of this case, because the company has never informed *itself* as to the need for such a warning.

As the district court ruled post-trial, "[d]espite years of colorable claims in the scientific community that Roundup causes [NHL], Monsanto presented minimal evidence suggesting that it was interested in getting to the bottom of those claims…" ER8.

The company's own internal emails admit the same. In 2003, Monsanto

spokesperson Donna Farmer stated, "you cannot say that Roundup is not a carcinogen…we have not done the necessary testing on the formulation to make that statement." PSER257-58. She repeated that statement in 2009. PSER244. To this day, Monsanto has *still* never tested whether Roundup causes cancer. How, then, can it claim to have "fully informed" the EPA of the need for such a warning? Short answer: it cannot.

Monsanto's failure to conduct cancer studies on Roundup was deliberate. As recounted above, after renowned scientist Dr. James Parry told Monsanto that Roundup could be ten times more toxic than glyphosate alone and implored Monsanto to study the "possibility of susceptible groups within the human population," Monsanto refused, stating "We simply aren't going to do the studies Parry suggests." PSER215; PSER236-37; PSER239. And Monsanto never submitted Dr. Parry's reports to EPA, in violation of FIFRA. *See* 40 C.F.R. §§159.152; PSER405.

Against this backdrop, Monsanto's claim to have satisfied the first *Merck* factor would be laughable, if it were not so offensive. Monsanto has not only persistently refused to study whether Roundup causes cancer, but—as the district court found—it "attacked or undermined people who raised concerns" and "tamp[ed] down safety inquiries and manipulat[ed] public opinion" regarding Roundup's risks. ER7-8.

Notably, Monsanto does not even try to show that it or anyone else "fully informed" EPA of the dangers of Roundup. Instead, the company plays sleight-of-hand with the facts, arguing that EPA conducted "in-depth scientific reviews of the evidence on *glyphosate's* safety," and thus was "fully informed" of "the evidence that *glyphosate* is allegedly carcinogenic [ ] when it determined that no cancer warning was warranted." MB34 (emphases added).

Here again, Monsanto is mixing apples with oranges, because—as Monsanto well knows—glyphosate is not Roundup. Whatever "in-depth scientific reviews" EPA has conducted with regard to glyphosate do not establish clear evidence of *anything* with regard to Roundup. The first prong of *Merck* is not met.

iii. EPA Has Never Rejected a Cancer Warning on Roundup.

Nor has Monsanto met its burden of showing clear evidence that EPA would reject a cancer warning on Roundup, as *Merck* requires. Monsanto argues that OPP's Letter shows that EPA "would not approve changing" Roundup's labeling to include a cancer warning. *Id*. at 35 (citing *Merck*, 139 S. Ct. at 1678). But all the Letter shows is that EPA—to use the agency's own words—will no longer approve pesticide labels "where the only basis for the warning is that [the product] contains glyphosate…" *Id.*

The Letter is irrelevant, because (again) Hardeman has never contended that

the "only basis" for a cancer warning on Roundup is that the product contains glyphosate. And EPA has never said that it would reject a warning on Roundup; in fact, it has repeatedly stated that it has never studied the carcinogenicity of GBFs—and that there is a need for such studies. *See supra* pp. 12-13. The second prong of *Merck* is not met.[20]

iv. EPA's Decisions Regarding Glyphosate Lack Force of Law.

Finally, even if the OPP Letter were relevant here, it lacks the requisite force of law to have preemptive effect under *Merck*. Agency actions only have preemptive effect if they "carry the force of law under [*United States v. Mead*, 533 U.S. 218 (2001)] and its progeny." *Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015).

Under *Mead*, an agency action has force of law when it results from "a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force"—typically, notice-and-comment rulemaking or formal adjudication. 533 U.S. at 230.

The OPP Letter is a paradigmatic example of what *lacks* force of law under *Mead*. The opinion in the Letter—that "pesticide products bearing the Proposition

[20] Monsanto's other decisions regarding glyphosate do not provide any basis for a finding of impossibility because, as explained above, EPA views glyphosate and GBFs as distinct. *See supra* pp. 9-10, 12-14.

65 warning statement due to the presence of glyphosate are misbranded"—was not the result of any formal or even quasi-formal agency procedure. And the timing of the Letter was suspicious, to say the least, coming directly on the heels of Monsanto's unsuccessful attempt to convince the district court to throw out the jury verdict in this case.

If this type of informal agency action could preempt state law, the implications for federalism (not to mention public safety) would be grave indeed. It would mean that state laws could be wiped out at an agency's whim, perhaps at the behest of industry, without any concern for, or input from, the public or the States. That would be unacceptable in any realm, but it is especially intolerable in the context of a statute like FIFRA, that was designed to ensure that States have concurrent authority over a dangerous product. *See Bates*, 544 U.S. at 437-40.

Fortunately, the law is clear that OPP's Letter does not possess preemptive effect. *Fellner*—cited approvingly in *Reid*, 780 F.3d at 964—makes this strikingly evident. *See* 539 F.3d 237. There, the defendant sought preemption based on a letter from FDA to California stating that a Proposition 65 warning on tuna would be misleading. *Id*. at 254. In rejecting that argument, the Court noted that FDA had not exercised any of its many congressionally authorized methods for enforcing the law's misbranding provisions, but instead "merely expressed an informal policy opinion in a letter, and it did so only after [the plaintiff's] injuries

were allegedly suffered." *Id*. at 255; *see also Wabash Valley Power Ass'n Inc. v. Rural Electrification Admin*., 903 F.2d 445, 454 (7th Cir. 1990) (holding regulatory letter from agency did not have preemptive effect).

Similarly here, Congress has provided at least two formal means for EPA to determine that a pesticide is misbranded: misbranding enforcement actions and registration-cancellation procedures. *See Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 36-37 (D.D.C. 2011).

EPA has done *neither* with respect to GBFs that bear Proposition 65 warnings—warnings, it should be noted, that the United States *admits* were initially approved by EPA. Rather, OPP merely issued a two-page letter declaring those products "misbranded" under FIFRA. Monsanto and the United States seek to deploy that Letter to retroactively preempt all three verdicts rendered against Monsanto in 2018 and 2019 (including this case), *and* to preempt future lawsuits against Monsanto.

But, as in *Fellner*, EPA cannot eschew the procedures Congress has provided in favor of an informal policy statement. That is true in any case, but especially here, where the position that Proposition 65 warnings are not permitted on GBFs is a reversal of EPA's decisions approving the addition of such warnings. *See Mead*, 533 U.S. at 228 (inconsistency makes an agency's views less worthy of deference); *Skidmore v. Swift & Co*., 323 U.S. 134, 140 (1944) (same).

Monsanto's only cited case on this point, *Reckitt Benckiser, Inc. v. EPA*, 613 F.3d 1131, 1138 (D.C. Cir. 2010), dealt with whether an EPA letter constituted final agency action for purposes of judicial review under the Administrative Procedures Act. As *Reid* makes clear, that is the wrong question to ask. When the right question is asked—"does the agency's action have sufficient force of law to preempt state law?"—the answer is clear: it does not.

b. EPA's Pre-Approval Authority Over Label Changes Does Not Impliedly Preempt Plaintiff's Claims.

Monsanto also argues that because EPA must approve most labeling changes under FIFRA, impossibility preemption applies with the same force here as in the context of generic drugs, where the FDA must pre-approve any labeling changes. MB37 (citing *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011)). This argument fails for several reasons.

First, as the district court recognized, this argument cannot be squared with the Supreme Court's holding in *Bates*. There, Dow could not have changed its label to add the warning advocated by the plaintiffs without prior EPA approval. Despite that, the Court held that tort claims challenging the label's statements regarding the product's efficacy would *not* be preempted so long as they mirror FIFRA's misbranding requirements. *See* 544 U.S. at 434-45. As the lower court

recognized, that holding necessarily disposes of Monsanto's impossibility argument based on EPA's prior-approval authority. *See* ER28.[21]

Second, Monsanto's prior-approval argument contradicts *Bates*' "narrow" reading of FIFRA's preemption clause. 544 U.S. at 452. *Bates* rejected the notion that "Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers *virtual immunity* from certain forms of tort liability." *Bates*, 544 U.S. at 450 (emphasis added). But that is exactly what Monsanto is seeking here: "virtual immunity" for pesticide manufacturers from *all* state failure-to-warn claims. That cannot be right in light of *Bates.*

Third, Monsanto's argument ignores that FIFRA permits a State to restrict or completely *ban* pesticide sales and use—including the State's perception that the label's warning is inadequate or the product is misbranded. 7 U.S.C. §136v(a). As the lower court observed, "if California can stop Monsanto from selling Roundup

[21] Monsanto tries to get around *Bates* by arguing that, "unlike Monsanto here, the manufacturer in *Bates* could have changed efficacy claims on its labeling without prior approval of the agency." MB 37. Not true. Although EPA has waived review of the underlying data for efficacy claims, any amendments to such claims must nonetheless be reviewed and approved by EPA, because the agency has reserved the right to require such data where circumstances warrant. *See, e.g.*, EPA *Label Review Manual*, https://tinyurl.com/rwxw838, at 4-7 (explaining that "labeling changes that require review" include "application[s] for an amendment to a currently registered pesticide where no data is required for review of the action.").

entirely, surely it can impose state-law duties that might require Monsanto to seek EPA approval before selling an altered version of Roundup in California." ER28. This aspect of FIFRA distinguishes it from the pharmaceutical and medical device cases Monsanto relies upon in support of its impossibility preemption argument. As the district court observed, "nothing in the [Federal Food, Drug, and Cosmetic Act] allows a state to ban a drug." ER28 (citations omitted).

Other aspects of FIFRA support this conclusion. In particular, FIFRA also provides that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under" FIFRA. 7 U.S.C. § 136(a)(f)(2). Rather, registration of a pesticide is merely "*prima facie* evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter." *Id*.

Fourth, and finally, Monsanto's prior-approval argument flies in the face of FIFRA's entire *raison d'être*: to protect the public from hazardous pesticides. *See Bates*, 544 U.S. at 437-40. Monsanto is asking this Court to hold that EPA's prior-approval authority over pesticide labels preempts *all* state-law warning claims, no matter how inadequate the label. If adopted, this would gravely threaten public health because EPA is entirely reliant on pesticide registrants to ensure the

adequacy of their own labels. *See Burke v. Dow Chem. Co.*, 797 F. Supp. 1128, 1134 (E.D.N.Y. 1992).[22]

Recognizing this danger, Congress designed FIFRA to "preserve a broad role for state regulation." *Bates*, 544 U.S. at 450. As *Bates* said, tort actions like this one help reinforce and support FIFRA's safety goals, both by unearthing the dangers of pesticides that EPA might not know about *and* by creating a financial incentive for pesticide manufacturers to do the right thing. *See id.* at 451.

If tort actions like this one are wiped out by preemption, the public will be at far greater risk of injury from inadequately labeled pesticides. As the United States has observed, at the time of FIFRA's enactment, "the number of deaths and injuries attributable to pesticides [ranged] from 200 to 800 deaths per year, and *60,000 to 80,000* injuries." U.S. *Etcheverry* Br. at 31 (emphasis added). Against this backdrop, the Unites States argued that "preemption of state tort law would *strongly conflict* with the central purpose of the 1972 FIFRA amendments—providing *increased public protection against pesticides*." *Id*. at 9 (emphases added).

[22] As *Bates* held, "[i]t is no answer that, even if all label-related claims are pre-empted under Dow's reading, other non-label-related tort claims would remain intact. Given the inherently dangerous nature of pesticides, most safety gains are achieved not through modifying a pesticide's design, but by improving the warnings and instructions contained on its label." 544 U.S. at 450 n.25.

If Monsanto has its way, the public will be almost entirely at the mercy of pesticide manufacturers to police their own labels. It is understandable why Monsanto might like this result, but it is a terrible outcome from the perspective of public safety—and it is directly contrary to FIFRA itself. It should be rejected.

II. THE DISTRICT COURT DID NOT ERR OR ABUSE ITS DISCRETION IN ADMITTING THE CAUSATION OPINIONS OF HARDEMAN'S EXPERTS.

Monsanto's argument that this case "never should have gone to the jury" because the district court misunderstood and misapplied *Daubert* is as flawed as its preemption argument.

A. The District Court Applied the Correct Standard for Determining Admissibility Under *Daubert*.

First, the district court applied the correct legal standard under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). Monsanto argues that Judge Chhabria violated *Daubert* by admitting testimony that he characterized as "borderline." MB41. But that is exactly what *Daubert* **requires:** "[T]he interests of justice favor leaving difficult issues in the hands of the jury and relying on the safeguards of the adversary system [] to 'attack[] shaky but admissible evidence.'" *Wendell*, 858 F.3d at 1237 (citations omitted) (quoting *Daubert*, 509 U.S. at 596); *accord Adams v. Laboratory Corp. of Am.*, 760 F.3d 1322, 1334 (11th Cir. 2014) ("shakiness goes to the weight of [an expert's] testimony, not its admissibility."); *Clark v. Heidrick*, 150 F.3d 912, 915 (8th Cir. 1998) (doubts regarding "'whether

an expert's testimony will be useful should generally be resolved in favor of admissibility.'") (quoting *Larabee v. MM&L Int'l Corp.*, 896 F.2d 1112, 1116 n.6 (8th Cir.1990)).

The only substantive basis for the argument is Monsanto's erroneous claim that the district court, in rendering its specific-causation ruling, misinterpreted *Wendell* and *Messick* as allowing experts to use clinical experience and judgment grounded in "scientific methods and procedures" (what Monsanto terms as "art"). According to Monsanto, that approach is allowed only in "exceptional circumstances" not present here—namely, cases involving "rare diseases" where there is insufficient data for epidemiology. MB44-46.

