No. 21-241

IN THE

Supreme Court of the United States

MONSANTO COMPANY,

Petitioner,

v.

EDWIN HARDEMAN,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR PETITIONER

THOMAS G. SPRANKLING
WILMER CUTLER PICKERING HALE AND DORR LLP
2600 El Camino Real
Suite 400
Palo Alto, CA 94306

SETH P. WAXMAN
Counsel of Record
DANIEL S. VOLCHOK
CLAIRE H. CHUNG
JAMES D. BARTON
SAMUEL M. STRONGIN
ALLISON M. SCHULTZ
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000
seth.waxman@wilmerhale.com

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INTRODUCTION

Respondent claims that the petition (1) seeks only error correction and (2) raises issues that matter only to Monsanto. Both assertions are wrong. The decision below is erroneous under this Court's precedent—an independent basis for review under this Court's Rule 10(c)—but as the petition explained, it also conflicts with other circuits' decisions. And the many amicus briefs supporting the petition show that the Ninth Circuit's errors would cause far-reaching harm—including "stifl[ing] innovation, driv[ing] up prices for consumers, and constrain[ing] the job-creating powers of American business," Chamber of Commerce Br. 5.

I. Nothing in respondent's opposition changes the fact that the Ninth Circuit's decision transfers control over a product's safety warning from the federal agency Congress chose to a California jury. That approach—which could create "50 different labeling regimes prescribing the … wording of warnings," *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005)—is barred by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and cannot be squared with this Court's and lower courts' interpretation of materially identical preemptive language in other federal statutes. Even respondent concedes (Opp.28) that the decision below permits a "patchwork of state-law labeling regimes for pesticides," creating consumer confusion and imposing substantial expense on the companies that make the products and on those that sell them, *see*, *e.g.*, Retail Litigation Center Br. 3 (discussing suit against a neighborhood hardware store).

II. Respondent has no persuasive answer to Monsanto's argument that the Ninth Circuit endorsed a

lenient standard for the admission of expert testimony that deviates from the law of other circuits and is not faithful to Federal Rule of Evidence 702 and *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). And by relieving experts of the need to establish that their opinions are rooted in reliable principles and methodology, the Ninth Circuit's standard will have a profound, inequitable impact on mass-tort and product-liability cases across the western United States.

ARGUMENT

I. THE DECISION BELOW DEPARTS FROM THIS COURT'S PRECEDENT AND ENSURES DISUNIFORMITY IN PESTICIDE LABELING

A. There Is No Meaningful Distinction For Purposes Of This Case Between Glyphosate And Roundup

Respondent attempts to evade review with an argument that is neither properly before this Court nor correct—i.e., EPA "has not reached any conclusions as to the carcinogenicity of" Roundup, as opposed to glyphosate. Opp.6-9. The Ninth Circuit made no such distinction and the district court squarely rejected it, explaining that respondent had provided "[in]sufficient evidence for a jury to conclude that" Roundup was carcinogenic even if "glyphosate alone is not." C.A.E.R.15 n.3.; *see also* C.A.E.R.128 (respondent's evidence was "exceedingly thin"). In any event, EPA approves each *pesticide's* formulation, 7 U.S.C. §136a(c)(5)(D), and it has approved Roundup labeling 44 times since 1991, Pet.2, 6 n.1. That alone preempts the verdict here.

B. The Ninth Circuit's Express-Preemption Holding Merits Review

The decision below conflicts with this Court's precedent and sows confusion regarding how to interpret both FIFRA and similar language in other statutes. Respondent's counterarguments are unpersuasive.

1. The Ninth Circuit's ruling conflicts with *Bates* and *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2007), because it permits juries to require a cancer warning for a pesticide that EPA has deemed inappropriate. Pet.12-18. As this Court has recognized, FIFRA's preemption provision should be interpreted consistently with the materially identical provision in the Medical Device Amendments (MDA) that this Court addressed in *Riegel*. *See Riegel*, 552 U.S. at 324 (citing *Bates* to interpret the MDA); *Bates*, 544 U.S. at 447 (citing MDA case law to interpret FIFRA). Accordingly, *Riegel*'s holding—that under the MDA, an agency's safety assessment of a specific product preempts contrary state law—should have governed this case.

