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

BRIEF OF CROPLIFE AMERICA AS AMICUS CURIAE IN SUPPORT OF PETITIONER MONSANTO COMPANY

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INTEREST OF AMICUS CURIAE[1]

CropLife America, established in 1933, is the national trade association for the plant science industry, representing developers, manufacturers, formulators, and distributors of crop protection chemicals and plant science solutions for agriculture and pest management. CropLife America's member companies produce, sell, and distribute crop protection products, including herbicides, insecticides, and fungicides, which farmers use to provide consumers with abundant food and fiber. CropLife America is committed to safe and responsible use of the industry's products.

CropLife America's members are deeply invested in the discovery and development of new crop protection products and product uses. They are intimately familiar with the comprehensive regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq*. When the Environmental Protection Agency ("EPA") makes a registration decision, it does so based on a thorough review of current scientific and technical information provided at significant cost to manufacturers. CropLife America's member

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[1] CropLife America provided timely notice of its intention to file this brief to the parties, who consented in writing to the filing. No counsel for either party authored this brief in whole or in part, nor did any party or other person or entity other than amicus curiae, its members, and its counsel make a monetary contribution intended to fund its preparation or submission. Petitioner Monsanto Company's parent company, Bayer Corp., is a member of CropLife America, but apart from the dues it pays as a member, did not contribute money intended to fund preparation or submission of this brief.

companies spend, on average, $286 million and 11.3 years on research, development, and registration of crop protection products that reach the marketplace.[2] These registration costs have increased in recent years, largely due to increased environmental safety and toxicology data required by regulators.

CropLife America's member companies urge the Court to grant the Petition. Our member companies have a keen interest in FIFRA's legal framework, especially the interrelationship between federal and state pesticide regulation. Member companies manufacture and distribute products containing glyphosate—the most widely used herbicide in the world.

The preemption issues addressed in the Petition reach well beyond this particular case. This case was selected as a bellwether, and the decision here affects CropLife America member companies' liability in literally thousands of pending cases. The Court of Appeals' FIFRA preemption holdings have the potential to affect countless other products regulated under FIFRA.

The fundamental question here is whether EPA's determination that glyphosate product labels should not contain a cancer warning—based on EPA's repeated expert determination that glyphosate does not cause cancer—can be overridden by lay juries

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[2] *See* Phillips McDougal, "The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010-2014," A Consultancy Study for CropLife International, CropLife America and the European Crop Protection Association 3-4 (March 2016), croplife.org/wp-content/uploads/2016/04/Cost-of-CP-report-FINAL.pdf.

under state law. The Ninth Circuit erroneously held that FIFRA does not preempt California state failure-to-warn tort claims. Because the implications of that decision are so far reaching and its conclusion so gravely wrong, this Court should grant the Petition to review the judgment below.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Court should grant the petition to address important questions of federal preemption that the Court of Appeals erroneously decided, to resolve a conflict of law among the lower courts, and to harmonize a body of preemption law that lower courts have struggled to apply with any consistency.

The decision below is manifestly wrong on an issue of substantial public importance. EPA, the expert federal agency charged by Congress with evaluating pesticide safety under FIFRA, has repeatedly and emphatically declared that glyphosate-based pesticides *do not* cause cancer. Thus, no such warnings are permitted on the product label. Yet the decision below upheld a massive jury verdict, complete with punitive damages, on a state-law claim that Monsanto violated California law by selling glyphosate-based pesticides without the very warning that EPA found unnecessary and unsupported. That decision was contrary to this Court's precedents: Because Plaintiff's failure-to-warn claim directly contradicts EPA's authoritative pronouncements in the exercise of its labeling authority under FIFRA, it is preempted.

First, plaintiff's California failure-to-warn claims are expressly preempted by FIFRA's command that states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" that statute. 7 U.S.C. § 136v(b). In light of EPA's repeated determinations that glyphosate-based pesticides do not cause cancer, federal law does not require that such pesticides carry a cancer warning. Yet the premise of the verdict here is that California law requires that same warning. Such a different state law requirement is expressly preempted.