Wendell and *Messick*, however, are not so limited. *Wendell* held that "expert testimony may still be reliable and admissible without peer review and publication." 858 F.3d at 1235. The Court noted that this is "*especially* true when dealing with rare diseases," but did not state that the premise is *only* true when dealing with rare diseases. *Id*. (emphasis added).

Messick held that "[m]edicine partakes of art as well as science, and there is nothing wrong with a doctor relying on extensive clinical experience when making a differential diagnosis"—which is, of course, exactly what Hardeman's experts did here. *Messick*, 747 F.3d at 1198; *see also* ER37-38. The word "rare" does not

even appear in *Messick*, and nothing in that opinion limits its applicability to rare injuries.

As to the supposed "exceptional circumstance" in *Messick* (MB44), Monsanto does not point to one. It attempts to distinguish *Messick* by claiming the expert there relied on "clinical experience" and "examination of medical literature and Messick's records." MB45. But that is no different from this case. If anything, Hardeman's experts relied upon *far* more data than the *Messick* expert, including powerful lines of evidence such as epidemiology, animal, and cell studies. ER37-38.

Monsanto also argues that because epidemiological studies were available to Hardeman's experts, and were *un*available in *Wendell* and *Messick*, Hardeman's experts' reliance upon clinical experience and judgment was improper as a matter of law. MB46. This argument fails on at least two levels.

First, it ignores that Plaintiff's specific-causation expert (Dr. Weisenburger) did rely upon epidemiology to support his specific-causation opinion, including a study, fully adjusted for other confounding variables, which reported a statistically significant odds ratio of 2.49 for diffuse large B-Cell Lymphoma, Hardeman's precise subtype of NHL. PSER113; PSER516; PSER202-05. That is important

because an odds ratio of over 2.0 is highly probative of more-likely-than-not causation.[23]

Second, Monsanto's argument is based on a flawed premise: that when available, epidemiological studies must *supplant* clinical experience and scientific judgment as the basis of any specific-causation opinion. But as Monsanto's own amici note, "while epidemiology is a useful tool in identifying the *possible* causes of a disease, it is, without more, ill-suited to establish the *specific* cause." Amici Curiae Brief of California Medical Association, et al. (Med. Ass'n Br.) at 27 (emphases in original). "[T]he question of specific causation requires a deeper analysis than epidemiology alone can answer." *Id*. at 28. Rather, the task of determining specific causation is necessarily "an inferential process of weighing evidence and using judgment to conclude whether or not an effect is the result of some stimulus. *Judgment is required, even with using sophisticated statistical methods*." *Id*. (emphasis added).

As other circuits have noted, differential diagnosis necessarily "involves far more elements of judgment than does a scientific study attempting to test a more

[23] As one court observed, "a relative risk of 2.0 implies a 50% probability that the agent at issue was responsible for a particular individual's disease. This means that a relative risk that is greater than 2.0 permits the conclusion that the agent was more likely than not responsible for a particular individual's disease." *In re Silicone Gel Breast Implants Products Liab. Litig*., 318 F. Supp. 2d 879, 893 (C.D. Cal. 2004) (citation omitted); *see also* MB52 (same).

general scientific proposition." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 758 (3d Cir. 1994). Rather, judgment, grounded in "scientific methods and procedures" and clinical experience, is an inextricable component of *any* reliable differential diagnosis. *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1058 (9th Cir. 2003).[24]

Equally flawed is Monsanto's argument that the district court erred as a matter of law because it purportedly allowed Hardeman's experts to *substitute* (rather than supplement) "clinical experience" for reliable scientific evidence on specific causation. MB47 (emphasis added). This argument assumes its own conclusion—that Hardeman's experts relied on no evidence that Roundup causes NHL apart from their own clinical experience. But as the district court observed at both stages, this is simply not the case. ER41; ER115-16. And because Plaintiff's experts relied on Hardeman's medical records, their clinical experience, Hardeman's exposure levels, and "admissible general causation opinions," in support of their specific-causation opinions, their clinical experience was not

[24] The inverse of Monsanto's argument illustrates this point: an expert attempting to offer a specific-causation opinion predicated *exclusively* upon epidemiological literature would face an impossible task because, as the district court observed, "[w]hether [an] agent *causes* [NHL]…cannot be proven by epidemiological studies alone." ER61 (emphasis original); *see also* Med. Ass'n Br. at 28 ("*This question, often referred to as specific causation, is beyond the domain of the science of epidemiology.*") (emphasis in original) (citation omitted).

substituted for other evidence but rather added to the large body of evidence they employed in rendering their opinions. *See* ER37-38.

* * *

In short, the district court applied the correct legal standard for evaluating the admissibility of Plaintiff's experts' opinions. The only remaining question is whether the Court abused its discretion in *applying* that standard to admit their testimony. It did not.

B. The District Court Did Not Abuse Its Discretion in Admitting Hardeman's General Causation Experts.

Monsanto's argument on general causation, boiled to its essence, is that the district court erred because Hardeman failed to produce "scientifically valid and reliable epidemiological opinions that glyphosate can cause [NHL]." MB 49. In other words, according to Monsanto, animal and cell studies are inadmissible *unless* the epidemiological link between glyphosate and disease is sufficiently probative of general causation *by itself* to pass *Daubert*. Because the epidemiology is lacking, says Monsanto, Plaintiff's experts' opinions—which holistically considered all three pillars of the general causation science: epidemiology, cell studies, *and* animal studies—should never have been admitted.

This argument fails for several reasons.

1. Hardeman's Experts Had a Reliable Basis to Extrapolate Results From the Animal and Cell Studies.

First, Monsanto's central premise is incorrect. As the district court found, animal and cell studies *may* be considered to determine causation so long as there is sufficient evidence of an *association* between a pesticide and a disease in humans within the epidemiological literature. ER83. Because the epidemiological evidence demonstrates an association between Roundup and NHL (more on this *infra* at (B)(2)), Hardeman's experts reliably extrapolated the results of animal and cell studies to support their general causation opinions. Monsanto points to nothing in the record to support its contention that there is "too great an analytical gap between the data and [the experts' opinions]." MB42 (citation omitted).

In fact, the district court explained precisely *why* extrapolations from the animal data are appropriate in this context. "Demonstrating that a chemical is carcinogenic in rodents would logically advance the [] argument that glyphosate is capable of causing NHL in humans" because "[r]odent cancer studies are routinely conducted to learn information that is useful in assessing whether substances cause cancer in humans." ER78.

As to the cell studies, no analytical leap was necessary to extrapolate the results to living humans because cell studies on live humans, exposed to GBFs in real world conditions, demonstrate evidence of genotoxicity—the mechanism by which Roundup causes NHL. ER82. Moreover, one of the studies cited by Plaintiff's experts observed genotoxicity in human lymphocytes, a significant

finding because lymphocytes are the very cells that mutate to cause NHL. ER569, 571, 577.

Even apart from these studies, Hardeman's experts relied upon a trove of *in vivo* and *in vitro* cell studies to prove that it is biologically plausible that Roundup causes NHL. ER94-95. These data bolster the experts' general-causation conclusions because, as the court recognized, "[e]vidence that glyphosate causes damage to genetic material in cells (genotoxicity)...supports the plaintiffs' argument that it is biologically plausible that glyphosate acts as a carcinogen." ER81. And the presence of a biologically plausible mechanism by which Roundup operates to cause NHL, supports the inference that the associations observed within the epidemiology are "genuine and causal." *See Milward v. Acuity Specialty Prod. Group, Inc.*, 639 F.3d 11, 26 (1st Cir. 2011).

The upshot is that the animal and cell studies strongly corroborate the association observed in the epidemiology. For example, while Dr. Portier testified that the epidemiology was "limited," the court observed that there is nothing improper with an expert relying upon animal and cell studies to "bolster a causal interpretation of [the epidemiology] studies that could not alone establish causation." ER84. In fact, outside of the courtroom, Monsanto's own expert epidemiologist employed the same methodology as Dr. Portier—"turn[ing] to

biological plausibility to assess study findings" when the epidemiology is insufficient to prove causation by itself. PSER538.[25]

In short, the court's consideration of the overall sufficiency of the evidence is not only consistent with fulfilling its role as gatekeeper, it is *required*. *U.S. v. W.R. Grace*, 504 F.3d 745, 765 (9th Cir. 2007).

* * *

Notably, Monsanto barely mentions the cell or animal studies in its brief. Instead, Monsanto attacks a straw-man, arguing that without reliable epidemiology, "the animal and cell studies *alone* are insufficient to satisfy Hardeman's burden to establish causation." MB49 (emphasis added). But Hardeman has never argued—and the district court did not find—that "animal and cell studies alone" are sufficient to establish causation. Rather, Hardeman has always maintained that such studies may properly be considered in context.

[25] Monsanto misstates the law by suggesting that epidemiology is required to satisfy *Daubert.* As this Court held in *Kennedy v. Collagen Corp*, 161 F.3d 1226, 1228 (9th Cir. 1998), it is not. *See also Milward*, 639 F.3d at 24 ("Epidemiological studies are not per se required as a condition of admissibility regardless of context"); *Rider v Sandoz Pharm. Corp.*, 295 F.3d 1194, 1193 (11th Cir. 2002) ("It is well-settled that while epidemiological studies may be powerful evidence of causation, the lack thereof is not fatal to a plaintiff's case."); Restatement (Third) of Torts: Phys. & Emot. Harm §28 (2010), rep.'s note to cmt. c(3) (noting biological-mechanism evidence may be sufficient).

As the district court recognized, all three pillars of causation are relevant where, as here, the epidemiology shows an association between a pesticide and a disease in humans. ER61-62. This is evident from the Bradford Hill criteria, which *necessarily* contemplate that the entire scientific body of evidence relating to a substance be viewed as a whole. *See* ER61 (observing "whether [Roundup] *causes* [NHL]…cannot be proven by epidemiological studies alone," but instead requires epidemiologists to exercise judgment about the import of [epidemiological] studies *and to consider them in context*.") (emphasis added). The district court's conclusion on this point was correct and should not be disturbed. *See Wendell*, 858 F.3d at 1233 (district court abused its discretion by failing to "take[] into account the broader picture of the experts' overall methodology.").

2. The Epidemiology Proves a Reliable Association Between GBFs and NHL.

The district court likewise did not abuse its discretion in finding that the epidemiology shows a reliable association between Roundup and NHL. Even a *single* epidemiology study finding a positive association can be sufficient to satisfy the first step of the Hill criteria. *See* Restatement (Third) of Torts: Phys. & Emot. Harm §28 (2010), rep.'s note to cmt. c(3) ("[T]he [Bradford Hill] factors were developed for the purpose of determining whether an inference of causation is justified based on *a study* finding an association.") (emphasis added). But here,

Hardeman's experts relied upon *multiple* epidemiology studies to demonstrate such an association. ER62-72.

As the court observed, virtually all of the case-control studies observed elevated risks following human exposure to GBFs. ER62-72. Two pooled studies, De Roos (2003) and the North American Pooled Project (NAPP), reported statistically significant, elevated risks for NHL after adjusting for other pesticides. ER65-71. The NAPP also reported a statistically significant odds ratio for Hardeman's subtype of NHL. PSER113; PSER516; PSER204-05. Multiple meta-analyses, including one commissioned by Monsanto to rebut IARC's classification of glyphosate, also reported elevated odds ratios. ER68-69; PSER535-36.

When viewed collectively, the epidemiology points in one direction—toward an association between human exposure to GBFs and NHL.

3. The District Court Did Not Abuse Its Discretion In Admitting Expert Opinions that Discounted the Deeply Flawed Agricultural Health Study.

Monsanto's main challenge to the foregoing is that Plaintiff's experts failed to give sufficient weight to the Agricultural Health Study (AHS), which Monsanto now contends is a "gold standard" epidemiology study. MB50.

Monsanto ignores the devastating fact that it largely *agreed* with Hardeman's experts' opinions on the methodology of the AHS before it knew the results would be favorable to its bottom line. The only epidemiologist Monsanto

ever employed wrote years before the AHS results were announced that "the exposure assessment in the AHS *will be inaccurate*" because the AHS "will most often obscure exposure disease relationships." PSER281 (emphasis added). Monsanto's head toxicologist, Donna Farmer, was even more blunt, calling the AHS a "flawed study" that some scientists characterized as "junk science." PSER286.

These statements mirror Plaintiff's experts' views of the AHS as deeply flawed and unreliable. *See* ER74-76; Plaintiffs' Supp. Br. re PTO 34, No. 3:16-md-02741, Dkt. 1135 at 7-13. It was only after AHS reported results favorable to Monsanto that it started touting the previously denigrated study as the "most powerful" evidence supporting its position. MB40.

That alone shows that the experts' opinions on the AHS are, as the district court found, within "the range where experts might reasonably differ." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 153 (1999); *S.M. v. J.K.*, 262 F.3d 914, 921 (9th Cir. 2001), *as amended*, 315 F.3d 1058 (9th Cir. 2003); *see also* ER 77 (holding that "the epidemiology evidence is open to different interpretations" such that "an expert who places more weight on the case-control studies than the AHS cannot be excluded as categorically unreliable for doing so."); *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 433 (7th Cir. 2013) ("Rule 702 [does] not

require, or even permit, the district court to choose between the studies at the gatekeeping stage.").[26]

4. Monsanto's Specific Critiques of the Epidemiology Studies Relied on by Plaintiff's Experts Lack Merit.

Monsanto's specific critiques of the studies relied on by Plaintiff's experts, discussed below, are just as flawed.

c. Monsanto Is Asking the Court to Ignore the Epidemiological Forest for the Trees.

