No. 24-1068

IN THE

Supreme Court of the United States

MONSANTO COMPANY,

Petitioner,

v.

JOHN L. DURNELL

Respondent.

On Petition for Writ of Certiorari to the Missouri Court of Appeals—Eastern District

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

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INTEREST OF AMICUS CURIAE

Established in 1933, CropLife America is the national trade association for the pesticide industry, representing developers, manufacturers, formulators, and distributors of pesticides and plant science solutions. CropLife America's member companies produce, sell, and distribute pesticides, including herbicides, insecticides, and fungicides, that American farmers use to provide consumers with abundant food and fiber. CropLife America is committed to safe and responsible use of the industry's products.[1]

CropLife America's members are deeply invested in the discovery and development of new pesticide products and product uses. The Environmental Protection Agency ("EPA") makes its pesticide registration decisions based on a thorough review of current scientific and technical information provided by pesticide manufacturers—including many CropLife America member companies—at significant cost to the manufacturer. EPA publishes a list of more than 300 possible scientific tests that may be required as part of a single pesticide's registration, with dozens

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[1] CropLife America provided timely notice of its intention to file this brief to the parties. 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. 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.

of those tests each costing in the hundreds of thousands of dollars and some tests costing in the millions.[2] Pesticide manufacturers spend, on average, $301 million and more than 12 years on research, development, and registration to bring each new active ingredient for crop protection products to the marketplace.[3]

Given that investment, CropLife America's members 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.* CropLife America member companies have a keen interest in FIFRA's legal framework, especially the interrelationship between federal and state pesticide regulation.

In light of its extensive experience with FIFRA's regulatory system—and its substantial interest in the outcome of the preemption questions presented—

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[2] For instance, EPA estimates the average cost of "Combined Chronic Toxicity/Carcinogenicity Testing of Respirable Fibrous Particles (inhalation route)," just one of the myriad tests required by EPA regulations, to exceed $5 million. U.S. Environmental Protection Agency, "Cost Estimates of Studies Required for Pesticide Registration," April 2025, https://www.epa.gov/system/files/documents/2025-04/test-cost-estimates-2025-04-25.pdf.

[3] *See* AgbioInvestor, "Time and Cost of New Agrochemical Product Discovery, Development, and Registration," A Study on Behalf of Crop Life International (Feb. 2024), Executive Summary 5-6, https://agbioinvestor.com/wp-content/uploads/2024/02/AgbioInvestor-CropLife-The-Cost-of-New-Agrochemical-Product-Discovery-Development-and-Registration.pdf.

CropLife America files this brief *amicus curiae* to assist the Court's understanding of FIFRA's pesticide registration and the registration review process. A comprehensive understanding of that process—which has resulted in EPA's repeated determinations that glyphosate-based pesticides are unlikely to cause cancer and that a cancer warning should not be included on the product labels—supports granting the Petition to review the important federal question presented.

SUMMARY OF ARGUMENT

CropLife America urges the Court to grant Monsanto Company's Petition without delay. Expeditious review is needed to resolve a clear and deepening conflict of authority, which is unlikely to go away without this Court's intervention. This Court's review is also needed to correct the persistent misinterpretation of FIFRA and its implementing regulations reflected in the Missouri Court of Appeals' decision. The decision below—and the federal court of appeals' decisions on which the Missouri court rested its preemption holding—have the potential to subject pesticide manufacturers to millions if not billions of dollars in unwarranted liability, imposed by lay juries acting contrary to EPA's expert scientific judgment and Congress's statutory design.

The fundamental question presented by the Petition is whether juries acting under state law can override EPA's determination that glyphosate product labels should not contain a cancer warning—a determination based on EPA's expert judgment that the scientific evidence does not support a link between glyphosate and cancer. An acknowledged conflict of

authority on this question has emerged among the federal courts of appeals and with the decisions of state courts. *Compare Schaffner v. Monsanto Corp.*, 113 F.4th 364 (3d Cir. 2024) (FIFRA preempts state law failure-to-warn claims involving glyphosate cancer risk warning) *with* Pet. App. 11 ("we do not find *Schaffner* persuasive"); *Hardeman v. Monsanto Co.*, 997 F.3d 941, 950 (9th Cir. 2021) (rejecting FIFRA preemption); *Carson v. Monsanto Co.*, 92 F.4th 980, 992-93 (11th Cir. 2024) (same).[4] That division of authority is well defined and will not benefit from further development. It invites this Court's prompt resolution.