Second, the verdict is impliedly preempted because it is "impossible for a private party to comply with both state and federal requirements." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019). FIFRA prohibits a pesticide's sale unless it bears an EPA-approved label. EPA may approve a label only if it concludes that the label's statements are not false or misleading. Having repeatedly determined that glyphosate-based pesticides do not pose a cancer risk, EPA necessarily deems a warning that they *do* pose such a risk to be false and misleading. EPA therefore could not approve a label bearing such a warning and has explicitly stated as much.[3] Nor could a pesticide manufacturer unilaterally add a cancer warning to the label. Because it would be impossible for a manufacturer to comply with its federal-law duty *not* to include a cancer warning on the label while also

[3] EPA, Letter to Glyphosate Registrants on California Proposition 65, at 1 (Aug. 7, 2019) ("EPA Letter"), www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf.

complying with the state-law duty to warn, any such state-law duty is preempted.

The Ninth Circuit recognized that EPA's cancer determinations would normally have the force of law, but concluded that 7 U.S.C. § 136a(f)(2) deprives them of that force. That conclusion conflicts with the Fifth Circuit's recognition that § 136a(f)(2) "has no bearing" on federal preemption. *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1027 n.4 (5th Cir. 1994).

In any event, § 136(f)(2) does not control here. That provision reflects the fact that EPA may not review every labeling claim a manufacturer makes during product registration. In *Bates v. Dow Agrosciences LLC*, this Court remanded state-law claims based on the *efficacy* of a pesticide, while raising doubts that such claims would be preempted by EPA's registration decision, *where EPA had waived efficacy review and not passed on those claims at all*. 544 U.S. 431, 440 (2005). But where, as here, EPA has applied its scientific expertise to the most current evidence to make a more granular determination that glyphosate does not cause cancer, that determination *is* binding on the States.

Finally, the preemption issues here are both legally and socially important. Monsanto alone faces tens of thousands of claims like this one, with more than 5,000 cases currently pending in federal court. The Ninth Circuit's decision will cause significant confusion for manufacturers, who now face the uncertainty of competing—and diametrically opposed—state and federal label requirements. Moreover, permitting lay juries to force manufacturers to add *false* cancer warnings to

glyphosate-based pesticides would do immeasurable harm, including by threatening to force products that EPA has deemed safe and economically vital off the market. There is a real-world cost, in both economic and public health terms, to "crying wolf."

This Court should grant certiorari.

BACKGROUND

FIFRA is a "comprehensive regulatory statute" (*Ruckelshaus v. Monsanto Co.*, 467 U.S. 987, 991 (1984)), governing the sale, use, and labeling of "pesticides." FIFRA's definition of "pesticide" includes "any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant," 7 U.S.C. § 136(u), and thus encompasses glyphosate-based herbicides like Monsanto's Roundup products.

A. FIFRA Registration

FIFRA prohibits the sale of "any pesticide that is not registered." 7 U.S.C. § 136a(a). FIFRA and its implementing regulations require registrants to provide substantial scientific data to support a pesticide's safety and health effects, including studies relating to the likelihood that a particular pesticide could cause cancer. 7 U.S.C. §§ 136a(c)(1)(F) & (c)(2)(A); 40 C.F.R. § 158.500(d); *see generally* 40 C.F.R. pt. 158.

EPA "shall register a pesticide" only if it determines that, "when considered with any restrictions imposed," the pesticide meets four general requirements: 1) its composition is such as to warrant the proposed claims for it; 2) its labeling complies with FIFRA's requirements; 3) it will perform its intended function without unreasonable adverse effects on the

environment; and 4) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment. 7 U.S.C. § 136a(c)(5).

FIFRA defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment," a calculus that requires EPA to balance the "economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb). It also includes consideration of any "human dietary risk from residues that result from a use of a pesticide" on food inconsistent with Food, Drug & Cosmetic Act standards. *See id.* FIFRA allows EPA to waive data requirements pertaining to—and register a pesticide without reviewing—product efficacy. *Id.* § 136a(c)(5)(D); *see Bates*, 544 U.S. at 440. EPA cannot similarly waive review for adverse human health and environmental effects; it must conduct this searching review, including toxicology review, in every registration.

Congress requires EPA to reevaluate a pesticide at least once every 15 years to determine whether it continues to satisfy FIFRA's registration standards. *See* 7 U.S.C. § 136a(g); 40 C.F.R. § 155.40 *et seq.* This process involves a review of the applicable science under public notice and comment procedures. *See* 40 C.F.R. § 155.50.