As a threshold matter, Monsanto's atomized criticisms of certain epidemiological studies—even if valid—do not support a conclusion that the district court abused its discretion. For Monsanto's argument to have purchase, it would have to demonstrate that the alleged shortcomings within individual epidemiology studies, all of which the district court explicitly considered, ER61-

[26] Monsanto's assertion that Dr. Ritz changed her view of the AHS study in light of the litigation is brazenly deceptive and false. MB53 n.19. Monsanto insinuates that prior to being retained as an expert, Dr. Ritz taught the AHS study to her students as an example of a "wonderful study." *Id.* This is precisely the opposite of how Dr. Ritz used the AHS in the classroom. Dr. Ritz's testimony, in context, reveals that she used the AHS as an example of the flaws inherent to such a study design. ER1521-1522. This is confirmed in Dr. Ritz' supplemental expert report, which explained that she "used the AHS as an example of problems that can arise in cohort studies." PSER528-29.

77, so pollute the experts' opinions that any reliance upon such a study renders the *entirety* of the experts' opinions unreliable.

That, however, is not the law. *See W.R. Grace*, 504 F.3d at 765. Rather, "[a] study's failure to establish causation goes to the weight it should be accorded," and does not prevent an expert from "rely[ing] on it in forming an opinion." *Id.* And because Hardeman's experts all reached their conclusions based on the entirety of the evidence, flaws in individual studies would not render their opinions invalid. Rather, as the district court determined, these criticisms go to weight, not admissibility. ER116.

d. Monsanto's Attack on the Individual Epidemiological "Trees" is Just as Flawed.

That aside, Monsanto's specific criticisms on the various case-control studies relied on by Plaintiff's experts lack merit.

i. Hardeman's Experts Expressly Considered the Issue of Latency in the De Roos Study.

Monsanto attacks De Roos (2003)—an important study that reported a statistically significant odds ratio of 2.1 fully adjusted for other pesticides, ER35—as failing to "properly account for [NHL's] latency period," saying this fact destroys the validity of the entire study. MB54-55.

Monsanto wrongly assumes that latency must be *at least* five years. MB54. As Dr. Weisenburger testified at trial, latency may be as short as two years.

ER532. Because the latency period is subject to legitimate debate among experts, the entire premise of Monsanto's argument fails. *See Milward*, 639 F.3d at 22 (the court may not "t[ake] sides on questions that are currently the focus of extensive scientific research and debate—and on which reasonably scientists can clearly disagree.").

Beyond that, Monsanto's argument fails because the latency issue was expressly considered by Hardeman's experts in forming their opinions and by the district court in admitting them. ER71-72; ER102; PSER167-80, PSER189-98; ER528-32 (Weisenburger discussing latency). As Dr. Ritz observed, Monsanto's latency argument highlights an important strength of the study—notwithstanding the shorter latency period, De Roos still observed a statistically significant doubling of the risk for those exposed to only Roundup. In other words, the design of the study only accounted for individuals who developed cancer rapidly after exposure, but the results still showed an elevated risk. ER71.

Moreover, Monsanto's failure to so much as suggest an alternative cause for the statistically significant, fully adjusted, association in the De Roos study leaves random chance as the only conceivable explanation for the observed association. This defies common sense. Although it is theoretically possible that the observed association is due to chance, because the results are statistically significant at a

95% level, that chance is only 1 in 20, much lower than the threshold for admissibility under Rule 702 and *Daubert*.[27]

ii. Contrary to Monsanto's Contention, Plaintiff's Experts Considered Confounding.

Monsanto also criticizes Hardeman's experts by arguing that, when evaluating the epidemiology, they did not consider confounding factors. Not true. For example, as the district court observed, "Dr. Portier addressed the most significant concern—the possibility that pesticides other than glyphosate caused the observed cases of NHL—*by focusing on data adjusted for potential confounding by various other pesticides.*" ER87 (emphasis added); *see also* ER97-98 (discussing Dr. Ritz); ER103 (discussing Dr. Weisenburger).

These experts emphasized "the consistency of the observed associations in the case control studies, which were primarily above 1.0 even if some were not statistically significant." ER99. This is important because where adjustment for other pesticides resulted in a loss of statistical significance, the results consistently indicated a positive association between GBFs and NHL, even if the association

[27] *See W.R. Grace*, 504 F.3d at 765 (9th Cir. 2007) ("conduct[ing] a document-by-document Rule 702 analysis that deconstructed the experts' testimony in a manner not contemplated by Rule 702" is an abuse of discretion); *McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092, 1114 (D. Or. 2010) ("An expert's obligation to explain the basis for a proffered opinion does not mean that each piece of data must support causation when considered in isolation.").

was no longer significant. ER65-68; ER85 (noting that Dr. Portier "concluded it was unlikely that so many studies would report results above 1.0, whether statistically significant or not, if there was no true association.").

* * *

In short, the district court did not abuse its discretion in allowing the jury to hear and weigh the general-causation evidence.

C. The District Court Did Not Abuse Its Discretion In Admitting Hardeman's Experts' Specific-Causation Opinions.

Monsanto's main specific-causation argument is that the district court abused its discretion because, in Monsanto's view, Hardeman's experts purportedly failed to reliably rule out the possibility that hepatitis C virus (HCV) caused his NHL or that his NHL had an idiopathic origin. MB56. This argument fails because the district court correctly determined that Hardeman's experts rejected these alternative hypotheses "using scientific methods and procedures." *Clausen*, 339 F.3d at 1058; ER37-38 (citing *Wendell*, 858 F.3d at 1235).

1. Hardeman's Experts Utilized Scientific Methods and Procedures to Rule Out HCV.

First, Hardeman's experts reliably determined that Hardeman's HCV was not active for at least a decade before his NHL. As the court reasoned, although "active hepatitis C is a known risk factor for NHL, it was highly unlikely that Mr. Hardeman's development of NHL was attributable to his past hepatitis C infection"

because he was diagnosed with NHL "almost a decade after he had a sustained virologic response—meaning the hepatitis C virus was no longer detected in his blood." ER38 n.4.

Nevertheless, Monsanto contends, "[Mr. Hardeman] remained vulnerable to cellular damage caused by the virus for many years." MB 62. This argument incorrectly assumes viruses and chemicals operate via the same mechanism to cause NHL. As Dr. Shustov explained, they do not. PSER157-164. To cause cancer, viruses must be active, and there is no evidence Hardeman's HCV virus was active for the entire decade preceding his NHL diagnosis. *See* ER38 n.4; *see also* ER1101-1104.

Plaintiff's experts further explained that because Hardeman suffered from an aggressive cancer, he had "at most one year from the development of lymphoma to his diagnosis." ER1134. In other words, if active HCV had caused Hardeman to develop cancer at an undetectable level in 2005, the cancer would have been detected or Hardeman would have died long before being diagnosed in 2015. The district court correctly observed that this "underlying methodology was sound." ER38 n.4.

2. Hardeman's Experts Reliably Ruled Out Idiopathy.

Apart from HCV, Monsanto does not contend that Hardeman's experts failed to consider any risk factors that may have caused his NHL. Rather

Monsanto argues that the district court erred because of the mere possibility that there may be a risk factor, entirely unknown to the scientific community (including both Monsanto and Hardeman's experts), that Hardeman *could* have been exposed to, and which *could* have caused his NHL. In other words, Monsanto argues that although Hardeman's experts considered, and ruled out, all generally accepted risk factors, their testimony should never have been admitted because there *might* be an equally plausible—albeit entirely unknown based on current scientific knowledge—explanation for Hardeman's NHL.

This argument proves too much. Hardeman's experts' "entire opinion[s] w[ere] directed to answering the question of whether [his] cancer had a known cause" or whether it was idiopathic. *Johnson & Johnson Talcum Powder Cases (Echeverria)*, 249 Cal.Rptr.3d 642, 674 (Ct. App. 2019).

And here, Monsanto admits that an expert may point to "a strong association between the disease and a known risk factor" as a sufficiently reliable reason for ruling out idiopathy. MB57. As the district court observed, this is precisely what Hardeman's experts did here, by relying on "general causation opinions…[that] *assert a robust connection between glyphosate and NHL*." ER37-38 (emphasis added). For example, Dr. Weisenburger explained that his opinion ruling in Roundup as a risk factor for NHL "was based on [his] review of all the material for general causation," which lead him "to the conclusion that *Roundup is a significant*

risk factor for non-Hodgkin lymphoma." PSER126-127 (emphasis added). This alone was sufficient basis for ruling out idiopathy.[28]

But there was more. As the district court observed, "[t]he experts relied heavily on [Hardeman's] exposure levels," in other words dose-response, "in drawing their conclusions." ER38. To that end, Hardeman's experts relied upon the McDuffie and Eriksson studies (in addition to others) to determine whether increased risk correlated with increased exposure (which it did), and to compare Hardeman's exposure levels to the corresponding thresholds observing such a response. ER1108 (Weisenburger); PSER146. And because these studies observed increased risk with greater exposure—amongst people applying GBFs like Hardeman—the observed dose response was unlikely due to other pesticides.

Regardless, and contrary to Monsanto's mischaracterization of the record, MB60-61, Dr. Weisenburger *did* rely upon fully-adjusted, statistically significant, epidemiology reporting an odds ratio of 2.49 for DLBCL, Hardeman's subtype of NHL—a more accurate characterization of *Hardeman's* risk than findings relating only to NHL *generally*. PSER113; PSER516; PSER202-205. This finding suggests

[28] As the California Court of Appeals observed in *Echeverria*, many of Monsanto's cases are distinguishable because, in those cases, the plaintiff's experts failed to provide admissible general-causation evidence such that "the experts could not reliably conclude the toxin caused the *plaintiff's* disease, even if other known causes were ruled out." 249 Cal.Rptr.3d. at 674-75 (citing *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674-75 (6th Cir. 2010)).

that people with similar exposures to Hardeman are at more than double the risk of DLBCL than similarly situated people with no Roundup exposure.

Equally groundless is Monsanto's suggestion that the district court erred because Hardeman's experts "could not differentiate [his] [NHL] from idiopathic [NHL]." MB58. Because the cause of NHL can be multi-factorial, as both Dr. Weisenburger and Monsanto's own expert Dr. Levine testified at trial (PSER89; PSER92; ER607-16), it is enough that Hardeman's experts established that his decades-long Roundup exposure was "a substantial causative factor" in his disease. *Messick*, 747 F.3d at 1199.

The way Monsanto's own expert analyzed specific causation illuminates the flaw in Monsanto's argument. Dr. Levine opined that HCV is a known cause of NHL and, to a reasonable degree of medical certainty, "[HCV] was the most likely cause or contributing factor in Mr. Hardeman's diffuse large B-cell lymphoma." ER231. But Dr. Levine testified (on direct) that "[t]here is nothing that distinguishes the hepatitis C diffuse large B-cell lymphoma from an idiopathic case." ER198. This did not stop Dr. Levine from concluding that the presence of a powerful risk factor, evaluated in light of Hardeman's medical history and her

clinical judgment, formed a reliable basis to reach a causal conclusion.[29] And while Dr. Levine's *conclusions* may be different, her methodology—reaching a causation conclusion based on Hardeman's medical history and evaluation of an "obvious and known risk factor"—is indistinguishable from the methodology Monsanto argues should have resulted in Hardeman's experts' exclusion. *See Daubert*, 509 U.S. at 595 ("The focus [of the admissibility inquiry], of course, must be solely on principles and methodology, *not on the conclusions that they generate*.") (emphasis added).

* * *

In short, the district court's decision to admit Hardeman's experts' testimony was correct. Monsanto's appeal only rehashes the same alleged flaws in Hardeman's experts' testimony that it proffered below. All were considered and rejected by the district court, which had the distinct advantage of hearing all the experts testify through the course of multiple rounds of exhaustive *Daubert* hearings. As the district court correctly reasoned, the same alleged flaws that are

[29] While Monsanto asserts "that 70% or more of cases of non-Hodgkin's lymphoma are idiopathic" (MB11), it is a logical fallacy to presume that there is a 70% chance any individual's NHL is *unknowable*. Even accepting Monsanto's 70% figure as true, that high percentage is due to the fact that many, if not most, oncologists simply do not inquire about exposures to known risk factors. Dr. Levine's testimony provides one such example: she does not ask her patients whether they were ever exposed to pesticides that could have caused their cancers, even though she recognizes pesticide exposure as a risk factor for NHL. PSER95.

subject to this appeal go to what weight to grant that testimony—a question for the jury.

III. THE DISTRICT COURT DID NOT ERR IN ADMITTING EVIDENCE ABOUT IARC'S CLASSIFICATION WHILE EXCLUDING CUMULATIVE EVIDENCE REGARDING SOME FOREIGN REGULATORY AGENCIES.

Monsanto's argument that the jury's verdict "cannot stand" because the district court erred in allowing evidence about IARC's classification but only "selectively admitt[ing]" evidence of foreign regulatory decisions disagreeing with IARC lacks any merit. MB63

In truth, Monsanto got the trial it wanted, just not the result. The "selective admission" of IARC and foreign regulatory approvals that Monsanto now contends constitute an abuse of discretion were, as the district court observed, "a function of the evidentiary parameters Monsanto itself requested, and was largely granted, in response to motions *in limine*." ER15.

These parameters included a bifurcated trial, which Monsanto argued was designed to "avoid the risk that the jury becomes distracted or misled by extraneous evidence of corporate conduct or by the complex regulatory record." Monsanto Mot. To Reverse Bifurcation, No. 3:16-md-02741, Dkt. 2282 at 7. Monsanto also successfully blocked Hardeman from introducing any evidence of its conduct after 2012, the last year Plaintiff used Roundup. ER44. This included,

as the court observed, an incriminating conversation between a Monsanto executive and an EPA official during which the official stated he "should get a medal" if he could "kill" an impending HHS investigation into glyphosate. ER17.

