FOR PUBLICATION

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

EDWIN HARDEMAN, *Plaintiff-Appellee/ Cross-Appellant*, v. MONSANTO COMPANY, *Defendant-Appellant/ Cross-Appellee.*	Nos. 19-16636 19-16708 D.C. Nos. 3:16-cv-00525-VC 3:16-md-02741-VC OPINION

Appeal from the United States District Court
for the Northern District of California
Vince G. Chhabria, District Judge, Presiding

Argued and Submitted October 23, 2020
San Francisco, California

Filed May 14, 2021

Before: Michael D. Hawkins, N. Randy Smith, and
Ryan D. Nelson, Circuit Judges.

Opinion by Judge R. Nelson;
Dissent by Judge N.R. Smith

SUMMARY*

Pesticides / Punitive Damages

The panel affirmed the district court's judgment in favor of Edwin Hardeman in his action alleging that Monsanto's pesticide, Roundup, caused his non-Hodgkin's lymphoma.

Roundup is pesticide with the active ingredient glyphosate. Since 2015, thousands of cancer victims sued Monsanto in state and federal court. This appeal arose out of the first bellwether trial for the federal cases consolidated in a multidistrict litigation. The jury awarded Hardeman $5,267.634.10 in compensatory damages, and $75 million in punitive damages. The district court reduced the punitive damages award to $20 million.

The panel held that Hardeman's state failure-to-warn claims based on Roundup's labeling were consistent with the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and thus were neither expressly nor impliedly preempted. Specifically, the panel affirmed the district court's conclusion that Hardeman's state failure-to-warn claims were "equivalent to" and "fully consistent with" FIFRA and therefore not expressly preempted. *Bates v. Dow Agrosciences LLC*, 554 U.S. 431, 449 (2005). In addition, because Monsanto could comply with both FIFRA and California law, FIFRA did not impliedly preempt Hardeman's state failure-to-warn claims.

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

The panel held that the district court ultimately applied the correct standard from *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and did not abuse its discretion in admitting Hardeman's expert testimony. Despite its incorrect assumption that this court was more permissive than others in admitting *Daubert* testimony, the district court still employed the correct legal standard for reliability when it admitted Hardeman's expert testimony. The panel held further that the district court did not abuse its discretion in concluding that Hardeman's experts reliably based their general causation opinions on epidemiological evidence showing a connection between glyphosate and cancer. The panel also held that the district court did not abuse its discretion in admitting Hardeman's expert testimony on specific causation to show that Hardeman's cancer was caused by glyphosate, rather than some other factor. Here, Hardeman's experts reliably used differential diagnosis because they ruled in glyphosate based on the epidemiological evidence supporting the general causation opinions and ruled out alternate causes, such as idiopathy and Hepatitis C (HCV).

The panel held that the district court did not abuse its discretion in admitting the International Agency for Research on Cancer's classification of glyphosate as probably carcinogenic and three regulatory rejections of that classification by excluding evidence from other regulatory bodies. The panel held further that even if these evidentiary decisions were erroneous, any error was harmless because it was more probable than not that the admission of the evidence did not affect the jury's verdict.

The panel held that the district court's jury instruction on causation was erroneous because it was inconsistent with the

Judicial Council of California Civil Jury Instructions and California case law, but it was harmless error.

The panel held that the district court properly denied Monsanto judgment as a matter of law because evidence showed the carcinogenic risk of glyphosate was knowable at the time of Hardeman's exposure.

The panel held that evidence supported a punitive damages award, punitive damages were properly reduced, and the reduced award – while close to the outer limit – was constitutional. Specifically, the panel held that punitive damages were permissible under California law because substantial evidence was presented that Monsanto acted with malice by, among other things, ignoring Roundup's carcinogenic risks. The panel held that the jury's $75 million punitive damages award was "grossly excessive" given the mitigating factors found by the district court. However, considering the evidence of Monsanto's reprehensibility, the district court's reduced $20 million punitive damages award (a 3.8 to 1 damages ratio), while at the outer limits of constitutional propriety, ultimately comported with due process.

The panel cautioned that although this appeal involved a bellwether trial, many of its holdings were fact-specific, and different Roundup cases may present different considerations, leading to different results.

Judge N.R. Smith dissented to section VII.B, concerning punitive damages. He would hold that Monsanto's low degree of reprehensibility cannot constitutionally justify the district court's substantial punitive damages award. The facts found by the district court did not support a 3.8:1 ratio to compensatory damages.

Case: 19-16636, 05/14/2021, ID: 12112919, DktEntry: 142-1, Page 5 of 74

COUNSEL

Seth P. Waxman (argued) and Paul R.Q. Wolfson, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, D.C.; Thomas G. Sprankling and Henry J. Becker, Wilmer Cutler Pickering Hale and Dorr LLP, Palo Alto, California; Leon T. Kenworthy, Clair H. Chung, James Barton, Samuel M. Strongin, and Rafael J. Gallardo Hevia, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, D.C.; Brian L. Stekloff and Rakesh Kilaru, Wilkinson Walsh and Eskovitz LLP, Washington, D.C.; Philip J. Perry and Richard P. Bress, Latham & Watkins LLP, Washington, D.C.; Michael X. Imbroscio and David M. Zionts, Covington & Burling LLP, Washington, D.C.; Lee Marshall, Bryan Cave Leighton Paisner LLP, San Francisco, California; for Defendant-Appellant/Cross-Appellee.

David J. Wool (argued) and Aimee H. Wagstaff, Andrus Wagstaff PC, Lakewood, Colorado; Leslie A. Brueckner, Public Justice, Oakland, California; Jennifer A. Moore, Moore Law Group PLLC, Louiseville, Kentucky; for Plaintiff-Appellee/Cross-Appellant.

Jonathan D. Brightbill (argued) and Eric Grant, Deputy Assistant Attorneys General; Jennifer Scheller Neumann, Varudhini Chilakamarri, and Matthew R. Oakes, Attorneys; Environment and Natural Resources Division, United States Department of Justice, Washington, D.C.; Erin S. Koch and Amber L. Aranda, Attorneys, EPA Office of General Counsel, Washington, D.C.; for Amicus Curiae United States.

Andrew Wiener (argued), Laura Zuckerman, and Dennis Ragen, Deputy Attorneys General; Harrison M. Pollack, Supervising Deputy Attorney General; Office of the

Case: 19-16636, 05/14/2021, ID: 12112919, DktEntry: 142-1, Page 6 of 74

Attorney General, Oakland, California; for Amicus Curiae State of California.

Shannen W. Coffin and Sara Beth Watson, Steptoe & Johnson LLP, Washington, D.C., for Amicus Curiae CropLife America.

Laura W. Brill, Nicholas F. Daum, and Sharon S. Song, Kendall Brill & Kelly LLP, Los Angeles, California, for Amicus Curiae Genentech Inc.

Douglas J. Peterson, Attorney General; Justin D. Lavene, Maegan L. Woita, and Joshua E. Dethlefsen, Assistant Attorneys General; Office of the Attorney General, Lincoln, Nebraska; Lawrence G. Wasden, Attorney General of Idaho; Jeff Landry, Attorney General of Louisiana; Wayne Stenehjem, Attorney General of North Dakota; Jason Ravnsborg, Attorney General of South Dakota; Ken Paxton, Attorney General of Texas; and Sean D. Reyes, Attorney General of Utah; for Amici Curiae States of Nebraska, Idaho, Louisiana, North Dakota, South Dakota, Texas, and Utah.

Curtis A. Cole, Cassidy C. Davenport, and Scott M. Klausner, Cole Pedroza LLP, San Marino, California, for Amici Curiae California Medical Association, California Dental Association, and California Hospital Association.

William R. Stein, Eric S. Parnes, Stephen R. Halpin III, and J. Chesley Burruss, Hughes Hubbard & Reed LLP, Washington, D.C.; Theodore V.H. Mayer, Hughes Hubbard & Reed LLP, New York, New York; Steven P. Lehotsky and Michael B. Schon, U.S. Chamber Litigation Center, Washington, D.C.; James C. Stansel and Melissa B. Kimmel, Pharmaceutical Research and Manufacturers of America,

ED_006453B_00000006-00006

Case: 19-16636, 05/14/2021, ID: 12112919, DktEntry: 142-1, Page 7 of 74

Washington, D.C.; for Amici Curiae Chamber of Commerce of the United States of America, and Pharmaceutical Research and Manufacturers of America.

Adina H. Rosenbaum and Allison M. Zieve, Public Citizen Litigation Group, Washington, D.C., for Amicus Curiae Public Citizen.

Matthew W.H. Wessler and Larkin Turner, Gupta Wessler PLLC, Washington, D.C.; Bruce Stern, President, American Association for Justice, Washington, D.C.; for Amicus Curiae American Association for Justice.

Ashley Keller, Travis Lenker, and Warren Postman, Keller Lenkner LLC, Chicago, Illinois; Ernest A. Young, Apex, North Carolina; for Amici Curiae Public Law Scholars.

Ryan D. Talbott, Center for Food Safety, Portland, Oregon, for Amici Curiae Center for Food Safety and Center for Biological Diversity.

Carrie Apfel, Earthjustice, Washington, D.C.; Alexis Andiman and Peter Lehner, Earthjustice, New York, New York; Patti Goldman, Earthjustice, Seattle, Washington; for Amici Curiae California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, Migrant Clinicians Network, Pesticide Action Network, United Farm Workers, and UFW Foundation.

Melanie Benesh and Caroline Leary, Environmental Working Group, Washington, D.C., for Amicus Curiae Environmental Working Group.

ED_006453B_00000006-00007

OPINION

R. NELSON, Circuit Judge:

Monsanto Company manufactures Roundup, a pesticide with the active ingredient glyphosate. Since 2015, thousands of cancer victims have sued Monsanto in state and federal court, alleging that Roundup caused their non-Hodgkin's lymphoma. This appeal arises out of the first bellwether trial for the federal cases consolidated in a multidistrict litigation.

The jury returned a verdict in favor of plaintiff Edwin Hardeman, awarding him $5,267,634.10 in compensatory damages and $75 million in punitive damages. The district court reduced the jury's punitive damages award to $20 million.

Monsanto appeals, arguing the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") preempts Hardeman's failure-to-warn claims; the district court made a series of evidentiary and jury instruction errors; the district court erred in denying judgment as a matter of law; and the punitive damages award violates California law and the Due Process Clause. Hardeman cross-appeals, arguing the jury's $75 million punitive damages award was constitutional.

We affirm the district court and hold that (1) Hardeman's state failure-to-warn claims are not preempted by FIFRA; (2) the district court ultimately applied the correct standard from *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and did not abuse its discretion in admitting Hardeman's expert testimony; (3) the district court did not abuse its discretion in admitting the International Agency for Research on Cancer's classification of glyphosate as probably carcinogenic and three regulatory rejections of that classification but excluding evidence from

other regulatory bodies; (4) the district court's jury instruction on causation, though erroneous, was harmless; (5) Monsanto was properly denied judgment as a matter of law because evidence shows the carcinogenic risk of glyphosate was knowable at the time of Hardeman's exposure; and (6) evidence supports a punitive damages award, punitive damages were properly reduced, and the reduced award—while close to the outer limits—is constitutional.

I

A

Under FIFRA, the United States Environmental Protection Agency ("EPA") enforces "the use, . . . sale[,] and labeling[] of pesticides." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 437 (2005) (citation omitted). A state may "not impose or continue in effect any requirements for labeling or packaging in addition to or different from those" required by FIFRA. 7 U.S.C. § 136v(b).

FIFRA requires pesticide manufacturers to register their products with EPA. 7 U.S.C. § 136a(a). EPA makes registration determinations after considering available scientific data, § 136a(c)(1)(F), (c)(2)(A); 40 C.F.R. § 158.500, and FIFRA requires EPA to re-review a pesticide's registration, including its effects on human health, every fifteen years, § 136a(g)(1)(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." § 136a(f)(2). Rather, "[a]s long as no cancellation proceedings are in effect," 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 can also institute cancellation proceedings, 7 U.S.C. § 136d(b), or take other enforcement action against the manufacturer of a registered pesticide if the agency determines the product is "misbranded." *Bates*, 544 U.S. at 439. Remedies for misbranding include civil and criminal penalties. *Id.* at 439 n.11 (citing 7 U.S.C. § 136l). A duly registered pesticide can be misbranded if 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). "Because it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded, manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements." *Id.* (citations omitted). This obligation includes a duty to seek approval to amend a label that does not contain all "necessary warnings or cautionary statements." *Id.* (citation omitted).

Starting in 1974, EPA registered pesticides containing glyphosate, the active ingredient in Roundup.[1] EPA, *Glyphosate Proposed Interim Registration Review Decision* 4 (Apr. 2019) ("*Proposed Interim Registration Review*"). In 1985, an EPA review of a mouse study found "[g]lyphosate was oncogenic in male mice," causing rare tumors. EPA classified glyphosate as a possible human carcinogen. Since then, however, EPA has repeatedly approved the use of glyphosate as a pesticide, each time concluding that it is not likely to be carcinogenic to humans. *See Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 905 (9th Cir. 2020).

[1] Though commonly referred to as an herbicide, Roundup is defined as a pesticide under 7 U.S.C. § 136(t), (u). Roundup contains glyphosate, water, and other ingredients called "surfactants."