B. FIFRA Labeling Requirements

A central focus of EPA's registration and registration review is the product's label. "Pesticide product labels provide critical information about how

to safely and legally handle and apply pesticides."[4] A "critical function of the label is to translate the results of the science evaluations into a set of conditions, directions, precautions, and restrictions that define who may use a pesticide, as well as where, how, how much, and how often it may be used."[5]

EPA's Label Review Manual notes that the accuracy of the label is "vital" to EPA's (and other agencies') management and mitigation of pesticide risks; to these agencies' enforcement of pesticide production, distribution, and use requirements; to registrants, including manufacturers and distributors; to applicators, who rely on the label for use instructions and hazard and safety information; and to the general public.[6]

FIFRA's regulations provide that a product label must include any "pertinent information which the [EPA] Administrator determines to be necessary for the protection of man and the environment." 40 C.F.R. § 156.10(*i*)(2)(x)(F); *see also id.* § 156.70(b). A product label "is required to bear hazard and precautionary statements for humans and domestic animals." *Id.* § 156.60. Any "[s]pecific statements pertaining to the hazards of the product and its uses must be approved by [EPA]." *Id.* § 156.70(c).

It is unlawful to distribute or sell any misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E). EPA will not

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[4] EPA, Office of Pesticide Programs, Label Review Manual at 1-2, www.epa.gov/sites/production/files/2021-02/documents/full-lrm_2-22-21.pdf.

[5] *Id.*

[6] *Id.*

register a pesticide unless it "has determined that the product is not misbranded . . . and its labeling and packaging comply with the applicable requirements" of FIFRA and its regulations. 40 C.F.R. § 152.112(f). A pesticide is misbranded if its labeling "bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular." 7 U.S.C. § 136(q)(1)(A); *see also* 40 C.F.R. § 156.10(a)(5). A pesticide is also misbranded if its label "does not contain a warning or caution statement which may be necessary and . . . is adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(G).

Once approved, a label must accompany the pesticide's sale, *id.* § 136j(a)(2)(A), and may generally be amended only with EPA's approval. 40 C.F.R. § 152.44(a).[7]

C. FIFRA Bars States From Imposing Different Labeling Requirements

Under FIFRA's "Uniformity" provision, a "state shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b); *see also Bates*, 544 U.S. at 452.

ARGUMENT

The Ninth Circuit decided a question of exceptional importance—both legally and economically—contrary to the decisions of this Court,

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[7] *See* EPA Pesticide Registration Notice (PRN) 2000-5: Guidance for Mandatory and Advisory Labeling Statements (May 10, 2000), www.epa.gov/pesticide-registration/prn-2000-5-guidance-mandatory-and-advisory-labeling-statements.

while creating a conflict with the Fifth Circuit along the way. Two distinct doctrines of federal preemption—express preemption and impossibility preemption—are fatal to Plaintiff's failure-to-warn claim and support granting the Petition.

I. FIFRA EXPRESSLY PREEMPTS ANY STATE-LAW REQUIREMENT THAT GLYPHOSATE-BASED PESTICIDES BEAR A CANCER WARNING

A. Plaintiff's Duty-to-Warn Claim Imposes a State Requirement Different from and in Addition to FIFRA

FIFRA expressly prohibits states from imposing "requirements for labeling . . . in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b). In *Bates*, this Court held that FIFRA "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." 544 U.S. at 443-44, 452. "[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA." *Id.* at 454.

The verdict below was premised on the notion that California common law required Monsanto to warn that its glyphosate-based Roundup products cause cancer. The question under § 136v(b) and *Bates*, then, is whether Monsanto was required to provide that cancer warning "under" FIFRA, making it "also liable for misbranding as defined by FIFRA." *Id.* If not, Plaintiff's state law claim is preempted.

Here, Monsanto is not "liable for misbranding as defined by FIFRA." *Id.* EPA has repeatedly determined that glyphosate-based pesticides like Roundup *do not pose a cancer risk*. As a matter of federal law, they are not misbranded for failure to warn of a disease that EPA has determined they do not cause. Nor can a lay jury in a state-law case override EPA's determination that a cancer warning is not required or even permitted in light of its finding that glyphosate-based pesticides do not cause cancer. That determination is supreme federal law binding upon the states.

