Nos. 19-16636, 19-16708

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

EDWIN HARDEMAN,
Plaintiff-Appellee/Cross-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellant/Cross-Appellee.

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

THIRD STEP BRIEF FOR MONSANTO COMPANY

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INTRODUCTION

The fundamental question in this case is whether a company can be severely punished for marketing a product without a cancer warning when the near-universal scientific and regulatory consensus is that the product does not cause cancer. As the United States has now confirmed, the warning Hardeman demands contradicts EPA's longstanding scientific conclusions, and thus his claims are preempted. The district court also misapprehended its responsibility under *Daubert* in allowing fundamentally unreliable expert testimony to reach the jury, and failed to apply limits on punitive damages under due process and California law. Although Hardeman and his amici employ sharp rhetoric to defend the result in this case—which, if affirmed, may affect thousands of cases in the federal MDL (and tens of thousands of other cases)—they fail to provide any basis for sustaining the flawed verdict. And Hardeman's submission that the punitive damages award allowed by the court was *too low* would only exacerbate the errors. This Court should reverse the judgment.

COUNTERSTATEMENT OF ISSUE FOR HARDEMAN'S CROSS-APPEAL[1]

Whether the district court correctly concluded that the jury's $75 million punitive damages award was so grossly disproportionate as to violate the Due Process Clause of the Fourteenth Amendment.

SUMMARY OF ARGUMENT FOR HARDEMAN'S CROSS-APPEAL

Hardeman has failed to show that this is one of the few exceptional cases where a punitive damages award may exceed a single-digit ratio between compensatory and punitive damages. Monsanto's conduct—selling Roundup without a cancer warning in good faith and in accordance with the scientific and regulatory consensus regarding glyphosate—was far from reprehensible. Moreover, the substantial compensatory damages award (roughly $5 million), combined with the absence of reprehensible conduct, strongly suggests that at most, a 1:1 ratio between compensatory and punitive damages is constitutionally permissible. Hardeman's arguments to the contrary disregard the district court's conclusions that Monsanto had no special knowledge about the carcinogenicity of Roundup and that the consensus view at the time of Hardeman's exposure was glyphosate was not carcinogenic.

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[1] Monsanto agrees with Hardeman's cross-appeal jurisdictional statement and standard of review section. While Monsanto disagrees with Hardeman's statement of the case, the relevant facts related to Hardeman's lone cross-appeal issue are already laid out in Monsanto's first-step brief. *See* Monsanto Br. 5-19.

ARGUMENT

I. HARDEMAN'S CLAIMS ARE PREEMPTED

Faced with the irreconcilable conflict between the warning he seeks and EPA's considered scientific judgment, Hardeman argues any state-law rule designed to further safety is consistent with FIFRA's general aims, and thus not preempted. That argument cannot be reconciled with the text of FIFRA, which bars any state labeling requirement "in addition to or different" from applicable federal requirements. 7 U.S.C. §136v(b). It also cannot be squared with principles of implied preemption, given EPA's deliberate and repeated rejection of a cancer warning for Roundup's labeling of the kind Hardeman demands.

A. Hardeman's Claims Are Expressly Preempted

FIFRA vests EPA with primary authority over labeling of federally registered pesticides. To ensure "uniformity" of labeling, FIFRA bars a state from "impos[ing] or continuing in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. §136v(b). Here, EPA has determined no cancer warning is warranted on Roundup's labeling. Because the jury's verdict necessarily reads California law to require such a warning, Hardeman's failure-to-warn claims are expressly preempted.[2]

[2] Hardeman claims in a footnote (at 36 n.18) that, even if his failure-to-warn claims are preempted, his "design-defect claim should survive" because that claim "encompassed more than [a] lack of [a] warning" as to Roundup's carcinogenicity.

1. *Bates* does not permit a state to impose a warning EPA has rejected

Hardeman contends (at 36) his claims are "entirely consistent with, and affirmatively reinforce, FIFRA's misbranding requirements." But as the United States confirms, EPA has determined Hardeman's preferred warning would be *contrary to* FIFRA's misbranding requirements, and would actually *constitute* misbranding. Hardeman tries to evade the force of EPA's expert judgment by arguing that, under *Bates v. Dow Agrosciences*, 544 U.S. 431 (2005), any state-law duty-to-warn claim that could be characterized as generally "consistent" with FIFRA's misbranding prohibition is not preempted, even if that claim turns on judgments about appropriate warnings EPA has rejected. That reading of *Bates* is mistaken.

For one, Hardeman disregards the context in which *Bates* arose. He notes the Supreme Court rejected the *Bates* defendant's argument that permitting juries to impose state-law labeling requirements might lead to a "crazy-quilt" of state-law

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That assertion is incorrect. As the district court explained, Hardeman made no attempt to establish liability on a design-defect claim separate from his failure-to-warn claim, *see* ER14-15, and the two claims "rise and fall together," ER13. Hardeman makes no real effort to show that the district court's understanding of the evidence was erroneous; his cursory footnote is not sufficient to defend the judgment on that ground. *See International Olympic Comm. v. San Francisco Arts & Athletics*, 781 F.2d 733, 738 n.1 (9th Cir. 1986).

rules, 544 U.S. at 448. But Hardeman misunderstands that passage. In *Bates*, EPA had taken no position on whether the specific warning sought by the plaintiffs (which concerned the efficacy, not the safety, of the pesticide) was warranted or would render the label misbranded—and in fact had a policy of *never examining* efficacy claims. *Id.* at 435-436. The question presented was thus whether a state jury could impose a labeling requirement in the face of EPA's silence. Reading the statute to preempt such a law, the *Bates* defendant argued, would "command[] the pre-emption of *all* state requirements concerning labeling." *Id.* at 449. This result could not be right, the Court reasoned, because it would effectively read the "in addition to or different from" language out of FIFRA. *Id.*

Bates did, however, hold that §136v(b) *would* preempt a state labeling requirement that "diverge[d] from" a requirement "set out in FIFRA and its implementing regulations." 544 U.S. at 452. Where EPA has exercised its delegated authority under FIFRA to determine a warning either is or is not required, a state may not enact a rule that "diverges from" that requirement. *Id.* As *Bates* explains, a state law requiring a particular label to "state[] 'DANGER'" where EPA has determined it should instead state only "'CAUTION'" would be preempted. *Id.* at 453. It therefore cannot be correct, as Hardeman suggests, that a state is permitted to impose a warning requirement EPA has rejected.

Hardeman and several amici argue that a state-law cause of action cannot be expressly preempted where it is "equivalent to, and fully consistent with, FIFRA's misbranding provisions." Hardeman Br. 36-38, 40-41; *see* Cal. Br. 8-9; Law Prof. Br. 4-14. Certainly, *Bates* holds that, for a state-law requirement to survive preemption, it must, at a minimum, "parallel" federal law in its broad outlines. 544 U.S. at 448-449. But that is a necessary condition for a state-law requirement to survive preemption, not a sufficient one. A state is also barred from *applying* such a requirement in a manner that contravenes the agency's authoritative exercise of federal law. It is clear from *Bates*, for instance, that a state jury could not contradict EPA's judgment that a label should say "DANGER" instead of "CAUTION," 544 U.S. at 453, *even if* the jury viewed itself as enforcing FIFRA's misbranding standards. Otherwise, a state could adopt the text of FIFRA as state law, but proceed to *enforce* FIFRA as it pleased—regardless of EPA's authoritative application of FIFRA. That would allow the disuniform imposition of labeling requirements that §136v(b) prohibits.

Hardeman concedes that *some* EPA actions giving content to FIFRA's labeling requirements preempt state labeling requirements, but he insists that rule is limited to notice-and-comment regulations. *See* Hardeman Br. 39-40. But the very example on which he relies (*Bates*'s "CAUTION" and "DANGER" labels) shows that cannot be so. Although EPA has promulgated regulations assigning the

warning labels "CAUTION" and "DANGER" to certain "toxicity categories," 40 C.F.R. §§156.62, 156.64, those regulations by themselves do not determine which pesticides should bear which degree of warning. For that, EPA makes a pesticide-by-pesticide determination, in the context of the registration process. Although not a rulemaking, that process has the hallmarks of formal agency action: It is prescribed by Congress, encompasses five distinct phases, entails the submission and review of voluminous data regarding the pesticide's safety and every claim made by the registrant regarding the pesticide, requires notice and comment, and yields a definitive determination by EPA about the warnings to appear on the pesticide's label. *See* 7 U.S.C. §136a; 40 C.F.R. §155.50(b)-(c).

Here, EPA has "give[n] content to FIFRA's misbranding standards" via those same procedures, *Bates*, 544 U.S. at 453, which yielded a conclusion equally authoritative. Since it first registered a glyphosate-based pesticide for sale in the United States in 1974, EPA has repeatedly concluded a cancer warning is not warranted for glyphosate-based pesticides. *See* Monsanto Br. 6-7; *see also* EPA, *Glyphosate: Interim Registration Review Decision* 10 (Jan. 2020) (reaffirming, after notice-and-comment procedures, that glyphosate poses "no risks to human health" and is "not likely to be carcinogenic to humans"), https://tinyurl.com/wnklu3d. And recently, EPA has reinforced those decisions by informing registrants of glyphosate-based pesticides that it would "exercise[] its

misbranding authority," *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 255 (3d Cir. 2008), to reject any label containing a cancer warning, *see* Letter from Michael L. Goodis, EPA, Office of Pesticide Programs (Aug. 7, 2019) ("August 7 Letter"), https://tinyurl.com/y552m94m.

Hardeman protests that EPA's "mere approval of a label" cannot "wipe out all state-law warning claims involving federally registered" pesticides. Hardeman Br. 40. But Monsanto's argument is not that the mere fact of registration automatically preempts state warning laws. Rather, a state-law warning requirement is preempted by §136v(b) where EPA has (1) reviewed the factual basis for the label statements at issue, and (2) made an authoritative agency determination rejecting the warning purportedly required by state law. Those requirements are met here. EPA has considered *all* of the studies on which Hardeman relies and concluded the warning Hardeman seeks would render Roundup misbranded. *See* Monsanto Br. 8-9.[3]

[3] Amicus California argues that, even if a state-law labeling requirement were preempted as applied to an actual labeling change, the state could still require a "point-of-sale warning that does not appear on labeling or packaging." Cal. Br. 9. That point has no relevance here, for Hardeman has not advanced any argument based on point-of-sale warnings. *See Maloney v. T3Media, Inc.*, 853 F.3d 1004, 1019 (9th Cir. 2017) ("[W]e do not review issues raised only by amicus curiae."). In any event, the argument fails in light of *Taylor AG Industries v. Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995), which held that FIFRA's preemption provision applies with equal force to point-of-sale warnings, given that any failure-to-warn claim "is premised ultimately upon the inadequacy of the product label."