Respondent does not dispute that the FIFRA and MDA preemption provisions are materially identical. Instead, he cites a different section of FIFRA, 7 U.S.C. §136a(f)(2), which provides that "registration of an article" is not "a defense for the commission of any offense" under FIFRA. Opp.3; *see also id.* at 22 n.5, 23, 27. (Page 23 of respondent's opposition quotes §136a(f)(2), but mistakenly cites §136v(a).) But as Monsanto explained (Pet.17-18), §136a(f)(2) is irrelevant to preemption of state law because it applies only to "offense[s]" *under FIFRA*. Indeed, in placing dispositive weight on §136a(f)(2), the Ninth Circuit split

with the Fifth, which correctly holds that §136a(f)(2) has "no bearing on" preemption, *MacDonald* v. *Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994).

Respondent also argues that *Bates* is inapposite because it purportedly held that state-law labeling requirements are preempted only when they directly conflict with a regulation. Opp.21-22. But *Bates* explained that if EPA determines that a particular label should include one warning (e.g., "CAUTION") but a jury concludes that state law requires another (e.g., "DANGER"), state law is preempted despite the lack of a direct conflict with a regulation. 544 U.S. at 453. Importantly, EPA does not make such wording decisions via regulation. Rather, it does so through a process *prescribed* by regulation. *See* 7 U.S.C. §136a(c)(5)(B); 40 C.F.R. §§156.62, 156.64. And each pesticide-specific determination made through that process constitutes "federal law" that manufacturers and sellers must obey. U.S. C.A. Amicus Br. 1. Respondent's reading of *Bates* thus cannot be correct.[1]

Respondent also argues (Opp.23) that *Riegel*'s holding (that a federal agency's labeling approval preempts state law) cannot apply to FIFRA because that would mean that *Bates* erred in finding no preemption. But *Bates* remanded rather than resolving the preemption question. 544 U.S. at 453. More importantly, *Bates* involved a statement regarding the product's efficacy, not its safety. That distinction mattered because EPA had taken no position on effectiveness, and in fact had promulgated a regulation

[1] To the extent the tentative statements respondent cites from the Third and Tenth Circuits (Opp.17) indicate that those courts view the scope of preemption differently, that underscores the need for review to clarify *Bates*'s meaning.

waiving its right to do so. *See Bates*, 544 U.S. at 435-436, 440; *see also* U.S. C.A. Amicus Br. 23-24 (EPA's "non-review of the pesticides' efficacy claims" in *Bates* meant there was no "established … legal standard for state law to conflict with").

2. The Ninth Circuit's express-preemption ruling also merits review because it deepens uncertainty over how to interpret the words "in addition to or different from"—language that recurs across federal statutes. Pet.18-20. The Ninth Circuit's reading of those words indisputably splits from four other circuits' reading of the virtually identical language in the MDA. Respondent's primary answer (Opp.18-20) is that the split is unworthy of review because the other circuits' cases involve a different statute. As explained, however, this Court routinely treats the MDA and FIFRA preemption provisions as interchangeable. *See supra* p.3.[2]

C. The Ninth Circuit's Conflict-Preemption Ruling Warrants Review

The decision below is inconsistent with this Court's holding that state law is implicitly preempted if (1) there is "clear evidence" that the relevant agency would not approve a warning required under state law, or (2) the warning could not have been added without prior approval. Pet.20-24 (citing *Merck Sharp & Dohme Corp.* v. *Albrecht*, 139 S. Ct. 1668, 1678-1679

[2] Respondent also suggests (Opp.20) that any confusion about the meaning of "in addition to or different from" should be addressed in an MDA case. But the MDA cases are uniform (and correct); the split arises from the Ninth Circuit's erroneous interpretation of *FIFRA*.