The Missouri court's decision—like the Ninth and Eleventh Circuit decisions that it follows—is also manifestly wrong on a legal question of substantial public importance. Because EPA has repeatedly determined that glyphosate-based pesticides *do not* cause cancer and thus regularly approves glyphosate-based product labels without requiring a cancer warning, FIFRA prohibits a contrary state-mandated warning label.

This follows from the interplay of two relevant statutory and regulatory provisions. First, FIFRA's "Uniformity" provision commands that States "shall

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[4] As the Petition notes, state appellate courts in two additional states—California and Oregon—have similarly concluded, contrary to the Third Circuit's *Schaffner* decision, that FIFRA does not preempt state failure-to-warn claims. *See* Pet. 2 (citing *Pilliod v. Monsanto Co.*, 282 Cal Rptr. 3d 679 (Ct. App. 2021), *appeal denied*, No. S270967 (Cal. Nov. 17, 2021); *Johnson v. Monsanto Co.*, 554 P.3d 290 (Or. App. 2024), *appeal denied*, 562 P.3d 237 (Or. Dec. 19, 2024).

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). Second, among the "requirements" of federal law guarded by FIFRA's Uniformity provision is EPA's label preapproval regulation, which provides that, once approved by EPA, a pesticide label generally may not be modified without EPA's review and approval. 40 C.F.R. § 152.44(a); *see also* 40 C.F.R. § 156.70(b). Read together, as the Third Circuit correctly did in *Schaffner*, those provisions prohibit a state from imposing liability for a pesticide manufacturer's refusal to provide a warning label different from the label approved by EPA. *See Schaffner*, 113 F.4th at 386-88.

The decision below nevertheless upheld a seven-figure jury verdict imposing liability on Monsanto under Missouri law for selling its glyphosate-based pesticide without a warning that EPA has explicitly and repeatedly found scientifically unsupported and unnecessary. The Missouri court's holding is based on its erroneous view that the only relevant federal "requirement" for purposes of applying FIFRA's Uniformity provision is the statute's command that a pesticide not be misbranded. *See* 7 U.S.C. § 136(q)(1)(G) ("[a] pesticide is misbranded if . . . the label does not contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment"). Under the Missouri court's view, FIFRA's Uniformity provision permits a state labeling requirement where the state law's purpose is also to protect public health and the environment through adequate labeling.

But this broad, generalized reading of FIFRA's Uniformity provision overlooks the critical scientific conclusions made by EPA in approving the contents of the label in the first instance. Where EPA determined that the science did not support a cancer warning and approved a label without such a warning, FIFRA's preapproval requirement explicitly prohibits a state from varying that label with a contradictory warning absent EPA approval. 40 C.F.R. § 152.44(a).

In short, a high-level consistency between the general purposes of EPA's misbranding provision and state label requirements is insufficient to overcome federal preemption. FIFRA's requirements *also* include the regulation's specific label preapproval requirement and forbid state law modifications absent EPA approval. As EPA itself often tells the public, once approved by EPA, "the label is the law."[5] 40 C.F.R. § 152.44(a). FIFRA thus preempts state-law requirements that seek to vary the label warnings approved by EPA after its own careful evaluation of the scientific evidence.

The preemption issues raised in the Petition are both legally and socially important. Monsanto alone faces tens of thousands of claims like this one. The multi-district litigation currently pending in the U.S. District Court for the Northern District of California has more than 4,300 active cases raising issues identical to those presented here. In its home state of Missouri, Monsanto is a defendant in tens of thousands of cases seeking relief for a failure to warn

[5] U.S. Environmental Protection Agency, "Introduction to Pesticide Labels" (April 2025), https://tinyurl.com/5n8kdeh2.

of the very cancer risk that EPA has found does not require a label warning. Pet. 17.

Pesticide manufacturers have been successful in defeating many of the dozens of cases that have gone to trial. But in a handful of those cases where a jury has been allowed to second-guess EPA's expert science-based labeling judgment, the awards have been staggering—with two recent jury verdicts exceeding $2 billion.[6] The potential for such astronomical verdicts puts enormous financial pressure on the pesticide industry. The legal and financial crisis facing the manufacturers of products that EPA has found safe and effective for widespread use calls for immediate review.