2. Hardeman cannot meaningfully distinguish this case from *Riegel*

Hardeman fails to refute the analogy between this case and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). That case held a state tort claim preempted under a similar statutory scheme because a federal agency (FDA) had actually reviewed and approved the safety of the medical device at issue. Like the FDA in *Riegel*, EPA here has repeatedly undertaken a safety review and, after doing so, rejected the warning Hardeman seeks. That specific review of the safety question at issue distinguishes this case from *Bates*, where EPA never reviewed the substance of the warning sought by the plaintiffs—making *Bates* more analogous to *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), where the Court found no preemption because FDA had made no such safety determination.

Hardeman argues *Riegel* is inapposite because the *Riegel* plaintiffs had waived any argument that their state-law claims actually paralleled federal law. *See* 552 U.S. at 330. The *Riegel* Court did assume the claim before the Court was premised on more than a mere "violation of FDA regulations." *Id.*; *see* Br. for Respondent 41, *Riegel*, 552 U.S. 312 (No. 06-179) (waived claim was whether defendants' product "did not comply with the federal requirements"). But Hardeman's claim is exactly the same. He does not assert that Monsanto has violated EPA's rules. Rather, Hardeman claims that Monsanto, like the defendant in *Riegel*, "violated state tort law *notwithstanding* compliance with the relevant

federal requirements," 552 U.S. at 330 (emphasis added)—exactly the claim the Court in *Riegel* held preempted.

Nor can Hardeman meaningfully distinguish the statutory provision in *Riegel*—which prohibits state labeling requirements "different from, or in addition to" federal requirements—from FIFRA's equivalent prohibition on the basis that FIFRA also authorizes states to "regulate the sale or use" of a federally registered pesticide. 7 U.S.C. §136v(a); Hardeman Br. 53-54. Congress has drawn a clear distinction between the power to regulate the *sale* and *use* of a pesticide and the power to regulate that pesticide's *label*, and has confined state power to the former. Under Hardeman's interpretation, a state could purport to exercise its authority over pesticide *use* under §136v(a) by conditioning the sale of a pesticide on compliance with a state labeling requirement. But that approach would nullify the requirement that state rules cannot be "different" from federal rules in the very next statutory provision (§136v(b)), because *any* labeling requirement could always be cast as a condition of sale. Congress's considered decision to preempt state labeling requirements that deviate from federal requirements cannot be circumvented so easily.[4]

[4] Hardeman also points to 7 U.S.C. §136a(f)(2), which provides that "registration of an article" shall not "be construed as a defense for the commission of any offense" under FIFRA. That provision has no relevance here: Monsanto has not been charged with an "offense" under FIFRA, and its preemption argument turns not on the fact that EPA *registered* Roundup but on the fact that EPA has

3. Hardeman cannot avoid express preemption by distinguishing between glyphosate and Roundup

Hardeman also argues that EPA's judgment that a cancer warning is not appropriate for *glyphosate* is not dispositive because EPA has not specifically addressed the carcinogenicity of *Roundup*. Br. 42-43. That argument fails for several reasons.

First, Hardeman's assertion that EPA considered only glyphosate in assessing the safety of Roundup is incorrect. When EPA reviews registration applications, it reviews the safety of active ingredients (such as glyphosate) and non-active or inert ingredients used in formulated products (including surfactants). "The registration … of pesticide products under FIFRA includes a determination that the pesticide product formulation meets the registration standard under FIFRA section 3. … *The entire formulation, including the inert ingredients*, must meet this standard." EPA, *Pesticide Registration Manual*: *Chapter 8 – Inert Ingredients* (emphasis added), *available at* https://bit.ly/2MajiBr (visited June 1, 2020); *see also* EPA, *Basic Information About Pesticide Ingredients*, *available at* https://bit.ly/2yM1Boy (visited June 1, 2020) ("All inert ingredients must be approved by EPA before they can be included in a pesticide. We review safety information about each inert ingredient before approval.").

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consistently concluded that no cancer warning is necessary or appropriate. *See supra* pp. 7-8.

EPA's review of the surfactants used in Roundup (alkyl amine polyalkoxylates (AAPs)) concluded that, when used outdoors and in appropriate quantities, "[t]here are no human health exposure or risk issues that would preclude" their use in connection with pesticides. FER128. In other words, "[t]here is no evidence that the AAPs are carcinogenic." FER129; *see also* FER124 (Monsanto witness testifying that EPA found that, with the surfactants in Roundup, "they had no concern [regarding] carcinogenicity"). As EPA explained in connection with its most recent re-registration decision, the agency had fully "evaluated the hazard potential (i.e., toxicity) of glyphosate and any inert ingredients with a battery of toxicity data from a multitude of studies throughout the risk assessment process." *See* EPA, *Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision* 6 (Jan. 16, 2020), https://bit.ly/2AwRLrm. Accordingly, the agency concluded that "all registered uses" of glyphosate are safe for human use, *see* EPA, *Interim Decision* 9—including Roundup.

Second, Hardeman's argument mischaracterizes the claim Hardeman actually tried to the jury. The evidence presented at trial did not establish a material distinction between glyphosate and Roundup. Hardeman did not, for example, call any expert witness to testify in detail to the differences between glyphosate and Roundup or to any conclusions that could be drawn from such

differences. And Hardeman repeatedly referred the jury to IARC's decision to classify *glyphosate*, not Roundup, as a probable carcinogen.[5]

As the district court explained, Hardeman's evidence on a supposed glyphosate/Roundup distinction was "exceedingly thin." ER128. It consisted primarily of Weisenburger's passing observation that two genotoxicity studies had found differences between Roundup and glyphosate. *See* ER573-577. That was a small part of Weisenburger's testimony, however, and he never testified to an opinion that Roundup is likely to be more carcinogenic than glyphosate itself. Nor could he have, because those studies were aimed at measuring *genotoxicity* (likelihood of damage to genetic material in cells), which—as one of Hardeman's experts acknowledged—is different from *carcinogenicity* (likelihood of causing cancer). *See* FER31 (Portier agreeing that "[g]enotoxicity assays are not used to establish that glyphosate causes NHL in people" and that "[j]ust having a genotoxic finding … does not lead to cancer").[6]

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[5] *See* ER991-992 ("And what you are going to hear is … that in 2014 and into the beginning of 2015 IARC reviewed glyphosate" and "they unanimously decided to list glyphosate as a Class 2 carcinogen"); ER189 ("And you heard something on [IARC] … and what they found was glyphosate was a Class 2A probable human carcinogen in 2015.").

[6] Internal Monsanto correspondence from a Monsanto scientist (Hardeman Br. 24 n.17, 29) does not suggest otherwise. In context, she was attempting to be extremely precise about the metes and bounds of Monsanto's testing at that point in time, not trying to suggest Roundup was more carcinogenic than glyphosate.

Ultimately, the district court concluded Hardeman had failed to provide "sufficient evidence for a jury to conclude that" Roundup was carcinogenic "while glyphosate alone is not." ER15 n.3. But that is precisely the argument Hardeman now advances to save his claims from express preemption. Hardeman should not be permitted to circumvent that ruling—which he does not even acknowledge—on appeal.

B. Hardeman's Claims Are Impliedly Preempted

Hardeman's claims are also preempted because it would be impossible for Monsanto to both add the warning Hardeman seeks and comply with federal law. Monsanto Br. 32-39.

1. *Bates* is silent on implied preemption

Hardeman first argues that "any finding of implied preemption is foreclosed by *Bates*" because that decision considered and rejected only express preemption, suggesting that an implied preemption theory could not have prevailed. Br. 43-44. Nothing in *Bates* supports that reading. The decision in *Bates* says *nothing* about implied preemption—a point Hardeman does not contest. And because the lower court decision in *Bates* turned on express preemption, *see Dow Agrosciences LLC v. Bates*, 332 F.3d 323, 329 (5th Cir. 2003), the Supreme Court had no obligation to consider implied preemption—especially given its ultimate decision, which remanded the case for further review. Hardeman cites a district court opinion

suggesting the Supreme Court "*had* to consider any arguments that, if successful, would have affirmed the lower court decision finding preemption," Br. 44, but the Supreme Court has no obligation to consider every alternative ground, especially one not passed on by the lower court. Indeed, the Court frequently cautions litigants not to assume it has ruled on "[q]uestions which merely lurk in the record." *See Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 170 (2004). Thus, nothing in *Bates* bars this Court from considering whether Hardeman's claims are impliedly preempted.

2. Monsanto cannot comply with both state law mandating a warning and federal law prohibiting that warning

State-law failure-to-warn claims are preempted if (1) the agency was "fully informed" of "the justifications for the warning" the plaintiff demands, (2) the agency has "informed the … manufacturer that [it] would not approve changing the … label to include that warning," and (3) the agency's action "carr[ies] the force of law." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678-1679 (2019). Here, each condition is met.

First, EPA was "fully informed" of the "justifications for the warning" that Hardeman seeks. *Merck*, 139 S. Ct. at 1678. The agency has repeatedly undertaken in-depth safety reviews of glyphosate and glyphosate-based products, each of which considered all available scientific evidence, and the most recent of

which considered every study cited in Hardeman's complaint and relied on by Hardeman's experts. Monsanto Br. 6-10.