In the early 1990s, EPA reevaluated glyphosate's effects on human health as part of its regular review of glyphosate's registration. After considering numerous carcinogenicity studies in rats and mice—including new evidence submitted by Monsanto—EPA changed its designation of glyphosate to a "Group E carcinogen" signifying "evidence of non-carcinogenicity in humans."

In 2015, a working group at the International Agency for Research on Cancer ("IARC"), an agency of the World Health Organization, issued a report classifying glyphosate as a "Group 2A" agent, meaning it is "probably carcinogenic to humans" based on glyphosate's "limited evidence" of cancer in humans and "sufficient evidence" of cancer in experimental animals. IARC's classification was a "hazard identification," the first step of a public health assessment designed to identify cancer hazards. That hazard determination asked whether glyphosate "is capable of causing cancer under some circumstances," but did not include a "risk assessment" gauging the carcinogenic effects from real-world human exposure. Since IARC's classification, other national and international agencies charged with reviewing pesticides—such as the European Union's European Chemicals Agency ("ECA"), European Food Safety Authority ("EFSA"), and the national health authorities of Australia, Canada, Germany, and New Zealand—have reported that scientific evidence does not show glyphosate causes cancer.

When the IARC report was released, EPA was conducting its registration review of glyphosate, during which it examined various scientific studies, including those IARC considered. In 2017, EPA published its proposed conclusion: Glyphosate was not likely to be carcinogenic to humans. But, that same year, pursuant to Proposition 65,

California law categorized glyphosate as a chemical known to the state to cause cancer. Cal. Off. of Env't Health Hazard Assessment, *Glyphosate*, ("Glyphosate Proposition 65"), https://oehha.ca.gov/proposition-65/chemicals/glyphosate. That classification triggered a state law requirement to attach a warning label to glyphosate products. *See id.*; Cal. Health & Safety Code § 25249.6.

In April 2019—one month after the jury verdict in this case—EPA noted that commenters "expressed concerns that glyphosate formulations are more toxic than glyphosate alone." *Proposed Interim Registration Review* at 10. EPA explained that "there are few research projects that have attempted to directly compare technical grade glyphosate to the formulations under the same experimental design," but "[i]f at any time, information becomes available that indicates adverse human health effects of concern for exposure to glyphosate or its formulations, EPA intends to review it and determine the appropriate regulatory action." *Id.* at 11.

About five months after the jury verdict, EPA issued a letter to all registrants of glyphosate-containing products. Letter from Michael L. Goodis, EPA, Office of Pesticide Programs (Aug. 7, 2019) ("2019 letter"). The 2019 letter was not the product of any formal proceeding, was not published in the Federal Register, did not cite any new scientific findings, and took no position on whether Roundup causes cancer. Instead, this letter challenged California's inclusion of glyphosate in Proposition 65 as contrary to "EPA's determination that glyphosate is 'not likely to be carcinogenic to humans.'" *Id.* at 1. Given this determination, EPA "considers the Proposition 65 warning language" that glyphosate is carcinogenic "to constitute a false and misleading statement" that violates FIFRA's

prohibition against "misbranded" substances. *Id.* 1–2 (citing § 136(q)(1)(A)). The letter concluded with EPA instructing registrants to remove such warning statements from labels of glyphosate-based pesticides. *Id.* at 2.

B

In 2016, Hardeman sued Monsanto alleging that his use of Roundup—which started in the 1980s and ended in 2012—led to his diagnosis of non-Hodgkin's lymphoma ("NHL") in early 2015. Hardeman's case is one of approximately 5,000 in federal court alleging that Roundup causes NHL. The Judicial Panel on Multidistrict Litigation consolidated those cases for pretrial proceedings in the Northern District of California. Hardeman's case was the first of these consolidated cases to go to trial.

NHL is a cancer that affects white blood cells in the immune system. Approximately 70% or more of NHL cases are idiopathic, meaning they develop for unknown reasons. However, some causes of NHL—such as hepatitis C ("HCV")—are well established. Hardeman had HCV for 25 to 40 years before developing NHL.

Hardeman alleged Monsanto's failure to warn him of the carcinogenic risks of Roundup caused his NHL. Monsanto moved to dismiss, arguing that Hardeman's claims were preempted by FIFRA given EPA's registration of glyphosate, approval of the Roundup label, and classification of glyphosate as non-carcinogenic. The district court denied Monsanto's motion. Monsanto raised preemption again in a motion for summary judgment, which the district court likewise denied.

The district court bifurcated the pretrial proceedings. The first phase addressed "general causation"—whether

glyphosate can cause NHL at exposure levels humans might experience. The second phase addressed "specific causation"—whether Hardeman's exposure to Roundup caused his NHL.

The district court granted in part and denied in part Monsanto's motion to exclude Hardeman's general causation experts, allowing three of Hardeman's experts to testify—Dr. Portier, Dr. Ritz, and Dr. Weisenburger. These experts introduced their general causation opinions with scientific evidence from epidemiology (study of disease in human populations), toxicology (animal studies), and genotoxicology (cell studies); applied the Bradford Hill criteria;[2] and used meta-analyses that combined and analyzed the results of case-control studies.

The district court, however, acknowledged that significant problems with Hardeman's experts' analyses made it a "very close question" whether their testimony was admissible to support general causation. *In re Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102, 1108 (N.D. Cal. 2018). The district court interpreted the Ninth Circuit's approach to *Daubert* as requiring "slightly more room for deference to experts in close cases than might be appropriate in some other Circuits." *Id.* at 1113 (citations omitted). Ultimately, the district court concluded Hardeman's three

[2] The Bradford Hill criteria are nine factors generally accepted as relevant to assessing causation, such as: (1) the strength of the association; (2) consistency; (3) specificity; (4) temporality; (5) biological gradient or dose response; (6) biological plausibility; (7) coherence with other scientific knowledge; (8) experimental evidence; and (9) analogy. *See In re Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102, 1116 (N.D. Cal. 2018) (citing Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 Proceedings of the Royal Society of Medicine 295 (1965)).

experts' opinions were relevant and reliable, satisfying Federal Rule of Evidence 702 and *Daubert*.

The district court later denied Monsanto's motion to exclude Hardeman's specific causation experts. Hardeman's experts performed 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 v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1234 (9th Cir. 2017). Hardeman's experts considered various risk factors beyond Roundup exposure that could explain his disease, including age, race, obesity, hepatitis B ("HBV"), and HCV, as well as idiopathic origin—i.e., no known cause. They concluded Roundup caused Hardeman's NHL by ruling in Roundup based on general causation expert opinions and ruling out HCV and idiopathy[3] as causes of Hardeman's NHL. The district court admitted the experts' opinions, noting this circuit affords experts "wide latitude in how they practice their art when offering causation opinions." *In re Roundup*, 358 F. Supp. 3d at 960 (citing *Wendell*, 858 F.3d at 1237).

Monsanto requested a bifurcated trial, with the first phase addressing whether Roundup caused Hardeman's cancer (without reference to any regulatory decisions regarding glyphosate or Roundup) and the second phase

[3] As to idiopathy, the district court held that "[i]t is sufficient for a qualified expert, in reliance on his clinical experience, review of a plaintiff['s] 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." *In re Roundup Prods. Liab. Litig.*, 358 F. Supp. 3d 956, 960 (N.D. Cal. 2019) (quoting *Wendell*, 858 F.3d at 1235).

addressing liability and damages (where the jury could see some of that evidence). Monsanto moved to exclude all evidence regarding IARC's report, which detailed the agency's classification of glyphosate as probably carcinogenic, as irrelevant and likely to confuse and distract the jury. But if IARC evidence were admitted, Monsanto argued, the district court should admit evidence that numerous regulatory agencies around the world concluded that glyphosate is safe.

Ultimately, the district court excluded IARC's report but admitted IARC's classification of glyphosate as probably carcinogenic to mitigate the prejudice caused to Hardeman due to bifurcation of the trial. The district court also admitted conclusions from EPA, EFSA, and ECA that glyphosate was safe but excluded conclusions from other regulatory bodies as cumulative.

At trial, Hardeman's experts testified that his exposure to glyphosate caused his NHL. Monsanto's experts testified that little evidence links glyphosate to cancer in humans and that Hardeman's HCV most likely caused his cancer or his cancer was idiopathic.

The district court issued a "substantial factor" causation instruction. The jury was instructed that, to rule for Hardeman, it must find that glyphosate exposure was a but-for cause of his cancer or one of two or more factors that independently could have caused his cancer.

After Phase One (on causation), the jury returned a verdict that Roundup exposure was a "substantial factor" in causing Hardeman's NHL. After Phase Two (on liability and damages), the jury found that Monsanto failed to warn about Roundup's NHL risk and Hardeman was entitled to punitive damages. The jury awarded Hardeman

$5,267,634.10 in compensatory damages and $75 million in punitive damages.

In post-trial motions, Monsanto argued that the district court improperly excluded evidence of foreign regulatory approvals of glyphosate, which allegedly deprived the jury of the scope of evidence reinforcing Monsanto's view of the science. The district court explained that such evidence about foreign regulators would have been cumulative under Federal Rule of Evidence 403 and denied Monsanto's motion to overturn the verdict and for judgment as a matter of law. But the district court reduced the punitive damages award of $75 million to $20 million. These appeals followed.

II

Whether Hardeman's state claims are preempted is reviewed de novo. *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1203 (9th Cir. 2002). Monsanto argues that Hardeman's failure-to-warn claims are preempted by FIFRA, under which states cannot "impose . . . any requirements for labeling or packaging *in addition to or different from*" the requirements in FIFRA itself. § 136v(b) (emphasis added); *see also* U.S. Const. art. VI, cl. 2 (federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"). We conclude that Hardeman's failure-to-warn claims based on Roundup's labeling are consistent with FIFRA and thus are neither expressly nor impliedly preempted.

A

FIFRA does not expressly preempt Hardeman's claims because FIFRA's requirement that a pesticide not be

misbranded is consistent with, if not broader than, California's common law duty to warn. *Bates* employs a two-part test to determine whether FIFRA preempts a state law claim. 544 U.S. at 444. First, the state law must be a requirement "*for labeling or packaging*." *Id.* (quoting § 136v(b)). Second, the state law must impose a labeling or packaging requirement that is "*in addition to or different from*" those required under FIFRA. *Id.* (quoting § 136v(b)). Because Hardeman's complaint is based on Monsanto's failure to provide an adequate warning on a label under California law, part one of this test is satisfied.

As to part two of the *Bates* test, "a state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447. State law is "equivalent to" and "fully consistent with" FIFRA where both impose "parallel requirements," meaning that a violation of the state law is also a violation of FIFRA. *Id.*; *see also id.* at 454 ("[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA."). Thus, if a violation of California's duty to warn would also be a violation of FIFRA's misbranding provision, then they impose parallel requirements fully consistent with each other. *Id.* at 454 ("To survive pre-emption, the state-law requirement need not be phrased in the *identical* language as its corresponding FIFRA requirement . . . ."). To that end, elements of California's duty to warn and FIFRA's misbranding provision are compared below.

FIFRA's misbranding provision requires a pesticide label "contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment." § 136(q)(1)(G). Similarly,

California common law requires a manufacturer to warn either of any health risk[4] that is "known or knowable" (in strict liability) or 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). Thus, FIFRA—which requires a warning "necessary" and "adequate to protect health"—is broader than California's requirement under negligence (no warning needed if unreasonable to do so)[5] and is, at minimum, consistent with California's requirement under strict liability (no warning needed if risk not known or knowable). *See id.*; § 136(q)(1)(G). Because FIFRA's misbranding requirements parallel those of California's common law duty, Hardeman's failure-to-warn claims effectively enforce FIFRA's requirement against misbranding and are thus not expressly preempted. *See* § 136(q)(1)(G); *Bates*, 544 U.S. at 447–48 (citing favorably Justice O'Connor's explanation in *Medtronic*, 518 U.S. 470, that "a state cause of action that seeks to enforce a federal requirement 'does not impose a requirement that is "different from, or in addition to," requirements under federal law'").

---

[4] Because a risk of cancer is a risk contemplated by FIFRA as "necessary" and "adequate to protect health," § 136(q)(1)(G), (x), (bb), we need not address the possibility that California common law may require a manufacturer to warn of a risk not contemplated by FIFRA's misbranding provision.

[5] Though "it may be necessary as a matter of [state] law to prove that th[e] violations were the result of negligent conduct . . . such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower 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." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

Monsanto, however, argues that because EPA repeatedly registered Roundup for sale without a cancer warning on the label, a jury's decision that Roundup should include such a warning would effectively impose a requirement "in addition to or different from" that required by FIFRA, and so the state law is preempted. Granted, EPA is highly involved in the pesticide registration process, which includes approval of product labels. And EPA will not register a pesticide unless it determines that the label "compl[ies] with" FIFRA's "requirements." § 136a(c)(5)(B). But this argument misses the point for two reasons.

First, EPA's approval of a label—one step in a larger registration process—is not conclusive of FIFRA compliance. FIFRA specifies:

> 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.

