No. 24-1068

IN THE
Supreme Court of the United States

MONSANTO COMPANY,
Petitioner,

v.

JOHN L. DURNELL,
Respondent.

On Writ of Certiorari to the Missouri Court of Appeals

BRIEF OF ROUNDUP AND PARAQUAT MDL LEADERSHIP AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

The Question Presented, as modified by the Court, is:

Whether the Federal Insecticide, Fungicide, and Rodenticide Act preempts a label-based failure-to-warn claim where EPA has not required the warning.

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Botham.Dep.	Deposition Transcript of Dr. Philip Botham, *Hoffmann v. Syngenta Crop Prot., LLC*, No. 17-L-517 (Ill. Cir. Ct., 20th Jud. Cir., St. Clair Cnty. Feb. 25-26 & June 17-19, 2020), *available at* https://www.thenewlede.org/wp-content/uploads/2022/11/Dr.-Botham-deposition-transcript-2020.pdf
Dixon.Dep.	Deposition Transcript of Syngenta, by and through its Representative Montague Dixon, *Hoffmann v. Syngenta Crop Prot., LLC*, No. 17-L-517 (Ill. Cir. Ct., 20th Jud. Cir., St. Clair Cnty. June 24, 2020), *available at* https://www.thenewlede.org/wp-content/uploads/2023/05/Monty-Dixon-deposition-2020.pdf
EPA	Environmental Protection Agency
FDCA	Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y
IARC	International Agency for Research on Cancer

MDAs	Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539
MDL	Multidistrict Litigation
Ouzts.Dep.	Deposition Transcript of Syngenta, by and through its Representative Clark Ouzts, *Hoffmann v. Syngenta Crop Prot., LLC*, No. 17-L-517 (Ill. Cir. Ct., 20th Jud. Cir., St. Clair Cnty. June 22 & Sept. 28, 2020), *available at* https://www.thenewlede.org/wp-content/uploads/2023/05/Clark-Ouzts-deposition-2020.pdf
Patterson.Dep.	Deposition Transcript of Timothy Patterson, *Hoffmann v. Syngenta Crop Prot., LLC*, No. 17-L-517 (Ill. Cir. Ct., 20th Jud. Cir., St. Clair Cnty. Jan. 22, 2021), *available at* https://www.thenewlede.org/wp-content/uploads/2023/05/Patterson-deposition-2021.pdf
Pet.App.	Appendix to Petition for Writ of Certiorari, *Monsanto Co. v. Durnell*, No. 24-1068 (U.S. Apr. 4, 2025)
POEA	polyethoxylated tallow amine
PPE	personal protective equipment
RA	Respondent's Appendix, *Durnell v. Monsanto Co.*, ED112410 (Mo. Ct. App. Nov. 7, 2024)

Tr.	Transcript on Appeal in No. ED112410 (Mo. Ct. App. June 13, 2024)
U.S. *Hardeman* Br.	Brief for the United States as Amicus Curiae, *Monsanto Co. v. Hardeman*, No. 21-241 (U.S. May 10, 2022)

INTEREST OF *AMICI CURIAE*[1]

Amici are the court-appointed leaders of MDLs involving plaintiffs harmed by the pesticides Roundup and paraquat. *See In re Roundup Prods. Liab. Litig.*, MDL No. 2741 (N.D. Cal.); *In re Paraquat Prods. Liab. Litig.*, MDL No. 3004 (S.D. Ill.). *Amici* represent more than 5,000 individuals who allege that glyphosate-based Roundup caused them to develop non-Hodgkin lymphoma. And *amici* represent approximately 6,525 individuals who allege that they developed Parkinson's disease following exposure to paraquat, a restricted-use herbicide banned in many countries.

Amici have a substantial interest in this case because Monsanto's preemption theory—that FIFRA bars failure-to-warn claims whenever EPA has not required a warning—would directly affect their clients' cases. Accepting Monsanto's position would allow manufacturers to invoke EPA's silence as a defense, even when the manufacturer failed to disclose material safety information to the agency. That concern is concrete here: *Amici*'s cases include evidence that Monsanto and Syngenta suppressed studies and withheld data from EPA, contributing to the absence of warnings on the labels they invoke as preemptive.