Hardeman's primary response (at 46-48) is that Monsanto failed to conduct sufficient testing to determine whether Roundup is actually carcinogenic. But the question under *Merck* is whether the agency was "fully informed" of the *existing* evidence that would "justif[y] … the warning required by state law," 139 S. Ct. at 1678, not whether the manufacturer conducted every test the plaintiff could imagine running. Here, in any event, Monsanto has complied with all of EPA's own testing requirements. *See* 7 U.S.C. §136a(c)(2); FER101. And Hardeman does not identify any *existing* evidence *EPA* failed to consider in determining that glyphosate does not cause cancer. *See supra* p. 8. Hardeman's disagreement with the agency provides no basis for questioning the preemptive force of EPA's judgment that a cancer warning for glyphosate is inappropriate.[7]

Second, EPA has "informed" Monsanto it "would not approve" adding the warning that Hardeman seeks to Roundup's label. *See Merck*, 139 S. Ct. at 1678. In keeping with its repeated findings that glyphosate is not carcinogenic, EPA in

[7] Hardeman's amici make similar attacks on EPA's handling of the relevant scientific evidence. *See, e.g.*, Center For Food Safety Br. 20-42; EWG Br. 6-27. But EPA concluded glyphosate is not carcinogenic based on all available evidence, and that expert judgment must be presumed correct when determining whether Hardeman's failure-to-warn claim conflicts with it. *See Taylor*, 54 F.3d at 561. Moreover, amici point to no study EPA failed to consider in making its decision.

August 2019 informed all glyphosate registrants that it would reject any proposed label that included such a warning. *See* August 7 Letter.[8] Hardeman does not contest EPA informed Monsanto that it would not approve adding a cancer warning, but argues the letter is irrelevant because it reflects only EPA's conclusion on the carcinogenicity of *glyphosate*—not Roundup. Hardeman Br. 48-49. But as the district court recognized, Hardeman did not argue below in any substantial way that the distinction was meaningful. *See supra* p. 14. The August 2019 letter—and the prior EPA determinations on which it rests—satisfy *Merck*.[9]

Finally, EPA's decisions in this context carry the force of law. *Merck*, 139 S. Ct. at 1679. Hardeman and his amici focus on the August 2019 letter, arguing it does not carry the force of law under *United States v. Mead*, 533 U.S. 218 (2001). Hardeman Br. 49-50. But that argument both ignores the many formal actions

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[8] Nor does it matter that Monsanto itself never formally sought permission to add a cancer warning to Roundup's label. A state-law warning requirement can be preempted if another registrant has sought and been denied permission to add the same warning. *See Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1169 (S.D. Cal. 2016). It would be pointless to require Monsanto to request permission to issue a warning it believes to be false from an agency that has made it clear it would deny that request.

[9] EPA's clerical oversight in approving two glyphosate labels containing Proposition 65 warnings does not alter this conclusion. As the United States has explained, those labels "did not receive" the appropriate level of review because the registrants failed to properly frame the warning as a "Human Hazard and Precautionary Statement[]." U.S. Br. 10. Accordingly, these approvals were "erroneous" "implementation mistakes," given that the warning was based on an alleged cancer risk that EPA has determined "does not exist." *Id.* at 10, 17.

EPA has taken in addition to the 2019 letter and contravenes Supreme Court precedent on what agency action carries the force of law. *Mead* recognizes that agency action other than rulemaking and formal adjudication can carry the force of law: "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 should underlie a pronouncement of such force." 533 U.S. at 230-231 (emphasis added). *Merck* likewise made clear agency action short of rulemaking or formal adjudication can also carry the force of law, citing several FDA processes that employ neither procedure. *See* 139 S. Ct. at 1679. For example, *Merck* cited FDA regulations that authorize the agency to communicate its official position on an individual drug to an applicant in a "complete response letter," 21 C.F.R. §§314.110(a), 314.125(b)(6), *cited in Merck*, 139 S. Ct. at 1679—similar to the formal, yet individualized, process EPA employs to register and approve the label of a pesticide like Roundup.

EPA's actions here are sufficiently formal to carry the force of law under *Merck*. First, EPA has issued numerous official decisions reiterating its conclusion that glyphosate does not cause cancer—including its registration of Roundup, its approval of Roundup's labeling, and, most recently, its decision to re-register glyphosate after notice-and-comment procedures. *See supra* pp. 7-8. Those decisions were made pursuant to specific administrative processes established by

Congress to direct authoritative agency action in an individualized manner—a process far *more* formal than the FDA's private, applicant-specific response letters cited in *Merck*. *See* 7 U.S.C. §§136a, 136a-1.

EPA's August 2019 letter—reinforced by the United States' brief to this Court—confirms the agency will not approve a cancer warning for glyphosate, making it unlawful for companies like Monsanto to add the warning Hardeman seeks. The EPA letter responded to requests from registrants to add a cancer warning for glyphosate-based products, and definitively informed the registrants of EPA's decision to *deny* those requests, explaining that including the warning would render the products misbranded. U.S. Br. 10. That "authoritative interpretation of [EPA's] FIFRA misbranding authority … has practical and significant legal effects." *Reckitt Benckiser, Inc. v. EPA*, 613 F.3d 1131, 1138 (D.C. Cir. 2010). It commits EPA to rejecting future requests to add such a cancer warning, and directs registrants to remove any such warnings currently on their labeling or face legal consequences, *see* 7 U.S.C. §136*l*. EPA's decision does not lack the force of law just because Monsanto had not formally sought permission to add the warning that Hardeman seeks. That would be an empty formality. *See San Francisco Herring Ass'n v. Department of Interior*, 946 F.3d 564, 578 (9th Cir. 2019) (announcement of "intent[] … to enforce" statute is final agency action);

Ipsen Biopharmaceuticals, Inc. v. Azar, 943 F.3d 953, 956 (D.C. Cir. 2019) (similar).

In any event, the August 2019 letter specifically invoked EPA's 2017 determination that glyphosate is not carcinogenic, made as part of the formal and statutorily authorized process discussed above. Thus, even were there doubt about the formality of the letter standing alone, the agency actions it invokes or otherwise confirms unquestionably carry the force of law. *See Mead*, 533 U.S. at 230-231. EPA's meticulous consideration of glyphosate over decades was done through "procedure[s] tending to foster … fairness and deliberation," *id.* at 230, and its authoritative decisions are more than mere "agency musings," Law Prof. Br. 18.

Hardeman cites three cases in which informal letters were held not to carry the "force of law," but all are readily distinguishable. In *Reid v. Johnson & Johnson*, 780 F.3d 952 (9th Cir. 2015), the letter indicated only that the agency *might* exercise its enforcement discretion. This Court found that document to be insufficiently formal in light of the "equivocal," "tentative," and "non-committal" terms of the letter. *Id.* at 965. There is no such issue here—EPA has been crystal clear. *See supra* pp. 7-8. In *Wabash Valley Power Ass'n v. Rural Electrification Administration*, 903 F.2d 445, 453 (7th Cir. 1990), the letter attempted to short-circuit an ongoing rulemaking in an area in which the court expressed "substantial doubt" that the agency had *any* authority to regulate. Finally, in *Fellner*, the letter

amounted to no more than an "informal explanation for [the agency's] decision not to regulate" and "did not purport to impose new legal obligations on anyone." 539 F.3d at 245, 247. But here, EPA officially informed pesticide registrants that they *may not* attach a cancer warning based on glyphosate, informed other registrants that they were required to eliminate existing cancer warnings, and told both groups that including a cancer warning would render the pesticide misbranded in violation of federal law.[10]

3. Monsanto cannot unilaterally change Roundup's label

Hardeman's claims are also impliedly preempted because, under EPA's regulations, Monsanto could not have unilaterally changed Roundup's label. *See* 40 C.F.R. §§152.44(a), 152.50; *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011)

[10] Hardeman argues this Court may not consider any EPA glyphosate decisions postdating Hardeman's injury in 2012—including EPA's August 2019 letter. Br. 45-46. He cites no binding authority for that proposition, and his two out-of-circuit cases did not consider the question. One expressly declined to decide the issue, *Fellner*, 539 F.3d at 255, and the other considered a wide range of evidence that arose after the plaintiffs were injured and the suit filed, *In re Avandia Mktg. Sales & Prods. Liab. Litig.*, 945 F.3d 749, 753-756 (3d Cir. 2019) (examining evidence from 2006 to 2014 in lawsuit filed in 2010). Indeed, in *Merck* itself the parties assumed that agency action that occurred after some plaintiffs were injured was relevant to the question whether all plaintiffs' claims were preempted. *See* 139 S. Ct. at 1673-1676 (examining evidence from 1995 to 2010; some plaintiffs injured in 1999). And in any event, the position EPA expressly stated in its August 2019 letter—that it would reject a cancer warning for glyphosate—flows inexorably from its longstanding view that glyphosate is not carcinogenic, reflected in many prior decisions. *See supra* pp. 7-8. These decisions make clear that EPA would have rejected that same warning had it been proposed earlier.

(finding preemption where "state law imposed a duty on" manufacturers to change label but manufacturers could not do so without the agency's approval).

Hardeman's principal response (at 52-53) is that this argument "cannot be squared" with *Bates* because (he asserts) the manufacturer there would also have been unable to unilaterally change its product's label. But, as explained, *Bates*, which did not consider implied preemption at all, arose in a distinctive context: The proposed label change concerned the product's *efficacy*, not its safety, and EPA has long waived review of efficacy claims. 544 U.S. at 440. Hardeman advances a convoluted theory that the *Bates* manufacturer would actually have had to seek agency approval before a label change. Br. 53 n.21. But *Bates* made no reference to any such requirement, *see* 544 U.S. at 440—likely because the section of the manual Hardeman cites for this point was updated in 2011, years after the events in *Bates*.[11]

[11] Amicus Public Citizen notes (at 29-30) EPA has previously allowed registrants to add Proposition 65 warnings to pesticide labels using the agency's "notification" process, which is generally reserved for "minor" modifications. Public Citizen's examples are inapposite, as all of them involved products that either EPA or HHS had previously concluded at least might cause cancer. Public Citizen does not identify a single example where EPA has allowed a registrant to use the notification process and where EPA found the relevant chemical was *not* carcinogenic, much less where it determined a cancer warning would render a label false and misleading.

Hardeman finally makes a broad appeal to FIFRA's purpose: "to protect the public from hazardous pesticides." Hardeman Br. 54-55. FIFRA, however, balances multiple congressional objectives—protecting public health, but also ensuring uniformity and consistency in how the risks and benefits of pesticides are conveyed. Indeed, by definition, a preemption provision in a federal safety statute limits states' authority to regulate further in the area. *See Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 103 (1992). Hardeman's argument, if accepted, would fracture the careful balance Congress struck in FIFRA.