1. EPA has repeatedly concluded, as a matter of federal law, that glyphosate-based pesticides do not cause cancer. EPA issued its initial glyphosate registration in 1974 and issued a Reregistration Eligibility Decision for the active ingredient glyphosate, after a thorough examination of the underlying data, in 1993.[8] In the nearly 50 years since the original registration, EPA has repeatedly concluded that glyphosate does not pose a cancer risk. Acting on the recommendation of a scientific peer review committee in the early 1990s, EPA found "evidence of non carcinogenicity for humans."[9] It

[8] *See* EPA, Ingredients Used in Pesticide Products: Glyphosate, www.epa.gov/ingredients-used-pesticide-products/glyphosate; EPA, Reregistration Eligibility Decision (RED): Glyphosate (Sept. 1993).

[9] *See* EPA, R.E.D. Facts, Glyphosate, at 2 (Sept. 1993), archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf.

reiterated that finding in a formal rule in 1997[10] and repeatedly in subsequent rulemakings.[11]

In 2009, EPA opened its current registration review, which has entailed extensive review of glyphosate's environmental safety and toxicology data after numerous rounds of public notice and comment. After review by both EPA's Cancer Assessment Review Committee and a Scientific Advisory Panel, EPA published a Revised Glyphosate Issue Paper evaluating the pesticide's carcinogenic potential.[12] This extensive review of "new science" included assessment of "63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies for the active ingredient glyphosate."[13] EPA concluded that "available data and weight-of-evidence clearly do not support the descriptors 'carcinogenic to humans'" or "'likely to be carcinogenic to humans.'"[14] Instead, the scientific evidence most strongly supports the description "not likely to be carcinogenic to humans."[15] EPA concluded this assessment *after* the

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[10] Final Rule: Glyphosate; Pesticide Tolerances, 62 Fed. Reg. 17,723, 17,724 (Apr. 11, 1997).

[11] Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,936 (Sept. 27, 2002); *see also* Final Rule: Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008).

[12] *See* EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017), usrtk.org/wp-content/uploads/2019/04/REVISED_GLYPHOSATE_ISSUE_PAPER_EVALUATION_OF_CARCINOGENIC_POTENTIAL-1.pdf.

[13] *Id.* at 144.

[14] *Id.*

[15] *Id.*

International Agency for Research of Cancer (IARC) announced its view, upon which glyphosate plaintiffs nationwide base claims, that glyphosate was a probable carcinogen.

EPA's scientific review led to its Draft Human Health Risk Assessment, which, after notice and comment, concluded that glyphosate was not likely to cause cancer.[16] After considering thousands of public comments, EPA issued its "Proposed Interim Registration Review Decision," reaffirming that its "independent evaluation of the carcinogenic potential of glyphosate . . . has determined that glyphosate is 'not likely to be carcinogenic to humans.'"[17] EPA expressly rejected IARC's cancer conclusion, explaining that EPA's "cancer evaluation is more robust than IARC's evaluation," which "only considered a subset of the studies included in the EPA's evaluation" and included "some studies that were not appropriate for determining the human carcinogenic potential of glyphosate."[18]

After this extensive process, EPA's Office of Pesticide Programs sent an August 2019 letter to all glyphosate registrants, reiterating that it "disagrees with IARC's assessment of glyphosate."[19] EPA noted

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[16] *See* EPA, Glyphosate: Draft Human Health Risk Assessment in Support of Registration Review, Case No. 0178 (Dec. 12, 2017), www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0068.

[17] *See* EPA, Glyphosate: Proposed Interim Registration Review Decision, Case No. 0178, at 7 (Apr. 2019), www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2344.