Amici offer a practical perspective. They have extensive experience with FIFRA's registration process, manufacturers' interactions with EPA, and the role of preemption defenses in mass tort litigation. That experience informs *amici*'s view that FIFRA preserves the "concurrent authority of the Federal and State Governments" and that state-law remedies "aid, rather than hinder, the functioning of FIFRA." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 450-51 (2005).

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[1] No counsel for a party authored this brief in whole or part. No person or entity other than *amici* or counsel made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

The Court granted certiorari to decide whether the Federal Insecticide, Fungicide, and Rodenticide Act preempts a label-based failure-to-warn claim where EPA has not required the warning. The answer is no.

I. FIFRA preserves a broad role for state regulation of pesticides—including the power to *ban* a federally registered pesticide. Against that backdrop, Monsanto's claim that FIFRA strips States of the lesser authority to require reasonable warnings lacks merit.

A. FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450. States may ban or restrict the use of any EPA-approved pesticide. 7 U.S.C. § 136v(a).[2] And they bear "primary enforcement responsibility" for pesticide use violations. § 136w-1. The one limit on that authority is a "narrow" preemption provision, *Bates*, 544 U.S. at 452, which bars only state labeling requirements that are "in addition to or different from" FIFRA's own requirements, § 136v(b). Because FIFRA does not give EPA final say over pesticide use, a state-law failure-to-warn claim based on inadequate instructions for a pesticide's safe use does not add to or differ from any preemptive federal requirement. Nor does a state-law claim that parallels FIFRA's misbranding provisions, which require warnings "adequate to protect health," § 136(q)(1)(G).

B. A fair accounting of FIFRA's registration scheme rebuts Monsanto's and the United States' arguments. Unlike the Medical Device Amendments at issue in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), FIFRA does not treat registration as a comprehensive federal safety determination that displaces

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[2] Except where noted, U.S. Code citations are to Title 7.

state authority. Registration is only "prima facie evidence" that a pesticide complies with the statute. § 136a(f)(2). It is not "a defense for the commission of any offense" under FIFRA, including misbranding. *Id.* The manufacturer—not EPA—drafts the label, submits the supporting data, and bears a continuing obligation to ensure the label is not misleading. *See Bates*, 544 U.S. at 438. That allocation of responsibility is the opposite of when agency approval immunizes a manufacturer from liability.

The need for state-law remedies is acute here because EPA has not meaningfully evaluated the risks underlying these cases. The agency never has assessed whether Roundup *as formulated*—including its surfactant and several carcinogenic contaminants—causes cancer. Nor has the agency properly assessed the cancer-causing potential of Roundup's active ingredient: When EPA determined that glyphosate alone is "not likely to be carcinogenic," the Ninth Circuit vacated that conclusion as "the hallmark of arbitrary action." *NRDC v. EPA*, 38 F.4th 34, 49, 51 (9th Cir. 2022). Similarly, EPA has failed to evaluate paraquat's capacity to cause Parkinson's disease. Despite decades of emerging evidence, the agency never has required neurotoxicity testing—but has cited the absence of such testing as proof of safety. Where EPA is silent on warnings imposed under state law, preemption is inappropriate.

II. Monsanto's implied-preemption arguments likewise do not withstand scrutiny. Unlike the generic-drug manufacturers in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), pesticide registrants bear primary responsibility for their own labels and can act independently to amend them. And there is no "clear evidence" that EPA would have rejected any adequate

warning. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009). Monsanto never proposed one—not a cancer warning, an instruction that consumers wear personal protective equipment like masks or gloves, or even an acknowledgment that authoritative scientific bodies have concluded glyphosate is carcinogenic.