[6] *See, e.g.*, Associated Press, "Georgia jury orders Monsanto parent to pay nearly $2.1 billion in Roundup weedkiller lawsuit," (Mar. 27, 2025) (compensatory damages award of $65 million and punitive damages of $2 billion), https://tinyurl.com/n5fx57y9; CNN.com, "Bayer ordered to pay $2.25 billion after jury concludes Roundup weed killer caused a man's cancer, attorneys say," (Jan. 30, 2024) (Pennsylvania jury award included $2 billion in punitive damages), https://tinyurl.com/yc6x867r.

BACKGROUND

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

CropLife America explains below the provisions of FIFRA relevant to pesticide registration and labeling.

A. FIFRA Requires Comprehensive EPA Review of Pesticide Safety and Health Effects as Part of Product Registration

FIFRA prohibits the sale of "any pesticide that is not registered." 7 U.S.C. § 136a(a). 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.*

EPA's Pesticide Registration Manual explains that "[b]efore any pesticide product that EPA has not exempted from registration requirements can be lawfully sold or distributed, EPA performs a rigorous, comprehensive scientific assessment of the product, resulting in a registration decision."[7] FIFRA and its implementing regulations require registrants to provide substantial scientific data to support a pesticide's safety and health effects. 7 U.S.C. §§ 136a(c)(1)(F) & (c)(2)(A); 40 C.F.R. § 158.500(d); *see* 40 C.F.R. pt. 158. A registrant must submit substantial data addressing the toxicology of the pesticide, including studies relating to the likelihood that a particular pesticide could cause cancer in laboratory rodents. 40 C.F.R. § 158.500(d).

FIFRA allows EPA to waive data requirements pertaining to—and register a pesticide without reviewing—product efficacy. *Id.* § 136a(c)(5)(D); *see Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 440 (2005). But EPA cannot similarly waive review for adverse human health and environmental effects; it must conduct this searching review in every registration.

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[7] *See* EPA Pesticide Registration Manual: Introduction, https://www.epa.gov/system/files/documents/2021-08/pesticide-registration-manual-introduction.pdf.

EPA must reevaluate a pesticide at least once every 15 years to determine whether it continues to satisfy 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 Grants EPA Primacy in Determining Pesticide 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."[8] 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."[9]

EPA's Label Review Manual notes that the accuracy of the label is "vital" to EPA's (and other governmental 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

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[8] EPA, Office of Pesticide Programs, Label Review Manual 1-2, https://www.epa.gov/system/files/documents/2024-12/label_review_manual_12122024.pdf.

[9] *Id.*

rely on the label for use instructions and hazard and safety information; and to the general public.[10]

FIFRA's regulations provide that a product label "shall 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). A product label "is required to bear hazard and precautionary statements for humans and domestic animals." *Id.* § 156.60; *id.* § 156.70(b). Critically, 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 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 sale of the pesticide, 7 U.S.C. § 136j(a)(2)(A), and may

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[10] *Id.*

generally be amended only with express EPA approval. 40 C.F.R. § 152.44(a) ("any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration"). EPA's regulations permit it to allow "minor modifications to registration having no potential to cause unreasonable adverse effects to the environment" by notification, without advance approval. 40 C.F.R. § 152.46(b). Those "minor modifications" cannot involve "change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use."[11] Consistent with 40 C.F.R. §§ 152.44(a) and 156.70(c), a registrant thus cannot add a new health hazard to the approved "precautionary statement" of the label without EPA approval. *See Schaffner*, 113 F.4th at 385; *id.* at 383 n.11.

C. FIFRA Bars States from Imposing Different Labeling Requirements

Congress addressed the States' role in pesticide regulation in the 1972 FIFRA amendments. *See Bates*, 544 U.S. at 439. While FIFRA provides the States certain leeway to regulate the sale and use of pesticides within their borders, it preserves the primacy of EPA's role and federal law. FIFRA grants

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[11] EPA, Office of Pesticide Programs, Pesticide Registration Notice 98-10: Notifications, Non-Notifications and Minor Formulation Amendments, at 8 (Oct. 22, 1998), https://www.epa.gov/sites/default/files/2014-04/documents/pr98-10.pdf.

the States authority to "regulate the sale or use of any federally registered pesticide or device in the State," but "only if and to the extent the [state] regulation does not permit any sale or use prohibited by this subchapter." 7 U.S.C. § 136v(a).