§ 136a(f)(2) (emphasis added).[6] Because EPA has not instituted any cancellation proceedings against Monsanto,

[6] Section 136a(f)(2) distinguishes this case from *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which held that the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") expressly preempted claims challenging the safety and effectiveness of a medical device that received premarket approval from the Food and Drug Administration ("FDA"). *Id.* at 315, 330. Like FIFRA's preemption provision, the MDA preempts certain state requirements that are different from, or in addition to, certain federal

EPA's approval of Roundup's label is prima facie evidence of FIFRA compliance. *See id.* And looking at FIFRA holistically, this makes sense—if mere EPA approval of a label were determinative of FIFRA compliance, then FIFRA's misbranding provision and regulations imposing a duty to report "additional factual information regarding unreasonable adverse effects" would serve no purpose. § 136d(a)(2); *see also* § 136(q)(1) (detailing when a pesticide is misbranded); 40 C.F.R. § 159.152 (imposing duty to report additional information on adverse effects). So even though EPA approved Roundup's label, a judge or jury could disagree and find that same label violates FIFRA. And because EPA's labeling determinations are not dispositive of FIFRA compliance, they similarly are not conclusive as to which common law requirements are "in addition to or different from" the requirements imposed by FIFRA. *See* § 136v(b); *cf. Bates*, 544 U.S. at 451 ("Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA."); *Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc.*, 617 F.3d 207, 222 (3d Cir. 2010) (explaining that *Bates* "established that mere inconsistency between the duty imposed by state law and the content of a manufacturer's labeling approved by the EPA at registration did not necessarily mean that the state law duty was preempted").

Second, the EPA actions that Monsanto alleges preempt Hardeman's claims do not carry the force of law. As noted in *Bates*, "[a] requirement is a rule of law that must be obeyed." 544 U.S. at 445. To establish requirements that

---

requirements. *See* 21 U.S.C. § 360k(a)(1). But the MDA does *not* contain a provision like FIFRA's § 136a(f)(2), which clarifies that the agency's approval of a label is not determinative of compliance with the statute.

can preempt state law under § 136v(b), agency action must have the force of law. *See Wyeth v. Levine*, 555 U.S. 555, 576, 580 (2009). In other words, only where there is a relevant EPA action *carrying the force of law* are state failure-to-warn claims prohibited from imposing requirements inconsistent with that action.[7] Monsanto tries to circumvent this caveat by arguing that although EPA's approval of Roundup's label was not a rulemaking, it happened "in the context of [a] registration process" that "has the hallmarks of formal agency action." *See* § 136a; 40 C.F.R. § 155.50(b)–(c). But, as explained above, FIFRA expressly states that EPA's decision to approve a label during the registration process raises only a rebuttable presumption that the pesticide and its label comply with FIFRA. § 136a(f)(2). It would defy logic to say a rebuttable presumption carries the force of law necessary to have preemptive effect, as doing so would deny any ability to rebut the presumption.

Nor does EPA's 2019 letter, sent after the conclusion of Hardeman's trial to all registrants of products containing glyphosate, carry the force of law. Generally, "Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that

[7] Monsanto relies on *Bates*'s explanation that a failure-to-warn claim alleging that a label should have stated "DANGER" instead of "CAUTION" would be preempted "because it is inconsistent with 40 C.F.R. § 156.64 (2004), which specifically assigns these warnings to particular classes of pesticides based on their toxicity." 544 U.S. at 453. But this example deals with agency action that has the force of law—FIFRA regulation 40 C.F.R. § 156.64. Here, however, neither EPA's approval of Roundup's label during registration nor EPA's 2019 letter carries the force of law necessary to preempt Hardeman's failure-to-warn claims.

should underlie a pronouncement of such force." *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001). But the 2019 letter—stating that EPA believes any pesticide label with a cancer warning due to the presence of glyphosate will be misbranded—did not follow any "formal administrative procedure" that would give the letter the force of law.[8] *See id.* The 2019 letter was issued without any written notice, gave no hearing or opportunity to respond, and lacked any sort of dispute-resolution process. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019). Instead, the 2019 letter is similar to the letter in *Fellner v. Tri-Union Seafoods, LLC*, which lacked preemptive effect because the FDA "merely expressed an informal policy opinion in a letter, and it did so only after [the plaintiff's] injuries were allegedly suffered." 539 F.3d 237, 255 (3d Cir. 2008).[9]

---

[8] EPA's 2017 determination that glyphosate is not carcinogenic does not magically give the "force of law" to this 2019 letter on misbranding. EPA's 2017 determination was given in the context of glyphosate "undergoing Registration Review" after evaluating glyphosate's carcinogenic potential. EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 12 (Dec. 2017) ("Registration Review also allows the agency to incorporate new science."). Even if the 2017 determination stems from more formal procedures, it is not necessarily at odds with the future failure-to-warn claim because it was made as part of EPA's registration decision, which only supports presumptive (not conclusive) compliance with FIFRA. *See* § 136a(f)(2).

[9] In contrast, EPA's cancellation proceedings, for example, may have the force of law given that § 136d(b) lays out a formal notice and hearing process, and no comparable prima facie evidence restriction applies. *See* § 136a(f)(2) (stating that registration is "prima facie evidence" of FIFRA compliance "[a]s long as no cancellation proceedings are in effect"). But no cancellation proceedings were in effect here.

Thus, we affirm the district court's conclusion that Hardeman's state failure-to-warn claims are "equivalent to" and "fully consistent with" FIFRA and therefore not expressly preempted. *See Bates*, 544 U.S. at 449 ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against preemption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly."). The Supreme Court decided *Bates* over fifteen years ago, and regulatory preemption in other contexts has developed considerably in the interim. For FIFRA preemption, however, currently *Bates* controls.

B

Because Monsanto could comply with both FIFRA and California law, FIFRA did not impliedly preempt Hardeman's state failure-to-warn claims.

1

A state failure-to-warn claim is impliedly preempted if the relevant federal and state laws "irreconcilably conflict." *Merck*, 139 S. Ct. at 1679 (quoting *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)). "[S]tate and federal law conflict where it is impossible for a private party to comply with both state and federal requirements." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (internal quotation marks and citation omitted). To demonstrate an "irreconcilabl[e] conflict," Monsanto must present "clear evidence" that (1) the agency was "fully informed" of "the justifications for the warning" the plaintiff demands, (2) the agency has "informed the . . . manufacturer that [it] would not approve changing the . . . label to include that warning," and (3) the agency's action "carr[ies] the force of law." *Merck*, 139 S.

Ct. at 1678–79. However, because EPA's actions—such as registering Roundup, approving Roundup's label, and issuing the 2019 letter—do not have the force of law, Monsanto fails part (3) of *Merck*'s "clear evidence" of "irreconcilabl[e] conflict" test and cannot show preemption. *See supra* Section II.A.

2

Monsanto also argues that Hardeman's claims are impliedly preempted because, under EPA's regulations, Monsanto could not have unilaterally changed Roundup's label, making it impossible for Monsanto to comply with both FIFRA and California's common law duty to warn. Monsanto relies primarily on *PLIVA*, a case concerning the federal regulatory scheme governing generic drugs. 564 U.S. 604. But, as explained in *PLIVA*, "different federal statutes and regulations may . . . lead to different preemption results." *Id.* at 626. Here, FIFRA's regulatory regime for pesticides differs meaningfully from the regulatory scheme governing generic drugs in *PLIVA* and, as a result, Monsanto's implied preemption argument fails.

Under the regulatory scheme at issue in *PLIVA*, generic drug manufacturers have an "ongoing federal duty of sameness," according to which they must use the same labeling as the corresponding name-brand drug. *Id.* at 613 (internal quotation marks and citations omitted). Generic drug manufacturers do not draft their products' initial labeling and do not have the power to revise labeling. *See id.* As the Supreme Court explained, "[i]f [the generic drug manufacturers] had [asked the FDA for help], and if the FDA decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the [generic drug] [m]anufacturers

would have started a Mouse Trap game that eventually led to a better label." *Id.* at 619. But, in *PLIVA*, the generic drug manufacturer could not "independently satisfy . . . state duties for pre-emption purposes" because it "cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency." *Id.* at 623–24 (explaining that "[t]he only action the [generic drug] [m]anufacturers could independently take" was "asking for the FDA's help").

Unlike the FDCA and FDA regulatory scheme for generic drug manufacturers, FIFRA and the EPA regulatory scheme provide that pesticide manufacturers are responsible for drafting their own product labels, § 136a(c)(1)(C), and do not need to maintain the same labeling as another manufacturer. Once a pesticide is registered, the manufacturer has a "continuing obligation to adhere to FIFRA's labeling requirements." *Bates*, 544 U.S. at 438 (citations omitted). When a label needs to be changed, the manufacturer has the responsibility to change the label by drafting and submitting the label to EPA for approval, 40 C.F.R. § 152.50(e), which EPA "shall" approve if it determines the change will not violate FIFRA, § 136a(f)(1). This is a far cry from the "special permission and assistance" needed from the FDA in *PLIVA* to change a generic drug label, a process constrained by a duty of sameness and the added step of agency deliberations with name-brand manufacturers. *See* 564 U.S. at 623–24.

Moreover, EPA permits pesticide manufacturers to make certain changes to labels without prior approval. *See id.* at 623. Specifically, manufacturers can make minor modifications to labeling without prior EPA approval if EPA is notified of the change. 40 C.F.R. § 152.46(a); EPA,

Office of Pesticide Programs, *Pesticide Registration Notice 98-10* (Oct. 22, 1998) ("PRN 98-10"). Thus, unlike the generic drug manufacturers in *PLIVA*, pesticide manufacturers "can act sufficiently independently under federal law" when amending a label. *See PLIVA*, 564 U.S. at 623.

Though Monsanto contends that "[a]dding a warning about cancer would hardly qualify as a 'minor modification,'" EPA has repeatedly permitted pesticide manufacturers to use the notification procedure to add notices related to cancer to their products' labels.[10] Nevertheless, Monsanto counters that there is no "single example where EPA has allowed a registrant to use the notification process" where EPA previously "found the relevant chemical was *not* carcinogenic, much less where it determined a cancer warning would render a label false and misleading," referring to the 2019 letter.

But neither EPA's 2017 finding that glyphosate is not carcinogenic nor the 2019 letter (which do not carry the force of law) divert Monsanto to a different process for amending

[10] For instance, pursuant to PRN 98-10, pesticide manufacturer Bayer CropScience notified EPA "of a minor labeling amendment for LARVIN Technical," informing EPA that "[a]s required by California Proposition 65, the following statement has been added to the label, 'This product contains a chemical known to the state of California to cause cancer.'" Letter from Larry R. Hodges, Registration Manager, Bayer CropScience, to EPA, Office of Pesticide Programs 4 (Nov. 29, 2012), www3.epa.gov/pesticides/chem_search/ppls/000264-00343-20131217.pdf. In response, EPA's Registration Division "conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10." Letter from Jennifer Gaines, EPA, Office of Pesticide Programs, to Larry Hodges, Bayer CropScience 2 (Dec. 17, 2012), www3.epa.gov/pesticides/chem_search/ppls/000264-00343-20131217.pdf.

a label beyond those normally followed by pesticide manufacturers under FIFRA and its regulations, as described above. Considering the responsibility FIFRA places on manufacturers to update pesticide labels and that EPA has allowed pesticide manufacturers to add cancer warnings to labels through the notification process without prior approval, it is not *impossible* for Monsanto to add a cancer warning to Roundup's label. *See PLIVA*, 564 U.S. at 623; *see also Wyeth*, 555 U.S. at 573 (explaining that "[i]mpossibility pre-emption is a demanding defense").

III

Whether the district court applied the correct legal standard under *Daubert* is reviewed de novo, and the district court's decision to admit expert testimony is reviewed for abuse of discretion. *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 462 (9th Cir. 2014) (en banc), *overruled on other grounds by United States v. Bacon*, 979 F.3d 766 (9th Cir. 2020) (en banc). We hold that the district court ultimately applied the correct legal standard under *Daubert* and did not abuse its discretion by admitting Hardeman's general and specific causation expert testimony.

A

Under Federal Rule of Evidence 702, expert testimony must be reliable to be admissible. *Daubert*, 509 U.S. at 589. Scientific evidence is reliable when "the principles and methodology used by an expert are grounded in the methods of science." *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1056 (9th Cir. 2003). When determining reliability, district court judges can consider the following non-exclusive factors: (1) "whether the theory or technique employed by the expert is generally accepted in the scientific community;" (2) "whether it's been subjected to peer review

and publication;" (3) "whether it can be and has been tested;" and (4) "whether the known or potential rate of error is acceptable." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (citing *Daubert*, 509 U.S. at 593–95). "Th[is] inquiry is 'flexible,'" *Wendell*, 858 F.3d at 1232 (quoting *Daubert*, 509 U.S. at 594), and "should be applied with a 'liberal thrust' favoring admission," *Messick v. Novartis Pharms. Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014) (quoting *Daubert*, 509 U.S. at 588).[11]

Monsanto contends that, by relying on a misguided reading of *Wendell* and *Messick*, the district court misinterpreted *Daubert* to be more forgiving of experts' extrapolations than this circuit allows. But, in reaching its conclusions, the district court followed this court's precedent and thus cannot be faulted for following binding case law. Monsanto's specific critiques are addressed below.