(2019), and *PLIVA Inc.* v. *Mensing*, 564 U.S. 604, 617-619 (2011)).

Respondent's first argument on this point is one that not even the Ninth Circuit embraced: that implied preemption is categorically inapplicable in FIFRA cases. Opp.24. And his lone authority is a two-Justice opinion, which itself does not support him because it recognized only that *Bates* had "decline[d] *to address*" implied preemption's applicability. *Bates*, 544 U.S. at 458 (Thomas, J., concurring in judgment and dissenting in part) (emphasis added). And it makes sense *Bates* would decline to do so, as an express-preemption provision "does not bar the ordinary working of conflict pre-emption principles." *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 869 (2000).

Next, respondent argues that *Merck* is inapposite because EPA might well approve a cancer warning if asked. Opp.24-26. EPA disagrees, explaining below that implied preemption "would … bar Mr. Hardeman's tort theory[] to the extent his theory is based on a labeling requirement." U.S. C.A. Amicus Br. 18 n.14. Indeed, EPA has repeatedly approved labeling for glyphosate-based products without any cancer warning, noting that such a warning would "constitute a false and misleading statement." Pet.6-9. Moreover, EPA's regulations require it to evaluate whether a pesticide is carcinogenic and, if so, to impose specific protective labeling requirements. 40 C.F.R. §§158.500, 156.60-156.70. That EPA has not applied those requirements to Roundup or any other glyphosate-

based product further underscores that EPA has rejected the state-law warning the verdict mandates.[3]

Finally, respondent argues that *PLIVA* is inapposite because it involved the Food, Drug, and Cosmetics Act (FDCA). Opp.27. But the only difference he identifies between FDCA and FIFRA is §136a(f)(2), which as discussed has no bearing on preemption, *see supra* pp.3-4. Respondent notably does not defend the Ninth Circuit's misunderstanding of EPA's procedures for allowing non-substantive changes to a label without prior approval. *See* Pet.23-24 & n.5. And while he contends (Opp.26-27) that "the Ninth Circuit's opinion did not turn on this point," the Ninth Circuit's error was the only reason the court gave for why Monsanto could comply with both federal law and the verdict here, Pet.App.20a-22a. That ruling will thus preclude all future litigants in the Ninth Circuit from arguing implied preemption under *PLIVA* in FIFRA cases.

D. As Respondent Concedes, The Decision Below Would Permit A "Patchwork Of State-Law Labeling Regimes For Pesticides"

The Ninth Circuit's ruling allows individual juries to dictate the wording of pesticide labels, meaning that any State can disregard EPA's expert decisions based on the views of a handful of jurors. Pet.24-26. Respondent does not dispute this. Instead, he argues that "Congress intended to tolerate … a 'crazy quilt' of different labeling standards," and that FIFRA's

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[3] Respondent notes (Opp.6-9, 24-25) that EPA approved cancer warnings in the past, but omits that this apparently happened only twice, each time because of a "mistake[]." U.S. C.A. Amicus Br. 18-19 n.14.

express-preemption provision ensures only that States use the same "'color' and 'font size'" on labels. Opp.28 (citing *Bates*). But what *Bates* said is that FIFRA "pre-empts competing state labeling standards … prescribing the color, font size, *and wording* of warnings." *Bates*, 544 U.S. at 452 (emphasis added). The "wording of warnings" is precisely what this case is about, and the Ninth Circuit's allowance of "competing state labeling standards" regarding such wording, *id.*, simply cannot be reconciled with *Bates*.

II. THE NINTH CIRCUIT'S UNIQUELY LENIENT ADMISSIBILITY STANDARD WARRANTS REVIEW

The decision below applied a standard for the admission of expert testimony that diverges from other circuits and is inconsistent with the *Daubert* doctrine and Federal Rule of Evidence 702. Pet.26-36. Respondent does not deny that certiorari is warranted if the Ninth Circuit strayed from other circuits' standards, or from *Daubert* and Rule 702. Instead, he argues that (1) the Court should take the Ninth Circuit's word that its admissibility standard is consistent with other circuits' and (2) his experts did not impermissibly rely on clinical experience or unverified intuition. Each claim is wrong.