The States' role is even more circumscribed with respect to product labeling. States may enforce only requirements that are fully consistent with EPA's labeling requirements: "Such state shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." *Id.* § 136v(b). As this Court reasoned in *Bates*, FIFRA's "requirements" include both the provisions of the statute and "its implementing regulations." *Bates,* 544 U.S. at 452.

ARGUMENT

I. REVIEW IS NEEDED TO RESOLVE A CLEAR CONFLICT AMONG STATE AND FEDERAL COURTS OF APPEALS

The conflict in the lower courts is fully developed, well defined and otherwise unlikely to be resolved without this Court's intervention.

In a thorough and thoughtful opinion, the Third Circuit recently held that, where EPA has approved labels that omit cancer warnings on glyphosate-based pesticides after its extensive review of the scientific evidence, FIFRA's Uniformity provision preempts state failure-to-warn claims seeking damages based on the failure to include such a warning on the EPA-approved label. *See Schaffner*, 113 F.4th at 370-71. *Schaffner* explicitly acknowledged that its decision conflicted with those of two sister circuits holding that

FIFRA does not preempt such state law claims. *Id.* at 389-90; *id.* at 399 (noting "our analysis differs from . . . our colleagues in other courts who have agreed with [the MDL court's] conclusion"). The Missouri Court of Appeals' decision adopts the holding of those other federal circuit courts and those of two other state courts, thus deepening a pre-existing split of authority. *See* Pet. App. 10-11; *see Hardeman*, 997 F.3d at 950; *Carson*, 92 F.4th at 992-93; *see also supra*, n.4. There is little reason to allow this conflict to percolate further. It stems from fundamentally differing interpretations of a number of relevant FIFRA provisions that have been fully aired in the lower courts.

The most basic difference between the approach adopted by the Missouri Court of Appeals (following the holdings of *Hardeman* and *Carson*) and the Third Circuit in *Schaffner* is their differing identification of the relevant federal "requirements" under FIFRA's Uniformity provision, 7 U.S.C. § 136v(b). *Hardeman* and *Carson* both concluded that the only relevant "requirement" of federal law for purposes of § 136v(b) was the statute's misbranding provision, 7 U.S.C. § 136j(a)(1)(E), which provides that a product is misbranded if it does not contain a warning necessary to protect human health and the environment. The Ninth and Eleventh Circuits thus held that, because state law merely sought to determine whether a missing warning was necessary to protect human health, the state cause of action was consistent with § 136j(a)(1)(E) and not preempted. *Hardeman*, 997 F.3d at 955-56; *Carson*, 92 F.4th at 991-92.

The Third Circuit disagreed that FIFRA's misbranding statute provided the only relevant federal requirement. While acknowledging that, at a high level of generality, the statute's misbranding standard and a state law duty-to-warn claim both seek to accomplish the same objective, the Third Circuit reasoned that § 136v(b) requires an examination of federal requirements at "the more specific level" of the regulations implementing FIFRA. *Schaffner*, 113 F.4th at 390. "The state-law duty cannot survive preemption simply because its standard of liability is equivalent to the broad statutory definition of misbranding." *Id.*

Instead, the Third Circuit reasoned that, under *Bates*, courts must *also* "examine 'EPA regulations that give content to FIFRA's misbranding standards.'" *Schaffner*, 113 F.4th at 381 (quoting *Bates*, 544 U.S. at 453). Those regulations, the Third Circuit concluded, include 40 C.F.R. § 152.44, the "Preapproval Regulation." *Schaffner*, 113 F.4th at 381. Like the labeling regulations discussed in *Bates,* "the Preapproval Regulation also gives content to FIFRA's misbranding standards." *Id.* at 391; *see Bates*, 544 U.S. at 453 (discussing example of FIFRA's "DANGER" and "CAUTION" labeling requirements). *Schaffner* concluded the Preapproval Regulation "prohibited Monsanto from modifying Roundup's Preapproved Label" to add a state-compelled cancer warning because the regulation prohibits the sale of a pesticide with a label different from that approved by EPA, absent an amended registration and EPA approval. *Id.* at 381, 382-85.