First, according to Monsanto, the district court erroneously stated there is "slightly more room for deference to experts" in close cases, *In re Roundup*, 390 F. Supp. 3d at 1113, and that courts in this circuit are "more tolerant of

[11] This liberal thrust favoring admission is not without limits. "Just as the district court cannot abdicate its role as gatekeeper, so too must it avoid delegating that role to the jury." *Estate of Barabin*, 740 F.3d at 464 (holding that district court erred by "pass[ing] its greatest concern about [the expert's] testimony to the jury to determine" and there was little "indication that the district court assessed, or made findings regarding, the scientific validity or methodology of [another expert's] proposed testimony"); *see also United States v. Valencia-Lopez*, 971 F.3d 891, 899 (9th Cir. 2020) (holding that district court erred in admitting expert testimony without making a reliability determination by dismissing the expert's deficiencies as "going to the weight, not admissibility, of [the expert's] testimony" (quoting *Nease v. Ford Motor Co.*, 848 F.3d 219, 230 (4th Cir. 2017))).

borderline expert opinions," *In re Roundup*, 358 F. Supp. 3d at 959.

As an initial matter, this court is not an outlier following a more flexible *Daubert* approach than other circuits. The cases on which the district court relied do not establish otherwise. For instance, in the Fourth Circuit case relied on by the district court, the expert failed to provide a proper scientific basis for her differential diagnosis by "focus[ing] almost exclusively on the fact that [plaintiff] took the drug and later developed the disease, rather than explaining what led her to believe that it was a substantial contributing factor as compared to other possible causes." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 892 F.3d 624, 645 (4th Cir. 2018). But if we compare the expert in *Lipitor* to, for instance, the expert in *Messick*, the cases are readily distinguishable. Unlike the *Lipitor* expert, the expert in *Messick* provided a scientific basis for his conclusion by "refer[ing] to his own extensive clinical experience as the basis for his differential diagnosis, as well as his examination of [plaintiff's] records, treatment, and history." 747 F.3d at 1198.

Similarly, in the Sixth Circuit case relied on by the district court, the expert's causation analysis was insufficient because literature had only hypothesized but did not find a link between the chemical and disease. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 677–78 (6th Cir. 2010). The *Tamraz* court explained, "the problem is not that [the expert] failed to cite studies about [the chemical] causing [the disease] . . . or could not quantify how much [of the chemical] would lead to how much [of the disease]; the problem is that he failed to cite *any* non-speculative evidence for his conclusion." *Id.* at 674. In contrast, the experts in *Wendell* did not present that deficiency, as they "relied not

just on . . . studies—which not only examined reported cases but also used statistical analysis to come up with risk rates—but also on their own wealth of experience and additional literature." 858 F.3d at 1236. Thus, the Fourth Circuit and Sixth Circuit cases on which the district court relied are not at odds with this court's *Daubert* approach.

To the extent the district court relied on *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, 858 F.3d 787, 800 (3d Cir. 2017), and *McClain v. Metabolife International, Inc.*, 401 F.3d 1233, 1244–45 (11th Cir. 2005), to show those courts adopted the any step principles,[12] those cases do not reveal a more flexible *Daubert* approach in this circuit. We have explained that "expert evidence is inadmissible where the analysis is the result of a faulty methodology or theory as opposed to imperfect execution of laboratory techniques whose theoretical foundation is sufficiently accepted in the scientific community to pass muster under *Daubert*." *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1047–48 (9th Cir. 2014) (internal quotation marks and citation omitted). Imperfect application of methodology may not render expert testimony unreliable because "'[a] minor flaw in an expert's reasoning or a slight modification of an otherwise reliable method' does not render expert testimony inadmissible." *Id.* at 1048 (quoting *Amorgianos*, 303 F.3d at 267 (adopting the any step principles)) (alteration in original). The reasoning guiding the any step principles is

[12] "The *Daubert* 'requirement that the expert testify to scientific knowledge—conclusions supported by good grounds for each step in the analysis—means that *any* step that renders the analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible*.'" *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994)); *see also Zoloft*, 858 F.3d at 797; *McClain*, 401 F.3d at 1245.

not dissimilar; namely, "[t]he judge should only exclude the evidence if the flaw is large enough that the expert lacks 'good grounds' for his or her conclusions." *Amorgianos*, 303 F.3d at 267 (quoting *Paoli*, 35 F.3d at 746).

Despite its incorrect assumption that this court is more permissive than others in admitting *Daubert* testimony, the district court still employed the correct legal standard for reliability when it admitted Hardeman's expert testimony. For instance, the district court's slight "deference to experts" with "borderline . . . opinions" was proper under *Daubert*: "[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 (quoting *Daubert*, 509 U.S. at 596) (alteration in original). The Supreme Court has not directed courts to follow a different rule since it first decided *Daubert* almost 28 years ago.

Second, Monsanto takes issue with the district court's suggestion that courts in this circuit can admit opinions "that lean strongly toward the 'art' side of the spectrum." *In re Roundup*, 358 F. Supp. 3d at 959 (citation omitted). Though that may seem strange out of context, the district court was only reiterating our precedent following *Daubert*. *See Messick*, 747 F.3d at 1198 ("Medicine partakes of art as well as science . . . ."). The district court did not suggest that courts in this circuit allow "art" as a separate, standalone category divorced from logic and science. Rather, in referencing "art," the district court followed *Wendell* and *Messick*'s instructions that a testifying expert can rely on his own extensive clinical experience under *Daubert*. *See Wendell*, 858 F.3d at 1237 ("Where, as here, two doctors who stand at or near the top of their field and have extensive clinical experience with the rare disease or class of disease

at issue, are prepared to give expert opinions supporting causation, we conclude that *Daubert* poses no bar based on their principles and methodology."); *Messick*, 747 F.3d at 1198 (allowing "extensive clinical experience" to form basis of differential diagnosis opinion).

Monsanto attempts to distinguish *Wendell* by arguing that it only allows experts to rely on clinical experience in exceptional circumstances not present here, particularly cases involving rare diseases with insufficient epidemiological data. Considering that *Wendell* drew the concept of "art" from *Messick*, a case which did not involve a rare disease, we do not find that the application of art is limited to exceptional circumstances.

The district court allowed experts to rely on clinical experience, or "art," only when conducting differential diagnosis to render specific causation opinions. Allowing experts to rely on clinical experience while conducting differential diagnosis, as the district court did here, is consistent with *Messick*. *See* 747 F.3d at 1198 ("[T]here is nothing wrong with a doctor relying on extensive clinical experience when making a differential diagnosis.").

Monsanto further tries to distinguish *Messick* by emphasizing that the expert there relied on clinical experience as well as an examination of medical literature and plaintiff's records. But Hardeman's experts did the same thing here, if not more, by relying on epidemiological, animal, and cell studies. Acknowledging this, Monsanto counters that "there are numerous epidemiological studies on the association between glyphosate and Hardeman's subtype of non-Hodgkin's lymphoma that obviated the need for any reliance on 'art.'" But Monsanto contradicts its own argument, asserting *Wendell* and *Messick* "state that experience can *supplement* reliable scientific studies and

medical literature." On this point, Monsanto is right: Hardeman's experts' clinical experience could supplement the epidemiological studies on which they relied.

Thus, the district court applied the correct legal standard under *Daubert* by following our precedent and fulfilling its "special obligation to determine the reliability of an expert's testimony." *Elsayed Mukhtar v. Cal. State Univ., Hayward*, 299 F.3d 1053, 1063 (9th Cir. 2002) (internal quotation marks and citation omitted), *overruled on other grounds by Estate of Barabin*, 740 F.3d 457.

B

To establish general causation, Hardeman's experts needed to show that glyphosate can cause NHL at exposure levels people realistically may have experienced. Here, Hardeman's general causation experts relied on three types of studies: epidemiological,[13] animal, and cellular. Animal studies are relevant evidence of causation where there is a sound basis for extrapolating conclusions from those studies to humans in real-world conditions. *See Domingo ex rel. Domingo v. T.K.*, 289 F.3d 600, 606 (9th Cir. 2002). Similarly, cell studies can support more substantial evidence of causation. Therefore, animal and cell studies can help show causation so long as there is evidence of an association between glyphosate and NHL in humans within the epidemiological literature. This means that to be admissible testimony, the experts must have reliably based their general causation opinions on epidemiological evidence showing a

[13] Epidemiology is "the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations." Michael D. Green et al., *Reference Guide on Epidemiology*, *in* Reference Manual on Scientific Evidence 551, 551 (3d ed. 2011) ("Reference Manual").

connection between glyphosate and cancer. As discussed below, the district court did not abuse its discretion in concluding that Hardeman's experts satisfied this requirement.

Monsanto maintains that the experts did not use the epidemiological evidence reliably because they (1) dismissed the Agricultural Health Study ("AHS") and (2) focused on case-control studies that did not sufficiently account for confounding factors. These criticisms, however, are not enough to render the expert opinions unreliable.

First, Monsanto criticizes Hardeman's experts for ignoring the AHS, which Monsanto considers to be the most powerful evidence on the relationship between glyphosate and NHL. That study was a cohort study conducted by the National Institutes of Health that considered a range of pesticide exposures on 57,000 participants over several years. The AHS found no statistically significant association between glyphosate and NHL and showed no dose-response relationship, meaning "no evidence of higher rates of [NHL] with more days of exposure."

Nonetheless, Hardeman's experts had a reasonable basis for placing less weight on the AHS. For instance, an epidemiologist employed by Monsanto wrote years before the AHS results were announced that "the exposure assessment in the AHS will be inaccurate" because the AHS will have "spurious exposure-disease findings due to exposure misclassification." Similarly, Monsanto's toxicologist, Donna Farmer, recognized that "[m]any groups have been highly critical of the study as being a flawed study, in fact some have gone so far as to call it junk science . . . . [T]he bottom line is scary . . . there will be associations identified . . . just because of the way this study is designed."

These criticisms from Monsanto employees resemble those from Hardeman's experts that the AHS is flawed and unreliable. Though Monsanto changed its tune on the AHS because the misclassification concerns were allegedly addressed using "sensitivity analyses" as the study progressed, the overlapping criticisms still show that Hardeman's expert opinions on the AHS are within "the range where experts might reasonably differ." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153 (1999). Accordingly, the district court did not abuse its discretion in concluding 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." *In re Roundup*, 390 F. Supp. 3d at 1126.

Second, Monsanto criticizes Hardeman's experts for relying on three case-control studies: De Roos (2003), McDuffie (2001), and Eriksson (2008), which allegedly contain serious flaws. Although case-control studies are "prone to recall bias,"[14] Hardeman's experts gave the district court valid reasons to discount this concern. For example, the experts explained that epidemiology studies overall found associations only between glyphosate and NHL, but not between glyphosate and other cancers asked about in the studies. The experts pointed out that, if participants were pre-disposed to think glyphosate caused cancer and consequently exhibited recall bias, the studies would have reported associations for glyphosate and other cancers.

[14] "[R]ecall bias[] occurs where people with a disease . . . are differently able to recall past exposures than are people who never get sick; generally, the assumption is that the cases will recall greater levels of exposure, as those who become ill are more likely to ruminate about the possible causes of their disease." Reference Manual at 585–86.

Hardeman's experts also relied upon studies that sought to validate self-reports of pesticide exposure and found similar recall accuracy between controls and cases. Considering this evidence, the district court did not abuse its discretion in finding the "possible presence of recall bias" is "not significant enough to require an expert categorically to weight [the case-control studies] less heavily than the AHS." *In re Roundup*, 390 F. Supp. 3d at 1133.

Monsanto criticizes the De Roos study specifically for "not properly account[ing] for [NHL's] latency period" because the study analyzed data collected between 1979 and 1986, but NHL takes "at least five to ten years to develop" and Roundup was put on the market in 1974. As the district court pointed out, a potential confounding variable[15] is an important reason a study might show an association between glyphosate and NHL shortly after glyphosate was put on the market.

The De Roos study, however, reduced the risk of confounding by adjusting for many other pesticides. While Hardeman's experts acknowledged that it is "always possible" that the observed association was the result of confounding not accounted for in De Roos, the adjustment for many other pesticides in De Roos made it "significantly less likely" that a pesticide other than glyphosate caused the observed association. As a result, the district court properly scrutinized the reliability of De Roos and did not abuse its discretion in concluding that, "at least for the studies that adjust for other pesticide exposures [i.e., De Roos], the relatively short period between glyphosate exposure and cancer development is not a concern so significant as to

[15] Confounding variables are other factors that could explain an observed association between a substance and the disease.

disqualify an expert who gives significant weight to the case-control studies in rendering a causation opinion." *In re Roundup*, 390 F. Supp. 3d at 1123.

Nonetheless, Monsanto argues that Hardeman's experts still did not sufficiently consider confounding factors while evaluating epidemiology. According to Monsanto, "McDuffie did not account for the effect of exposure to pesticides beyond glyphosate *at all*" and, "while Eriksson did provide some results adjusted for the effect of other pesticides, the adjusted results did not show a statistically significant link between glyphosate and [NHL]."

But while the district court acknowledged that "exclusive consideration of numbers unadjusted for other pesticides, when adjusted numbers are available, would be disqualifying," *In re Roundup*, 390 F. Supp. 3d at 1140, Hardeman's experts did not do that here. For instance, "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." *In re Roundup*, 390 F. Supp. 3d at 1133; *see also id.* at 1140–41, 1143 (discussing Dr. Ritz and Dr. Weisenburger). Further, even where adjustment for other pesticides resulted in loss of statistical significance, the results still showed a positive association between glyphosate and NHL.[16] Thus, contrary

[16] Monsanto criticizes Dr. Weisenburger for relying on a single favorable odds ratio from the "earliest iteration" of the North American Pooled Project. But such reliance is not enough to render Dr. Weisenburger's entire testimony unreliable. *See, e.g.*, *Wendell*, 858 F.3d at 1233 (explaining that district courts should not look "too narrowly at each individual consideration, without taking into account the broader picture of the experts' overall methodology"). The district

to Monsanto's criticisms, the general causation expert opinions were sufficiently supported by reliable epidemiological evidence, so admitting these experts' testimony was not an abuse of discretion.