These significant evidentiary victories blocked Hardeman from presenting what the district court described as "a significant portion of [his] case involv[ing] attacks on Monsanto for attempting to influence regulatory agencies." PSER3. As the court observed, this was "good trial strategy on Monsanto's part," because it meant that the jury would never learn about "Monsanto's attacks on IARC [and its] attempts to influence U.S. regulators"—evidence that led to "the recent damages awards [totaling over $2 billion] against Monsanto in San Francisco and Alameda County state courts, following trials where virtually all this evidence was admissible." ER17.

Against this backdrop, Monsanto now asks this Court to disregard the district court's "wide latitude" in determining the admissibility of evidence under Rule 403. *United States v. Joetzki*, 952 F.2d 1090, 1094 (9th Cir. 1991) (citation omitted). Specifically, Monsanto argues that the court abused its discretion by (1) allowing Plaintiff to make fleeting references at trial to the mere fact of IARC's classification; and (2) allowing Monsanto to introduce evidence of three regulatory decisions made in response to IARC but excluding a handful of other foreign regulatory decisions as cumulative. Particularly in light of the "considerable

deference" accorded to admissibility determinations, *id*., neither argument succeeds.

A. IARC's Classification Was Properly Admitted to Counter the Prejudice from Bifurcation.

Even though the district court gave Monsanto nearly everything it asked for in structuring the trial, Monsanto complains that because IARC's classification has "minimal probative value on causation," the district court abused its discretion by admitting the mere fact of IARC's classification in Phase One. MB64.

1. This argument ignores the very reason the court admitted IARC's classification in the first place: to counter the structural prejudice created by the unusual bifurcation procedure Monsanto requested and was granted. ER42. Bifurcation, the court held, could prejudice Hardeman because "jurors will be left wondering, during the causation phase, how glyphosate could possibly be dangerous if it has gone largely unregulated for decades." PSER3. Minimal information about IARC was properly admitted to counter this concern. PSER3-4.

Moreover, as the court stated, "for the most part, only the fact of the IARC classification was admitted, not the details underlying the classification." ER16. At the same time, "the fact that [other] regulators [EPA, the European Food Safety Authority, and the European Chemicals Agency] continued to approve glyphosate following the IARC classification *was* admitted…" ER16 (emphasis added).

"Therefore," said the court, "the jury was fully aware that the regulators were not swayed by the IARC classification." ER16.

Although Monsanto now argues that the IARC evidence was unduly prejudicial, Monsanto *conceded* below that the IARC and regulatory evidence were "appropriately limited" during Phase One. PSER97; *see also* PSER102 (Monsanto agreeing that the district court's proposed instruction explaining "hazard" and "risk" assessments "doesn't need to happen given the testimony.") PSER1-2. Monsanto's about-face on this point is baseless.

2. Monsanto fares no better in arguing that the district court abused its discretion by not allowing the jury to hear about all the foreign agencies that supposedly disagreed with IARC. MB67. The court correctly excluded this evidence pre-trial and reaffirmed that decision post-trial, noting that the fact that the jury "wasn't presented with the entire regulatory landscape…is primarily a function of the evidentiary parameters Monsanto itself requested, and was largely granted, in response to motions in limine." ER15. In other words, Monsanto made its own evidentiary bed; it should not complain about being required to lie in it.

In so ruling, the district court properly recognized that admitting every foreign regulatory decision would have opened the door to the very evidence Monsanto argued so hard to exclude from Phase 1. As the court observed, "[i]n particular, Monsanto wanted to avoid introduction of evidence about its aggressive

attempt to discredit the 2015 IARC decision…as well as evidence of its efforts to influence U.S. regulators...” ER16. But selectively admitting foreign regulatory evidence, all after Hardeman stopped using Roundup, “would have been unfair to Mr. Hardeman,” because doing so would “allow Monsanto to introduce the details of various regulatory decisions” while denying the jury the complete picture of “Monsanto’s efforts to discredit IARC and to influence U.S. regulators.” ER16-17.

Admitting all foreign regulatory conclusions would have also undermined the purpose for bifurcating the trial. Monsanto unwittingly illustrates this point, contending that more regulatory decisions were necessary to “show the jury that IARC’s conclusion stood alone and so was entitled to little weight.” MB68. But inviting the jury to weigh competing findings is exactly what bifurcation was intended to avoid. As Monsanto put it (before trial), “[a]llowing all regulatory evidence to come” would tempt the jury “to simply adopt one side of the alleged debate between regulators and IARC rather than undertaking the necessary job of independently assessing the scientific evidence.” Monsanto Mot. To Reverse Bifurcation, No. 3:16-md-02741, Dkt. 2282 at 7.

Monsanto got what it asked for (bifurcation) by arguing that the jury’s determination of causation should not be influenced by regulatory conclusions. It now wants a reversal because the court allowed regulatory conclusions to be admitted, but not a cumulative amount. Monsanto cannot have it both ways.

Beyond that, Monsanto's contention that it was prejudiced by the admission of IARC's classification ignores that the district court admitted *three* powerful regulatory decisions (including that of the EPA) that all considered and diverged from IARC's finding. ER46-47. This more than tipped the balance of external organizations in Monsanto's favor.

3. Even if the IARC classification was admitted in error—it was not—the error was harmless. For starters, Hardeman's attorney barely referenced IARC during closing argument at the first phase of trial. PSER62. And there is no reason to believe the jury weighed brief references to IARC more heavily than the overwhelming causation evidence Hardeman presented through his experts.

Moreover, any hypothetical error was cured by the district court's jury instruction. The district court initially proposed a limiting instruction with nearly identical language to what Monsanto requested before trial. *Compare* PSER1 to PSER496. Prior to closing, Monsanto asked the court to include references to IARC and the three regulatory agencies whose decisions were admitted. PSER98-99. Over Hardeman's objections, the court sided with Monsanto and issued the following instruction:

> You have heard testimony that [EPA], [IARC], the European Food Safety Authority (EFSA), and the European Chemicals Agency (ECHA) have reached conclusions about glyphosate. You should not defer to any such conclusions. They are not a substitute for your own independent assessment of the evidence presented in this case.

ER1722.

Monsanto now insists that this instruction, which it practically dictated to the court, was "neither as forceful nor as comprehensive as warranted under the circumstances." MB69. But at trial Monsanto's attorneys said the same instruction "would be fine with us." PSER100. In light of this background, the notion that Monsanto was prejudiced because the district court allowed a few fleeting references to IARC is untenable.

IV. THE CAUSATION INSTRUCTION WAS PROPER.

The district court properly instructed the jury it could find for Hardeman if it found that Roundup was a substantial factor in causing his NHL.

A. The Causation Instruction Properly Encapsulated California's Substantial-Factor Test for Causation.

First, contrary to Monsanto's contention, there was nothing improper about combining Cal. Civ. Jury Instruction (CACI) 430 (which sets out a but-for test for causation) with CACI 431 (which sets out a test for concurrent independent causes).[30]

When taken as a whole, the causation instruction correctly stated California law, which follows the "substantial factor" test of the Restatement (Second) of Torts. *Rutherford v. Owens-Illinois, Inc.*, 941 P.2d 1203, 1214 (Cal. 1997).

[30] Available at https://www.courts.ca.gov/partners/317.htm.

Under that standard, a defendant's alleged tortious conduct must be *a* cause of a plaintiff's injuries, but it need not be the *only* such cause.

The causation instruction here comported with that standard. Indeed, the first paragraph of the instruction mirrors precisely the language set forth in CACI 430, which allows a jury to find for a plaintiff upon a showing that a defendant's conduct was a "substantial factor in causing harm." The latter paragraphs incorporate CACI 431, which instructs jurors that "[i]f you find that [the defendant]'s negligence was a substantial factor in causing [plaintiff]'s harm, then [the defendant is responsible for the harm] [even if] some other person, condition, or event was also a substantial factor in causing [plaintiff]'s harm."

Contrary to Monsanto's contention, there is nothing improper about combining these instructions: California courts routinely uphold cases where the trial court included *both* CACI 430 and CACI 431 in jury instructions. *See*, *e.g.*, *Uriell v. Regents of Univ. of Cal.*, 184 Cal.Rptr.3d 79 (Ct. App. 2015); *Logacz v. Limansky*, 84 Cal.Rptr.2d 257 (Ct. App. 1999).

Unsurprisingly, Monsanto cites no cases to support its argument that the instruction "contravenes" California law. The reason is clear: it does not.[31]

[31] Monsanto's reliance on the "Directions for Use" set forth in CACI 430 (MB72) is misplaced. There, the Judicial Council suggested that courts should omit the "last optional sentence" of that instruction (which states that "[c]onduct is not a

B. The Causation Instruction Did Not Lessen Hardeman's Burden of Proof.

Monsanto's second argument—that the causation instruction "effectively lessened Hardeman's burden of proof" (MB73)—is also incorrect.

First, California law is clear that "one cannot escape responsibility for his negligence on the ground that identical harm would have occurred without it." *Mitchell v. Gonzales*, 819 P.2d 872 (Cal. 1991). Thus, "where a defendant's negligence is a concurring cause of injury, the law regards it as a legal cause of injury, regardless of the extent to which it contributes to the injury." *Espinosa v. Little Co. of Mary Hosp.*, 37 Cal.Rptr.2d 541, 549 (Ct. App. 1995).

In this way, California law "provides for an exception" to the traditional but-for standard if concurrent independent causes are present. *Viner v. Sweet*, 70 P.3d 1046, 1051 (Cal. 2003). And while the two tests "frequently lead to the same result," where "concurrent independent causes" are present "substantial factor leads to the correct result; but-for does not." *Major v. R.J. Reynolds Tobacco Co.*, 222 Cal.Rptr.3d 563, 581 (Ct. App. 2017).

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substantial factor in causing harm if the same harm would have occurred without that conduct") when combining CACI 430 and 431 into one instruction. Monsanto suggests that, because the court did not omit this "last optional sentence" when it combined the two standards, its instructions contravened California law. Monsanto ignores that the court accomplished the same thing by adding the phrase "*Subject to the additional instructions below*" prior to the last sentence of CACI 430. ER1721.

The district court's instruction accurately reflected California law. The instruction told the jury it should find for Hardeman if it believed Roundup was "sufficient on its own to cause his NHL," even if the jury thought that other factors might also have been sufficient on their own to cause his NHL. ER1721. This instruction allowed the jury to find for Hardeman if it determined that Roundup was *a* legal cause of his cancer, regardless of whether it was the *only* cause. This is exactly what the law requires. *Major*, 222 Cal.Rptr.3d at 579 (the but-for test "does not apply to concurrent independent causes").

Second, contrary to Monsanto's contention, the evidence supported a finding for Hardeman under this instruction. Monsanto's argument to the contrary is centered on the theory that the jury could not logically find that Roundup and HCV were independent concurrent causes of Hardeman's cancer, such as in a case where two fires combine to burn down a single building. But, as the district court recognized, a finding that Roundup caused Hardeman's cancer does not rule out the possibility that some "other fire"—e.g., HCV or some other risk factor(s)—might "eventually" have caused the same injury. ER234.[32]

[32] Monsanto also confuses concurrent causes with concurrent *independent* causes. MB72-73. The district court only precluded Hardeman from arguing that concurrent causes combined to cause his NHL, not that concurrent independent causes were supported by the evidence. ER307.

Put another way, nothing about the jury believing Roundup caused Hardeman's NHL *requires* the jury to reject the portion of Monsanto's theory that there was a second fire (so to speak) sufficient on its own to eventually burn down the barn. The jury could reasonably believe both.[33]

The district court got it right when it carefully crafted an instruction that would not allow the jury to exonerate Monsanto if it found that Roundup caused his NHL but that Hardeman might "eventually" have gotten NHL for some other reason. After hearing the same evidence presented to the jury the court explained: "the thing I'm worried about here is what if the jury says, well, I think the Roundup caused his cancer, but it would have—he would have eventually got the cancer anyway from hep C." ER240.

[33] Monsanto relies on the fact that Drs. Weisenburger and Levine both conducted differential diagnoses to reach their conclusions as to the cause of Hardeman's NHL, in which they each necessarily "ruled out" the opposing party's theory of causation. What Monsanto forgets is that Dr. Levine did not even consider Roundup as *potentially* capable of causing NHL, because that possibility was ruled out by Monsanto's experts at the general-causation phase. In other words, she never ruled Roundup either "in" or "out" of her differential diagnosis because she never considered it a possibility to begin with. Dr. Weisenburger, on the other hand, concluded that Roundup can and did cause Hardeman's NHL, although he acknowledged that *other* risk factors, including HCV, obesity, age, and race, could possibly have caused or contributed to the disease. And he certainly did not rule out the possibility that some other risk factor might have "eventually" given Hardeman NHL. ER456-57.

As the district court recognized, nothing in California law allows Monsanto to prevail by convincing the jury that a second fire would have eventually burned down the barn anyway. *Mitchell*, 819 P.2d at 876 (Cal. 1991).

The factually analogous case of *Logacz v. Limansky*, 84 Cal.Rptr.2d 257 (Ct. App. 1999), is instructive. In *Logacz*, as here, both plaintiffs and defendant introduced "conflicting [evidence] on the issue of legal cause" and the plaintiffs requested that the trial court instruct the jury on concurring causes, which the trial court refused. *Id.* at 261.