[18] *Id.*

[19] EPA Letter 1.

that its cancer classification is "consistent with other international expert panels and regulatory authorities," including government regulators in Canada, Australia, Germany, and New Zealand, as well as the European Food Safety Authority and European Chemical Agency.[20] EPA notified registrants that glyphosate products that *do* bear a cancer warning would be "misbranded pursuant to" FIFRA.[21]

In January 2020, following another comment period, EPA issued its interim registration review decision.[22] EPA confirmed its longstanding conclusion

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[20] *Id.*; *see, e.g.*, European Food Safety Authority, Glyphosate: EFSA Updates Toxicological Profile (Nov. 12, 2015) (glyphosate is "unlikely to pose a carcinogenic hazard to humans"), www.efsa.europa.eu/en/press/news/151112; European Chemicals Agency, Glyphosate Not Classified as a Carcinogen by ECHA (Mar. 15, 2017) ("available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen"), echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa; Federal Institute for Risk Assessment (BfR, Germany), BfR Comm'cn No. 007/2015, Does Glyphosate Cause Cancer? (assessment "supported by competent national, European and other international institutions for health assessment"), www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer.pdf.

EPA's determination is even consistent with the conclusions of "other agencies within the World Health Organization," aside from IARC, "that there is insufficient or no evidence that glyphosate causes cancer." *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247, 1252 (E.D. Cal. 2020).

[21] EPA Letter 1.

[22] *See* EPA, Glyphosate: Interim Registration Review Decision, Case No. 0178, at 5 (Jan. 2020), www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf.

that glyphosate does not cause cancer in humans: "None of the open literature studies identified for the agency's consideration were found to have an impact on the glyphosate hazard characterization, cancer assessment, or human health risk assessment."[23] EPA reaffirmed that it had "thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans."[24]

In a recent Ninth Circuit brief, EPA reiterated that it stands by its "conclu[sion] that glyphosate is not likely to be a human carcinogen and that it does not pose human-health risks of concern." EPA Br. 17, *NRDC v. EPA*, Nos. 20-70787, 20-70801 (9th Cir. May 18, 2021); *see also, e.g.*, *id.* at 30. It did so even as it asked the Ninth Circuit for "partial voluntary remand of the portions of the Interim Decision that do not relate to its conclusions on human health risks." EPA Motion for Partial Remand Without Vacatur 1-2, *NRDC v. EPA*, Nos. 20-70787, 20-70801 (9th Cir. May 18, 2021).

2. The Ninth Circuit recognized this consistent EPA finding, but rejected it out of hand on the grounds that the EPA determinations do not have "the force of law." Pet. App. 15a-17a. For the reasons stated in the Petition, however, the Court of Appeals asked the

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[23] *Id.* at 6-7.

[24] *Id.* at 10; *see also id.* at 9 (EPA "thoroughly assessed risks to humans from exposure to glyphosate from all registered uses and all routes of exposure and did not identify any risks of concern"); *id.* at 15.

wrong question. Pet. at 16. But even assuming that the "force of law" question is an inquiry appropriate to express preemption, the Court of Appeals simply got it wrong: EPA's repeated non-carcinogenicity determinations do, in fact, have the force of law.

Generally, "Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001). The pinnacle of "formal administrative procedure" under federal law is "the notice-and-comment procedures of the Administrative Procedure Act," which Congress "designed to assure due deliberation." *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 741 (1996).

Numerous EPA pronouncements that glyphosate-based pesticides do not pose a cancer risk qualify under the *Mead* standard as "administrative action with the effect of law." 533 U.S. at 230. EPA's interim registration review decision, in the agency's own words, "finalizes" its most recent re-affirmation that "there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans."[25] EPA reached that conclusion in the exercise of its expert scientific judgment only after several rounds of notice and comment regarding the health effects of glyphosate. At the interim registration decision phase alone, the agency reviewed "[o]ver 12,000 unique

[25] Interim Registration Review Decision 10.

submissions" from a 120-day comment period; and it finalized its proposed decision in a second decision that considered and addressed relevant comments.[26] The agency concluded that no mitigation measures were necessary to address the non-existent cancer risk.[27] By any reckoning, this was a "relatively formal administrative procedure tending to foster . . . fairness and deliberation." *Mead*, 533 U.S. at 230.

