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

SUPPLEMENTAL BRIEF FOR PETITIONER

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INTRODUCTION

The government's brief provides no sound reason to deny review of either question presented.

As to express preemption, the government reverses course—based on a "change in Administration" (U.S. Br. 6)—from the position it took below. Now, the government rejects this Court's conclusion in *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005), regarding the "important[] role" that the express-preemption provision in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) plays in ensuring nationwide uniformity of pesticide labeling, *id.* at 452. *Bates* explained that FIFRA "pre-empts competing state labeling standards … that would create" a wholly unworkable system, namely "50 different labeling regimes prescribing the … wording of warnings" on pesticide labels. *Id.* The government, however, now embraces that 50-state approach, citing with approval a new letter from the Environmental Protection Agency (EPA) that endorses a California-specific label for glyphosate-based pesticides.

That label, moreover, recites a finding by the International Agency for Research on Cancer (IARC) that glyphosate *is* carcinogenic, before noting EPA's own finding that it is *not*. *See* U.S. Br. 14 (citing Letter (Apr. 8, 2022), tinyurl.com/mth52bbe ("April 2022 letter")). The notion that California—and potentially 49 other States—can marginalize in this way EPA's "repeated statements that glyphosate is unlikely to be carcinogenic to humans [and] its approval of [glyphosate-based] pesticide labeling without cancer warnings" (U.S. Br. 13) cannot be squared with either FIFRA or *Bates*. FIFRA prohibits state-imposed labeling requirements that are "in addition to or

different from" labeling requirements imposed "under" FIFRA, 7 U.S.C. §136v(b), and neither the government nor anyone else has ever suggested that FIFRA requires a cancer warning on glyphosate products. California's requirement of such a warning is thus unquestionably "in addition to or different from" the labeling that FIFRA requires. *Id.* *Bates*, meanwhile, explicitly stated that a state-law mandate for a more aggressive warning than EPA's "more subdued" label—precisely what California's label imposes—"would be pre-empted." 544 U.S. at 453.

The government's arguments regarding conflict preemption are also infirm. For example, EPA's April 2022 letter, on which the government relies, supports Monsanto's position that California law is preempted because Monsanto could not have "independently do[ne] … what state law requires," *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 620-621 (2011)—i.e., unilaterally add a cancer warning to the Roundup label. That is because the letter states (at 1) that California's wording cannot be used until it is "approved by EPA." Moreover, the government has no answer to the fact that when respondent Edwin Hardeman stopped using Roundup in 2012 (three years before the IARC report and five years before California's determination that Roundup may be carcinogenic), all available evidence—including "EPA's longstanding assessment" that glyphosate is likely not carcinogenic to humans, U.S. Br. 15—indicated that EPA would refuse to approve the requested cancer warning. This "clear evidence" demonstrates implicit preemption. *Wyeth* v. *Levine*, 555 U.S. 555, 571 (2009).

Finally, as to the admissibility of respondent's expert testimony, the government repeats respondent's error of trying to wave away the circuit

conflict by pointing to *factual* distinctions among the cases, without addressing the fact that the Ninth Circuit's *legal* standard for admission is both a clear outlier, *see* Pet. App. 84a, and inconsistent with this Court's precedent. This division warrants review.

ARGUMENT

I. PREEMPTION

A. Express Preemption

The government largely just reiterates the Ninth Circuit's preemption-related reasoning, the flaws in which Monsanto's petition and reply addressed. But the fact that the United States blesses the decision below, and thereby announces a new national policy that will govern every EPA pesticide-labeling decision going forward, only underscores the need for review.

1. Contrary to its position below, the government argues (Br. 8-9) that federal and California law are "parallel[]" for FIFRA-preemption purposes because both generally require manufacturers to include warnings about health risks. That narrow reading of FIFRA's "in addition to or different from" language is inconsistent with *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2007), which interpreted materially identical language to mean that an agency's safety assessment of a specific product preempts contrary state law, *id* at 323, 330. Nor can the government's argument be reconciled with *Bates*, which established that FIFRA preemption turns on whether state law requires a specific warning—for a specific pesticide label—that EPA has not mandated. Pet. 15-17; Reply 3. The government notes (Br. 9) that EPA has not promulgated a *regulation* prohibiting a cancer warning on glyphosate-based products, but EPA never makes

product-specific wording decisions via regulation. It does so through a process *prescribed* by regulation. Reply 4. And once approved and registered, a "pesticide's label is a legal document[:] The label is the law!" EPA, *Pesticide Registration Manual*, tinyurl.com/EPAregistrationmanual (updated May 17, 2022); *accord* EPA, *Introduction To Pesticide Labels*, tinyurl.com/yc5wfxax (updated May 3, 2021) ("Unlike most other types of product labels, pesticide labels are legally enforceable[.]").