The appellate court reversed, holding that "[o]ne purpose of [the multiple causation instruction] is to explain to the jury that plaintiff need not prove that the defendant's negligence was the sole cause of plaintiff's injury in order to recover." *Id*. at 263. "Rather," the court held, "it is sufficient that defendant's negligence is *a* legal cause of injury, even though it operated in combination with other causes, whether tortious or non-tortious." *Id.*

Logacz is on all fours with this case because, as the district court observed, the jury could reasonably conclude that although Roundup caused Hardeman's NHL, "he would have eventually got the cancer anyway" from other risk factors. ER240. Accordingly, not only was it proper for the district court to instruct the jury on independent concurrent causation, it would have been reversible error had

the district court *not* instructed the jury on multiple causation. *See Logacz*, 84 Cal.Rptr.2d at 263.[34]

[34] Even if the instruction was error, the error was harmless because there was substantial evidence that Roundup was a but-for cause of Hardeman's injury and the district court's instruction included such language in the first paragraph. *See Lambert v. Ackerley*, 180 F.3d 997, 1008 (9th Cir. 1999).

V. THE EVIDENCE ON PLAINTIFF'S FAILURE-TO-WARN CLAIM SATISFIED CALIFORNIA LAW.

Monsanto also argues that Plaintiff's failure-to-warn claim fails "as a matter of law" because (1) "there was no evidence that Monsanto 'was in fact aware that glyphosate causes cancer' at the time of Hardeman's exposure" (MB74 (citing ER8)); and (2) such a link was not "knowable" when Hardeman was last exposed to Roundup (2012). *Id.* This argument warrants little discussion.

First, as Monsanto admits, the standard under California law is not whether a link between a product and a disease is "known"—rather, it is sufficient that such a link was "knowable." *See* MB74 (citing *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 558 (Cal. 1991)).

There is no question that the link between Roundup and NHL was "knowable" as of 2012. As early as 1985, EPA had classified glyphosate as possibly carcinogenic. By 1998, Monsanto was aware of an epidemiological study showing increased risk of NHL in humans following Roundup exposure that was validated by other epidemiological studies showing a similar link in the early to mid-2000s. PSER411-39. And certainly by 2012, dozens of independent scientific studies showed a link between GBFs and NHL—a link that Monsanto had spent decades trying to disclaim and suppress. ER65-69, 78-82. Given these facts, it was certainly "knowable" to Monsanto that GBFs like Roundup caused NHL.

Of course, we also know from the evidence at trial that Monsanto, in defiance of the advice of a hand-selected world-renowned genotoxicologist, refused to study the cancer risks of Roundup in order to *avoid* knowing the full extent of the product's dangers. In light of these facts, Monsanto's argument that the risks of Roundup were not "knowable" is specious.

VI. THE JURY'S PUNITIVE DAMAGE AWARD WAS PROPER UNDER CALIFORNIA LAW AND THE U.S. CONSTITUTION.

A. The Punitive Damage Award Comported with California Law.[35]

The jury's decision to award $75 million in punitive damages was fully in accord with California law. For a jury to award punitive damages, it need only find that the defendant acted with malice, oppression or fraud. *See* Cal. Civ. Code §3294(a). "[M]alice" does not require actual intent to harm; rather, "[c]onscious disregard for the safety of another may be sufficient where the defendant is aware of the probable dangerous consequences of [its] conduct and [it] willfully fails to avoid such consequences. *Pfeifer v. John Crane, Inc*., 1 Cal.Rptr.3d 112, 135 (Ct. App. 2013), *as modified on denial of reh'g* (Nov. 27, 2013) (quoting *Angie M. v. Superior Ct.*, 44 Cal.Rptr.2d 197, 204 (Ct. App. 1995)).

[35] Given page constraints, this brief summarizes a few of the many facts supporting punitive damages.

A jury's award of punitive damages under this standard must be affirmed if this Court, "review[ing] the evidence in the light most favorable to [Hardeman]," finds that the record contains "substantial evidence" to support the jury's determination. *Id*. (citation omitted).

This standard is met here. As the district court put it, "the evidence easily supported a conclusion that Monsanto was more concerned with tamping down safety inquiries and manipulating public opinion than it was with ensuring its product is safe." ER7. That "easy" conclusion was supported by "strong evidence…that Monsanto does not particularly care whether its product is in fact giving people cancer, focusing instead on manipulating public opinion and undermining anyone who raises genuine and legitimate concerns about the issue." ER30. This conduct is indeed "despicable" and worthy of punishment under California law. *See West v. Johnson & Johnson Products, Inc*., 220 Cal.Rptr. 437, 460-61 (Ct. App. 1985) (affirming punitive damages where evidence showed that adequate testing would have revealed association between tampon use and toxic shock, that manufacturer's testing was inadequate, and manufacturer decided not to do any further testing even when faced with consumer complaints); *Boeken v. Philip Morris Inc.*, 26 Cal.Rptr.3d 638, 677 (Ct. App. 2005) ("[I]ntentionally marketing a defective product knowing that it *might* cause injury and death is highly reprehensible.") (emphasis added; citation omitted).

Monsanto tries to avoid this conclusion by arguing, first, that it was wrong for the jury to punish it because it "met its regulatory obligations related to Roundup, repeatedly obtaining EPA's approval to market Roundup without a cancer warning." MB79. Even if Monsanto *had* met its regulatory obligations regarding Roundup (it has not), it is well established that a defendant's compliance with regulatory standards does not absolve it from liability for punitive damages. *E.g.*, *Silkwood v. Kerr–McGee Corp.*, 769 F.2d 1451, 1456-58 (10th Cir. 1985). That should be especially true where, as here, a defendant has blindfolded itself *and* federal regulators as to whether its product poses a serious threat to public safety.[36]

As Dr. Parry told Monsanto in 1999, there was scientific evidence at the time showing a link between GBFs and NHL, yet Monsanto refused to do the tests recommended by Dr. Parry and instead ghostwrote scientific articles designed to show that Roundup was safe. *See supra* pp.28-30.

Monsanto's refusal to test the carcinogenicity of Roundup despite knowing that its active ingredient causes tumors in mice is reason enough to sustain an

[36] Monsanto's flagship case on punitives—*Johnson & Johnson Talcum Powder Cases (Echeverria)*, 249 Cal.Rptr.3d 642 (Ct. App. 2019) (MB78-80)—is not to the contrary. *See id.* at 678 (citation omitted) (that "A defendant's compliance with, or actions consistent with, governmental regulations or determinations about a product do not necessarily eviscerate a claim for punitive damages.").

award of punitive damages. *West*, 220 Cal.Rptr. at 460-61; *see also Pfeifer*, 164 Cal.Rptr.3d at 121 (evidence that Defendant "never tested its products to determine whether those methods generated concentrations of asbestos fibers exceeding the regulatory limits" supportive of punitive damages.); *Romo v. Ford Motor Co*., 6 Cal.Rptr.3d 793, 806 (Ct. App. 2003) (evidence that Defendant "declined to test the strength of the roof before placing it in production" is relevant to punitive damages).

But if there were any doubt on this point, Monsanto's ghostwriting campaign would readily dispel it. *See Wyeth*, 244 P.3d at 784. (affirming punitive damages of $58 million where "Wyeth's strategy to undermine scientific studies linking an increased risk of breast cancer to estrogen-progestin hormone therapy included ghostwriting multiple articles.").

Monsanto also attacks the jury's verdict on the ground that the company was not "in fact aware that glyphosate caused cancer." MB80. But here again, Monsanto ignores that Plaintiff's harm resulted from Monsanto's *intentional refusal* to study the link between Roundup and NHL. PSER257-258.

Monsanto's third argument is that the jury was wrong to punish it because "the record…presents a close case" on causation, just as in *Echeverria*, *supra*. MB80 (citing 249 Cal.Rptr.3d at 678). But the strongest scientific support the *Echeverria* plaintiff could muster was a "2B" designation from IARC (indicating a

"possible association") and inconsistent testimony from the plaintiff's treating oncologist and epidemiological expert. *Echeverria*, 249 Cal.Rptr.3d at 650, 677.

Here, in contrast, after decades of studies indicating a connection between glyphosate and NHL, IARC designated glyphosate "2A," a "probable carcinogen." And Plaintiff's experts, some of the top independent scientists in the world, all support Plaintiff's case. Further, unlike in *Echeverria*, Monsanto here has actively sought to undermine and discredit scientists involved in researching the link between glyphosate and NHL.

As a result of this despicable conduct, there is no question that the jury's decision to award punitive damages comports with California law. *See Boeken*, 26 Cal.Rptr.3d at 680 ("The national marketing of a defective product, knowing that ordinary consumers expect it to be less hazardous, knowing that thousands of people will die due [to its use], is probative of a willful and conscious disregard of the danger to human life.").

B. The Amount of Punitive Damages Awarded by the Jury was Constitutionally Sound.

Nor is there any sound basis for concluding that the punitive damages awarded by the jury—$75 million, roughly 15 times compensatory damages—was constitutionally excessive.

"A jury's award of punitive damages is not to be lightly disturbed." *Caudle v. Bristow Optical Co.*, 224 F.3d 1014, 1028 (9th Cir. 2000), *as amended on denial of reh'g* (Nov. 2, 2000) (citation omitted). The district court failed to follow this edict, slashing the jury's award by nearly 75%, to $20 million (four times compensatory damages). That was error for three reasons.

First, the district court placed undue emphasis on the Supreme Court's statement "that 'in practice, few awards exceeding a single-digit ratio' will satisfy due process." ER9 (quoting *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 425 (2003)). The court failed to recognize that the Supreme Court has also made clear that there is no prohibition on higher ratios. *Id.* ("We decline again to impose a bright-line ratio which a punitive damages award cannot exceed."); *see also BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 583 (1996) (same); *Simon v. San Paolo U.S. Holding Co.*, 113 P.3d 63, 77 (Cal. 2005) (same and noting that punitive awards exceeding a "single-digit" ration may be imposed in case of "extreme reprehensibility").[37]

As *State Farm* explained, the appropriate comparison should be "between the actual *or potential harm* suffered by the plaintiff and the punitive damages

[37] In both *State Farm* and *BMW*, the ratios between compensatory and punitive damages were far greater than this case, where the ratio is roughly 15:1. *See State Farm*, 538 U.S. at 425, 429 (ratio of 145:1); *BMW*, 517 U.S. at 582 (ratio of 4,000,000:1); *accord Simon*,113 P.3d at 77 (ratio of 340:1).

award." 538 U.S. at 418 (emphasis added); *see also BMW*, 517 U.S. at 582 (same and noting no threat of potential additional harm).

Here, where Monsanto's conduct led to the very real possibility of Plaintiff's death and could still be fatal (*see* ER5), the potential harm caused by Monsanto's misconduct far exceeds the $5 million compensatory award. *Cf. BMW*, 517 U.S. at 576 (striking down punitive award four million times compensatory where the "harm BMW inflicted on [plaintiff] was purely economic in nature [and] BMW's conduct evinced no indifference to or reckless disregard for the health and safety of others.").

Beyond that, the "very conduct that injured [Hardeman] was directed at all [consumers] in the United States, repeated over many years with knowledge of the risk to human life and health, and is probative of intentional deceit." *Boeken*, 26 Cal. Rptr. 3d at 680 (citing *State Farm*, 538 U.S. at 423–24). And Roundup is *still* on the market and is *still* being touted by Monsanto as safe. If this conduct is not reprehensible enough to warrant a sizeable punitive award, it is hard to know what would be. *Id.*[38]

[38] Many cases have approved punitive damages awards far in excess of Plaintiff's ratio here. *See Neal v. Farmers Ins. Exchange*, 582 P.2d 980, 990 (Cal. 1978) (upholding punitive damages award 74 times greater than amount of compensatory damages on verdict of insurance bad faith); *Weeks v. Baker & McKenzie*, 74 Cal.Rptr.2d 510, 534 (Ct. App. 1998), *as modified on denial of reh'g*

Second, the district court failed to take proper account of the fact that defendant's financial condition is an essential factor in fixing an amount sufficient to serve these goals without becoming excessive. *See Simon*, 113 P.3d at 79 (citing *State Farm*, 538 U.S. at 428, for proposition that use of wealth as factor is not "unlawful or inappropriate"). As one court has observed, "the function of deterrence...will not be served if the wealth of the defendant allows him to absorb the award with little or no discomfort." *Neal*, 582 P.2d at 990.

Here, even a punitive award of $75 million could be absorbed with "little or no discomfort." *Id.* Bayer paid $63 *billion* to acquire Monsanto. PSER14. In June 2018, Monsanto's net worth was $7.8 billion and it had $2.4 billion dollars cash on hand. *Id*. A punitive damages award of $75 million is thus less than 0.1% of Monsanto's net worth.

To a company Monsanto's size, this amounts to little more than pocket change, particularly when compared to the enormous *future* profits Monsanto stands to make by continuing to sell Roundup. The district court's failure to take this factor into full account when slashing the punitive award by $55 million was

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(June 2, 1998) (upholding punitive damages award "70 times greater than the compensatory damages award" despite absence of physical harm). Even where a defendant's conduct caused bed-bug bites, not grave physical injury or death, a 37:1 ratio was upheld. *Mathias v. Accor Economy Lodging, Inc*., 347 F.3d 672, 676, 678 (7th Cir. 2003).

error. *See Neal*, 582 P.2d at 990-91; *Lane v. Hughes Aircraft Co.*, 993 P.2d 388, 402 (Cal. 2000) (Mosk, J., concurring) ("[P]unitive damage awards should not be a routine cost of doing business that an industry can simply pass on to its customers through price increases, while continuing the conduct the law proscribes.") (Brown, J., concurring).[39]

Third, the district court gave inordinate weight to factors that it believed "mitigat[ed]" the reprehensibility of Monsanto's misconduct: "the scientific debate" regarding "whether glyphosate causes NHL," and the absence of any evidence that Monsanto has hidden actual knowledge "that glyphosate cause[s] cancer." ER7-8.