II. THE DISTRICT COURT ERRED BY ADMITTING THE CAUSATION TESTIMONY OF HARDEMAN'S EXPERTS

Hardeman's causation case faced two fundamental obstacles. As to general causation, the epidemiological evidence did not support an association between glyphosate and non-Hodgkin's lymphoma. As to specific causation, at least 70% of non-Hodgkin's lymphoma cases cannot be attributed to any cause, and Hardeman previously had hepatitis C, a well-established cause of non-Hodgkin's lymphoma.

To avoid those problems, Hardeman's experts abandoned the principles of sound science. First, they cherry-picked from the epidemiological literature to support their conclusions, while elevating exploratory animal and cellular studies above the robust human studies that on the whole did not support their opinions. Monsanto Br. 48-55. Second, Hardeman's experts bootstrapped their unreliable

general causation conclusions as the methodological basis of their differential diagnosis, and ruled out all unknown factors and hepatitis C as the cause of Hardeman's cancer in a flawed methodology that would always yield glyphosate as the cause. *Id.* at 55-63.

Despite cataloguing many of the experts' methodological flaws, the district court forgave those transgressions under the misimpression that the Ninth Circuit applies a uniquely permissive *Daubert* standard. Pointing to two Ninth Circuit decisions involving exceptional circumstances not present here, the district court relaxed the ordinary *Daubert* standard, and concluded (1) Hardeman's experts could testify about an epidemiological association between glyphosate and non-Hodgkin's lymphoma, and (2) those experts could rely on their subjective judgment to identify glyphosate as the specific cause of Hardeman's cancer. But those cases are far removed from the facts of this case: Both glyphosate and non-Hodgkin's lymphoma have been widely studied, and Hardeman's experts have no particular experience that allows them to offer unique insights in this case—certainly none that could lead them to a conclusion different than the near-universal scientific consensus that glyphosate is not carcinogenic. This case presents no basis, therefore, for the methodological shortcuts Hardeman's experts took and the district court tolerated.

A. The District Court Applied An Improperly Permissive *Daubert* Standard

Hardeman notably does not argue his experts would satisfy the *Daubert* standard this Court—and other circuits—ordinarily apply. Instead, he clings (at 56-61) to the district court's misguided reading of *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227 (9th Cir. 2017), and *Messick v. Novartis Pharmaceuticals Corp.*, 747 F.3d 1193 (9th Cir. 2014). ER36-38, 56-57. But those cases did not announce any general principle that an expert's "clinical judgment" may substitute for rigorous scientific methodology. Rather, they allowed experts to rely on their clinical judgment under exceptional circumstances that bear no similarities to this case. Monsanto Br. 44-47.

Unlike the "exceedingly rare" cancer and the absence of epidemiological studies in *Wendell*, 858 F.3d at 1236, non-Hodgkin's lymphoma is common and has been extensively studied in epidemiological literature. Monsanto Br. 45-46 & n.15; *see* ER504-505 (Weisenburger). In other words, this is precisely the kind of case involving "a plethora of peer reviewed evidence" that should be subject to the traditional *Daubert* standard. *Wendell*, 858 F.3d at 1237.

Further, the asserted causal association and mechanism in *Wendell* was "well known" and accepted by '"the entire medical community."' Wendell Br. 13, 16, No. 14-16321, Dkt. 11 (9th Cir.). One of the experts—who had "seen more cases of the [rare] disease than 99% of oncologists in the country," 858 F.3d at 1233-

1234—also explained, based on the scientific literature, that the risk of developing the cancer was "one in six million" in the general population, *id.* at 1234, but 270 times more likely with exposure to one of the drugs at issue, Wendell Br. 13-14. The *Messick* expert's opinion was likewise supported by his "extensive" clinical experience, as well as "appropriate scientific" sources, all of which supported the expert's conclusion that use of the drugs was a "necessary" cause of her illness. 747 F.3d at 1197-1199. By contrast, Hardeman's principal expert, Weisenburger, admitted (1) he could not identify *any* peer-reviewed published article characterizing glyphosate as a "generally accepted" cause of non-Hodgkin's lymphoma, and (2) the level of glyphosate exposure sufficient to make it a substantial cause of non-Hodgkin's lymphoma is not connected to any specific dose, but is merely a "subjective decision." ER1093-1095, 1099.

Hardeman's other arguments defending the district court's *Daubert* standard fail. Although Hardeman argues (at 58) that his experts "relied upon *far* more data than the *Messick* expert," that does not make this case resemble *Wendell* and *Messick*. Despite copious epidemiological evidence regarding glyphosate, Hardeman's experts could not say that his exposure was "necessary to" cause his cancer, *Messick*, 747 F.3d at 1197, or that it increased his risk of developing the cancer by any particular multiple, Wendell Br. 13-14—because any such statements would have lacked scientific basis. The experts admitted Hardeman

could well have developed cancer *without* glyphosate exposure. Monsanto Br. 46.[12]

Hardeman asserts (at 58-59) that his experts' testimony—like the testimony in *Wendell* and *Messick*—rested on reliable epidemiological evidence and relied on judgment and experience only to supplement it. That is simply not the case: The only example Hardeman offers (at 58-59) is Weisenburger's plucking of a single odds ratio from an unpublished, non-peer-reviewed study from the North American Pooled Project (NAPP), which as explained below reflected a fundamentally unscientific methodology. *See infra* pp. 31-32.

Ultimately, Hardeman urges (at 56-57) that even if his experts' opinions were "'borderline,'" that goes only to their weight, not admissibility. But they were borderline (at best) only under the district court's impermissibly lenient approach to *Daubert*. The district court acknowledged it was applying a more lenient standard that would make a difference in a "close case[]" such as this one. ER56-57; *see* ER49 (general causation is "a very close question"); ER36 (specific

[12] For similar reasons, Hardeman is wrong to characterize (at 59) Monsanto as arguing that "epidemiological studies must *supplant* clinical experience and scientific judgment as the basis of any specific-causation opinion." What *Wendell* and *Messick*—like other decisions of this Court—require is that any subjective judgment or clinical experience be grounded in reliable science. That standard is not met where, as here, a party relies on an "expert's bald assurance of [the] validity" of his own opinion. *See Daubert v. Merrill Dow Pharm., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995).

causation opinions may well be inadmissible "[u]nder a strict interpretation of *Daubert*"). And while Hardeman emphasizes (at 56-57, 61) a district court's discretion in considering an expert opinion, application of an incorrect legal standard is necessarily an abuse of discretion. *Las Vegas Sands, LLC v. Nehme*, 632 F.3d 526, 532 (9th Cir. 2011).

B. Under The Correct *Daubert* Standard, The Opinions Of Hardeman's Experts Would Have Been Inadmissible

Under a correct approach to *Daubert*, the district court should have excluded the causation opinions of Hardeman's experts at general causation, and certainly at specific causation.

1. General causation

As Hardeman concedes (at 17, 62), a threshold issue for general causation is whether "there was an association between Roundup and NHL within the epidemiological literature." In other words, Hardeman could not prevail on general causation if his experts could not reliably determine an epidemiological association between glyphosate and non-Hodgkin's lymphoma—even if they presented other evidence, like animal and cell studies.

Hardeman's experts failed to reliably establish that threshold association. Monsanto Br. 50-55. Regulators broadly agree that glyphosate is not associated with non-Hodgkin's lymphoma. *See, e.g.*, *National Ass'n of Wheat Growers v. Zeise*, 2018 WL 3000488, at *2 (E.D. Cal. June 12, 2018) (noting that "the

overwhelming majority" of national and international health authorities "have determined [glyphosate] is not a cancer risk"). Despite this consensus, Hardeman's experts cherry-picked a few isolated datapoints to find an association, without adequately accounting for the broader epidemiological landscape. *See Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005) (experts must address "a large body of contrary epidemiological evidence" with "[a] medically reliable and scientifically valid methodology"). Making matters worse, Hardeman's experts asymmetrically evaluated the epidemiological evidence, rejecting the robust studies finding no association for unsupportable reasons, while overlooking significant flaws in the studies that favor their conclusion.

Two examples highlight those profound methodological flaws. First, Hardeman's key expert, Weisenburger, treated studies inconsistently based on whether they favored his preferred result. As the district court recognized, "the most powerful evidence regarding the relationship between glyphosate and NHL" is the Agricultural Health Study (AHS), which has consistently reported no statistically significant association between glyphosate and non-Hodgkin's lymphoma. ER73-74. Weisenburger criticized AHS for an alleged latency issue—having "too short a [follow-up] time" between the exposure and the study "to detect a meaningful increase in NHL." ER2110. Tellingly, Weisenburger excused

a very similar latency problem in De Roos, whose results he favors. ER2110-2111; Monsanto Br. 53-54.

Weisenburger himself had no adequate explanation for this discrepancy. Hardeman tries after the fact (at 69-70) to defend Weisenburger's reliance on De Roos, on the theory that non-Hodgkin's lymphoma may appear just two years after exposure to a harmful substance, ER532. But as the district court explained, Weisenburger "repeatedly suggested, including in materials prepared outside of this litigation, that glyphosate-induced NHL was likely to have a long average latency period, on the order of *20 or more years*." ER102 (emphasis added); *see also* ER2110. Such inconsistency between in-court and out-of-court statements is a hallmark of unreliability under *Daubert*. An expert who shifts his views on methodology to achieve a desired result is hardly acting in a reliable manner. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993) ("[T]he trial judge must ensure that any and all scientific testimony … admitted is not only relevant but reliable."). Weisenburger's maneuvering was made all the more striking when at trial he shifted the focus of his criticism of AHS away from latency to an alleged misclassification issue after the 2018 follow-up study to AHS resolved any potential latency issue. *Compare* ER2110-2111 *with* ER552-557. While Weisenburger's misclassification argument fails on its own terms, *infra* p.

33, his shifting criticisms of AHS underscore the results-oriented nature of his methodology.

The same is true of Weisenburger's testimony regarding the NAPP study, which he co-authored. NAPP's analyses (which were unpublished at the time of trial) were presented in three evolving, non-peer-reviewed slide decks, each of which reported different odds ratios—often for the *same parameters*. *Compare, e.g.*, FER90 *with* FER43. Weisenburger selectively relied on a single favorable odds ratio from the "earliest iteration" of NAPP—2.49, ER362; *see* PSER113, 202-205, even though that ratio did not survive the subsequent iterations, *see* FER33-60, 61-77. Indeed, the 2.49 ratio was not included in the published version.[13]

Even more troublingly, Weisenburger emphasized the 2.49 ratio without accounting for numerous other ratios from the study that contradicted his position. *See* FER93 (no statistically significant association for self-respondents who ever used glyphosate); FER58 (same); FER92 (no statistically significant association as measured by lifetime days); FER45 (same). For example, NAPP showed the odds

[13] Pahwa et al., *Glyphosate use and associations with non-Hodgkin lymphoma major histological sub-types: findings from the North American Pooled Projec*t, 45 Scand. J. Work Environ. Health, 600 (2019), https://tinyurl.com/yanxlng3.

of contracting Hardeman's subtype of non-Hodgkin's lymphoma sometimes *decreased* with more use of glyphosate. *See* FER43, 90.