The government objects (Br. 11-12) that EPA "does not typically use the registration process to address th[e] harms [associated with long-term exposure] by requiring chronic-risk warnings on pesticide's labeling." The government cites no authority for this factual assertion—one that constitutes another reversal for the government, which explained below (C.A. Br. 24) that "carcinogenicity is a risk that EPA indisputably *does (and did)* evaluate under FIFRA." And even if EPA does not *always* address potential carcinogenicity through labeling, it has done so here, exhaustively studying glyphosate for decades and repeatedly deeming a cancer warning on glyphosate-based products unwarranted. Pet. 6-9. This conclusion has been reaffirmed by numerous administrations, including the current one. *Id.*

Lastly, the government's statement (Br. 10) that FIFRA does not "specifically address warnings for chronic health risks like carcinogenicity" is a red herring. FIFRA and its implementing regulations require EPA to ensure a pesticide poses *no* unreasonable risk of adverse effects on human health before permitting it to be registered. Pet. 4-5. The government identifies no exception to that mandate for "chronic health risk" warnings. Indeed, a pesticide is

misbranded if labeling is "[in]adequate to protect health." *E.g.*, 7 U.S.C. §136(q)(1)(F). And EPA has repeatedly placed such warnings (including cancer warnings) on other pesticides.[1]

2. The government denies that its position is inconsistent with *Bates*, for two reasons. Neither has merit.

First, the government attempts to distinguish *Bates*'s explanation that "a failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of … 'CAUTION' would be pre-empted," 544 U.S. at 453, on the ground that mandating "DANGER" would be "'inconsistent with' a specific EPA regulation," U.S. Br. 10 n.1, 17-18. That is incorrect; the regulation *Bates* cited (40 C.F.R. §156.64 (2004)) merely identified the general characteristics of pesticides that would warrant a "DANGER," "CAUTION," or "WARNING" label. The regulation standing alone does not require EPA to apply particular wording to a particular pesticide and thus creates no conflict with state law. Rather, the regulation applies to "*[a]ny* pesticide product" that fits the criteria (a finding that would logically have to be made by EPA) and, in any event, leaves the ultimate choice of wording to "the Agency['s] determin[ation]" in some instances. 40 C.F.R. §156.64(a), (b)(1) (2004) (emphasis added). A conflict with state law would arise

[1] *E.g.*, https://www3.epa.gov/pesticides/chem_search/ppls/000524-00314-20070927.pdf at 2 (Alachlor); https://www3.epa.gov/pesticides/chem_search/ppls/083070-00011-20150115.pdf at 2 (Advan Minerva Duo); https://www3.epa.gov/pesticides/chem_search/ppls/061470-00001-20140911.pdf at 6 (Coal Tar Creosote).

only where EPA decided that a specific pesticide label should say "CAUTION."[2]

Second, the government notes (Br. 10-11) that *Bates* permitted litigation of a failure-to-warn claim predicated on the defendant's failure to include "cautionary language" that did not appear on the EPA-approved label. But *Bates* involved pesticide *efficacy* rather than safety, a critical distinction because EPA had not evaluated statements regarding efficacy and indeed had promulgated a regulation waiving its right to do so. Reply 4-5; *accord* U.S. C.A. Amicus Br. 23-24. While the government says (Br. 10 n.1) that *Bates* did not expressly limit its ruling to efficacy cases, that is irrelevant. This Court issues decisions based on "[t]he record facts before" it, *Capitol Square Review & Advisory Bd.* v. *Pinette*, 515 U.S. 753, 760 (1995), and has cautioned that questions "neither brought to the attention of the court nor ruled upon"—here, *Bates*' applicability outside the context of efficacy statements—"are not to be considered as having been … decided," *Cooper Indus., Inc.* v. *Aviall Servs., Inc.*, 543 U.S. 157, 170 (2004).