The district court's first "mitigating" consideration is expressly within the jury's purview: A jury is "entitled to" "reject[] the testimony of [the defendant's] experts." *Buell-Wilson v. Ford Motor Co.*, 46 Cal.Rptr.3d 147, 175 (Ct. App. 2006), *vacated on other grounds*, 550 U.S. 931 (2007).[40] So here, where the jury

[39] *See also Century Surety Co. v. Polisso*, 43 Cal.Rptr.3d 468, 501 (Ct. App. 2006), *as modified on denial of reh'g* (June 16, 2006) (upholding punitive award of over $56 million because it was "only 3.2 percent of [defendant's net worth" and noting that a smaller award "would not amount to much more than a slap on the wrist.").

[40] Although this opinion was vacated with respect to constitutional limits of punitive damage awards, the California Supreme Court continues to cite this case

was presented with all facets of the "scientific debate" regarding glyphosate, it was permitted to (and did) reject Monsanto's representation of the science, and punished Monsanto accordingly.

The district court's second "mitigating" factor was the absence of evidence that "Monsanto was in fact aware that glyphosate caused cancer but concealed it"—a fact that, in the court's view, "distinguish[es] this case from the many cases adjudicating the conduct of the tobacco companies." ER8. This ruling ignores that Monsanto willfully blinded itself to the risks of Roundup by refusing to do the tests Dr. Parry urged it to conduct, pressuring scientists to downplay the risks of Roundup, and ghostwriting articles to manipulate the science. *See supra* pp 28-30, 47.

In short: the district court should not have disturbed the jury's award of punitive damages. Even $75 million is insufficient to punish Monsanto for its appalling disregard of public safety.[41]

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with respect to the availability of punitive damage awards. *See Boeken v. Philip Morris USA, Inc.*, 230 P.3d 342, 347 (Cal. 2010).

[41] Even if the court did not find "extreme reprehensibility" or other factors justifying a compensatory-punitive damages ratio above single digits (*see Bullock v. Philip Morris USA, Inc.*, 131 Cal.Rptr. 382, 387 (Ct. App. 2011)), it should not have reduced the jury's punitive damages award beyond the point at which it became constitutionally "suspect": i.e., ratios "significantly greater than 9 or 10 to 1." *Simon*, 113 P.3d at 77; *see also id.* at 395 n.7 ("the presumption of

C. Monsanto's Due-Process Challenge to the Punitive Damages Award Lacks Merit.

Against this backdrop, it should be clear that Monsanto's due-process challenge to the punitive award lacks merit. Monsanto starts by claiming that its behavior was "not reprehensible." MB83-87. Enough has already been said on that score; Monsanto's conduct was beyond reprehensible, as the jury found.

Monsanto's second argument is that "the punitive damages award [do] not bear 'a reasonable relationship to [the] compensatory damages' awarded." MB83 (quoting *BMW*, 517 U.S. at 581). Tell that to Hardeman, who has undergone immense suffering and could still die from his exposure to Roundup. ER5 (noting that Plaintiff will "need lifelong monitoring…to watch for a recurrence of cancer. And with lifelong monitoring comes lifelong anxiety: Mr. Hardeman will live the rest of his life with the fear associated with an increased risk of cancer.").[42]

Monsanto's final argument is that the absence of any governmental "criminal or civil penalties" for its misconduct shows that the punitive damages

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unconstitutionality applies only to awards exceeding the single-digit level '*to a significant degree*.'") (citing *State Farm*, 538 U.S. at 425) (emphasis added). Therefore, to accord with due process—avoiding both "fail[ing] to adequately punish" and "overpunish[ing]"—the district court should not have awarded less than $52,676,341 (i.e. ten times the compensatory award). *Delos v. Farmers Grp., Inc.*, 155 Cal. Rptr. 843, 859 (Ct. App. 1979).

[42] Moreover, the ratio of the reduced award is well within the single-digit ratio Monsanto insists on, at approximately 4:1.

award violates due process. MB84 (quoting *BMW*, 517 U.S. at 582). This argument fails, first, because it does not account for Monsanto's intentional refusal to study whether Roundup causes cancer—conduct that was designed to *prevent* imposition of such penalties by keeping regulatory entities in the dark about the hazards of Roundup. Second, as the district court observed, "[b]ecause both state and federal law calculate penalties per violation, it seems entirely possible that Monsanto's liability could, over time, become quite high." ER10. That Monsanto has thus far managed to avoid such penalties is no reason to find the jury's award constitutionally excessive. The district court's conclusion this point was correct and should not be disturbed.

CONCLUSION

The jury's verdict should be affirmed. The district court did not err or abuse its discretion in any respect except with regard to its decision to reduce the punitive damages award by 75 percent, which should be reversed.

March 16, 2020

Respectfully submitted,

Leslie A. Brueckner, Esq.
Public Justice
475 14th St. Suite 610
Oakland, CA 94612
(510) 622-8205
lbrueckner@publicjustice.net

s/ David J. Wool
David J. Wool, Esq.
Aimee H. Wagstaff, Esq.
Andrus Wagstaff, PC
7171 W. Alaska Dr.
Lakewood, CO 80226
(866) 795-9529
Aimee.wagstaff@andruswagstaff.com
David.wool@andruswagstaff.com

Jennifer Moore, Esq.
Moore Law Group, PLLC
1473 South 4th St.
Louisville, KY 40208
(502) 717-4080
Jennifer@moorelawgroup.com

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FOR THE NINTH CIRCUIT

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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. § 136a

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

7 U.S.C. § 136a(f)(2)

(f) Miscellaneous

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation

proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

7 U.S.C §136a(q)(1)(F) &(g)

(q) Misbranded

(1) A pesticide is misbranded if--

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

7 U.S.C. § 136k

(a) Stop sale, etc., orders

Whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the provisions of this subchapter, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been canceled by a final order or has been suspended, the Administrator may issue a written or printed "stop sale, use, or removal" order to any person who owns, controls, or has custody of such pesticide or device, and after receipt of such order no person shall sell, use, or remove the pesticide or device described in the order except in accordance with the provisions of the order.

(b) Seizure

Any pesticide or device that is being transported or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any State, or that is imported from a foreign country, shall be liable to be proceeded against in any district court in the district where it is found and seized for confiscation by a process in rem for condemnation if--

(1) in the case of a pesticide—

(A) it is adulterated or misbranded;

(B) it is not registered pursuant to the provisions of section 136a of this title;

(C) its labeling fails to bear the information required by this subchapter;

(D) it is not colored or discolored and such coloring or discoloring is required under this subchapter; or

(E) any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration;

(2) in the case of a device, it is misbranded; or

(3) in the case of a pesticide or device, when used in accordance with the requirements imposed under this subchapter and as directed by the labeling, it nevertheless causes unreasonable adverse effects on the environment.

In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

7 U.S.C. § 136l

(a) Civil penalties

(1) In general

Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.

(2) Private applicator

Any private applicator or other person not included in paragraph (1) who violates any provision of this subchapter subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense, except that any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or uses dilutions of registered pesticides, only to provide a service of

controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than $500 for the first offense nor more than $1,000 for each subsequent offense.

(3) Hearing

No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged.

(4) Determination of penalty

In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

(5) References to Attorney General

In case of inability to collect such civil penalty or failure of any person to pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in the appropriate United States district court.

(b) Criminal penalties

(1) In general

(A) Any registrant, applicant for a registration, or producer who knowingly violates any provision of this subchapter shall be fined not more than $50,000 or imprisoned for not more than 1 year, or both.

(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, who knowingly violates any provision of this subchapter shall be fined not more than $25,000 or imprisoned for not more than 1 year, or both.

(2) Private applicator

Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this subchapter shall be guilty of a misdemeanor and shall on conviction be fined not more than $1,000, or imprisoned for not more than 30 days, or both.

(3) Disclosure of information

Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 136a of this title, shall be fined not more than $10,000, or imprisoned for not more than three years, or both.

(4) Acts of officers, agents, etc.

When construing and enforcing the provisions of this subchapter, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.

7 U.S.C. § 136v

(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.

28 U.S.C. § 1291

The courts of appeals (other than the United States Court of Appeals for the Federal Circuit) shall have jurisdiction of appeals from all final decisions of the district courts of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, and the District Court of the Virgin Islands, except where a direct review may be had in the Supreme Court. The jurisdiction of the United States Court of Appeals for the Federal Circuit shall be limited to the jurisdiction described in sections 1292(c) and (d) and 1295 of this title.

40 C.F.R. § 159.152

(a) Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) states: “If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.”

(b) Section 152.50(f)(3) of this chapter requires applicants to submit, as part of an application for registration, any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on humans or the environment, which would be required to be reported under section 6(a)(2) if the product were registered.

(c) Compliance with this part will satisfy a registrant's obligations to submit additional information pursuant to section 6(a)(2) and will satisfy an applicant's obligation to submit additional information pursuant to § 152.50(f)(3) of this chapter.

40 C.F.R. §156.64 (2004)

(a) Requirement. Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal word, reflecting the highest Toxicity Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in § 156.62. The signal word must also appear together with the heading for the human precautionary statement section of the labeling (see § 156.70).

(1) Toxicity Category I. Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word "DANGER." In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word "Poison" must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word "Poison."

(2) Toxicity Category II. Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word "WARNING."

(3) Toxicity Category III. Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word "CAUTION."

(4) Toxicity Category IV. A pesticide product meeting the criteria of Toxicity Category IV by all routes of exposure is not required to bear a signal word. If a signal word is used, it must be "CAUTION."

(b) Use of signal words. In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such

labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

Cal. Civ. Code §3294(a)

(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.

Cal. Health & Safety Code § 25249.5

No person in the course of doing business shall knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into any source of drinking water, notwithstanding any other provision or authorization of law except as provided in Section 25249.9.

Restatement (Third) of Torts: Phys. & Emot. Harm § 28 (2010), Reporter's Note to Comment c(3)

(3) General causation.

The concepts of general causation and specific causation are widely accepted among courts confronting causation issues with toxic agents. See, e.g., Norris v. Baxter Healthcare Corp., 397 F.3d 878, 881 (10th Cir. 2005) (applying Colorado law); In re Ephedra Prod. Liab. Litig., 478 F.Supp.2d 624, 632 (S.D.N.Y. 2007) (applying Texas law); Kelley v. Am. Heyer-Schulte Corp., 957 F.Supp. 873, 875-876 (W.D. Tex. 1997)(recognizing the different concepts of general and specific causation), appeal dismissed, 139 F.3d 899 (5th Cir. 1998); Cavallo v. Star Enter., 892 F.Supp. 756, 771 n.34 (E.D. Va. 1995), aff'd in part and rev'd in part, 100 F.3d 1150 (4th Cir. 1996); Casey v. Ohio Med. Prods., 877 F.Supp. 1380, 1382 (N.D. Cal. 1995); Merrell Dow Pharms., Inc. v. Havner, 953 S.W.2d 706, 714-715 (Tex. 1996). But see Donaldson v. Cent. Ill. Pub. Serv. Co., 767 N.E.2d 314 (Ill. 2002) (rejecting use of "generic" and specific causation; plaintiff need only prove cause in fact).

When the connection between an agent and disease is strong and well documented, general-causation issues fade into the background. Thus, in asbestos cases, the general-causation question does not arise with regard to mesothelioma, asbestosis, and lung cancer because the causal connection between asbestos and those diseases is quite well established. See, e.g., Karjala v. Johns-Manville Prod. Corp., 523 F.2d 155, 160 (8th Cir. 1975) (applying Minnesota law); Bertrand v. Johns-Manville Sales Corp., 529 F.Supp. 539, 544 (D. Minn. 1982) ("[I]t is clear that it is appropriate to estop litigation on the issue of whether asbestos dust can cause diseases such as asbestosis and mesothelioma. This proposition is so firmly entrenched in the medical and legal literature that it is not subject to serious dispute."); Flatt v. Johns-Manville Sales Corp., 488 F.Supp. 836, 841 (E.D. Tex. 1980)(holding that asbestos exposure causes asbestosis and mesothelioma, as a matter of law). Although general causation may not be an issue for one or several diseases caused by an agent such as asbestos, general causation may be an issue with regard to other diseases, as is the case with asbestos and colon and gastrointestinal cancers. See In re Joint E. & S. Dist. Asbestos Litig., 52 F.3d 1124 (2d Cir. 1995) (applying New York law); Landrigan v. Celotex Corp., 605 A.2d 1079 (N.J. 1992); Grassis v. Johns-Manville, 591 A.2d 671 (N.J. Super. Ct. App. Div. 1991).

Occasionally, an ailment may be so strongly associated with a specific agent and so rarely (if ever) associated with any other cause that it is called a "signature disease." Examples of signature diseases are vaginal adenocarcinoma in the daughters of mothers exposed to DES and asbestosis in those exposed to asbestos. Once a signature disease is identified, there is no need for proof of either general causation or specific causation, as the existence of the disease is tied to exposure to the signature agent. See Daniel A. Farber, *Toxic Causation*, 71 MINN. L. REV. 1219, 1251-1252 (1987); Kenneth S. Abraham & Richard A. Merrill, *Scientific Uncertainty in the Courts*, ISSUES SCI. & TECH., Winter 1986, at 93, 101.

Cases involving signature diseases are, however, rare. In cases in which group studies are employed as proof, proof of causation proceeds in two steps: general causation and specific causation. Cases accepting the proposition that relevant epidemiologic studies are acceptable evidence to support proof of general causation are legion. See, e.g., Smith v. Ortho Pharm. Corp., 770 F.Supp. 1561, 1571 (N.D. Ga. 1991) (explaining increased reliance of courts on epidemiologic evidence in toxic-substances litigation); Stevens v. Sec'y of HHS, 2001 WL 387418, at *12-13 (Fed. Cl. 2001); James v. Chevron U.S.A., Inc., 694 A.2d 270, 280 (N.J. Super. Ct. App. Div. 1997), aff'd, 714 A.2d 898 (N.J. 1998); see generally Michael D. Green et al., *Reference Guide on Epidemiology*, *in* FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333, 335 n.2 (2d ed. 2000).