Because *Bates* requires courts applying FIFRA's express preemption provision to measure state-law requirements "against any relevant EPA regulations" that give content to the statute's misbranding requirement (*Bates*, 544 U.S. at 453), the Third Circuit held that the preemption provision's parallel-requirements test "must involve a comparison to the Preapproval regulation." *Schaffner*, 113 F.4th at 381-82. Concluding that EPA's omission of a cancer warning meant that such a warning could not be added under state law "without violating the Preapproval Regulation," the Third Circuit, expressly disagreeing with its sister circuits, held that "the Pa. Duty to Warn is not equivalent to the Federal Comparator, and it is thus preempted under section 136v(b)." *Id*. at 382.[12]

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[12] The Ninth and Third Circuits also differed in their reading of the Preapproval Regulation, which allows EPA to permit "minor modifications" to a label by notice without EPA approval. 40 C.F.R. § 142.56(a). Citing that provision, the Ninth Circuit noted that "EPA has repeatedly permitted pesticide manufacturers to use the notification procedure to add notices related to cancer to their products' labels." *Hardeman*, 997 F.3d at 959. The Third Circuit disagreed with the Ninth Circuit's suggestion, reasoning that the minor modifications regulation was not self-executing. Based on subsequent guidance by EPA, *Schaffner* concluded that the minor modifications provision would not permit a registrant to add an actual cancer *warning* without EPA approval. *Schaffner*, 113 F.4th at 385; *id.* at 384 n.11 (disagreeing with *Hardeman*'s analysis of the minor modifications provision). The Eleventh Circuit noted the Preapproval Regulation (*see Carson,* 92 F.4th at 990, but did not consider it in its "requirements" analysis. *See Schaffner*, 113 F.4th at 389 n.15 (noting that *Carson* "[gave] no explanation for that choice.").

The disagreement among lower courts also stemmed from their different treatment of 7 U.S.C. § 136a(f)(2). That subsection provides that the registration of a pesticide shall not "be construed as a defense for the commission of any offense under this subchapter," but serves as "prima facie evidence" that the pesticide and its labeling comply with FIFRA's registration provisions. 7 U.S.C. § 136a(f)(2).

Both the Ninth and Eleventh Circuits relied on this statutory provision in concluding that FIFRA does not preempt state failure-to-warn laws. *See Hardeman*, 997 F.3d at 956; *Carson*, 92 F.4th at 993. But *Schaffner* reasoned that § 136a(f)(2) did not affect the express preemption analysis. While recognizing that "the mere fact of registration" cannot serve as a defense to a misbranding action, the Third Circuit reasoned that the registration of a pesticide also "affects the content of the requirements imposed under FIFRA, as registration determines what label the pesticide must bear." *Schaffner*, 113 F.4th at 397. Unlike its sister circuits, the Third Circuit did not read § 136a(f)(2) "to indicate that the registration process cannot play any role in determining the content of a requirement imposed under FIFRA." *Id.* In that respect, the Third Circuit's decision was consistent with an earlier decision of the Fifth Circuit, which concluded that § 136a(f)(2) "has no bearing" on federal preemption. *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1027 n.4 (5th Cir. 1994).

Finally, there is disagreement among the federal circuit courts on whether EPA's action must have the "force of law" to have preemptive effect under § 136v(b). The Ninth Circuit and Eleventh Circuit

concluded that only those EPA actions having the "force of law" fall within the preemptive scope of FIFRA's Uniformity provision. *Hardeman*, 997 F.3d at 956; *Carson*, 92 F.4th at 993. *Schaffner* disagreed, reasoning that, when Congress has expressly authorized the preemption of state law by statute, "the meaning of the express-preemption provision … triggers preemption." 113 F.4th at 398. Because "Congress has decreed in the text of that provision that federal 'requirements' have preemptive force, no further analysis is necessary." *Id.*

By contrast, in finding no preemption here, the Missouri Court of Appeals relied upon *Hardeman* and *Carson* and expressly rejected the Third Circuit's analysis in *Schaffner*. The court concluded that "we do not find *Schaffner* persuasive and choose to follow the weight of the authority in holding that Plaintiff's failure to warn claim is not expressly preempted by federal law." Pet. App. 11. This decision deepens the pre-existing conflict of authority on both the main holding of express preemption and the subsidiary questions on which the federal courts of appeals have differed. This Court should grant the Petition to resolve this conflict of authority and the uncertainty that it has engendered in courts throughout the country.