C

To establish specific causation, experts needed to show that Hardeman's NHL was caused by glyphosate, rather than some other factor. To do so, Hardeman's experts—Dr. Weisenburger, Dr. Shustov, and Dr. Nabhan—used "differential diagnosis," which starts with ruling in "all potential causes, then rul[ing] out the ones as to which there is no plausible evidence of causation, and then determin[ing] the most likely cause among those that cannot be excluded." *Wendell*, 858 F.3d at 1234; *see also Clausen*, 339 F.3d at 1057. Here, Hardeman's experts reliably used differential diagnosis because they ruled in glyphosate based on the epidemiological evidence supporting the general causation opinions and ruled out alternative causes, such as idiopathy and HCV.

1

Monsanto argues that Hardeman failed to adequately rule out idiopathy, considering that 70% or more of NHL cases have unknown causes. Monsanto acknowledges that an expert can rule out idiopathy by reliably concluding that the known factor (here, glyphosate) is a "substantial cause," which can be shown when a strong association exists between the disease and that known risk factor. *See Wendell*, 858 F.3d at 1235, 1237 (even though expert "was not entirely

---

court properly considered this issue before concluding Dr. Weisenburger's testimony was sufficiently reliable.

able to rule" out idiopathy, he could conclude a "known risk factor[]" was a substantial cause because "literature show[ed] that patients exposed to" the drugs in question were "at an increased risk for" the disease). But here, Monsanto argues that Hardeman's experts did not reliably conclude that glyphosate was a substantial cause because no strong association existed between glyphosate and NHL, forcing the experts to rely on two flawed studies and their own subjective judgment.

Specifically, Monsanto argues that Hardeman's experts did not rule in glyphosate as a substantial cause because, unlike the experts in *Wendell*, they did not show a sharp enough increased risk of cancer for those exposed to glyphosate. Monsanto focuses on Hardeman's experts' inability to present a study with an adjusted odds ratio above 2.0. But we have never suggested that a hardline increase in a risk statistic, or even an adjusted odds ratio above 2.0, is necessary for finding a strong association. *See id.* at 1234. To the contrary, flexibility is warranted considering the contextual nature of the *Daubert* inquiry. Thus, it was not an abuse of discretion to admit expert testimony—that glyphosate is a substantial cause—partly based on the epidemiological studies from the general causation opinions, where the general causation opinions showed a "robust connection between glyphosate and NHL." *In re Roundup*, 358 F. Supp. 3d at 960.

Next, Monsanto criticizes Hardeman's experts for relying on "two flawed studies"—McDuffie and Eriksson—linking glyphosate and NHL. Monsanto focuses on the experts' two attempted uses for those studies: (1) to assign a quantified risk to Hardeman based on the studies' "unadjusted numbers" and (2) to show that Hardeman's risk ratio must have exceeded 2.0 because he exceeded the

exposure minimums from the two studies (i.e., two days per year or ten lifetime days of exposure). But this focus is misplaced. Though relying on McDuffie and Eriksson for those propositions may have been problematic, that is not what happened here. The district court explicitly considered these issues and properly exercised its gatekeeping function by precluding the experts from using the studies in those two ways.

Instead, the district court allowed Hardeman's experts to rely on McDuffie and Eriksson to show a dose-response relationship between glyphosate and NHL. And Hardeman's experts presented a sufficient basis for using these studies (though unadjusted for other pesticides) to show such a relationship. For instance, Dr. Weisenburger clarified, if a chemical "shows a dose response, it's very likely an etiologic agent because it's . . . unusual that a chemical would cause a disease and not have a dose response. So when you see a dose response, that gives you some assurance that it really is causing the disease."

Had the experts relied only on McDuffie and Eriksson to show glyphosate is a substantial cause of NHL, their specific causation opinions may have been unreliable. However, Hardeman's experts relied not only on McDuffie and Eriksson but also other epidemiological evidence (like De Roos) supporting a strong association, as well as their clinical experience and review of plaintiff's medical records. Thus, as a whole, the evidence provided a sufficient basis for reliably ruling out idiopathy by concluding glyphosate was a substantial cause of Hardeman's NHL. *See Wendell*, 858 F.3d at 1233–34 (ruling out idiopathy for disease with 70% idiopathy rate where expert relied on clinical experience, literature, and medical records).

2

Monsanto also argues that Hardeman's experts did not reliably rule out HCV as an alternate cause. HCV is an established cause of NHL. Even though Hardeman was treated for HCV in 2005 and 2006, Monsanto claims that he was vulnerable to cellular damage caused by the virus for many years, including NHL. But, as Dr. Weisenburger explained, to cause cancer, the virus must be active, and there was no evidence that Hardeman's HCV had been active for the decade preceding his NHL diagnosis. And this conclusion, as determined by the district court, had significant support in the scientific literature.

Further, Dr. Weisenburger's underlying methodology for reaching this conclusion was sound. He relied on Hardeman's medical records and his clinical experience and reviewed scientific literature (including seven studies) as the basis for ruling out HCV. *See Messick*, 747 F.3d at 1199 ("[D]ifferential diagnosis grounded in significant clinical experience and examination of medical records and literature can certainly aid the trier of fact and cannot be considered to be offering 'junk science.'"). Thus, Dr. Weisenburger reliably ruled out HCV as an alternate cause of Hardeman's NHL, and the district court did not abuse its discretion in admitting Hardeman's expert testimony on specific causation.

IV

The district court's decision to admit IARC's glyphosate classification as a "probable carcinogen" but exclude contrary conclusions from other regulatory bodies is reviewed for abuse of discretion. *Estate of Barabin*, 740 F.3d at 462. The district court made that decision to

mitigate prejudice to Hardeman after granting Monsanto's request to bifurcate the trial.

Monsanto argues that admitting IARC's classification was an error because the classification's minimal probative value was outweighed by unfair prejudice and juror confusion, which was allegedly exacerbated by the district court's exclusion of various foreign regulatory agencies' rejections of IARC's classification. We disagree.

Under Rule 403, the district court can "exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. "A district court's Rule 403 determination is subject to great deference, because the considerations arising under Rule 403 are susceptible only to case-by-case determinations, requiring examination of the surrounding facts, circumstances, and issues." *United States v. Hinkson*, 585 F.3d 1247, 1267 (9th Cir. 2009) (en banc) (internal quotation marks and citation omitted).

According to Monsanto, IARC's classification had minimal probative value because it did not rely on new data or gauge cancer risk from real-world glyphosate exposure. But this misses the point: IARC's classification was admitted to mitigate prejudice to Hardeman from the trial's bifurcation. Monsanto had specifically requested bifurcation to preclude evidence of its "attempting to influence regulatory agencies and manipulate public opinion regarding glyphosate." Without IARC's classification, "jurors w[ould] be left wondering, during the causation phase, how glyphosate could possibly be dangerous if it ha[d] gone largely unregulated for decades." Further, the district court minimized the risk of prejudice to Monsanto by

only admitting IARC's classification, not the underlying details, and admitting the continued approval of glyphosate from three other regulators—EPA, EFSA, and ECA. Importantly, the district court instructed the jury to "not defer" to the conclusions of any of these regulatory bodies because they were not a substitute for the jurors' "own independent assessment of the evidence." While other regulatory agencies had also rejected IARC's classification, the district court did not err in concluding that evidence of additional regulators' post-IARC conclusions would have been cumulative. Admitting all foreign regulatory conclusions would have invited the jury to weigh competing regulatory findings rather than independently assess the scientific evidence.

Even if these evidentiary decisions were erroneous, any error was harmless because it was "more probable than not that the . . . admission of the evidence did not affect the jury's verdict." *United States v. Ramirez-Robles*, 386 F.3d 1234, 1244 (9th Cir. 2004) (internal quotation marks and citations omitted). Considering the strong limiting instruction and the expert testimony linking glyphosate to cancer, the jury would likely have reached the same causation verdict even without evidence of IARC's classification or with more evidence of regulatory agency rejections of that classification. Therefore, we affirm the decision to admit the conclusions from IARC, EPA, EFSA, and ECA, and to exclude evidence from additional regulatory agencies.

V

Monsanto also challenges the district court's causation jury instruction. We review de novo whether that instruction correctly states the law. *Peralta v. Dillard*, 744 F.3d 1076, 1082 (9th Cir. 2014) (en banc). We conclude that the district

court's causation jury instruction was inconsistent with the Judicial Council of California Civil Jury Instructions ("CACI") and California case law. We conclude, however, that any error was harmless. *See Caballero v. City of Concord*, 956 F.2d 204, 206 (9th Cir. 1992).

The district court's causation jury instruction included a substantial factor and but-for causation instruction, drawing from CACI 430, and a concurrent independent causes instruction.[17] The first paragraph of this instruction (on substantial factor and but-for causation) adopted the same

[17] The jury was instructed as follows:

> To prevail on the question of medical causation, Mr. Hardeman must prove by a preponderance of the evidence that Roundup was a substantial factor in causing his non-Hodgkin's lymphoma. A substantial factor is a factor that a reasonable person would consider to have contributed to the harm. It must be more than a remote or trivial factor. It does not have to be the only cause of the harm. Subject to the additional instructions below, conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct.
>
> The following additional instructions apply if you believe that two or more NHL-causing factors operated independently on Mr. Hardeman:
>
> If you conclude that Mr. Hardeman has proven that his exposure to Roundup was sufficient on its own to cause his NHL, then you must find for Mr. Hardeman even if you believe that other factors were also sufficient on their own to cause his NHL. On the other hand, if you conclude that Mr. Hardeman has not proven that his exposure to Roundup was sufficient on its own to cause his NHL, then you must find for Monsanto.

language as CACI 430, the model "substantial factor" instruction. The district court's instruction included CACI 430's final optional sentence on but-for causation that reads, "[c]onduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct." But CACI 430's "Directions for Use" instruct courts to "not include the [but-for instruction] in a case involving concurrent independent causes," which the district court did here. As such, "the but-for test is inappropriate in cases when two forces are actively operating and each is sufficient to bring about the harm." *Lopez v. The Hillshire Brands Co.*, 254 Cal. Rptr. 3d 377, 383–84 (Ct. App. 2019) (quoting *Major v. R.J. Reynolds Tobacco Co.*, 222 Cal. Rptr. 3d 563, 579 (Ct. App. 2017)). And this makes sense considering that the two instructions tend to contradict each other when used together.

Here, the district court's causation jury instruction erroneously incorporated the optional final sentence of CACI 430. The concurrent independent causation instruction was appropriate—otherwise, the jury might not have found causation, even if it thought Roundup caused Hardeman's cancer, because HCV may have been an additional cause. *See Viner v. Sweet*, 70 P.3d 1046, 1051 (Cal. 2003) (explaining there is an exception to but-for cause for "multiple forces operating at the same time and independently, each of which would have been sufficient by itself to bring about the harm"). But because the concurrent independent causation instruction inherently conflicted with but-for causation, the district court's jury instruction did not state the law entirely correctly. *See Peralta*, 744 F.3d at 1082. We recognize the district court tried to alleviate this conflict by adding the introductory language of "[s]ubject to the additional instructions below," before providing the but-

for causation instruction, but we still find that language confusing, such that the instruction was "misleading." *Id.*

An erroneous instruction does not require reversal, however, when "the error is more probably than not harmless." *Caballero*, 956 F.2d at 206 (citation omitted). That standard is "less stringent than review for harmless error in a criminal case" and "more stringent than review for sufficiency of the evidence." *Id.* at 207. Because the instruction given likely did not prejudice Monsanto, the harmlessness standard is met. For instance, if the jury did not view the but-for instruction as a bar to finding causation, then it applied the appropriate causation standard. And even if the jury interpreted the optional but-for sentence from CACI 430 to mean Hardeman could only prevail if Roundup was a but-for cause, then it would have also found legal causation under the more flexible concurrent independent causation standard. Thus, we affirm because the error in the causation instruction was likely harmless.

VI

Monsanto argues it was entitled to judgment as a matter of law on the failure-to-warn claims because it did not know and could not have known that glyphosate caused cancer in 2012 (when Hardeman stopped using Roundup). But reviewing de novo and "view[ing] the evidence in the light most favorable to [Hardeman] . . . and draw[ing] all reasonable inferences in h[is] favor," *Lakeside-Scott v. Multnomah Cnty.*, 556 F.3d 797, 802 (9th Cir. 2009), we conclude that sufficient scientific evidence was presented to the jury to support that the association between glyphosate and cancer was "knowable" by 2012.

To prevail on his failure-to-warn claim, Hardeman was required to prove that the link between Roundup and cancer

was "known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Anderson v. Owens–Corning Fiberglas Corp.*, 810 P.2d 549, 558 (Cal. 1991). While the "scientific landscape" was "more favorable" to Monsanto before 2012, there was sufficient scientific evidence presented to the jury that the link between glyphosate and cancer was "knowable."