However, even when epidemiology finds an association, the observational (rather than experimental) nature of these studies requires an examination of whether the association is

truly causal or spurious and due to random error or deficiencies in the study (bias).The same problems may produce a study that does not find an association when there truly is a causal relationship between the agent and the disease in question. See Michael D. Green et al., *Reference Guide on Epidemiology*, *in* FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333, 374-375 (2d ed. 2000); In re Neurontin Mktg., Sales Practices, and Prods. Liab. Litig., 612 F.Supp.2d 116 (D. Mass. 2009); Berry v. CSX Transp., Inc., 709 So.2d 552, 558 (Fla. Dist. Ct. App. 1998); Zandi v. Wyeth a/k/a Wyeth, Inc., 2007 WL 3224242 (Minn. Dist. Ct. 2007); Schafersman v. Agland Coop., 631 N.W.2d 862, 871 (Neb. 2001). Criteria for assessing whether an association is causal were proposed by Sir Austin Bradford Hill. One formulation of these criteria is:

- (1) Is the temporal relationship correct? Does the "effect" follow the "cause"?
- (2) Is there evidence from true experiments in humans?
- (3) Is the association a strong one?
- (4) Is the association consistent from study to study?
- (5) Is there a dose-response gradient?
- (6) Is the association specific?
- (7) Does the association make biological sense?
- (8) Is there an appropriate analogy to other known causal relationships?

See Austin Bradford Hill, *The Environment and Disease: Association or Causation*?, 58 PROC. ROYAL SOC'Y MED. 295 (1965). For discussion of these criteria and their respective strengths in informing a causal inference, see 3 DAVID L. FAIGMAN ET AL., MODERN SCIENTIFIC EVIDENCE§ 23:40 to:45 (2007-2008 ed.); LEON GORDIS, EPIDEMIOLOGY 235-239 (4th ed. 2009); DAVID E. LILIENFELD ET AL., FOUNDATIONS OF EPIDEMIOLOGY 263-266 (3d ed. 1994); Douglas L. Weed, *Epidemiologic Evidence and Causal Inference*, 14 HEMATOLOGY/ONCOLOGY CLINICS N. AM. 797 (2000); see also Cook v. Rockwell Int'l Corp., 580 F.Supp.2d 1071 (D. Colo. 2006)(recognizing that not all of the Hill factors must be satisfied to support an inference of causation). For a definition of, and critical inquiry into, what is meant by the seventh criterion, biologic plausibility, see Douglas L. Weed & Stephen D. Hursting, *Biologic Plausibility in Causal Inference: Current Methods and Practice*, 147 AM. J. EPIDEMIOLOGY 415 (1998) (examining use of this criterion in contemporary epidemiologic research and distinguishing between a plausible hypothesis and one supported by evidence supplied from research employing molecular biology and molecular epidemiology).

In a number of cases, experts attempted to use the Hill guidelines to support the existence of causation in the absence of any epidemiologic studies finding an association. See, e.g., Rains v. PPG Indus., Inc., 361 F.Supp.2d 829, 836-837 (S.D. Ill. 2004)(explaining Hill criteria and proceeding to apply them even though there was no epidemiologic study that found an association); Soldo v. Sandoz Pharms. Corp., 244 F.Supp.2d 434, 460 (W.D. Pa. 2003). The Hill factors were developed for the purpose of determining whether an inference of causation is justified based on a study finding an association, and their use to provide the sole basis for proof of general causation does not reflect accepted

epidemiologic methodology. See Dunn v. Sandoz Pharms. Corp., 275 F.Supp.2d 672, 678-679 (M.D.N.C. 2003) ("The greater weight of authority supports Sandoz' assertion that the Bradford Hill criteria is a method for determining whether the results of an epidemiological study can be said to demonstrate causation and not a method for testing an unproven hypothesis."); Soldo supra, 244 F.Supp.2d at 514 (Hill criteria "were developed as a mean[s] of interpreting an established association based on a body of epidemiologic research for the purpose of trying to judge whether the observed association reflects a causal relation between an exposure and disease."(quoting report of court-appointed expert)).

The first case to employ an epidemiologic threshold for proof of agent-disease causation was Brock v. Merrell Dow Pharms., 874 F.2d 307, 315 (5th Cir.) (applying Texas law), modified on rehearing, 884 F.2d 166 (5th Cir. 1989). The genesis for that requirement was the Bendectin litigation in which, in the face of a developing body of scientific evidence tending to exonerate Bendectin, courts sought a means to prevent submission of those cases to a jury. When a substantial body of epidemiologic evidence exists that tends to exonerate the alleged agent, other evidence of causation is far less persuasive. The Bendectin and silicone-gel breast-implant cases, the latter of which involve autoimmune diseases, teach this lesson. Thus, in Norris v. Baxter Healthcare Corp., 397 F.3d 878 (10th Cir. 2005), the court held that in light of a substantial body of epidemiologic evidence that found no reliable association between silicone-gel breast implants and systemic disease, plaintiff could not satisfy her burden of proof on general causation without responding to and overcoming the epidemiologic evidence, which her experts failed to do. Earlier, in In re "Agent Orange" Prods. Liab. Litig., 611 F.Supp. 1267 (E.D.N.Y. 1985), Judge Weinstein had denigrated the animal studies on which plaintiffs sought to rely in the course of granting defendants summary judgment, thereby implying that epidemiologic evidence would be required. After *Brock*, several district courts in the Fifth Circuit employed it as a precedent, requiring epidemiologic evidence, and courts have used a variety of techniques to squelch Bendectin plaintiffs in the face of a substantial body of exonerative epidemiology. See JOSEPH SANDERS, BENDECTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION 89 (1998) (concluding that "the substantial weight of the scientific evidence fails to support the conclusion that Bendectin causes birth defects"); Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience*, 18 COLUM. J. ENVTL. L. 181 (1993); Michael D. Green, *The Road Less Well Traveled (And Seen): Contemporary Lawmaking in Products Liability*, 49 DEPAUL L. REV.377 (1999). For applications of the same principle in non-Bendectin cases, see Norris v. Baxter Healthcare Corp., 397 F.3d 878 (10th Cir. 2005) (applying Colorado law) (extensive body of exonerative epidemiologic evidence must be confronted and plaintiff must provide scientifically reliable contrary evidence); Conde v. Velsicol Chem. Co., 24 F.3d 809 (6th Cir. 1994) (applying Ohio law)("Nineteen epidemiological studies in humans have found little evidence of long-term adverse health effects from chlordane doses hundreds of times higher than those the [plaintiffs] were subject to under a worst-case scenario.").

A quite substantial body of case law and commentary rejects an epidemiologic threshold for sufficient proof of general causation. Many courts find that requiring proof by scientific evidence that does not exist and is not reasonably available to the plaintiff when other, reasonably probative evidence exists is an overbroad method for screening cases. See Norris v. Baxter Healthcare Corp., 397 F.3d 878, 882-883 (10th Cir. 2005) (applying Colorado law)(acknowledging that epidemiology is not required to prove causation but that when a substantial body of exonerative epidemiologic evidence exists, it cannot be ignored, and other evidence proferred to prove causation); Rider v. Sandoz Pharms. Corp., 295 F.3d 1194, 1198 (11th Cir. 2002) (applying Georgia law)("It is well-settled that while epidemiological studies may be powerful evidence of causation, the lack thereof is not fatal to a plaintiff's case."); In re Berg Litig., 293 F.3d 1127, 1130 (9th Cir. 2002) (Price-Anderson Act case in which Washington law adopted); Hollander v. Sandoz Pharms. Corp., 289 F.3d 1193, 1211-1212 (10th Cir. 2002) (applying Oklahoma law) (agreeing with the proposition that plaintiffs need not, in all circumstances, provide evidence of general causation with epidemiologic studies); Bonner v. ISP Tech., Inc., 259 F.3d 924, 929 (8th Cir. 2001) (applying Missouri law); Kennedy v. Collagen Corp., 161 F.3d 1226, 1230 (9th Cir. 1998) (applying California law); Zuchowicz v. United States, 140 F.3d 381, 389-390 (2d Cir. 1998) (Connecticut law in Federal Tort Claims Act case; acute response to a drug); Ambrosini v. Labarraque, 101 F.3d 129, 138-139 (D.C. Cir. 1996) (applying District of Columbia law) (permitting plaintiff's expert to testify in the absence of epidemiological evidence); Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378 (4th Cir. 1995) (applying Virginia law); McCullock v. H.B. Fuller Co., 61 F.3d 1038 (2d Cir. 1995) (applying Vermont law); Hopkins v. Dow Corning Corp., 33 F.3d 1116 (9th Cir. 1994) (applying California law); Glaser v. Thompson Med. Co., 32 F.3d 969 (6th Cir. 1994) (applying Michigan law); Mendes-Silva v. United States, 980 F.2d 1482 (D.C. Cir. 1993) (Federal Tort Claims Act case in which District of Columbia law was adopted); Kennedy v. Collagen Corp., 974 F.2d 1342 (9th Cir. 1992) (applying California law); Wells v. Ortho Pharm. Corp., 788 F.2d 741, 745 (11th Cir. 1986) (applying Georgia law) (pre-*Daubert* case); In re Ephedra Prods. Liab. Litig., 393 F.Supp.2d 181, 186 (S.D.N.Y. 2005); In re Meridia Prods. Liab. Litig., 328 F.Supp.2d 791 (N.D. Ohio 2004); Brasher v. Sandoz Pharms. Corp., 160 F.Supp.2d 1291, 1296-1297 (N.D. Ala. 2001); Globetti v. Sandoz Pharms., Corp., 111 F.Supp.2d 1174 (N.D. Ala. 2000); Graham v. Playtex Prod., Inc., 993 F.Supp. 127, 132 (N.D.N.Y. 1998) (permitting testimony on cause of toxic-shock syndrome in the absence of epidemiologic evidence); Lakie v. SmithKline Beecham, 965 F.Supp. 49, 56 (D.D.C. 1997)(acknowledging significance of epidemiology but denying its absence is dispositive); Pick v. Am. Med. Sys., Inc., 958 F.Supp. 1151, 1158 (E.D. La. 1997) (observing that while epidemiologic studies are a "most useful and conclusive type of evidence," they are not a "necessary element in all toxic tort cases"); Bowers v. N. Telecom, Inc., 905 F.Supp. 1004 (N.D. Fla. 1995); Villari v. Terminix Int'l, Inc., 692 F.Supp. 568 (E.D. Pa. 1988); Marsee v. U.S. Tobacco Co., 639 F.Supp. 466 (W.D. Okla. 1986); Pafford v. Sec'y of Dept. of Health & Human Servs., 64 Fed. Cl. 19 (2005), aff'd, 451 F.3d 1352 (Fed. Cir. 2006); U.S. Sugar Corp. v. Henson, 823

So.2d 104 (Fla. 2002); Earl v. Cryovac, 772 P.2d 725 (Idaho Ct. App. 1989); Donaldson v. Cent. Ill. Pub. Serv. Co., 767 N.E.2d 314 (Ill. 2002); Bloomquist v. Wapello County, 500 N.W.2d 1, 5 (Iowa 1993); Kuhn v. Sandoz Pharms. Corp., 14 P.3d 1170, 1184-1185 (Kan. 2000); Callahan v. Cardinal Glennon Hosp., 863 S.W.2d 852 (Mo. 1993); Lindquist v. City of Jersey City Fire Dep't, 814 A.2d 1069 (N.J. 2003) (agent-disease causation in workers'-compensation case; supporting the idea that causation should be determined based upon the scientific evidence that is currently available); Rubanick v. Witco Chem. Corp., 593 A.2d 733 (N.J. 1991); Valentine v. PPG Indus., Inc., 821 N.E.2d 580 (Ohio Ct. App. 2004); Jennings v. Baxter Healthcare Corp., 14 P.3d 596 (Or. 2001); Reese v. Stroh, 874 P.2d 200 (Wash. Ct. App. 1994); Easum v. Miller, 92 P.3d 794 (Wyo. 2004); David L. Faigman et al., *How Good Is Good Enough?: Expert Evidence Under* Daubert *and* Kumho, 50 CASE W. RES. L. REV. 645, 663 (2000) ("It is now clear that courts will not exclude causal opinions based on non-epidemiological evidence in situations where a body of such data does not exist."); see also Norris v. Baxter Healthcare Corp., 397 F.3d 878 (10th Cir. 2005)(holding opinions of plaintiffs' experts who ignored a substantial body of exonerative epidemiologic evidence were properly ruled inadmissible but denying that positive epidemiologic evidence is universally required).

Commentators have generally been unsympathetic to the imposition of an epidemiologic threshold for proof of causation. See David L. Faigman et al., *How Good Is Good Enough?: Expert Evidence Under* Daubert *and* Kumho, 50 CASE W. RES. L. REV. 645, 663 (2000); Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 339 (1999); Mark Geistfeld, *Scientific Uncertainty and Causation in Tort Law*, 54 VAND. L. REV. 1011 (2001); Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of* Agent Orange *and Bendectin Litigation*, 86 NW. U. L. REV. 643 (1992); see also Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience*, 18 COLUM. J. ENVTL. L. 181 (1993) (arguing epidemiologic evidence should not be required in cases involving infrequent or isolated exposures but that when large numbers of people are exposed, epidemiologic evidence is, and should be, required). Even more antithetical to an epidemiologic threshold are commentators who advocate some form of burden shifting on agent-disease causation. See Margaret Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117 (1997); Heidi Li Feldman,*Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 45 (1995); Ariel Porat & Alex Stein, *Liability for Uncertainty: Making Evidential Damage Actionable*, 18 CARDOZO L. REV. 1891 (1997); Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773 (1997).