Hardeman's *post hoc* attempt to defend his experts' inconsistent, results-oriented approach does not withstand scrutiny. Although Hardeman asserts that his experts relied on "*multiple* epidemiology studies," he discusses only De Roos and NAPP. *See* Br. 65-66, 69-71. That is double-counting, because NAPP aggregated the studies included in De Roos. ER68. And NAPP is unhelpful to Hardeman because, as the district court noted, many of the odds ratios from NAPP showed no statistically significant association between glyphosate and non-Hodgkin's lymphoma. ER66-67; *see* FER58, 93. Statistical significance is how the scientific community measures potential error in a testing method, ER63, and yet Hardeman's experts cast aside that fundamental norm, *see* ER1951-1955 (Portier professing a "strong association across the six core studies" although five of those study results lacked statistical significance); ER99 (district court noting that Ritz relied on the "consistency" of case-control studies' observations, even though some "were not statistically significant").[14]

[14] Hardeman argues (at 71-72) that the "'consistency'" of the observed associations in epidemiological studies supported the experts' opinions. But while statistically insignificant evidence may be used *in combination with other reliable evidence* to support general causation, *cf. Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 40-41 (2011), here there was no reliable additional evidence. Similarly, Hardeman's argument (at 68-69) that the "forest" of epidemiological studies supported the experts' opinions even if the individual "trees" were flawed

Hardeman's sole, litigation-driven criticism of AHS (at 66-67) likewise fails. It relies solely on twenty-year-old remarks from Monsanto personnel expressing concern, as AHS's glyphosate evaluation was first being formulated, that the eventual study might misclassify whether a study subject was a user or non-user of glyphosate, which in turn could skew the results. *See* ER791-792. But these misclassification concerns were addressed as the study progressed. The 2018 update to AHS conducted "a range of sensitivity analyses" "[t]o address potential biases," which found that any systemic misclassification is unlikely and that the AHS results were accurate. FER132-133.[15]

In the end, Hardeman is left with only a strawman argument—his assertion that epidemiology is not always needed to show causation. Br. 64 n.25. But the question is not whether causation opinions are always inadmissible in the absence of epidemiology, but rather whether—as in this case—an expert can unreliably discount existing, large-scale epidemiological evidence. Hardeman does not

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fails, because the "trees" Hardeman discusses specifically—De Roos and NAPP—were unreliable. *See Grodzitsky v. American Honda Motor Co.*, 957 F.3d 979, 986 (9th Cir. 2020) (exclusion of expert opinion was appropriate where the expert "cobble[d] together some form of generalized opinion" that was "riddled with scientific and methodological flaws").

[15] Hardeman claims (at 68 n.26) that Monsanto unfairly quoted Ritz's remark that AHS is a "wonderful study," ER1522. But Ritz, who chaired the advisory committee for AHS, in fact described AHS as a "wonderful study" that produced a lot of "useful data," ER1522, and began criticizing AHS after she was retained as Hardeman's expert, *see* ER874-876; *see also* ER926.

dispute that where, as here, reliable epidemiological evidence exists, experts cannot subordinate it to less reliable animal and cell studies. *See Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1336 n.8 (11th Cir. 2010); *see also* ER61. And because Hardeman's experts could not reliably find an association in the epidemiological literature, the animal and cell studies that Hardeman discusses (at 62-63) are irrelevant. Had the district court exercised a proper gatekeeping function under *Daubert*, it would have excluded the experts' general causation opinions.

2. Specific causation

As Monsanto explained (at 55-63), Hardeman's experts purported to engage in differential diagnosis to rule in glyphosate as a cause and rule out other causes of non-Hodgkin's lymphoma. But Hardeman's experts applied differential diagnosis unreliably, employing an "always glyphosate" approach that essentially ignored idiopathy and did not account for Hardeman's hepatitis C. *Id.* Hardeman's defense of his experts' specific causation testimony—and the district court's cursory treatment of that issue, ER36-38, even after the court's warning that specific causation may well pose "a daunting challenge" for Hardeman, ER51—does not withstand scrutiny.

a. Hardeman's experts failed to reliably rule out idiopathy

Daubert requires experts conducting differential diagnosis rule out alternative causes for the illness based on reliable scientific evidence. *See Clausen*

v. M/V NEW CARISSA, 339 F.3d 1049, 1058 (9th Cir. 2003). That ruling-out requirement applies to idiopathy—cases of an illness where the cause is unknown. Thus, when there is a high rate of idiopathy for a disease, experts must identify a scientific reason why idiopathy does not explain the illness, just as they must identify reasons why an alternative risk factor does not explain the illness. Monsanto Br. 57-58 & n.23; *see also Daubert v. Merrill Dow Pharm., Inc.*, 43 F.3d 1311, 1320 (9th Cir. 1995) ("*Daubert II*") (specific causation is "made more difficult" where most cases of the condition at issue "occur for no known reason").

Hardeman claims his experts addressed idiopathy in three ways. First, Hardeman contends (at 74-76) that the experts could rely on the same general causation evidence used to rule in glyphosate to also rule out idiopathy. But an expert may not bootstrap general causation evidence to satisfy specific causation; indeed, differential diagnosis "assumes the existence of general causation, and focuses instead on" the separate question whether the substance at issue actually caused the harm alleged. *Kilpatrick*, 613 F.3d at 1342. In other words, even if glyphosate "*could cause* [non-Hodgkin's lymphoma] in someone like" Hardeman, that "does not show that [glyphosate] *did cause*" Hardeman's cancer specifically. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670-671 (6th Cir. 2010). This limitation is especially apt here because, as the district court observed, Hardeman's general causation evidence was "rather weak" and "too equivocal," ER50. For an

expert to rule out idiopathy for a specific plaintiff based solely on general causation evidence, the expert would have to show a much more robust association. Monsanto Br. 57-58; *see* ER36.

Wendell shows why (and how far) Hardeman's experts fell short. The experts in that case were able to rule out idiopathy based on the extraordinary strength of the association between the drugs in question and the type of cancer at issue. Whereas the rare cancer occurred in the general population at a rate of "one in six million," 858 F.3d at 1234, the rate became "1 in 22,000" for those exposed to one of the drugs in question—a 270-fold increase in risk. Wendell Br. 13-14, 41.[16] Based on that sharply increased risk, the experts statistically eliminated idiopathy as far less likely than the drugs to be the cause. This Court's opinion, particularly in light of its questions at oral argument, suggests it approved of the experts' reliance on increased risk to rule out idiopathy. Oral Argument 12:12-13:52, 14:49-15:27, No. 14-16321 (9th Cir. Sept. 16, 2016) (Audio); *see also* 858 F.3d at 1234-1235, 1237.

Hardeman's experts pointed to nothing remotely similar—not even a reliable odds ratio exceeding 2.0 that Hardeman seems to concede (at 58-59 & n.23) his experts needed to support a specific causation opinion. The strongest association

[16] *See* Wendell Br. 41-42 (the studies both experts relied on showed the drugs at issue increased the risk of the illness "three to several hundred-fold").

Hardeman cites (at 75-76) is the odds ratio of 2.49 from the earliest version of NAPP, which as discussed above reflected only an interim analysis and did not survive in the published paper, *supra* p. 31.

Hardeman relies (at 75) on McDuffie and Eriksson, but as the district court recognized, any assertion that those studies demonstrate a "quantif[iable] … risk … to a particular plaintiff" "is not scientifically sound" given that "those studies did not adjust for the use of other pesticides." ER39-40; *see* ER98; *see also* Monsanto Br. 58-60. Hardeman notably does not defend his experts' misuse of McDuffie and Eriksson, but instead speculates (at 75) that "because [McDuffie and Eriksson] observed increased risk with greater exposure … the observed dose response was unlikely due to other pesticides." Not only does this argument appear nowhere in the record, but it contradicts basic scientific principles. If a study did not adjust for other pesticides and reported a positive dose response, it means that greater exposure to *some other substance* could have led to the higher risk. ER39-41, 63-64. It does not somehow cure the failure to adjust for other pesticides.

Second, Hardeman argues (at 73-74) that it "proves too much" to require ruling out idiopathy when an expert can point to purported known risk factors for the illness. But experts are required to do exactly that, *see Wendell*, 858 F.3d at 1234-1235, 1237, and for good reason. Although Hardeman tries to minimize

idiopathy by characterizing it (at 74) as "the mere possibility that there may be a risk factor," the reality is science has not yet identified the causes of non-Hodgkin's lymphoma in the *substantial majority* of cases. *Cf. Tamraz*, 620 F.3d at 668 (as scientists discovered more causes of an illness, they needed to "rely less frequently on 'idiopathic designations'"). Accounting for idiopathy does not mean (as Hardeman implies) speculating about any number of unknown factors that could have caused one's illness, but it means experts must account for the *predominant likelihood* that the cause is unknown.[17] Otherwise, as long as a plaintiff used Roundup and later developed non-Hodgkin's lymphoma, Hardeman's experts could always point to Roundup as the cause of the illness. There would be no need to explain how idiopathy could be ruled out, because under their methodology Roundup would always supersede idiopathy.