II. THE MISSOURI COURT'S HOLDING, LIKE THOSE OF THE CIRCUIT COURTS THAT IT FOLLOWS, MISAPPLIES CONTROLLING AUTHORITY AND MISCONSTRUES THE EFFECT OF EPA'S LABELING DETERMINATIONS

This Court should grant the Petition because the decision below, like that in *Hardeman* and *Carson*, misapplies this Court's decision in *Bates*. As the *Schaffner* court correctly recognized, *Bates* holds 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 (emphasis added). Thus, state labeling requirements must "be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." 544 U.S. at 453. But *Hardeman* and *Carson*—and the Missouri Court of Appeals in adopting the holding of those decisions—did not adequately examine FIFRA's regulations in their preemption analysis. Had they done so, those courts would have been required to find the state causes of action preempted.

In several places, EPA's FIFRA regulations set *requirements* for EPA approval of health warnings and changes to health warnings on product labels. For instance, 40 C.F.R. § 156.70, sets out requirements for human hazard and related precautionary statement on pesticide labels, prescribing both the content and location for these required statements. Critically, the regulation requires EPA pre-approval of any statement

pertaining to the hazards of a product or its uses. 40 C.F.R. § 156.70(c).

Once the EPA approves a pesticide label, the label generally may not be changed without express EPA approval. Under 40 C.F.R. § 152.44(a), "any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration." As *Schaffner* properly held, this provision means EPA *must approve* in advance any change to existing health warnings on pesticides. *See* 113 F. 4th at 399. A *state-imposed* warning is necessarily inconsistent with this requirement.

In this case, EPA's decision *not* to require a cancer warning was no accident. It was the result of decades of evaluation of the relevant scientific evidence. The label reflects EPA's repeated conclusion 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.[13] In the 50 years since the original registration, EPA has concluded again and again 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

[13] *See* EPA, Ingredients Used in Pesticide Products: Glyphosate, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate; EPA, Reregistration Eligibility Decision (RED): Glyphosate (Sept. 1993), https://tinyurl.com/4rewtdnp.

humans."[14] It reiterated that finding in a formal rule in 1997 and again in subsequent rulemakings.[15]

In 2009, EPA opened its most recent 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.[16] 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."[17] 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.'"[18] Instead, the scientific evidence most strongly supports the description "not likely to be carcinogenic to

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

[15] Final Rule: Glyphosate; Pesticide Tolerances, 62 Fed. Reg. 17,723, 17,724 (Apr. 11, 1997); *see also* Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,936 (Sept. 27, 2002); Final Rule: Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008).

[16] *See* EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487&Lab=OPP.

[17] *Id.* at 144.

[18] *Id.*

humans."[19] EPA concluded this assessment *after* the International Agency for Research of Cancer (IARC) announced its view, upon which glyphosate plaintiffs nationwide base their 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.[20] 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.'"[21] 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."[22]

After this extensive process, EPA's Office of Pesticide Programs sent an August 2019 letter to all

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[19] *Id.*

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

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

[22] *Id.*

glyphosate registrants, reiterating that it "disagrees with IARC's assessment of glyphosate."[23] EPA noted that its cancer classification is "consistent with other international expert panels and regulatory authorities," including government regulators in Canada, Australia, and New Zealand, as well as the European Food Safety Authority and European Chemical Agency.[24] EPA notified registrants that glyphosate products that *do* bear a cancer warning would be "misbranded pursuant to" FIFRA.[25]

In January 2020, following another comment period, EPA issued its interim registration review decision, reaffirming its longstanding conclusion that that glyphosate does not cause cancer in humans.[26] It is currently reviewing that determination in light of a

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[23] EPA, Letter to Glyphosate Registrants on California Proposition 65, at 1 (Aug. 7, 2019) ("EPA Letter"), https://tinyurl.com/53eb7685.

[24] *Id.*; *see, e.g.*, European Food Safety Authority, Glyphosate: no critical areas of concern; data gaps identified (July 6, 2023) ("In 2022, the European Chemicals Agency (ECHA) carried out a hazard assessment of glyphosate and concluded that it did not meet the scientific criteria to be classified as a carcinogenic, mutagenic or reprotoxic substance."), https://tinyurl.com/ywbkvdus; European Chemicals Agency, Glyphosate: no change proposed to hazard classification (May 30, 2022) ("the committee again concludes that classifying glyphosate as a carcinogen is not justified"), https://tinyurl.com/yeywmrfz.

[25] EPA Letter 1.