For courts that have confronted the situation in which epidemiologic studies cannot feasibly be conducted because an insufficient number of persons have been exposed, see Dawsey v. Olin, 782 F.2d 1254 (5th Cir. 1986) (workers exposed to accidental release

of phosgene gas); Weeks v. E. Idaho Health Servs., 153 P.3d 1180 (Idaho 2007) (medication erroneously infused into catheter in the brain rather than an intravenous line); Donaldson v. Cent. Ill. Pub. Serv. Co., 767 N.E.2d 314 (Ill. 2002) (very few cases of disease, neuroblastoma; difficulty in retrospective determinations of exposure); Trach v. Fellin, 817 A.2d 1102 (Pa. Super. Ct. 2003)(pharmacy assistant's negligence in providing plaintiff incorrect drug resulted in his taking more than 3 times the maximum recommended dose of drug); Oukrop v. Wasserburger, 755 P.2d 233 (Wyo. 1988) (error in prescription resulted in plaintiff being exposed to dose 25 times the ordinary dose); see also In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig., 612 F.Supp.2d 116 (D. Mass. 2009) (explaining the difficulty of conducting an epidemiologic study that would achieve statistical significance because of infrequency of suicide, the outcome of interest). Even when an individual is uniquely exposed to an overdose such as in the *Oukrop* case, studies of the adverse effects of the drug with normal doses may provide evidence supportive of the claim that the overdose caused the plaintiff's disease. The studies may not, however, if there is a threshold dose above the therapeutic dose required before the disease can occur in humans, or if the incidence of the disease occurring at therapeutic doses is so rare that studies are inadequate to reveal the effect of the agent. Another instance in which epidemiologic studies are inadequate on general causation is when the background incidence of the disease is very low and any increased risk is modest. For commentators' views that the market and legal rules provide inadequate incentives to undertake the sorts of studies that provide information about agent-disease causation, see Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1810-1825 (1989) (public-good aspect of information); Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 784-796 (1997) (identifying inadequacies in market, regulatory, and common-law incentives for adequate production of evidence of toxicity). The experience of defendants in the Bendectin and silicone-gel breast-implant cases, in which plaintiffs managed substantial success until the litigation drove the development of science that tended to exonerate the agents, may provide incentives for some manufacturers for which these commentators fail to account.

While courts have permitted proof of general causation with something less than epidemiologic evidence, case reports—reports of an instance of disease in an individual following exposure to a given agent—have been found insufficient by themselves as proof of general causation. See Hollander v. Sandoz Pharms. Corp., 289 F.3d 1193, 1211 (10th Cir. 2002) (applying Oklahoma law); Siharath v. Sandoz Pharms. Corp., 131 F.Supp.2d 1347, 1361-1362 (N.D. Ga. 2001) (citing cases), aff'd, 295 F.3d 1194 (11th Cir. 2002); Susan R. Poulter, *Science and Toxic Torts: Is There a Rational Solution to the Problem of Causation?*, 7 HIGH TECH. L.J. 189, 216 (1992) (case reports and clusters of disease, while necessary, may only reflect coincidence due to random chance rather than a causal relationship). But see Jennings v. Baxter Healthcare Corp., 14 P.3d 596, 607 (Or. 2000) (suggesting that in an unusual case, with an especially powerful agent, case reports may be sufficient to establish causation). For current scientific thinking about the

methodology for reasoning from case reports to causation, see Judith K. Jones, *Determining Causation from Case Reports*, in PHARMACOEPIDEMIOLOGY 525 (Brian L. Strom ed., 3d ed. 2000). For a discussion of the other types of evidence bearing on general causation, see 3 DAVID L. FAIGMAN ET AL., MODERN SCIENTIFIC EVIDENCE§ 23:2 to:25 (2007-2008 ed.) (explaining animal toxicology, in vitro, and structure-activity studies); see also A TEXTBOOK OF MODERN TOXICOLOGY (Ernest Hodgson, ed., 3d ed. 2004); MICHAEL A. KAMRIN, TOXICOLOGY: A PRIMER ON TOXICOLOGY PRINCIPLES AND APPLICATIONS (1988); Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience*, 18 COLUM. J. ENVTL. L. 181, 218-231 (1993); Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, *in* FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 401 (2d ed. 2000); Jack L. Landau & W. Hugh O'Riordan, *Of Mice and Men: The Admissibility of Animal Studies to Prove Causation in Toxic Tort Litigation*, 25 IDAHO L. REV. 521 (1989); Ellen K. Silbergeld, *The Role of Toxicology in Causation: A Scientific Perspective*, 1 CTS., HEALTH SCI. & L. 374 (1991). For sources discussing the admissibility and sufficiency of toxicologic evidence, see FAIGMAN, supra, at § 27-1.1 n.11 (concluding "[i]t is impossible to reconcile all of the cases in this area").

The point about general causation existing in a background sense in all tort cases was drawn from Joseph Sanders & Julie Machal-Fulks, *The Admissibility of Differential Diagnosis Testimony to Prove Causation in Toxic Tort Cases: The Interplay of Adjective and Substantive Law*, 64 LAW & CONTEMP. PROBS. 107, 110 n.13 (2001); see also Richard W. Wright, *Causation, Responsibility, Risk, Probability, Naked Statistics, and Proof: Pruning the Bramble Bush by Clarifying the Concepts*, 73 IOWA L. REV. 1001, 1046 (1988)("Thus, to prove that a specific condition was a cause of a particular result, one obviously must establish … that some credible causal generalization links conditions of that type to results of that type.").

Even when satisfactory evidence of general causation exists, such evidence generally supports proof of causation only for a specific disease. The vast majority of toxic agents cause a single disease or a series of biologically related diseases. See Bernard D. Goldstein, *Toxic Torts: The Devil is in the Dose*, 16 J.L. & POL'Y 551, 556 (2008). (However, many different toxic agents may be combined in a single product, such as cigarettes.) When biological-mechanism evidence is available, it may permit an inference that a toxic agent caused a related disease. Otherwise, proof that an agent causes one disease is generally not probative of its capacity to cause other unrelated diseases. Thus, while there is substantial scientific evidence that asbestos causes lung cancer and mesothelioma, whether asbestos causes other cancers would require independent proof. Courts refusing to permit use of scientific studies that support general causation for diseases other than the one from which the plaintiff suffers unless there is evidence showing a common biological mechanism include Christophersen v. Allied-Signal Corp., 939 F.2d 1106, 1115-1116 (5th Cir. 1991) (applying Texas law)(epidemiologic connection

between heavy-metal agents and lung cancer cannot be used as evidence that same agents cause colon cancer); Cavallo v. Star Enters., 892 F.Supp. 756 (E.D. Va. 1995), aff'd in part and rev'd in part, 100 F.3d 1150 (4th Cir. 1996); Boyles v. Am. Cyanamid Co., 796 F.Supp. 704 (E.D.N.Y. 1992); Watts v. Radiator Specialty Co., 990 So.2d 143, 147-149 (Miss. 2008); see also Taylor v. Airco, Inc., 494 F.Supp.2d 21 (D. Mass. 2007) (holding that plaintiff's expert could testify to causal relationship between vinyl chloride and one type of liver cancer for which there was only modest support given strong causal evidence for vinyl chloride and another type of liver cancer). In Austin v. Kerr-McGee Refining Corp., 25 S.W.3d 280, 290 (Tex. Ct. App. 2000), the plaintiff sought to rely on studies showing that benzene caused one type of leukemia to prove that benzene caused a different type of leukemia in her decedent. Quite sensibly, the court insisted that before the plaintiff could do so, she would have to submit evidence that both types of leukemia had a common biological mechanism of development. Accord In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., 524 F.Supp.2d 1166, 1183 (N.D. Cal. 2007); Magistrini v. One Hour Martinizing Dry Cleaning, 180 F.Supp.2d 584, 603 (D.N.J. 2002).

For cases in which courts reached opposite conclusions on the value and adequacy of biological-mechanism evidence, compare Siharath v. Sandoz Pharms. Corp., 131 F.Supp.2d 1347 (N.D. Ga. 2001) (biological-mechanism evidence of effect of Parlodel, a drug that suppresses lactation, insufficient to permit plaintiff's expert witnesses to testify to general causation), aff'd, 295 F.3d 1194 (11th Cir. 2002), with Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528 (6th Cir. 1993) (applying Kentucky law) (plaintiff's expert relied predominantly on pathogenic evidence); Globetti v. Sandoz Pharms. Corp., 111 F.Supp.2d 1174 (N.D. Ala. 2000) (crediting expert witnesses who reasoned that, because Parlodel is a vasoconstrictive agent, it has the capacity to cause spasms that result in a heart attack); Stevens v. Sec'y of HHS, 2001 WL 387418, at *14 (Fed. Cl. 2001) (identifying infrequent instance when use of pathological-mechanism evidence is available and sufficiently probative to establish causation); Weeks v. E. Idaho Health Servs., 153 P.3d 1180 (Idaho 2007) (effect of increase in intracranial pressure resulting from medication erroneously infused into catheter in the brain rather than an intravenous line). However, scientists report that there is no methodology for assessing the strength or reliability of biological-mechanism evidence. It may vary from quite compelling to no more than hypothesis, with little supporting the latter other than some biologic knowledge and a fertile imagination. See generally Douglas L. Weed & Stephen D. Hursting, *Biologic Plausibility in Causal Inference: Current Methods and Practice*, 147 AM. J. EPIDEMIOLOGY 415 (1998) (distinguishing between a plausible biological-mechanism hypothesis and biological-mechanism evidence based on research employing molecular biology and molecular epidemiology); Susan R. Poulter, *Science and Toxic Torts: Is There a Rational Solution to the Problem of Causation?*, 7 HIGH TECH. L.J. 189, 230 (1992).

One final observation about the uncertainties of group observational studies and their use in civil litigation as proof of causation may assist those who do not regularly work in this area. The observational nature of epidemiologic studies virtually always results in concerns

about the results being skewed by biases or unidentified confounders. Sampling error is also always possible in group studies, whether observational or experimental. Sometimes potential confounders can be identified and data gathered that permits analysis of whether confounding exists. Unidentified confounders, however, cannot be analyzed. Often potential biases can be identified, but assessing the extent to which they affected the study's outcome is problematic. Even sampling error, which is analyzed using quantitative statistical methods, only provides a range of outcomes (associations) that might have been produced by sampling error even if there is no association between the agent and disease. Thus, interpreting the results of epidemiologic studies requires informed judgment and is subject to uncertainty. Unfortunately, contending adversarial experts, because of the pressures of the adversarial system, rarely explore this uncertainty and provide the best, objective assessment of the scientific evidence. The extent of judgment involved in making causal assessments and the range of uncertainty often involved augur for making that judgment with neutral, court-appointed experts, where feasible, whose expertise, judgment, and honest assessment of the degree of uncertainty involved can better be developed. An increasing number of judges, confronted with these issues, have chosen to employ court-appointed experts. See, e.g., Soldo v. Sandoz Pharms. Corp., 244 F.Supp.2d 434 (W.D. Pa. 2003); Miller v. Pfizer, Inc., 196 F.Supp.2d 1062, 1094 (D. Kan. 2002); Hall v. Baxter Healthcare Corp., 947 F.Supp. 1387 (D. Or. 1996).

Complicating appropriate assessment of uncertainty and its implications for sufficiency of the evidence is that scientists generally do not think or express their judgments in probabilistic terms. While testimony as an expert in court is sometimes an exception, when scientists are asked to make an assessment of the degree of uncertainty based on existing evidence, they often have difficulty responding. An example of this phenomenon occurred in an Institute of Medicine Committee that had been requested to examine the evidence bearing on a causal relationship between rubella vaccine and arthritis. The Committee report stated that the “evidence is consistent” with a causal relationship. Only after further inquiries were made did the Committee clarify that it meant that the Committee “favors acceptance of” a causal relationship. The court interpreting the latter categorization interpreted it to mean more likely than not. See Snyder v. Sec'y of HHS, 2002 WL 31965742 (Fed. Cl. 2002).

Model Jury Instructions published by California’s Judicial Counsel Advisory Committee

CACI 430 Causation: Substantial Factor

A substantial factor in causing harm 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.

[Conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct.]

CACI 431 Causation: Multiple Causes

A person's negligence may combine with another factor to cause harm. If you find that [*name of defendant*]'s negligence was a substantial factor in causing [*name of plaintiff*]'s harm, then [*name of defendant*] is responsible for the harm. [*Name of defendant*] cannot avoid responsibility just because some other person, condition, or event was also a substantial factor in causing [*name of plaintiff*]'s harm.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 17. Statement of Related Cases Pursuant to Circuit Rule 28-2.6

Instructions for this form: http://www.ca9.uscourts.gov/forms/form17instructions.pdf

9th Cir. Case Number(s) 19-16255, 19-16253, 19-16636, 19-16708

The undersigned attorney or self-represented party states the following:

○ I am unaware of any related cases currently pending in this court.

○ I am unaware of any related cases currently pending in this court other than the case(s) identified in the initial brief(s) filed by the other party or parties.

◉ I am aware of one or more related cases currently pending in this court. The case number and name of each related case and its relationship to this case are:

Appeal No. 19-16253 (Hardeman v. Monsanto); Appeal No. 19-16255 (Hardeman v. Monsanto); Appeal No. 19-16636 (Hardeman v. Monsanto); Appeal No. 19-16708 (Hardeman v. Monsanto).

These appeals arise out of the orders from the trial in the case Hardeman v. Mosnanto (l 6-cv-00525-VC, l 6-md-027 41-VC).

Signature s/ David J. Wool **Date** 3/16/2020

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

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of March 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/ David J. Wool
David J. Wool