This deficiency came to a head in the *Daubert* hearing, where Weisenburger—Hardeman's only testifying expert on specific causation at trial—admitted Hardeman's cancer could have been idiopathic, but wrongly dismissed it

[17] Hardeman speculates (at 77 n.29) that the idiopathic rate is high in part because oncologists do not ask their patients about exposures to risk factors. But as Weisenburger acknowledged, oncologists "would want to know" that "glyphosate or Roundup caused their patient's cancer if that were true." ER348-349. At any rate, the fact remains that at least 70% of individuals develop the cancer for no known reason, and experts must accordingly account for the possibility that the plaintiff is one of the vast majority of idiopathic cases. *See Tamraz*, 620 F.3d at 671.

on account of a purported dose-response relationship drawn from McDuffie and Eriksson. FER8-13; *see* ER38-41. When pressed, Weisenburger shifted positions and admitted that the level of sufficient exposure that would make glyphosate a substantial cause of Hardeman's cancer is "a subjective decision." ER1093-1095. On appeal, Hardeman turns to experts who *did not* testify, Shustov and Nabhan, but their opinions, never admitted into evidence, cannot sustain the verdict. Fed. R. Civ. P. 50(a); *Weisgram v. Marley Co.*, 528 U.S. 440, 455-456 (2000). Indeed, Shustov and Nabhan admitted they *did not* actually rule out idiopathy, because they believed experts may disregard idiopathy as long as they can point to a purported known risk factor for the disease, FER15-17, 19-21, which as explained above, is incorrect.[18]

b. *Hardeman's experts did not reliably rule out hepatitis C*

Unlike glyphosate, hepatitis C is a well-established cause of non-Hodgkin's lymphoma, including Hardeman's subtype. Monsanto Br. 61. Hardeman's experts purported to use differential diagnosis to rule out hepatitis C, but their theories ignored scientific literature showing that Hardeman's chronic hepatitis C could

[18] Hardeman suggests (at 76-77) that his experts' methodology was "indistinguishable from" the methodology used by Monsanto's expert, Dr. Levine. But Levine did not apply differential diagnosis (FER2-3); she was not even attempting to establish causation, which was Hardeman's burden. The point of Levine's testimony was instead to explain that Weisenburger failed to reliably rule out idiopathy and that based on scientific literature, hepatitis C was "the most likely cause or contributing factor." ER230-231; *see* FER5-6.

readily have caused his cancer despite his treatment in 2005-2006. Their opinions were therefore so unreliable as to be inadmissible. *Daubert II*, 43 F.3d at 1317 ("proposed expert testimony" must "amount[] to good science").

Hardeman insists (at 72-73) that hepatitis C was appropriately ruled out because the virus must be active to cause non-Hodgkin's lymphoma and it was not active after his treatment in 2005-2006. But he discusses primarily Shustov's proffered opinion, and Shustov neither testified at trial nor provided specific scientific support for his position. ER2413 (report); ER1132-1135 (*Daubert* hearing). By contrast, Weisenburger—who did testify at trial—acknowledged that, according to a scientific study, Hardeman's risk of non-Hodgkin's lymphoma would not have been reduced from his treatment in 2005-2006 because he had suffered from chronic hepatitis C infection for decades prior. ER2392; *accord* ER444-446. Indeed, the trial testimony showed that hepatitis C had likely caused genetic mutations in Hardeman over a 39-year period, *see* ER437-439 (Weisenburger), and as Monsanto's expert explained, "[o]nce he had that mutation, it didn't matter at all if his virus had been completely eradicated or not" after the treatment—Hardeman was still at a higher risk of non-Hodgkin's lymphoma, ER231; *see also* ER438-439 (Weisenburger acknowledging Hardeman's hepatitis C infection could have caused genetic mutations before treatment, and that genetic mutations can cause non-Hodgkin's lymphoma). Given that the latency period for

developing non-Hodgkin's lymphoma after exposure to hepatitis C ranges from 5 to 35 years (with a median of 15 years), *e.g.*, ER1097-1098, 1100-1101 (Weisenburger), the hepatitis C virus in Hardeman before his treatment could certainly have caused his cancer years later.

* * *

This Court has long held that an expert's statement "doesn't become 'scientific knowledge' just because it's uttered by a scientist[,] nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive." *Daubert II*, 43 F.3d at 1315-1316. *Wendell* and *Messick* did not change that basic *Daubert* principle. Yet the district court read those cases to compel it to allow Hardeman's experts to testify based on the experts' *ipse dixit*. Because Hardeman failed to present reliable expert testimony to establish that exposure to glyphosate caused *his* non-Hodgkin's lymphoma (or indeed causes non-Hodgkin's lymphoma at all), the jury's verdict cannot stand.

III. THE DISTRICT COURT ABUSED ITS DISCRETION BY ADMITTING EVIDENCE OF IARC'S CLASSIFICATION WITHOUT ALSO ADMITTING EVIDENCE OF REGULATORS' REJECTION OF THAT CONCLUSION

As Monsanto has explained, the district court erred by admitting evidence during Phase One of the trial that IARC had termed glyphosate a "potential carcinogen" while excluding evidence of the near-universal regulatory consensus rejecting that determination. Monsanto Br. 64-65. IARC's classification was of

minimal probative value on causation because it was not based on any independent study or new data and did not gauge the risk of cancer from real-world exposure to glyphosate. *Id.* Its "probable carcinogen" designation, moreover, was highly prejudicial because it was misleading and allowed Hardeman to harness the prestige of IARC's status to support his causation case. *Id.* at 65-67. At a minimum, the court should have also admitted evidence that numerous regulatory agencies had rejected IARC's conclusion. *Id.* at 67-69.

Hardeman's chief response (at 80-83) is that the district court's error is Monsanto's fault for asking to bifurcate the trial. But wanting a fair opportunity to litigate causation devoid of unfounded attacks on Monsanto's conduct should not mean Monsanto had to relinquish an evenhanded presentation of the evidence.

Hardeman contends the court admitted evidence of IARC's classification during the causation phase as a prophylactic measure to avoid jurors wondering why glyphosate was unregulated if it was so dangerous. But the court primarily addressed that "relatively minor concern" through its jury instruction not to defer to regulatory agencies, PSER3, and did not mention that rationale when it ultimately admitted evidence of IARC's classification, ER 42.

Moreover, the court's decision to admit IARC's classification at Phase One was fundamentally inconsistent with the purpose of bifurcating the trial between the causation inquiry and other issues. As the district court itself explained,

allowing evidence about regulatory actions during Phase One was likely to cause a "distraction," because the jury was required to focus on the scientific data concerning causation and not IARC's or regulators' conclusions about that data. PSER3. Contrary to Hardeman's claim that bifurcation *necessitated* admitting IARC's classification during Phase One, bifurcation shows why that evidence should have been *excluded* during Phase One—and the IARC conclusion was particularly prejudicial, given the undue weight the jury was likely to give the conclusion of that international body.

Having erred by allowing evidence of IARC's conclusion at Phase One, the court compounded that error by rejecting Monsanto's efforts to place that conclusion in proper context—in particular, to inform the jury that regulatory agencies throughout the world had rejected IARC's conclusion. Hardeman argues (at 81-82) that if that foreign regulatory agency evidence had been admitted, Monsanto would have had to agree to admit Hardeman's purported evidence of Monsanto's efforts to undermine IARC's conclusion and its communications with other regulators. But Monsanto did not advocate for admission of foreign regulators' conclusions in the first instance. It sought to admit that evidence during Phase One *only if* IARC's classification was admitted, to mitigate prejudice. Dkt. 2610-1 at 1, 4-5; Dkt. 2595 at 2-3. Had the district court not erroneously

admitted IARC's classification, *no regulatory evidence* would have been at issue during Phase One.

Hardeman inadvertently illustrates this point. He complains that admitting additional regulatory evidence would have "tempt[ed] the jury 'to simply adopt one side of the alleged debate between regulators and IARC rather than undertaking the necessary job of independently assessing the scientific evidence.'" Hardeman Br. 82. But that was exactly Monsanto's point, and that is why admitting IARC's classification—which encouraged the jury to adopt "one side's" position (IARC's) rather than weigh the scientific evidence—was error.[19]

Finally, Hardeman argues (at 83) any evidentiary error was harmless because the court instructed the jury not to defer to the conclusions of regulatory bodies.[20] But the instruction was intended to assuage *Hardeman's* concern that the jury would defer to EPA—not Monsanto's concern that the jury would give undue

[19] Hardeman's contention (at 81) that Monsanto acceded to the admission of the IARC evidence is meritless. Monsanto merely noted it was appropriate to *limit* that evidence once it was conclusively admitted over Monsanto's objection. PSER97. It was not required to repeatedly re-object. *Dream Games of Ariz., Inc. v. PC Onsite*, 561 F.3d 983, 989 n.3 (9th Cir. 2009).

[20] Hardeman argues that, because the court adopted Monsanto's request that it specifically name IARC in that instruction, Monsanto waived any objection. *See* Br. 83. The request that the court name IARC and the other regulatory agencies was intended to avoid jury confusion, since other organizations, such as the American Cancer Society, were also discussed at trial. PSER95-97.

weight to IARC. Monsanto made clear that even a limiting instruction would only "mitigate *some* of the confusion and prejudice inherent in admitting evidence of IARC's inapposite and incomplete assessment," but that evidence of IARC's conclusion would remain unfairly prejudicial. Dkt. 2610-1 at 5 (emphasis added). Hardeman plainly thought the IARC classification was important, for his counsel featured it in both opening and closing, ER 16-17, 67, 189, 991-992, calling it evidence the jury could not "ignore[]" when deciding "whether or not exposure to Roundup can cause cancer," PSER63. Because there can be no "fair assurance" that the admission of the IARC classification—and the exclusion of the mitigating foreign regulatory evidence—was harmless, the jury's verdict should be reversed. *See Guillory v. City of Anaheim*, 1992 WL 341338, at *2-3 (9th Cir. Nov. 19, 1992).

IV. THE CAUSATION INSTRUCTION WAS ERRONEOUS

Hardeman fails to rehabilitate a causation jury instruction both disconnected from the evidence introduced at trial and so "inconsistent with California law" that his counsel warned it could not "withstand appellate scrutiny." ER1729. The resulting prejudice to Monsanto was palpable.

The causation instruction, an amalgamation of two different pattern instructions, was wrong for two independent reasons. First, it presented the jury with a theory of liability—concurrent independent causes—that neither party

pressed. Second, it ran counter to the California Judicial Council's directive against pairing the but-for causation language in California Civil Jury Instruction ("CACI") 430 with the concurrent independent causes language in CACI 431. *See* Monsanto Br. 71-73.

Hardeman does not dispute he never offered the jury any evidence in support of a "two fires" concurrent independent causes theory. Instead, he now defends (at 88) the instruction on the theory that the jury could have "reasonably believe[d] both" parties' liability theories. But Hardeman's after-the-fact appellate defense cannot be reconciled with his position at trial.