A. Respondent Cannot Reconcile The Circuits' Divergent Admissibility Standards

Respondent contends (Opp.31) that there is no circuit conflict because the Ninth Circuit characterized its *Daubert* standard as "no different from other circuits." But courts cannot insulate their decisions from review by simply proclaiming their correctness. And as the district court explained, Ninth Circuit cases are "impossible to read without concluding that" courts

in that circuit "must be more tolerant of borderline expert opinions" and should admit "a wider range of expert opinions (arguably much wider)" than courts elsewhere. Pet.App.84a; *accord* Chamber of Commerce Br. 18-21; Washington Legal Foundation Br. 7-15; PLAC Br. 21-22; Atlantic Legal Foundation Br. 19-20.

As Monsanto explained, moreover (Pet.30-32), the Ninth Circuit's attempt to distinguish conflicting cases *factually* does not change the disparate *legal standards* those courts apply. For example, the Sixth Circuit views experts' clinical experience with healthy skepticism because "what science treats as a useful but untested hypothesis the law should generally treat as inadmissible speculation." *Tamraz* v. *Lincoln Elec. Co.*, 620 F.3d 665, 677 (6th Cir. 2010). By contrast, the Ninth Circuit defers to experts' clinical experience on the theory that "untested hypothes[e]s" (encompassed within the category of "art," Pet.App.83a-84a) are part of medicine. Thus, in the Ninth Circuit, when "doctors who stand at or near the top of their field and have extensive clinical experience with" the illness at issue "are prepared to give" causation opinions, "*Daubert* poses no bar based on their principles and methodology." Pet.App.26a-27a.

Similarly, the Tenth Circuit requires that experts seeking to offer causation opinions address "a large body of contrary epidemiological evidence" with a reliable methodology. *Norris* v. *Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005). In contrast, the Ninth Circuit had no problem with respondent's experts identifying glyphosate as the cause of respondent's illness despite the district court's finding that the evidence "seems too equivocal," including because "the largest and most recent" study evinces "no link at all." Pet.App.93a.

Despite these different legal standards across the circuits, respondent asserts (Opp.14, 30, 32) that the Ninth Circuit applies "the universal *Daubert* standard" because it recited the language of *Daubert* and Rule 702, namely that an expert's opinion must be "grounded in the methods of science." But reciting the correct standard is not enough; courts must actually *apply* it. *Cf. Price* v. *Vincent*, 538 U.S. 634, 639 (2003) (reversing a decision that "recited" the correct standard but applied a different one). The standard the Ninth Circuit applied here was assuredly not the one it recited.

Respondent further argues that the Sixth and Tenth Circuits reached "different outcomes" than the decision below due to "factual differences"—specifically, that the expert opinions in *Tamraz* and *Hall* were speculative or wrong, whereas respondent's experts' opinions were purportedly supported by evidence. Opp.32-34 (emphases omitted). Insofar as respondent is defending the experts' *conclusions* in those cases, that misses the mark; admissibility is not about conclusions, but about the methodology for reaching those conclusions. In any event, the Sixth and Tenth Circuits applied an admissibility standard that, if employed here, very likely would have rendered the testimony of respondent's key causation expert (Dr. Dennis Weisenburger) inadmissible. Pet.28-32.