3. In any event, *Bates* holds that state labeling requirements must "be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." 544 U.S. at 453. The *Bates* Court provided an illustration: "For example, a failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted because it is inconsistent with 40 CFR § 156.64 (2004), which specifically assigns these warnings to particular classes of pesticides based on their toxicity." *Id.*

The verdict here is similarly inconsistent with FIFRA regulations that give content to the statute's misbranding requirements. FIFRA expressly charges EPA with applying its "requirements" in registration and registration review proceedings: "The [EPA] Administrator shall register a pesticide if the Administrator determines that [among other things] its labeling . . . compl[ies] with the requirements of [FIFRA]." 7 U.S.C. § 136a(c)(5)(B). Those requirements include not only the misbranding

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[26] *Id.* at 5.

[27] *See id.* at 15.

provision itself but FIFRA's related labeling regulations.

Relevant here is FIFRA's requirement that the label must contain warnings "necessary" and "adequate to protect the public health and the environment." *Id.* § 136(q)(1)(G) (defining "misbranded"). EPA has implemented that requirement by requiring that a label contain, among other things, any pertinent information that the agency determines is "necessary for the protection of man and the environment." 40 C.F.R. § 156.10(*i*)(2)(x)(F); *see also id.* § 156.70 (addressing precautionary statements). EPA applied that requirement here to determine that no cancer warnings are required because glyphosate-based pesticides do not pose a cancer risk. That determination "give[s] content to FIFRA's misbranding standards" in the same way as "Warning" or "Caution" requirements discussed in *Bates*. 544 U.S. at 453. It operates in precisely the same manner: The regulation sets a general standard, and EPA determines how it applies to a particular pesticide in its registration review. *See* Pet. 15-16.

EPA's repeated pronouncements, in the course of this formal administrative process, that glyphosate-based pesticides do not pose a cancer risk compel the conclusion that, as a matter of federal law, such pesticides are not misbranded when they lack a cancer warning—and, indeed, *would* be misbranded if they *did* bear a cancer warning. Plaintiff's claim that state law requires such a warning is expressly preempted under § 136v(b).

B. The Ninth Circuit Erred By Placing Undue Weight on 7 U.S.C. § 136a(f)(2)

The court below wrongly held that FIFRA does not expressly preempt state-law claims for failure to include cancer warnings on glyphosate-based pesticides. The Ninth Circuit acknowledged that "EPA has repeatedly approved the use of glyphosate as a pesticide, each time concluding that it is not likely to be carcinogenic to humans." Pet. App. 4a. And it did not deny that EPA has reached this conclusion in registration and registration review proceedings that would generally carry the force of law under *Mead*. *See id.* at 17a n.8 (acknowledging that "the 2017 determination stems from more formal procedures").

The Ninth Circuit nevertheless concluded that those actions are deprived of the force of law by 7 U.S.C. § 136a(f)(2), a FIFRA provision which states: "In no event shall registration of an article be construed as a defense for the commission of any offense under" FIFRA. 7 U.S.C. § 136a(f)(2). The Ninth Circuit read this language to mean that EPA's determinations made in the context of registration and registration review proceedings do not carry the force of law, even though they would have such force absent this provision. Pet. App. 15a-17a.

The Ninth Circuit's holding directly conflicts with the Fifth Circuit's holding in *MacDonald v. Monsanto Co.* that § 136a(f)(2) "has no bearing on" federal preemption of state law. 27 F.3d at 1025-26 n.4. "As § 136a(f)(2) clearly states, it prohibits a manufacturer from using the fact that a label is registered with the EPA as a defense to '*any offense under [FIFRA]*.'" *Id.* "A claim grounded in state common law is not an

offense under FIFRA. Thus, § 136a(f)(2) does not apply." *Id.* This Court's review is necessary to resolve the circuit conflict and confirm that § 136a(f)(2), which says nothing about the impact of FIFRA registration on state law, does not override, *sub silentio*, FIFRA's separate express preemption provision in § 136v(b).

The Ninth Circuit's construction ignores the distinction between the mere fact of the agency's "registration of an article" and the authoritative scientific determinations that the agency makes in the course of a proceeding related to registration. Section 136a(f)(2) speaks only of the former. Monsanto does not contend that EPA's *mere registration* of glyphosate-based pesticides means that such pesticides are not misbranded under FIFRA. What matters here is that EPA has made an authoritative determination, based on its thorough review of the most current science, that glyphosate does not cause cancer and thus that no cancer warning is required.