At trial, Hardeman and Monsanto asserted mutually exclusive theories for the cause of Hardeman's cancer. Hardeman pointed to Roundup—and *only* Roundup—as the cause and Monsanto argued Roundup could *not* have been a cause. *See* Monsanto Br. 17-18, 72-73; ER236; *see also* PSER72-73 (Hardeman's counsel asserting Hardeman had "no hepatitis C" and any "[a]bnormal cells [were] gone" by 2006).

This case therefore did not present a "two fires" situation. *Cf.* Hardeman Br. 87-88. Hardeman made the strategic decision to present evidence that the sole cause of his non-Hodgkin's lymphoma was Roundup and that every other theory was incorrect. Hardeman cannot retroactively buttress a jury instruction that bore no connection to the evidence or argument he presented at trial simply because it is

now in his interests to do so. *See, e.g.*, *Peralta v. Dillard*, 744 F.3d 1076, 1082 (9th Cir. 2014) (en banc) ("Jury instructions must be supported by the evidence" adduced at trial); *see also Wilkerson v. Wheeler*, 772 F.3d 834, 838, 840-842 (9th Cir. 2014) (applying *Peralta* in the context of erroneously delivered instructions).

The instruction also contravened the principle that the but-for causation language in CACI 430 should not be combined with CACI 431 into a single instruction. Monsanto Br. 72. Hardeman does not dispute that California's model jury instructions warn against exactly what the district court did. Instead, he argues the error should be excused for two meritless reasons.

Hardeman first points to two California decisions that permitted the type of instruction delivered here. *See* Br. 85 (citing *Uriell v. Regents of Univ. of Cal.*, 184 Cal. Rptr. 3d 79 (Ct. App. 2015), and *Logacz v. Limansky*, 84 Cal. Rptr. 2d 257 (Ct. App. 1999)). But those cases do not even mention the Judicial Council's prohibition on mixed CACI 430/431 instructions. Indeed, *Logacz* predated the adoption of the CACI by four years. In contrast, courts that have expressly considered the Judicial Council's guidance have concluded the two instructions should not be paired. *See Major v. R.J. Reynolds Tobacco Co.*, 222 Cal. Rptr. 3d 563, 580 (Ct. App. 2017) ("but-for [causation] sentence [in CACI 430] should not be given in cases of concurrent independent causes"); *cf. Lopez v. The Hillshire Brands Co.*, 254 Cal. Rptr. 3d 377, 383-384 (Ct. App. 2019) (instructing on the

but-for test is "inappropriate" in cases where "'two forces are actively operating and each is sufficient to bring about the harm'").

Hardeman also argues in a brief footnote (at 86 n.31) that the jury instruction's use of the phrase "[s]ubject to the additional instructions below" before the but-for cause language cured any confusion about what causation standard applied. In context, however, that sentence makes the instruction *more* confusing; it suggests the jury should apply two conflicting theories of causation without explaining to the jury how to do so. Indeed, *Hardeman's counsel* argued that the "alternative language" was "likely [to] confuse the jury," and "implore[d] the Court to stick to the standard CACI instructions" rather than this hybrid. ER1729-1730. As Hardeman rightly explained, such a hybrid instruction "[can]not withstand appellate scrutiny." ER1730.

Moreover, the flawed causation instruction—which implicated the central issue at trial—was prejudicial. The jury spent *five days* deliberating on causation. As the district court ruled, Hardeman's causation evidence, at its best, "barely" met the *Daubert* threshold for admissibility. Given the weaknesses in Hardeman's case, a properly instructed jury could not have fallen back on a "both-parties-can-be-right" conclusion to find in Hardeman's favor. *See Caballero v. City of Concord*, 956 F.2d 204, 207 (9th Cir. 1992) (instructional error requires reversal unless it was "more probably than not harmless").

Hardeman's principal response (at 90 n.34)—that "there was substantial evidence that Roundup was a but-for cause of Hardeman's injury"—misstates the harmless-error inquiry. Whether there was "substantial evidence" adequate to survive a sufficiency challenge does not resolve whether an instructional error was likely harmless. Hardeman's own authority (*id.*) found an instructional error harmless only where "the evidence before the jury strongly support[ed]" liability and indeed "'would have supported a verdict for the plaintiff'" regardless of the error. *See Lambert v. Ackerly*, 180 F.3d 997, 1008 (9th Cir. 1999) (en banc).

V. HARDEMAN FAILED TO PRESENT SUBSTANTIAL EVIDENCE TO SUPPORT HIS FAILURE-TO-WARN CLAIMS

To prevail on a failure-to-warn claim under California law, Hardeman was required to prove two points: (1) the alleged connection between Roundup and non-Hodgkin's lymphoma was "known or knowable" in 2012, and (2) that connection was the product of "generally recognized and best prevailing scientific and medical knowledge available" at the time Hardeman used the product. *See* Monsanto Br. 74 (quoting *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 558 (Cal. 1991)). Hardeman's evidence satisfied neither requirement.

Hardeman produced no evidence that the purported link between glyphosate and non-Hodgkin's lymphoma was knowable in light of "*best prevailing* scientific and medical knowledge" as of 2012. Hardeman's own expert was unable to identify for the jury even a single peer-reviewed article as of 2012 suggesting that

it was "generally accepted" that glyphosate caused non-Hodgkin's lymphoma. ER1099 (Weisenburger).

Hardeman points (at 91) to various studies that, he claims, should have put Monsanto on notice of a possible connection between glyphosate and non-Hodgkin's lymphoma. But many of those studies postdate 2012 and thus cannot reflect the "prevailing" view at the relevant time. *See, e.g.*, *Saller v. Crown Cork & Seal Co.*, 115 Cal. Rptr. 3d 151, 167 (Ct. App. 2010) (differentiating failure-to-warn claims premised on early "medical attitudes" that had not yet "crystallize[d]" and those premised on later-promulgated "strict exposure standards").

The pre-2012 studies from which Hardeman has selected isolated findings—such as De Roos and McDuffie—did not state that glyphosate was a generally accepted cause of non-Hodgkin's lymphoma. As the district court recognized, the "scientific landscape" in 2012 was "favorable to Monsanto" in light of "repeated approvals of glyphosate by the EPA, the European Chemicals Agency, Health Canada, and other worldwide regulatory agencies." ER8. At that time, *every* regulatory agency that had examined the scientific evidence had concluded glyphosate was likely not carcinogenic. *Id.* No reasonable understanding of the scientific record before 2012 would allow the conclusion that causation was "generally recognized" and supported by the "best prevailing scientific and

medical knowledge available." Hardeman therefore presented insufficient evidence to support his failure-to-warn claims.[21]

VI. THE PUNITIVE DAMAGES AWARD VIOLATED CALIFORNIA LAW AND THE U.S. CONSTITUTION

As Monsanto has explained, Hardeman is not entitled to any punitive damages whatsoever. *See* Br. 76-86. At a minimum, he is not entitled to the $75 million he seeks on cross-appeal.

A. Hardeman Is Not Entitled To Any Punitive Damages

1. Monsanto did not engage in "despicable" conduct akin to a crime

Hardeman failed to prove by clear and convincing evidence that Monsanto had exhibited "malice"— "despicable conduct" that generates the kind of "outrage frequently associated with crime," and is carried on "with a willful and conscious disregard of the rights or safety of others." *See* Monsanto Br. 77-78. The California Court of Appeal has recently held that punitive damages should not be awarded in cases like this one, where the scientific evidence of the carcinogenicity of a product was not clear, the defendant had no special knowledge about the purported dangerousness of its product, and the case for a failure to warn was

[21] As explained *supra* n.2, Hardeman's purported design-defect claim is just a failure-to-warn claim by another name. Accordingly, a reversal on failure-to-warn grounds requires reversing the entire verdict.

close. *See Johnson & Johnson Talcum Powder Cases (Echeverria)*, 249 Cal. Rptr. 3d 642, 677-679 (Ct. App. 2019).

Hardeman notes that *Echeverria* involved a substance IARC designated as having a "possible association" with cancer, rather than the "probable association" designation in this case. Br. 95-96. But nothing in *Echeverria* turned on that distinction. The key question was whether there was uncertainty in the scientific community about carcinogenicity, not the precise ranking IARC assigned the substance. *See* 249 Cal. Rptr. at 677 (noting "it was not universally accepted in the scientific or medical community" that talc was carcinogenic). On that score, Monsanto's position is stronger here, given the consensus at the time of Hardeman's exposure supporting the view that glyphosate was *not* carcinogenic. *See supra* pp. 50-51.

Hardeman tries to analogize this case to three California cases where punitive damages were upheld because, among other things, the product manufacturer had failed to take adequate steps to ensure its products were safe. *See* Br. 93-95. All three are inapposite. *West v. Johnson & Johnson Prods., Inc.*, 220 Cal. Rpr. 437 (Ct. App. 1985), predates the modern punitive damages statute, which demands clear and convincing evidence and requires the jury to find that the conduct at issue was "despicable," *see* Cal. Civ. Code §3294. That 1987 legislation "represent[s] a new substantive limitation on punitive damages awards,"

and requires "circumstances that are 'base,' 'vile,' or 'contemptible.'" *College Hosp. v. Superior Court*, 882 P.2d 894, 907 (Cal. 2009); *see also Pacific Gas & Elec. Co. v. Superior Court*, 235 Cal. Rptr. 3d 228, 236 (Ct. App. 2018) (despicable conduct has "the character of outrage frequently associated with crime").

Boeken v. Philip Morris, 26 Cal. Rptr. 3d 638 (Ct. App. 2005), concerned a tobacco company that had "manufactured a dangerous product, knowing that it was a dangerous product—one that caused addiction and disease—and … added chemicals to the product to make it … *more* dangerous," *id.* at 678. As the district court here recognized, cases involving tobacco companies are inapposite because even assuming Roundup is carcinogenic, "Hardeman [did not] present any evidence that Monsanto was in fact aware that glyphosate caused cancer but concealed it." ER8; *see* ER129.[22]

Pfeifer v. John Crane, Inc., 164 Cal. Rptr. 3d 112 (Ct. App. 2013), involving asbestos, is also inapposite. As the *Echeverria* court pointed out, "it was widely accepted during [the] relevant time period that [the] product was carcinogenic" and it was undisputed that there was a "causal connection" between the harm suffered

[22] *Wyeth v. Rowatt*, 244 P.3d 765 (Nev. 2010), is inapposite for similar reasons—the Court found Wyeth had both "knowledge of the probable harmful consequences of its wrongful acts" and "tried to hide any potential harmful consequences of its products," *id.* at 784.

and asbestos. 249 Cal. Rptr. 3d at 334. There was—and is—no such consensus about glyphosate.