3. The government next attempts (Br. 17-19) to distinguish *Riegel* (and various circuit decisions) on the ground that they interpreted the Medical Device Amendments (MDA) rather than FIFRA. But as the government does not dispute, the two statutes' express-preemption provisions are materially identical—so much so that this Court has relied on

[2] The government also cites (Br. 18) a regulation not discussed in *Bates*—40 C.F.R. §156.62 (2004)—which the government says "classifies pesticides into various toxicity categories." That too is wrong. The regulation does not classify specific pesticides; it lays out metrics for EPA to determine pesticides' toxicity levels.

MDA case law to interpret FIFRA and vice versa. Reply 3; *see* Pet. 18.

The government contends, however (Br. 17-19), that FIFRA is different because 7 U.S.C. §136a(f)(2) provides that registration of a pesticide is "prima facie evidence" that the pesticide's labeling "comp[lies] with the registration provisions of this subchapter." The government admits (Br. 8) that §136a(f)(2) "does not directly address preemption of state law"; *see also MacDonald* v. *Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994) (§136(f)(2) has "no bearing on" preemption). It nonetheless asserts (Br. 8-9) that "the fact that 'EPA's labeling determinations are not dispositive of FIFRA compliance' supports the court of appeals' conclusion that … those determinations 'similarly are not conclusive'" for preemption. But in fact, the opposite is true: That §136a(f)(2) imposes an express limit on the effect of registration "cautions against inferring the same limitation in another provision," i.e., the preemption provision. *State Farm Fire & Cas. Co.* v. *United States ex rel. Rigsby*, 137 S. Ct. 436, 442 (2016) (quotation marks omitted). In any event, Monsanto's preemption argument turns not on registration alone but also on the fact that EPA has consistently found that no cancer warning is necessary and that Monsanto's label complies with that determination. Pet. 17.

The government also says (Br. 19) the MDA differs from FIFRA because under the former "the federal agency ha[s] … directly addressed the question at issue in the state-law litigation." That is no distinction at all. As the government concedes (Br. 3, 12-13), EPA has squarely concluded that "glyphosate is unlikely to be carcinogenic to humans" and has consequently "registered pesticides containing glyphosate since

1974" without requiring any cancer warning. Those two points—whether glyphosate caused respondent's lymphoma and whether Monsanto should have included a cancer warning on Roundup's labeling—were the central questions for the jury to decide. *See* Opp. 11; Pet. App. 10a. In ruling for respondent, the jury thus necessarily rejected EPA's views on carcinogenicity and labeling.

4. Finally, the government appears to argue (Br. 20) that this case is not a good vehicle to address FIFRA's express-preemption provision because it is supposedly not clear that the jury's verdict required Monsanto to place a warning on a label. Yet again the government is reversing course, as it represented below—based on "the United States' review of the closing arguments"—that respondent sought "a label warning," i.e., that this case *was* litigated on the theory that respondent's claim mandated a label change. U.S. C.A. Amicus Br. 14-16 (emphasis omitted). Even its brief in this Court, moreover, quotes (Br. 20) the Ninth Circuit's statement that "Hardeman's complaint is based on Monsanto's failure to provide an adequate warning *on a label* under California law." Pet. App. 12a (emphasis added). There is no obstacle to this Court reaching and answering whether such a labeling claim is expressly preempted.

B. Conflict Preemption

The government fares no better in responding to Monsanto's two conflict-preemption arguments—each of which independently warrants certiorari.

1. The government makes no real attempt to defend the Ninth Circuit's holding that respondent's claim was not preempted under *PLIVA* because

Monsanto could have unilaterally altered Roundup's labeling to include a cancer warning. *Compare* U.S. Br. 16 *with* Pet. 23-24 *and* Reply 7. Rightly so: Even EPA's April 2022 letter (cited by the government to show that the agency would not necessarily reject a cancer statement for glyphosate) underscores (at 1) that the agency must "approve" such a warning before it can be added.

The government's only argument for why *PLIVA* does not apply to this action (and the myriad other Roundup cases pending in courts around the country) is the assertion (Br. 16) that the approval process in *PLIVA* "involved a different statute and a different regulatory-approval program." But the government fails to explain why this distinction matters. And, like respondent, the government 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; Reply 7.

2. The government contends that, for two reasons, Monsanto has not adduced the "clear evidence" (Br. 14) *Wyeth* requires that EPA would reject a cancer warning for glyphosate-based products. Each reason lacks merit.