It makes sense that EPA registration is not, in itself, a defense to a misbranding action. Registration does not, in itself, establish that the manufacturer actually used the approved label. Nor does it show that EPA has actually considered and rejected every potential misbranding argument that might later be made. For instance, because EPA can "register a pesticide without confirming the efficacy claims made on its label," product registration generally "does not reflect any determination on the part of EPA that the pesticide will be efficacious." *Bates*, 544 U.S. at 440.

That was the situation in *Bates*: The state-law claim there was that a pesticide's label erroneously

claimed that it worked well on peanuts "in all areas." *Id.* EPA had "never passed on the accuracy of th[at] statement," so jurors in that case were in no way second-guessing EPA's authoritative scientific judgment. *Id.* "Particularly given that Congress amended FIFRA to allow EPA to waive efficacy review," the Court found it "unlikely" that Congress intended to preempt state-law efficacy claims where EPA had indeed waived review. *Id.* at 450.

This case is the polar opposite of *Bates*. As the Ninth Circuit recognized, EPA *has* thoroughly "passed on the accuracy" (*Bates*, 544 U.S. at 440) of statements connecting glyphosate with cancer. Based on its review of the same body of scientific evidence before the jury here, EPA has repeatedly concluded that glyphosate "is not likely to be carcinogenic to humans." Pet. App. 4a. It is *those* repeated determinations, made by the expert federal agency pursuant to notice-and-comment procedures, that establish conclusively as a matter of federal law that glyphosate-based pesticides are not required under FIFRA to bear a cancer warning. Nothing about the science has changed since those determinations were made, and § 136a(f)(2) does not deprive them of legal force.

II. FIFRA IMPLIEDLY PREEMPTS ANY STATE-LAW REQUIREMENT THAT GLYPHOSATE-BASED PESTICIDES BEAR A CANCER WARNING

The Petition also raises an important issue of implied preemption. Implied preemption occurs where "it is 'impossible for a private party to comply with both state and federal requirements.'" *Merck*, 139 S. Ct. at 1672. This Court has repeatedly

recognized that state duty-to-warn claims are impliedly preempted where there is "clear evidence" that the relevant federal agency would not have approved the warning that the state-law claim would require. *See id*. at 1676; *Wyeth v. Levine,* 555 U.S. 555, 571 (2009).

The Court recently explained what it means for a state duty-to-warn claim to conflict with federal law. In *Merck*, federal law permitted a drug manufacturer to change a label without advance FDA approval if the changes were necessary to reflect newly acquired information. 139 S. Ct. at 1679. The FDA could then reject any label changes made by the manufacturer. *Id*. On the basis of that self-amendment process, the Court reasoned that a drug manufacturer "ordinarily" would not be able to show a conflict between state and federal law because it could always take matters into its own hands to comply with state law.[28] *Merck* nevertheless reasoned that state duty-to-warn claims would be preempted if there was "clear evidence" that the FDA, when fully informed of the risks at issue, would decline to approve any labeling change required by state law. *Merck*, 139 S. Ct. at 1678-79; *see also Wyeth*, 555 U.S. at 571.

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[28] Pesticide manufacturers—unlike the drug manufacturer in *Merck*—have little discretion to unilaterally amend their labels without agency approval. *See Bates*, 544 U.S. at 438-39 (noting that "manufacturer may seek approval to amend its label") (citing 7 U.S.C. § 136a(f)(1)). Therefore, the "ordinary" presumption against preemption applicable in the circumstances of *Merck* would not apply in the FIFRA labeling context. *Compare Merck*, 139 S. Ct. at 1679, *with PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618-19 (2011) (impossibility preemption where generic drug manufacturer unable to change label unilaterally).

That standard is met here. EPA's August 2019 letter clearly states that a glyphosate label containing a cancer warning would be "false and misleading," and thus mislabeled. While the August 2019 EPA letter provides an emphatic response to the question posed by *Merck*—whether a fully informed EPA would approve the warning that Plaintiff demands—EPA had *already* plainly answered that question on numerous occasions. *See* discussion, *supra,* at 11-16. That scientific judgment dooms Plaintiff's claims.

In reaching the opposite conclusion, the Ninth Circuit erroneously held that EPA's repeated pronouncements that glyphosate-based pesticides do not pose a cancer risk lack the force of law. Pet. App. 18a-19a. As discussed above, that conclusion, which rests on the Ninth Circuit's mistaken reading of § 136a(f)(2), is simply wrong.