Hardeman next contends that punitive damages are warranted because, he claims, Monsanto intentionally failed to investigate a possible link between Roundup and non-Hodgkin's lymphoma. That argument is both legally flawed and factually unsupported. The cases Hardeman cites involved a litany of egregious conduct, not a mere failure to test a substance. *See John Crane*, 164 Cal. Rptr. 3d at 121 (company used asbestos even though it was undisputed at the time that asbestos was linked to cancer); *Romo v. Ford Motor Co.*, 6 Cal. Rptr. 3d 793, 806 (Ct. App. 2003) (automobile manufacturer ignored its own safety standards by selling a car without a steel roll-bar). The third case—*West*—relied on an outdated version of the punitive damages statute. *See supra* p. 53.

Moreover, Hardeman misstates the record in arguing Monsanto failed to do sufficient testing of Roundup. Monsanto conducted a wide array of tests—indeed, all of the tests necessary for EPA repeatedly to approve Roundup for use. FER101; *see* Monsanto Br. 6-9.[23] Hardeman argues that Monsanto "refused to do"

[23] Hardeman alleges Monsanto "kn[e]w" that glyphosate "causes tumors in mice." Br. 94. Hardeman is apparently referring to his unfounded assertion that Monsanto manipulated the results of a 1983 mouse study to secure EPA approval of Roundup. *See* Br. 27. In reality, there were issues with the methodology of the 1983 mouse study—including a flawed control group—that rendered its results inconclusive. FER23-24. EPA accordingly ordered and approved Monsanto to do a follow-up study involving rats. FER24. Based on *that* study, the EPA found in

specific tests recommended by Dr. Parry. Br. 94-95. But all the scientific investigation Dr. Parry wanted done was ultimately done—in some cases by Monsanto, in others by a third party. Hardeman's own expert conceded this point at trial. *See* FER30 ("I think somebody has done most of" Dr. Parry's recommendations for testing); *see also* FER111 (Monsanto witness testifying that 2008 article included "the answers to each of the[research] questions" posed by Dr. Parry).

More broadly, glyphosate is one of the most studied chemicals in the world, and there are many genotoxicity studies beyond the four Parry was asked to consider. EPA looked at nearly 90 genotoxicity studies, including the four that Parry reviewed, in reaching its ultimate conclusion of no association between glyphosate and cancer. *See* ER1861; Monsanto Br. 8-9; *see also* EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 115, 122, 125-129 (Dec. 12, 2017), *available at* https://tinyurl.com/eparevdglyphosate (citing, as part of a broader analysis, the four studies Parry viewed).

Finally, Hardeman argues that Monsanto ghostwrote scientific articles to supports its view regarding Roundup's non-carcinogenicity. Br. 95. But the only article Hardeman discusses disclosed Monsanto's involvement, FER102-103, and

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1991 that glyphosate was not carcinogenic. FER25-26. Hardeman has identified no problems with the second study.

there is no evidence that article was used improperly to influence regulatory treatment of glyphosate. Indeed, as the district court held in a finding Hardeman does not challenge, there is no evidence at all that Monsanto deceived regulators into approving glyphosate. ER8.

In sum, Hardeman did not come close to satisfying his heavy burden to prove that Monsanto's conduct was "despicable." As *Echeverria* makes clear, cases in which the evidence of a product's safety is (at best) close should not be converted into vehicles for punitive damages where the company believed, in light of the scientific evidence of the time, that its product was safe. The award therefore cannot be sustained under California law.

2. The punitive damages award violates due process

As Monsanto has explained, the imposition of any punitive damages award here—and certainly, a $20 million award—violated the Fourteenth Amendment's Due Process Clause. *See* Monsanto Br. 80-84. Hardeman presents no persuasive argument to the contrary.

First, as just explained, Monsanto's behavior—selling Roundup without a cancer warning in good faith and in accordance with the scientific and regulatory consensus regarding glyphosate—was not reprehensible in any sense. Hardeman's response is that compliance with regulatory standards is insufficient to avoid punitive damages. Br. 94, 102. But the regulatory standards in this case reflected

prevailing scientific evidence that glyphosate is not carcinogenic, and Monsanto, which had no knowledge to the contrary, acted accordingly. For Monsanto to have done so was neither blameworthy nor reprehensible.

The primary case Hardeman invokes, *Silkwood v. Kerr-McGee Corp.*, 769 F.2d 1451 (10th Cir. 1985), was decided under Oklahoma law[24] and does not address federal due process standards for punitive damages awards, which were articulated by the Supreme Court a decade later. *See, e.g.*, *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003). It thus has no bearing on the scope of those demanding constitutional limits. And *Silkwood* involved radiation poisoning caused by misplaced nuclear material, 769 F.3d at 1455, a substance that, unlike Roundup, is universally acknowledged to be dangerous to human health.

Second, the $20 million punitive damages award does not bear a "reasonable relationship" to the already-substantial $5 million compensatory damages award. The Supreme Court has explained that in cases like this one, where "compensatory damages are substantial, then a lesser ratio, *perhaps only equal to compensatory damages*" are permissible under the Due Process Clause. *See State Farm*, 538 U.S.

[24] Oklahoma, unlike California, did not require a showing of despicable or reprehensible conduct. 769 F.2d at 1455 (in Oklahoma, "[t]he requisite malice [for punitive damages] may be inferred from gross negligence … or a reckless disregard for the safety of others").

at 425-426 (emphasis added). While Hardeman's illness was serious, he has been awarded millions of dollars in compensatory damages. He fails to explain why this case is so unusual as to merit quadruple punitive damages.

Third, there can be no comparison to "civil or criminal penalties that could be imposed for comparable misconduct," *BMW*, 517 U.S. at 583, because Monsanto did not behave improperly given scientific knowledge at the time, *see* Monsanto Br. 84. Hardeman's primary response—that Monsanto intentionally refused to study Roundup's carcinogenicity, *see* Br. 103—is inaccurate, as discussed above, *see supra* pp. 55-56. And while Hardeman clings to the district court's speculation that it is "possible" that civil fines could be high, he ignores the court's actual holding—that this guidepost "is not particularly helpful here." *Compare* Hardeman Br. 103 *with* ER10.

B. Hardeman Has Not Established That The District Court's Reduction Of The Punitive Damages Award Should Be Set Aside

The district court correctly held that, in light of Monsanto's conduct, which was supported by the views of regulatory agencies across the world and did not involve actual knowledge or concealment of carcinogenicity, Hardeman was not entitled to $75 million in punitive damages—*fifteen times* greater than the $5 million compensatory damages award. ER7-10. On his cross-appeal, Hardeman raises three points to argue he was entitled to that massive award. Br. 96-101. None is persuasive.

First, Hardeman contends that this case is one of the "'few'" that the Supreme Court has indicated may constitutionally exceed a single-digit ratio between compensatory and punitive damages. *See* Br. 97-98 (quoting *State Farm*, 538 U.S. at 425). That assertion is unsustainable: As noted above, Monsanto did not behave reprehensibly and Hardeman's factual arguments regarding Monsanto's purported failure to test the carcinogenicity of Roundup are meritless. *See supra* pp. 51-57.

Hardeman claims (at 98 n.38) that "[m]any cases have approved punitive damages awards far in excess" of a 15:1 ratio, but he identifies only three, none of which helps him. Two predate the Supreme Court's articulation of due process principles governing punitive damages, and all three involved compensatory damages awards far lower than here. *See Neals v. Farmers Ins. Exchange*, 582 P.2d 980, 990 (Cal. 1978) ($10,000 compensatory damage award); *Weeks v. Baker & McKenzie*, 74 Cal. Rptr. 2d 510, 514 (Ct. App. 1998) ($50,000); *Mathias v. Accor Economy Lodge*, 347 F.3d 672, 676, 687 (7th Cir. 2003) ($5,000).[25]

[25] Indeed, *Mathias* observed that an award of "very substantial compensatory damages … greatly reduce[s] the need for giving [a plaintiff] a huge award of punitive damages ($145 million) as well in order to provide an effective remedy." 347 F.3d at 677. The award was justifiable in that case precisely because the compensatory damages were small, even though the defendant's conduct was "outrageous." *Id.*

Second, Hardeman disputes two of the district court's conclusions—that there is an ongoing scientific debate over whether glyphosate causes non-Hodgkin's lymphoma, and that Monsanto had no actual knowledge of glyphosate's purportedly carcinogenic nature—arguing they are in tension with the jury's verdict. *See* Hardeman Br. 100-101. But judges have a constitutional responsibility to scrutinize whether a punitive damages award is consistent with due process. *See Cooper Indus, Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 434-435 (2001). The due process analysis is a question of law reserved to judges. *See Bains LLC v. Arco Prods. Co.*, 405 F.3d 764, 777 (9th Cir. 2005) ("The level of punitive damages is not a finding of 'fact' that must be determined by the jury; it may be determined de novo by the court.").

Finally, Hardeman contends the court failed to account for Monsanto's financial condition. Br. 99-100. But while a defendant's financial condition may be considered in assessing punitive damages, it "cannot justify an otherwise unconstitutional damages award." *State Farm*, 538 U.S. at 427. And Hardeman's argument (at 99) that $75 million is "pocket change" for Monsanto ignores that tens of thousands of pending cases allege that Roundup causes non-Hodgkin's lymphoma. Whereas a jury must focus only on the case before it, a court reviewing the constitutionality of a punitive damages award must consider the implications of affirming an award of this size in all of them. Setting a precedent

that could enable thousands of litigants *each* to recover $75 million in punitive damages based on the same conduct would threaten the solvency of any company. Such a result would "further[] no legitimate purpose and constitute an arbitrary deprivation of property." *See State Farm*, 538 U.S. at 417.

CONCLUSION

The district court's judgment should be reversed. If this Court reaches the cross-appeal, the order reducing the punitive damages award should not be disturbed.

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Respectfully submitted,

s/ Seth P. Waxman

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g)(1), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f), the brief contains 14,000 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 365 in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

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CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of June 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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