B. The Decision Below Contravenes *Daubert* And Rule 702

1. Respondent argues (Opp.38) that the Ninth Circuit "always requires experts to employ a reliable methodology, no matter their clinical experience or other qualifications." To the contrary, the court here expressly reaffirmed that "*Daubert* poses *no bar* based

on … principles and methodology" so long as a testifying doctor is qualified and experienced. Pet.App.26a-27a (emphasis added). That deference is particularly evident in how the Ninth Circuit addressed differential diagnoses regarding specific causation. Although the court has ostensibly required experts to "provide reasons for rejecting alternative hypotheses," Opp.39, it has also held that mere clinical experience can provide a reason, *see Messick* v. *Novartis Pharms. Corp.*, 747 F.3d 1193, 1198 (9th Cir. 2014); *see also* Pet.App.27a (noting that it is particularly appropriate for experts to rely on clinical experience in conducting differential diagnosis).[4]

Respondent emphasizes (Opp.39-40) that a *Daubert* inquiry requires "flexibility." But *Daubert's* flexibility is relative to the rigid test that preceded it, Pet.34, and, in any event, that flexibility speaks to the district court's discretion to decide reliability, *see Kumho Tire Co.* v. *Carmichael*, 526 U.S. 137, 141-142 (1999). Yet Ninth Circuit precedent wrongly limits district courts' discretion in that regard, holding that trial courts "*must* be more tolerant of" and "*should* typically admit" borderline expert opinions. Pet.App.83a-84a (emphases added).

2. Respondent's argument that his experts' opinions had ample support is indefensible. He contends (Opp.35) that "only one expert,"

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[4] Besides *Messick*, respondent cites (Opp.39) only one even semi-recent precedential decision for the point that the Ninth Circuit requires experts to provide reasons for rejected alternative hypotheses. But that decision—*Avila* v. *Willits Environmental Remediation Trust*, 633 F.3d 828 (9th Cir. 2011)—addressed the point only in dicta, as the expert was excluded as unqualified, *see id.* at 839.

Weisenburger, relied on clinical experience. But Weisenburger is the only expert who testified on specific causation, meaning respondent could not have established causation without him. Pet.29. And while respondent asserts (Opp.35) that Weisenburger invoked clinical experience "merely to *supplement* the larger body of evidence," Weisenburger himself admitted both that he could not "identify *any* peer-reviewed published article" characterizing glyphosate as a "generally accepted" cause of non-Hodgkin's lymphoma and that he was making a "subjective decision" regarding the level of exposure sufficient to make glyphosate the cause, Pet.32-33 (emphasis added).

Contrary to respondent's suggestion, that "subjective decision" cannot be justified by Weisenburger's assertion that he relied on epidemiological data. As Monsanto explained (Pet.34), Weisenburger's analysis prioritized what respondent calls "two limited studies that did not adjust for confounding" (Opp.36), and did so without offering a sound reason for disregarding the wealth of contrary reliable data. That *compounds* the subjective nature of his testimony. Respondent's argument that Weisenburger also consulted other "epidemiological *studies*" that are "fully adjusted," *id.* (emphasis added), is misleading. His three appendix citations are all to the same study, one that even his experts "implicitly acknowledge[d]" was problematic, Pet.App.119a, because it focused on people diagnosed with non-Hodgkin's lymphoma at a time when glyphosate would not likely have been the cause. That makes any causal opinions based on that study (in the district court's words) "more difficult to swallow." Pet.App.121a.

In sum, despite the regulatory consensus that glyphosate is not carcinogenic, the Ninth Circuit—

because it employed an admissibility standard that materially differs from that of other circuits—allowed respondent's experts to tell the jury, based on their purported clinical experience, that glyphosate caused his illness. Pet.26-28. That decision, like the Ninth Circuit's preemption ruling, merits review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

THOMAS G. SPRANKLING
WILMER CUTLER PICKERING
HALE AND DORR LLP
2600 El Camino Real
Suite 400
Palo Alto, CA 94306

SETH P. WAXMAN
Counsel of Record
DANIEL S. VOLCHOK
CLAIRE H. CHUNG
JAMES D. BARTON
SAMUEL M. STRONGIN
ALLISON M. SCHULTZ
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, D.C. 20006
(202) 663-6000
seth.waxman@wilmerhale.com

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