For instance, as early as 1985, EPA classified glyphosate as a possible human carcinogen after reviewing a mouse study finding that "[g]lyphosate was oncogenic in male mice," causing rare tumors. Even though EPA changed its designation of glyphosate to non-carcinogenic in 1991, several studies found an association between glyphosate and cancer in the 1990s. In the late 1990s, Monsanto hired Dr. Parry, a genotoxicologist, who found evidence that glyphosate may be genotoxic and urged Monsanto to conduct specific tests on Roundup's genotoxicity. Though Monsanto never conducted all the tests Dr. Parry requested,[18] various independent scientific studies linking glyphosate and cancer were released by 2012. Thus, sufficient evidence was presented to the jury that the association between glyphosate and cancer was, at minimum, "knowable" by 2012, and Monsanto was therefore not entitled to judgment as a matter of law.

VII

Finally, we address both parties' challenges to the punitive damages award. We review whether California law

[18] Years later, in 2009, Monsanto toxicologist Donna Farmer said, "you cannot say that Roundup does not cause cancer . . . [because] we have not done carcinogenicity studies with 'Roundup.'"

permits a jury's decision to award punitive damages for substantial evidence. *Kaffaga v. Estate of Steinbeck*, 938 F.3d 1006, 1013 (9th Cir. 2019). We review de novo, with an "[e]xacting appellate review," the constitutionality of a punitive damages award. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418 (2003) (citing *Cooper Indus., Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 436 (2001)). "[W]e defer to the district court's 'findings of fact unless they are clearly erroneous.'" *Arizona v. ASARCO LLC*, 773 F.3d 1050, 1054 (9th Cir. 2014) (quoting *Cooper Indus.*, 532 U.S. at 440 n.14). Based on this review, we hold that (1) California law permits a punitive damages award because substantial evidence was presented to the jury that Monsanto acted with malice, and (2) though the $75 million punitive damages award was constitutionally excessive, the reduced $20 million award comports with the outer limits of the Due Process Clause.

A

Punitive damages were permissible under California law because substantial evidence was presented that Monsanto acted with malice by, among other things, ignoring Roundup's carcinogenic risks. *See Kaffaga*, 938 F.3d at 1018.

Punitive damages are permissible under California law when there is "clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice." Cal. Civ. Code § 3294(a). As relevant here, "malice" means "despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others." § 3294(c)(1).

That definition of malice requires that we examine what constitutes "despicable conduct" and "conscious disregard."

"Despicable conduct" is conduct "so vile, base, contemptible, miserable, wretched or loathsome that it would be looked down upon and despised by most ordinary decent people." *Pac. Gas & Elec. Co. v. Super. Ct.*, 235 Cal. Rptr. 3d 228, 236 (Ct. App. 2018) (internal quotation marks and citation omitted). "Conscious disregard" requires that the defendant "have *actual knowledge* of the risk of harm it is creating and, in the face of that knowledge, fail to take steps it knows will reduce or eliminate the risk of harm." *Id.* (internal quotation marks and citation omitted). But whether a "defendant is aware of the probable dangerous consequences of [its] conduct and [it] willfully fails to avoid such consequences" can be "proved either expressly through direct evidence or by implication through indirect evidence from which the jury draws inferences." *Pfeifer v. John Crane, Inc.*, 164 Cal. Rptr. 3d 112, 135 (Ct. App. 2013) (quoting *Angie M. v. Super. Ct.*, 44 Cal. Rptr. 2d 197, 204 (Ct. App. 1995)).

Substantial evidence of Monsanto's malice was presented to the jury, supporting punitive damages under § 3294(a). For example, internal emails were presented supporting that Monsanto was consciously aware of the potential health risks associated with Roundup. One email, from Monsanto toxicologist Mark Martens, read, "I don't know for sure how suppliers would react—but if somebody came to me and said they wanted to test Roundup I know how I would react—with serious concern." A second email, from Monsanto toxicologist William Heydens, read, "[g]lyphosate is OK but the formulated product (and thus the surfactant) does the damage." And a third email, from Monsanto toxicologist Donna Farmer, read, "you cannot say that Roundup is not a carcinogen . . . [because] we have not done the necessary testing on the formulation to make that statement." These emails provide the substantial evidence

necessary to support punitive damages based on Monsanto's awareness that Roundup posed a potential health risk.

There was also substantial evidence sufficient for a jury to find that Monsanto "fail[ed] to take steps it kn[ew] w[ould] reduce or eliminate the risk of harm." *Pac. Gas & Elec. Co.*, 235 Cal. Rptr. 3d at 236 (internal quotation marks and citation omitted). For instance, after its own hired expert, Dr. Parry, found that glyphosate—alone and when mixed with other chemicals in Roundup—had increased genotoxic risks, evidence was sufficient to infer that Monsanto largely failed to perform further studies. Instead, Monsanto helped author an article downplaying glyphosate's health and safety concerns. Even though "it is also possible to draw a contrary conclusion" that Monsanto was ignorant or negligent (but not malicious),[19] the "jury's verdict must be upheld [because] it is supported by substantial evidence" that Monsanto consciously disregarded Roundup's potential harm. *See Pavao v. Pagay*, 307 F.3d 915, 918 (9th Cir. 2002).

B

We next turn to the amount of punitive damages that would still comport with the Due Process Clause. Hardeman argues that the district court erred by reducing the jury's $75 million punitive damages award to $20 million. And Monsanto contends that even the reduced punitive damages award was unconstitutional under the Due Process Clause.

[19] Monsanto also argues that it cannot be deemed to have acted with malice because it complied with regulations. But "[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." *Johnson & Johnson Talcum Powder Cases*, 249 Cal. Rptr. 3d 642, 678 (Ct. App. 2019).

Consistent with our "[e]xacting appellate review," *State Farm*, 538 U.S. at 418 (citing *Cooper Indus.*, 532 U.S. at 436), we lay out some fundamental principles underlying the constitutionality of punitive damages awards.

"Compensatory damages and punitive damages serve different purposes; compensatory damages redress concrete loss caused by the defendant's wrongful conduct, while punitive damages are aimed at deterrence and retribution." *Planned Parenthood of Columbia/Willamette Inc. v. Am. Coal. of Life Activists*, 422 F.3d 949, 953 (9th Cir. 2005) (citing *State Farm*, 538 U.S. at 416; *Cooper Indus.*, 532 U.S. at 432). Further, "[t]he Supreme Court has instructed us to go 'no further' if a 'more modest punishment' for the 'reprehensible conduct' at issue 'could have satisfied the State's legitimate objectives' of punishing and deterring future misconduct." *Lompe v. Sunridge Partners, LLC*, 818 F.3d 1041, 1065 (10th Cir. 2016) (quoting *State Farm*, 538 U.S. at 419–20). Ultimately, we are mindful that in applying the Due Process Clause, it is "a *constitution* we are expounding." *Tabares v. City of Huntington Beach*, 988 F.3d 1119, 1122 (9th Cir. 2021) (quoting *McCulloch v. Maryland*, 17 U.S. 316, 407 (1819)).

When punitive damages are "grossly excessive," they violate the Due Process Clause. *State Farm*, 538 U.S. at 416. Whether punitive damages are "grossly excessive" depends on three factors: "(1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases." *Id.* at 418 (citing *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 575 (1996)).

1

The weightiest factor is "the degree of reprehensibility of the defendant's conduct." *Gore*, 517 U.S. at 575. The district court found "Monsanto's approach to the safety of its product was indeed reprehensible." *In re Roundup Prods. Liab. Litig.*, 385 F. Supp. 3d 1042, 1047 (N.D. Cal. 2019). The district court's finding was reasonable and supported by the facts presented to the jury. Thus, the question is to what degree Monsanto's actions were reprehensible. We determine the reprehensibility of Monsanto's conduct by considering the following five factors: whether "[1] the harm caused was physical as opposed to economic; [2] the tortious conduct evinced an indifference to or a reckless disregard of the health or safety of others; [3] the target of the conduct had financial vulnerability; [4] the conduct involved repeated actions or was an isolated incident; and [5] the harm was the result of intentional malice, trickery, or deceit, or mere accident." *State Farm*, 538 U.S. at 419 (citing *Gore*, 517 U.S. at 576–77).

Several aggravating factors associated with reprehensible conduct are present based on the evidence at trial. First, the harm inflicted on Hardeman—cancer—was physical, not purely economic. Hardeman has already been well compensated for damages resulting from his physical injury. Indeed, $5,066,667 of the compensatory damages—about 96% of the jury's $5,267,634.10 total compensatory award—was based on noneconomic harm. *See In re Roundup*, 385 F. Supp. 3d at 1045. The district court found the $2 million in compensatory damages related to future noneconomic harm were "borderline" high because Hardeman's cancer was in remission. *Id.* And while remission is "no guarantee," testimony showed his cancer is unlikely to return. *Id.* But, as the district court explained,

this concern was "mitigate[d]" because "the jury likely intended the future award to compensate a longer period of suffering." *Id.* These factual findings by the district court, which are reasonable and not clearly erroneous, highlight the reprehensibility of causing serious physical harm and the need to deter future harm. While Hardeman was well compensated for past and future harm, the serious nature of the harm supports finding that Monsanto's actions were reprehensible.

Second, the district court's factual conclusion that Monsanto ignored safety risks is not clearly erroneous and also supports reprehensibility. For example, the district court found that "Monsanto's behavior betrayed a lack of concern about the risk that its product might be carcinogenic." *Id.* at 1047. In addition, it found that "the evidence at trial painted the picture of a company focused on attacking or undermining the people who raised concerns, to the exclusion of being an objective arbiter of Roundup's safety." *Id.* But the district court also found mitigating evidence. Notwithstanding the jury's verdict for Hardeman, the district court explained that "the metaphorical jury is still out on whether glyphosate causes NHL." *Id.* Indeed, "there is credible evidence on both sides of the scientific debate" which "surely diminish[es]—to a degree—Monsanto's culpability." *Id.* Moreover, "[t]he scientific landscape was even more favorable to Monsanto during the time Mr. Hardeman was using Roundup." *Id.*

We also agree with the district court that no evidence was presented that Monsanto knew Roundup in fact caused cancer. Monsanto never conducted studies that may have indicated (as its scientists suspected) that Roundup was carcinogenic. And regulators, like EPA, have repeatedly found glyphosate to not have carcinogenic risks. But, as the

district court found, the evidence supports that Monsanto knew Roundup *might* cause cancer, hence its concern and reluctance to, for instance, conduct Dr. Parry's recommended studies. We have no quibble with any of the district court's findings of fact. Ultimately, evidence of Monsanto's conduct—downplaying concerns and failing to fully assess Roundup's safety after being alerted to possible risks—supports that Monsanto acted with "indifference to or a reckless disregard of the health or safety of others." *State Farm*, 538 U.S. at 419.

Third, *State Farm* asks us to look at Hardeman's financial vulnerability. *Id.* It goes without saying that this is a case of a large corporation and an individual—not two corporations on equal footing. Having said that, this factor is not particularly relevant in a mostly noneconomic damages case like this one. *See Lompe*, 818 F.3d at 1066 ("But as a practical matter, the financial vulnerability factor does not have particular relevance . . . where the harm [plaintiff] suffered was physical rather than a reprehensible exploitation of financial vulnerability through fraud or other financial misconduct."). The district court below did not analyze this factor. We do not find this factor helpful one way or another to establish reprehensibility.

Fourth, the district court did not clearly err in finding that Monsanto's "conduct involved repeated actions" instead of "an isolated incident." *See In re Roundup*, 385 F. Supp. 3d at 1047 (quoting *State Farm*, 538 U.S. at 419). Evidence was presented that Monsanto repeatedly sold Roundup without a warning label. *Id.* Thus, this factor supports reprehensibility because "repeated misconduct is more reprehensible than an individual instance of malfeasance." *Gore*, 517 U.S. at 577.

Fifth, the district court recognized Monsanto's actions exhibited malice but also made findings of fact that mitigated this factor. The district court noted there was no evidence "that Monsanto hid evidence from the EPA or, alternatively, that it had managed to capture the EPA." *See In re Roundup*, 385 F. Supp. 3d at 1047. There was also no evidence "that Monsanto was in fact aware that glyphosate caused cancer but concealed it, thus distinguishing this case from the many cases adjudicating the conduct of the tobacco companies." *Id.* Nonetheless, there was evidence of Monsanto's malice. As the district court found, "[d]espite years of colorable claims in the scientific community that Roundup causes NHL," emails showed "Monsanto employees crassly attempting to combat, undermine or explain away challenges to Roundup's safety." *Id.* And "not once was [the jury] shown an email suggesting that Monsanto officials were actively committed to conducting an objective assessment of its product." *Id.* We do not find the district court's findings of fact clearly erroneous.

Based upon the district court's findings, four of the five factors support that Monsanto's actions were reprehensible. But in two of those factors, there were significant mitigating considerations which suggest that Monsanto's actions, while reprehensible, were not "particularly egregious." *See Gore*, 517 U.S. at 582.

2

We next examine the disparity between harm to Hardeman and the punitive damages award by looking to the Supreme Court's guidelines on appropriate ratios. *State Farm*, 538 U.S. at 424. The Supreme Court has explained that "[s]ingle-digit multipliers are more likely to comport with due process, while still achieving the State's goals of deterrence and retribution." *Id.* at 425. "[A]n award of more

than four times the amount of compensatory damages might be close to the line of constitutional impropriety." *Id.* (citing *Pac. Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 23–24 (1991)). But there are "no rigid benchmarks that a punitive damages award may not surpass" and greater ratios might "comport with due process where 'a particularly egregious act has resulted in only a small amount of economic damages.'" *Id.* (quoting *Gore*, 517 U.S. at 582).