In any event, EPA's determinations plainly suffice for purposes of *Merck*'s impossibility preemption analysis. What *Merck* says is that "the only agency actions that can determine the answer to the pre-emption question . . . are agency actions taken pursuant to the [agency's] congressionally delegated authority." 139 S. Ct. at 1679. This Court was "mak[ing] only the obvious point that, whatever the means the [agency] uses to exercise its authority, those means must lie within the scope of the authority Congress has lawfully delegated." *Id.* As discussed above, that standard is met with respect to scientific determinations made in the course of EPA's registration-related proceedings (including registration review), because Congress expressly

required such proceedings in FIFRA. *E.g.*, 7 U.S.C. §§ 136a(c), (g).

The Ninth Circuit further reasoned that it was not impossible to add a cancer warning to the label because manufacturers are permitted to ask EPA to approve label changes. Pet. App. 19a-20a. But the Ninth Circuit itself acknowledged that EPA may approve a proposed change only "if it determines the change will not violate FIFRA." *Id.* at 20a. EPA's consistent view that glyphosate-based pesticides do not pose a cancer risk would plainly have compelled it to reject a cancer warning as violative of FIFRA's misbranding prohibition.

The Ninth Circuit's suggestion that adding a cancer warning is a "minor modification" that a manufacturer could make without EPA approval (Pet. App. 20a-21a) fares no better. The "minor modification" provision would not allow changes that are expressly contradicted by EPA's repeated scientific pronouncements. And EPA's own guidance makes clear that "[r]egistrants may modify or add mandatory or advisory labeling statements for currently registered products *only by submitting an application for amended registration*" to EPA. PRN 2000-5 (emphasis in original).

III. THE PETITION PRESENTS AN EXCEPTIONALLY IMPORTANT PREEMPTION QUESTION

As the court below explained: "Since 2015, thousands of cancer victims have sued Monsanto in state and federal court, alleging that Roundup caused their" cancer. Pet. App. 2a. "Hardeman's case is one of approximately 5,000 in federal court alleging that Roundup causes" cancer. *Id.* at 7a. And the

manufacturer has faced approximately 125,000 total filed and unfiled claims.[29] The trial in this case was "the first bellwether trial for the federal cases consolidated in [the] multidistrict litigation." *Id.* at 2a. The jury awarded the plaintiff over $5 million in compensatory damages and punitive damages subsequently reduced by the district court to $20 million. *See id.* The threat of such immense liability multiplied across so many cases could easily drive an economically vital product off the market—indeed, Bayer had already removed the product from the household consumer market as a result—despite EPA's repeated findings that it poses no cancer risk.

The decision below imposes substantial real-world costs. EPA has repeatedly found glyphosate to be a highly effective herbicide with a broad spectrum of "use in agriculture, including horticulture, viticulture, and silviculture, as well as non-agricultural sites including commercial, industrial and residential areas."[30] Glyphosate is the leading active ingredient used to control noxious and invasive weeds in aquatic systems, pastures and range lands, forestry, and rights-of-way.[31]

Imposing a state-law warning requirement where EPA has found that glyphosate does not cause cancer discourages socially and economically useful

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[29] *See* Bayer, "Bayer announces agreements to resolve major legacy Monsanto litigation" (June 24, 2020), media.bayer.com/baynews/baynews.nsf/id/Bayer-announces-agreements-to-resolve-major-legacy-Monsanto-litigation.

[30] *See* Proposed Interim Registration Review Decision, *supra* n.17, at 34.

[31] *Id.* at 35.

applications. Unsupported warnings may lead consumers to avoid buying useful products that do not pose a risk. A cancer risk warning would discourage the widespread use of glyphosate with a resulting loss of crop yields and other benefits from use.

Dissonant requirements at the federal and state levels also place manufacturers in an untenable position. It is difficult to imagine how a manufacturer could thread the needle between EPA and California warning requirements in this case, given that EPA has specifically rejected any cancer warning for glyphosate as mislabeling. Congress's uniform labeling provision was designed to avoid such conflicting state and federal standards.

CONCLUSION

This Court should grant the petition.

Respectfully submitted,

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