First, the government argues (Br. 15) that EPA's April 2022 letter shows that Monsanto could have crafted a warning EPA would have approved in "the period during which respondent was exposed to glyphosate," by "advising consumers both of California's determination that Roundup poses cancer risks and of EPA's disagreement with that determination." That is manifestly wrong. Respondent's exposure to glyphosate ceased in 2012, U.S. Br. 15—five years before California categorized

glyphosate as carcinogenic and three years before the IARC report that triggered that categorization, *id.* at 3-4. Monsanto thus could not have known to propose the kind of warning the government suggests. And even if it had, all the available evidence from 2012 and earlier demonstrates clearly that EPA would have rejected it. Pet. 7. The government does not argue otherwise.

EPA's April 2022 letter, moreover, confirms that it would *still* reject any warning that goes further than noting that IARC has classified glyphosate as probably carcinogenic while EPA and others have found the opposite. The letter reaffirms (at 2) EPA's August 7, 2019 conclusion that a warning stating glyphosate is known to cause cancer would be misbranded—precisely the kind of warning respondent sought. *See* Pet. App. 7a (respondent alleged "Monsanto's failure to warn [him] of the carcinogenic risks of Roundup caused his" illness). It would have been (and indeed remains) impossible for Monsanto to comply with both federal law and the jury's verdict.

Second, the government contends (Br. 15) that EPA's 2019 letter "does not impose an independent legal barrier to inclusion of a cancer warning." Monsanto has never said it does. Rather, the 2019 letter *confirms* what has long been clear from EPA's practice: The agency believes glyphosate is not likely to be carcinogenic to humans and should not include a cancer warning, *see* Pet. 21-23.[3]

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[3] The government asserts (Br. 14) that the 2019 letter is "inconsistent with prior EPA approvals of manufacturer requests to include cancer warnings on the labels of their glyphosate-containing products." The government has explained, however,

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The government's new position empowers a California jury—as well as juries and legislatures in the 49 other States—to rewrite a product's safety warning, even with language contradicting the expert analysis of the agency to which Congress has delegated authority on this issue. That not only conflicts with FIFRA, *Bates*, and *Riegel*, but also will create confusion for consumers and businesses alike, Pet. 25-26; Retail Litigation Center ("RLC") Br. 8-16, and impose "substantial" and "onerous" costs on the thousands of businesses that are "subject to comprehensive regulatory schemes like FIFRA," Chamber of Commerce Br. 4-5. Avoiding all those consequences is why this Court's review is "imperative." *Id.* at 7; *see also* RLC Br. 4 ("This case is … not a first, small step on a slippery slope; it is a headlong tumble.").

II. ADMISSIBILITY OF EXPERT TESTIMONY

The government's arguments regarding the second question presented also fail.

The government dismisses the second question presented as involving "factbound application" of an established rule (Br. 20), denying that there are any "material[]" differences in the circuits' standards for the admission of expert testimony. But like the Ninth Circuit, the government distinguishes the conflicting circuit cases on their facts, ignoring those courts' disparate legal standards. Pet. 30-32; Reply 9-10. For example, while the Sixth Circuit treats "untested hypotheses" as "inadmissible speculation," *Tamraz* v. *Lincoln Elec. Co.*, 620 F.3d 665, 677 (6th Cir. 2010), the

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that (1) this happened only twice and (2) each time because of a "mistake." *See* Reply 7 n.3.

Ninth Circuit defers to such hypotheses as part of an expert's clinical experience, Pet. App. 83a-84a. The decision below even acknowledged that, for a qualified and experienced doctor, "*Daubert* poses no bar based on … principles and methodology," Pet. App. 26a-27a—a sweeping statement the government ignores. The district court was therefore correct to state that courts within the Ninth Circuit "must be more tolerant of borderline expert opinions" than courts elsewhere. Pet. App. 84a. That disuniformity in the application of *Daubert* and Federal Rule of Evidence 702 warrants review.

The government also suggests (Br. 22-23) that two proposed amendments to Rule 702 may provide "additional clarification." But it does not explain how—because there is no such explanation. One amendment involves allocation of the burden of persuasion for establishing admissibility, not the legal test for admitting expert testimony. U.S. Br. 23. The other merely "'emphasiz[es] that a trial judge must exercise gatekeeping authority.'" *Id.* That too does not address the standard for admission. Such generic "guidance," *id.*, will not correct the Ninth Circuit's divergence from other courts.

A quarter-century ago, this Court made clear the importance of trial courts' gatekeeping role in the admission of expert testimony. Pet. 26-27. Courts remain divided on precisely what gatekeeping entails. This case (which will provide the rule for thousands of other cases) provides an ideal opportunity to resolve that question.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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