Here, the jury awarded $5,267,634.10 in compensatory damages and $75 million (approximately 14.2 times the compensatory amount) in punitive damages. But Monsanto's conduct—though plausibly viewed as reprehensible—was not "particularly egregious" as to warrant a damages ratio above the single-digit range, especially considering the absence of evidence showing a *known* safety risk was intentionally concealed. *See id.* Thus, we have little trouble holding that the jury's 14.2 to 1 ratio violated due process.

The $5,267,634.10 compensatory damages award was substantial. *See, e.g.*, *Ramirez v. TransUnion LLC*, 951 F.3d 1008, 1037 (9th Cir. 2020), *cert. granted in part on other grounds*, No. 20-297, 2020 WL 7366280 (U.S. Dec. 16, 2020) (describing $8 million compensatory damages award as "quite substantial"); *Lompe*, 818 F.3d at 1069 ("[C]ompensatory damages have often been considered 'substantial' when they are over $1,000,000."). "When compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *State Farm*, 538 U.S. at 425. But "*State Farm*'s 1:1 compensatory to punitive damages ratio is not binding, no matter how factually similar the cases may be." *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1014 (9th Cir. 2004).

Considering these precedents, we have held that "[i]n cases where there are significant economic damages and punitive damages are warranted but behavior is not particularly egregious, a ratio of up to 4 to 1 serves as a good proxy for the limits of constitutionality." *Planned Parenthood*, 422 F.3d at 962.

Even though "substantial" compensatory damages were awarded here, the evidence justifies a damages ratio higher than 1 to 1. Monsanto intentionally downplayed and ignored calls to test Roundup's carcinogenic risks, and the jury determined that Roundup caused Hardeman's cancer. Coupled with the physical damage—cancer—these factors suggest a damages ratio up to 4 to 1 "serves as a good proxy for the limits of constitutionality." *Id.*; *see State Farm*, 538 U.S. at 425 ("The precise award in any case, of course, must be based upon the facts and circumstances of the defendant's conduct and the harm to the plaintiff.").

3

Third, the district court speculated that fines for failure to warn of a product's risk under FIFRA and the California Health and Safety Code could potentially "over time[] become quite high" because "both state and federal law calculate penalties per violation." *In re Roundup*, 385 F. Supp. 3d at 1048; *see also* 7 U.S.C. § 136j(a)(1)(E); 40 C.F.R. § 19.4; Cal. Health & Safety Code § 25249.7. We note the need to avoid speculation in analyzing this factor. *See State Farm*, 538 U.S. at 428 (rejecting consideration of speculative future penalties unrelated to plaintiffs' harm). The parties failed below, and again on appeal, to explain what the relevant civil fines are, how they would be calculated, and even whether they would be warranted. *See In re Roundup*, 385 F. Supp. 3d at 1048. Monsanto points out, however, that no civil or criminal fines have been

imposed, apparently by any federal or any state agency, including California.

Though California in 2017 categorized glyphosate as a chemical known to the state to cause cancer, *see* Glyphosate Proposition 65, it is also not clear that Monsanto would have been subject to civil fines under California law in 2012. Because neither party presents argument or evidence, we agree with the district court that this guidepost is not "particularly helpful here." *See id.* at 1048 ("[A]bsent an explanation from either party about how these penalties would be calculated, it is difficult to use them as a benchmark.").

* * *

We hold that the jury's $75 million punitive damages award was "grossly excessive" given the mitigating factors found by the district court. *See State Farm*, 538 U.S. at 416. Considering the evidence of reprehensibility, however, we hold that the district court's reduced $20 million punitive damages award (a 3.8 to 1 damages ratio), while at the outer limits of constitutional propriety, ultimately comports with due process. *Planned Parenthood*, 422 F.3d at 962; *see also Ramirez*, 951 F.3d at 1037 (upholding 4 to 1 ratio where $8 million compensatory damages awarded).

Though we uphold the district court's $20 million punitive damages award, we emphasize that the award is "close to the line of constitutional impropriety." *See State Farm*, 538 U.S. at 425. Considering the number of cases pending in this Roundup multidistrict litigation, we recognize a smaller punitive damages award in other cases may safely satisfy due process concerns by still imposing the appropriate punishment and achieving the goals of deterrence and retribution. *Cf. Lompe*, 818 F.3d at 1065

("The Supreme Court has instructed us to go 'no further' if a 'more modest punishment' for the 'reprehensible conduct' at issue 'could have satisfied the State's legitimate objectives' of punishing and deterring future misconduct." (quoting *State Farm*, 538 U.S. at 419–20)); *see, e.g.*, *Johnson v. Monsanto Co.*, 266 Cal. Rptr. 3d 111, 129 (Ct. App. 2020), *as modified on denial of reh'g* (Aug. 18, 2020), *review denied* (Oct. 21, 2020) (reducing punitive damages award in a Roundup case to a 1 to 1 ratio with compensatory damages of $10.3 million and where facts of Monsanto's reprehensibility were likely stronger than this case).

VIII

We are aware this appeal involves a bellwether trial with potentially thousands of federal cases to follow. But many of our holdings are fact-specific. Different Roundup cases may present different considerations, leading to different results. For example, were there evidence that EPA took certain enforcement action against Monsanto after a cancer warning was added to Roundup's label, perhaps the preemption analysis would lead to a different outcome. And while our holding that expert testimony was admissible here may be applicable to other Roundup cases, much of this expert testimony was unique to Hardeman's specific case. Thus, it would not be unreasonable for the district court to revisit the admissibility of expert testimony based upon the facts raised in future cases. Similarly, despite the punitive damages upheld here, a smaller punitive damages award in future cases may better comport with due process. Ultimately, we agree that the district court in this case either reached the correct result or need not be reversed.

AFFIRMED.

N.R. SMITH, Circuit Judge, dissenting to section VII.B.

After a *mandated* de novo review of the district court's punitive damages award, determining if the amount was constitutionally excessive (not simply determining whether the award was acceptable or reasonable), I must dissent. Let me explain.

Punitive damages are "'quasi-criminal,' operat[ing] as 'private fines' intended to punish the defendant and to deter future wrongdoing." *Cooper Indus., Inc. v. Leatherman Tool Grp.*, Inc., 532 U.S. 424, 432 (2001) (quoting *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 19 (1991)). "Exacting appellate review ensures that an award of punitive damages is based upon an 'application of law, rather than a decisionmaker's caprice.'" *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418 (2003). As the majority has stated, "the Supreme Court has instructed us to go 'no further' if a 'more modest punishment' for the 'reprehensible conduct' at issue 'could have satisfied the State's legitimate objectives' of punishing and deterring future misconduct." *Lompe v. Sunridge Partners, LLC,* 818 F.3d 1041, 1065 (10th Cir. 2016) (quoting *State Farm,* 538 U.S. at 419–20). In order to determine de novo whether the punishment is "grossly excessive," the Supreme Court requires us "to consider three guideposts: (1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases." *State Farm*, 538 U.S. at 417–18. Of course, we always defer to the district court's findings of fact unless they are clearly erroneous. *Cooper Indus.*, 532 U.S. at 440 n.14.

The district court made the following findings of fact, upon which one must make the analysis:

a. The jury found it was more likely than not that Roundup (the glyphosate therein) was a "substantial factor" in causing Hardeman's NHL. In order to evidence that Roundup was a substantial factor in this cause, Hardeman's experts only performed a differential diagnosis. Differential diagnosis is 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."

b. NHL is a cancer that affects white blood cells in the immune system. Approximately 70% or more of the NHL cases are idiopathic, meaning they develop for unknown reasons. However, some causes of NHL, such as hepatitis C (HCV), are well established. Hardeman had HCV for 25 to 40 years before developing NHL.

c. Hardeman was diagnosed with NHL in early 2015. He started using Roundup in the 1980s but ended his use in 2012. During the time Hardeman was using Roundup, the scientific landscape (of whether it could cause cancer) was more favorable to Monsanto than at the time of trial. In 2012, EPA had little to no

evidence that glyphosate was at all carcinogenic in humans. Not until 2015 did the International Agency for Research on Cancer ("IARC") suggest that glyphosate was probably carcinogenic to humans.

d. Even today, there is credible evidence on both sides with regard to whether glyphosate causes NHL as documented by the repeated approvals of glyphosate by EPA, the European Chemicals Agency, Health Canada, and other worldwide regulatory agencies.

e. There is no evidence that Monsanto was in fact aware that glyphosate caused cancer; that Monsanto concealed it from EPA; or that Monsanto somehow had "captured" those in EPA, such that EPA would not take a position contrary to Monsanto.

f. The record at best shows that Monsanto knew Roundup might cause cancer but made minimal efforts to determine whether the scientific evidence (finding glyphosate may cause NHL) was accurate.

g. However, Monsanto did attack or undermine those who raised concerns for Roundup's safety.

Case: 19-16636, 05/14/2021, ID: 12112919, DktEntry: 142-1, Page 64 of 74

h. Monsanto has sold Roundup without a warning label.[1]

i. The award of future noneconomic damages was not based on physical pain or impairment but was limited to "anxiety, mental suffering, loss of enjoyment of life, emotional distress, and inconvenience."

j. Hardeman's NHL is now in remission, his prognosis is "very good" and it is "extremely unlikely" that his NHL will return.

See In re Roundup Prod. Liab. Litig., 385 F. Supp. 3d 1042, 1047 (N.D. Cal. 2019).

1. The degree of reprehensibility of Monsanto's conduct.

Considering each of the three guideposts, the degree of reprehensibility is "[t]he most important indicium of the reasonableness of a punitive damages award." *See State Farm*, 538 U.S. at 419. The degree of reprehensibility is determined by considering (1) "the harm caused was physical as opposed to economic"; (2) "the tortious conduct evinced an indifference to or a reckless disregard of the health or safety of others"; (3) the target of the conduct had financial vulnerability"; (4) "the conduct involved repeated actions or was an isolated incident"; and (5) "the harm was

[1] The district court noted that Monsanto continues to sell Roundup without a warning label. However, "the conduct that harmed [plaintiff] is the only conduct relevant to the reprehensibility analysis." *State Farm*, 538 U.S. at 424.

the result of intentional malice, trickery, or deceit, or mere accident." *Id.* Applying the facts (as determined by the district court) de novo to these five considerations, Monsanto's conduct from the 1980s to 2012 did not constitute the degree of "reprehensible conduct" that would warrant an award of punitive damages at a 3.8:1 ratio. *See id.* Reviewing these five considerations instead demonstrates a low degree of reprehensibility.

First, while Hardeman suffered from physical harm (NHL), he was well compensated for it by the jury. Importantly, the physical harm suffered was not based on acts or threats of violence, *see Florez v. Delbovo*, 939 F. Supp. 1341, 1348 (N.D. Ill. 1996) (explaining that "acts of violence or threats of bodily harm" are "the most reprehensible" (citing *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 575 (1996)), or "from some physical assault or trauma," *see State Farm*, 538 U.S. at 426. Further, (as demonstrated below) Monsanto did not engage in deliberate conduct to exploit Hardeman and expose him to a risk of cancer. *Cf. Bullock v. Philip Morris USA, Inc.*, 131 Cal. Rptr. 3d 382, 396 (Ct. App. 2011) (concluding "that in a case involving physical harm, the physical or physiological vulnerability of the target of the defendant's conduct is an appropriate factor to consider in determining the degree of reprehensibility, particularly if the defendant deliberately exploited that vulnerability").

Second, one must determine whether Monsanto's conduct evinced "indifference to or a reckless disregard of the health or safety of others." *State Farm*, 538 U.S. at 419. In California, Hardeman had to demonstrate that Monsanto "had been guilty of oppression, fraud, or malice," in order to be awarded punitive damages from Monsanto. Cal. Civ. Code § 3294(a). Section 3294(c)(1) outlines that

Monsanto's conduct must have been undertaken "with a willful and conscious disregard of the rights or safety of others." A conscious disregard "requires that the defendant have actual knowledge of the risk of harm it is creating and, in the face of that knowledge, fail[ed] to take steps it kn[ew would] reduce or eliminate the risk of harm." *Ehrhardt v. Brunswick, Inc.*, 231 Cal. Rptr. 60, 65 (Ct. App. 1986). Given this standard, although ignoring evidence that Roundup might cause cancer could be substantial evidence to establish punitive damages against Monsanto, there was and still exists "credible evidence on both sides of the debate" about whether Roundup actually does cause cancer. During the time that Hardeman used Roundup, the evidence was scant that Roundup may cause cancer, but Monsanto did disregard it. However, its conduct does not demonstrate (nor did the court find) that Monsanto intentionally targeted Hardeman.