[26] *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.

subsequent Ninth Circuit decision vacating the interim decision. *See Nat. Res. Def. Council v. U.S.* EPA, 38 F.4th 34, 52 (9th Cir. 2022). But even after the Ninth Circuit decision, EPA continues to maintain that its "longstanding finding that glyphosate is not likely to be carcinogenic to humans" may be used to support future decisions.[27]

As the Petition notes, EPA continues to approve glyphosate-based pesticide labels without including cancer warnings. Pet. 11-12. And it has not approved any relevant amendment to accommodate the contrary jury determination applying Missouri law in this case. Under FIFRA's Uniformity provision, Missouri state law *cannot* require a cancer warning not approved for inclusion on the label by EPA. The Missouri Court of Appeals' determination that state law survives FIFRA preemption is fatally flawed. This Court should grant the Petition.[28]

III. THE PETITION PRESENTS AN EXCEPTIONALLY IMPORTANT QUESTION

"Since 2015, thousands of cancer victims have sued Monsanto in state and federal court, alleging that

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[27] EPA website "Glyphosate," https://www.epa.gov/ingredients-used-pesticide-products/glyphosate.

[28] CropLife America agrees with Petitioner's suggestion that the Court should also review the Missouri court's determination that FIFRA does not impliedly preempt state law. Application of state law where EPA has made a clear determination on the content of the label creates insoluble conflicts with EPA's label approval and its amendment regulations. *See* Pet. 28-31.

Roundup caused their" cancer. *Hardeman*, 997 F.3d at 950. Monsanto has faced more than 125,000 filed and unfiled claims.[29] While it has settled many of those claims, thousands more persist, with more than 4,400 MDL cases currently pending and tens of thousands more in state courts throughout the country. *See* Pet. 10, 32.

The jury in this case awarded $1.25 million in damages, but even that sizeable award is eclipsed by massive jury awards in other glyphosate cases. In the last two years, two different plaintiffs have been awarded more than $2 billion in compensatory and punitive damages.[30] Though Monsanto has prevailed in the majority of cases that have gone to trial, it does not take many multi-billion-dollar awards to endanger a company's—and an industry's—existence.

The threat of such immense liability multiplied across so many cases could easily drive an economically vital product off the market, despite EPA's repeated findings that it poses no cancer risk and is safe and effective for widespread use. Indeed, Bayer, Monsanto's parent company, has already removed glyphosate-based products from residential lawn and garden applications.

Should the continued risk of large verdicts based on flawed legal theories lead to similar decisions for

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[29] *See* Bayer, "Bayer announces agreements to resolve major legacy Monsanto litigation" (June 24, 2020), https://www.bayer.com/media/en-us/bayer-announces-agreements-to-resolve-major-legacy-monsanto-litigation/.

[30] *See supra*, n.6.

commercial applications, the result would be devastating to U.S. agricultural production. 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."[31] Increased agricultural use has resulted in corresponding increases in crop yield. Glyphosate is also the leading active ingredient used to control noxious and invasive weeds in aquatic systems, pastures and range lands, forestry, and rights-of-way.[32] These applications are "critical to maintaining vital infrastructure and safety for transportation, distribution of goods and services (railways and roadways) and utilities (electric and gas)."[33]

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

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[31] *See* U.S. EPA, Office of Chem. Safety & Pollution Prevention, "Glyphosate: Response to Comments, Usage, and Benefits," at 2 (April 18, 2019), https://www.epa.gov/sites/default/files/2019-04/documents/glyphosate-response-comments-usage-benefits-final.pdf.

[32] *Id.* at 2.

[33] *Id.*

Dissonant state and federal requirements also place manufacturers in an untenable position. It is difficult to imagine, for instance, how a manufacturer could thread the needle between EPA's and Missouri's warning requirements, given that EPA has specifically rejected any cancer warning for glyphosate as mislabeling. *See Bates*, 544 U.S. at 452 (warning against "50 different labeling regimes prescribing the color, font size, and wording of warnings" and the "significant inefficiencies for manufacturers" such a legal regime would entail).

Congress designed FIFRA's Uniformity provision to avoid conflicting state and federal labeling standards. The holding below, like the decisions it follows, results in disharmony rather than uniformity. This Court should grant review to harmonize state and federal law and to resolve the growing conflict on the important federal question presented.

CONCLUSION

This Court should grant the petition.

Respectfully submitted,

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