Third, there is no evidence in the record that the target of the conduct (Hardeman) had financial vulnerability. *See Clark v. Chrysler Corp.*, 436 F.3d 594, 604 (6th Cir. 2006) ("The financial vulnerability of a target is particularly relevant when the harm inflicted is economic in nature."). The wealth of Monsanto cannot justify an award of punitive damages absent a connection of its "financial resources and the physical injury suffered" by Hardeman. *See id.*

Fourth, Monsanto's failure to place a warning on Roundup's label does not constitute "repeated actions."[2] *See Gore*, 517 U.S. at 577. "[E]vidence that a defendant has repeatedly engaged in prohibited conduct while knowing or suspecting that it was unlawful would provide relevant

[2] As previously noted, the district court seems to rely on conduct that occurred post 2012 in determining the reprehensibility.

support for an argument that strong medicine is required to cure the defendant's disrespect for the law." *Id.* at 576–77. At the time Hardeman used the product, Monsanto was not engaging in unlawful conduct. At that time, EPA had little to no evidence that glyphosate was carcinogenic in humans. In fact (again), there is credible evidence (to this day) on both sides with regard to whether glyphosate causes NHL. Notably, IARC did not decide to classify glyphosate as "probably carcinogenic to humans" until 2015 (three years after Hardeman stopped using Roundup). *See In re Roundup Prod. Liab. Litig.*, 385 F. Supp. 3d at 1047. Further, after California's passage of Proposition 65 (requiring a warning label for glyphosate), Michael L. Goodis, EPA, Office of Pesticide Programs, sent a letter to registrants (like Monsanto) challenging Proposition 65 as contrary to "EPA's determination that glyphosate is 'not likely to be carcinogenic to humans.'" *Proposed Interim Registration Review* at 11. The letter charged that the Proposition 65 warning was a "false and misleading statement" and violated the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").

Fifth, Monsanto did not act with "intentional malice, trickery, or deceit." *See State Farm*, 538 U.S. at 419. As the district court found, Monsanto acted with indifference, but Monsanto did not engage in intentional acts, trickery, or deceit.[3] *See Williams v. First Advantage LNS Screening*

[3] Even the majority does not conclude that Monsanto acted with "intentional malice, trickery, or deceit." *See* Maj. Op. 53. Rather, it describes Monsanto's conduct as "malice." *Id.* at 56. However, "malice," as found by the district court, means a "conscious disregard of the rights or safety of others." *See In re Roundup Prod. Liab. Litig.*, 385 F. Supp. 3d at 1046 (quoting Cal. Civ. Code § 3294(c)(1)). Thus, there is no evidence that the harm suffered by Hardeman was the "result of intentional malice"; Monsanto did not "*intend*[] to cause injury" to

Sols. Inc, 947 F.3d 735, 754 (11th Cir. 2020) (concluding that "[a]t worst, Defendant acted recklessly, but without any intent to harm Plaintiff"). In fact, Monsanto's actions were not contrary to "government regulations." *See Johnson & Johnson Talcum Powder Cases*, 249 Cal. Rptr. 3d 642, 678 (Ct. App. 2019), *review denied* (Oct. 23, 2019). Although compliance with regulations cannot "eviscerate a claim for punitive damages," *id.*, it does evidence that the harm "was [not] the result of intentional malice, trickery, or deceit," *State Farm*, 538 U.S. at 419. As the district court found, the association between Roundup and NHL "remains under scientific investigation" and there was no evidence of intentional acts on the part of Monsanto. *Id.*; *cf. Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1316–17 (5th Cir. 1995) (precluding punitive damages when there was a genuine dispute in the scientific community).

Lastly, in reviewing these considerations, "some wrongs are more blameworthy than others," such as "violence," "trickery and deceit," or "intentional malice" and are more deserving of a higher punitive damages ratio. *See Gore*, 517 U.S. at 575. We have suggested that this "hierarchy of reprehensibility" starts "with acts and threats of violence . . . , followed by acts taken in reckless disregard for others' health and safety, affirmative acts of trickery and deceit, and finally, acts of omission and mere negligence." *Swinton v. Potomac Corp.*, 270 F.3d 794, 818 (9th Cir. 2001) (citation

---

Hardeman. *See Gober v. Ralphs Grocery Co.*, 40 Cal. Rptr. 3d 92, 106 (Ct. App. 2006). Nevertheless, despite a lack of evidence of this "important criterion," the majority still concludes that a punitive damages award at outer constitutional boundaries for this case of significant compensatory damages was appropriate. *See Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 345 F.3d 1366, 1371 (Fed. Cir. 2003) (noting that this "factor has become an important criterion of what the Constitution accepts as reprehensible conduct").

and quotation marks omitted). Thus, "[i]n order to justify a substantial punitive damage award, a plaintiff ordinarily must prove that the defendants' conduct falls at the upper end of the blameworthiness continuum, or, put another way, that the conduct reflects a high level of culpability." *Zimmerman v. Direct Fed. Credit Union*, 262 F.3d 70, 82 (1st Cir. 2001).

No review of these considerations reflects "a high level of culpability." *Id.* Thus, Monsanto's low degree of reprehensibility cannot constitutionally justify the district court's substantial punitive damages award.

2. The disparity between harm suffered and punitive damages award.

"The second and perhaps most commonly cited indicium of an unreasonable or excessive punitive damages award is its ratio to the actual harm inflicted on the plaintiff." *Gore*, 517 U.S. at 580. In determining punitive damages for each case, the Supreme Court has outlined that "the precise award" of such damages "must be based upon the facts and circumstances of the defendant's conduct and the harm to the plaintiff." *State Farm*, 538 U.S. at 425. Although the Court has not drawn a "bright-line ratio" for punitive damages, the Court's jurisprudence suggests "that, in practice, few awards exceeding a single digit-ratio between punitive and compensatory damages, to a significant degree, will satisfy due process." *Id.* "A higher ratio may . . . be justified in cases" where (1) "the injury is hard to detect," (2) "the monetary value of noneconomic harm might have been difficult to determine," or (3) "a particularly egregious act has resulted in only a small amount of [compensatory] damages." *Gore*, 517 U.S. at 582. The Court then clarified the outer boundaries for such an award: "an award of more than four times the amount of compensatory damages might

be close to the line of constitutional impropriety." *Id.* However, it also emphasized an outermost limit in making such an award, stating "when compensatory damages are substantial, then a lesser ratio [less than 4:1], perhaps only equal to compensatory damages, can reach the *outermost limit of the due process guarantee.*" *Id.* (emphasis added).

The compensatory damages in this case are substantial ($5,267,634.10) and the reasons to justify a higher ratio do not exist. Thus, a punitive damages amount equal to compensatory damages reaches the Supreme Court's outermost limit for punitive damages.

The California Supreme Court provides further guidance, especially focusing on a case where there is a relatively low reprehensibility. It said that "a ratio of one to one might be the federal constitutional maximum in a case involving . . . relatively low reprehensibility and a substantial award of noneconomic damages: 'When compensatory damages are substantial, then a lesser ratio, *perhaps only equal to compensatory damages*, can reach the outermost limit of the due process guarantee.'" *Roby v. McKesson Corp.*, 219 P.3d 749, 769 (Cal. 2009) (quoting *State Farm*, 538 U.S. at 425). In this case, the district court reduced the jury's 14.2:1 punitive damages award to nearly a 4:1 ratio, which is generally reserved for a higher degree of reprehensible conduct. *Id.* Monsanto's conduct here did not include (1) acts or threats of violence; or (2) acts of trickery or deceit, evidencing a low degree of reprehensibility.

Even in a case that involved conduct that was highly reprehensible, the California Court of Appeal concluded that "the permissible ratio of punitive to compensatory damages" should be reduced when the noneconomic damages "appear[ed] to include a punitive component." *See*

Bankhead v. ArvinMeritor, Inc., 139 Cal. Rptr. 3d 849, 866–67 (Ct. App. 2012) (allowing punitive damages award at a 2.4:1 ratio). The Supreme Court agrees. *See State Farm*, 538 U.S. at 425–26, 429 (explaining that "in light of the substantial compensatory damages awarded (a portion of which contained a punitive element), a punitive damages award at or near the amount of compensatory damages" was justified).

The jury awarded substantial past and future noneconomic damages totaling $5,066,667, which contain a punitive element. The district court recognized this fact when it noted that the $2,000,000 in future noneconomic damages was "borderline," because it was "somewhat difficult to rationalize the conclusion that the suffering he will face is, effectively, two-thirds of the suffering he has already endured." *In re Roundup Prod. Liab. Litig.* 385 F. Supp. 3d. at 1045. Thus, a punitive damages award of 3.8:1 exceeded the constitutionally permissible limits. *See State Farm*, 538 U.S. at 425; *Roby*, 219 P.3d at 769. The ratio of punitive damages should be reduced to a 1:1 ratio. *See id.*

3. The difference between the punitive damages awarded and the civil penalties authorized or imposed in similar cases.

The third guidepost also supports punitive damages equal to the compensatory damages award. Sanctions for comparable misconduct can be determined by either the "civil or criminal penalties that could be imposed for comparable misconduct," *Gore*, 517 U.S. at 583, or "the existence of other civil awards against the defendant for the same conduct," *Haslip*, 499 U.S. at 22; *see also Ismail v. Cohen*, 899 F.2d 183, 186 (2d Cir. 1990) ("Reference to other awards in similar cases is proper.").

One has difficulty comparing civil or criminal penalties with this punitive damages award. During the time Hardeman used Roundup, there were no federal or state criminal or civil penalties for Monsanto's conduct. Neither the federal government nor the State of California had imposed any penalties for the possibility that glyphosate may cause cancer.[4] Although Monsanto's conduct following the harm can be considered in setting the punitive damages award, *see Johnson & Johnson Talcum Powder Cases*, 249 Cal. Rptr. 3d at 678, California did not list glyphosate as a chemical known to cause cancer until 2017.[5] It is similarly difficult to determine how the federal government or California would apply or calculate fines (which is probably one of the reasons neither party really addressed this issue).

Comparing this case to the only other litigated case against Monsanto regarding the sale of Roundup supports a 1:1 ratio. *See Johnson v. Monsanto Co.*, 266 Cal. Rptr. 3d 111, 135 (Ct. App. 2020). In *Johnson*, the plaintiff developed cancer in 2014 after using Roundup. *Id.* at 116–17. Johnson sought damages, based on Monsanto's knowledge regarding Roundup's carcinogenicity. *Id.* at 117.

---

[4] Criminal and civil penalties may be imposed under federal and state law. *See* 7 U.S.C. §§ 136j(a)(1)(E), 136*l*(a)(1); 40 C.F.R. § 19.4; Cal. Health & Safety Code §§ 25249.6, 25249.7(a). Under federal law, civil penalties may be assessed up to $5,000 for each offense. 7 U.S.C. § 136*l*(a)(1); *see also* 40 C.F.R. § 19.4 (2012). Criminal penalties may result in either imprisonment of one year, a $50,000 fine, or both. *Id.* § 136*l*(b)(1). California law imposes a civil penalty up to $2,500 per day for each violation. Cal. Health & Safety Code § 25249.7(a).

[5] California Health & Safety Code section 25249.6 prohibits any "person in the course of doing business [from] knowingly and intentionally expos[ing] any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual."

Reviewing the evidence, the district court reduced compensatory damages to $10,253,309.32 and awarded punitive damages at a 1:1 ratio. *Id.* at 129. The damages awarded (for essentially "the same conduct") in *Johnson* provide a worthy comparison in assessing the constitutionality of this punitive damages award. *See Haslip*, 499 U.S. at 22; *see also* Restatement (Second) of Torts § 908 cmt. e (1979) (noting that "[i]t seems appropriate to take into consideration both the punitive damages that have been awarded in prior suits and those that may be granted in the future, with greater weight being given to the prior awards").

Finally, our sister circuits have come to similar conclusions when dealing with substantial compensatory damages (even when the conduct is highly reprehensible). For example, in *Boerner v. Brown & Williamson Tobacco Co.*, the Eighth Circuit concluded that, despite American Tobacco's "highly reprehensible" conduct, the "punitive damages award [of $15,000,000] [wa]s excessive when measured against the substantial compensatory damages award [of $4,025,000]." 394 F.3d 594, 603 (8th Cir. 2005). Thus, it "conclude[d] that a ratio of approximately 1:1 would comport with the requirements of due process." *Id.*; *Saccameno v. U.S. Bank Nat'l Ass'n*, 943 F.3d 1071, 1090 (7th Cir. 2019), *cert. denied sub nom. Saccameno v. Ocwen Loan Servicing, LLC*, 140 S. Ct. 2674 (2020) (holding that "a considerable compensatory award for the indifferent, not malicious, mistreatment" and evidence that the "award reflects emotional distress damages that 'already contain [a] punitive element'" "should not exceed 1:1"); *Bridgeport Music, Inc. v. Justin Combs Pub.*, 507 F.3d 470, 490 (6th Cir. 2007) ("Given the large compensatory damages award of $366,939, a substantial portion of which contained a punitive element, and the low level of reprehensibility of

defendants' conduct, a ratio of closer to 1:1 or 2:1 is all that due process can tolerate in this case."); *see also Clark*, 436 F.3d at 607 (holding that "because the compensatory damage award here is not particularly large, a 1:1 ratio is inappropriate. But due to the lack of several of reprehensibility factors, any ratio higher than 2:1 is unwarranted").

4. Conclusion:

I start where I began. Because we are mandated to review de novo the district court's award of punitive damages, one must undertake the review. In light of the three guideposts, the district court's $20,000,000 punitive damages award exceeds the line of constitutionality. The facts found by the district court do not support a 3.8:1 ratio to compensatory damages. Most notably, Monsanto's conduct is not particularly reprehensible in light of the ongoing scientific debate. The compensatory damages are substantial; thus, punitive damages in an amount equal to compensatory damages reaches the outermost limit of the due process guarantee. Criminal and civil penalties and punitive damages awarded in other cases do not suggest a higher award. We then should go no further; this punishment will satisfy the State's legitimate objectives for imposing such damages.