III. State-law tort actions serve FIFRA's purposes by exposing undisclosed dangers and giving manufacturers "added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product." *Bates*, 544 U.S. at 451. That function is critical here, where the statutory scheme depends heavily on manufacturer disclosure. The record shows that manufacturers withheld safety data from EPA for years—a fact that surfaced only through private litigation, not agency oversight. Accepting Monsanto's preemption theory would invert that framework: rewarding nondisclosure, converting manufacturer-created regulatory gaps into immunity, and leaving injured individuals with no remedy for harms that adequate warnings could have prevented.

STATEMENT

A. Statutory And Regulatory Background

1. In 1947, Congress enacted FIFRA to protect against adulterated and ineffective pesticides. FIFRA initially had no health or environmental protections. Congress amended the statute in 1972, in the wake of Rachel Carson's *Silent Spring* and the controversy over DDT, to require EPA to consider risks to health and the environment when deciding whether to register a pesticide. *See* Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, § 2, 86 Stat. 973, 984. FIFRA today governs "the use, as well as the sale and labeling, of pesticides." *Bates* 544 U.S. at 437. Congress has not amended FIFRA in any material respect since this Court's 2005 *Bates* decision.

FIFRA requires manufacturers to "register" their pesticides with EPA. § 136a(a) ("Requirement of registration"). EPA registration confers a limited license to market a pesticide. FIFRA provides that EPA "shall" register a pesticide if it determines that the label complies with the statute's requirements, the manufacturer's claims about the product's composition are warranted, the pesticide will perform its intended function, and its use "will not generally cause unreasonable adverse effects" on human health or the environment. § 136a(c)(5).

The manufacturer bears the burden of making that showing, although it is not a demanding one. The manufacturer must submit data demonstrating that the proposed pesticide satisfies FIFRA's standards. § 136a(a), (c). As to carcinogenicity, EPA's regulations require only two rodent studies. *See* 40 C.F.R. § 158.500(d) (Table, Guideline No. 870.4200).

Based on those submissions, EPA then determines whether the product meets FIFRA's standards,

including whether it will avoid unreasonable harm to human health and the environment and whether its label is not "misbranded." § 136a(c)(5)(B)-(D). A pesticide is "misbranded" if its label contains a statement that is "false or misleading in any particular," § 136(q)(1)(A), or omits adequate instructions for use, necessary warnings, or cautionary statements, § 136(q)(1)(F), (G).

2. FIFRA leaves the drafting of the label to the registrant. § 136a(c)(1)(C). This feature distinguishes FIFRA from other laws, including "the cigarette labeling law at issue in *Cipollone* [*v. Liggett Group, Inc.*, 505 U.S. 504 (1992)], which prescribed certain immutable warning statements." *Bates*, 544 U.S. at 451; *see also* 15 U.S.C. §§ 1333, 4402(a)(1). EPA's regulations also do not dictate the language to be used for the bulk of each label. *Cf.* 21 C.F.R. § 801.430(c) (specific toxic-shock warnings).

Because EPA relies on manufacturer-submitted data and labeling language, and does not conduct its own tests on a pesticide's health and environmental effects, FIFRA imposes requirements on registrants:

First, a registrant may not knowingly falsify any part of a registration application, and it may not make false or misleading statements in its labeling. §§ 136(q)(1)(A), 136j(a)(1)(E), 136j(a)(2)(C), (M).

Second, after registration issues, the registrant must provide EPA with information about unreasonable adverse effects on health or the environment. § 136d(a)(2); 40 C.F.R. pt. 159.

Third, the registrant remains responsible for ensuring that its registration and labeling comply with FIFRA. "Because it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded, manufacturers have a continuing obligation

to adhere to FIFRA's labeling requirements." *Bates*, 544 U.S. at 438; *see* §§ 136(q), 136j(a)(1)(E).

3. Registration does not insulate a manufacturer from liability. FIFRA provides that "[i]n no event shall registration of an article be construed as a defense" to a violation of the Act. § 136a(f)(2). Rather, registration is only "prima facie evidence" that the pesticide and its labeling comply with the statute. *Id.*

If EPA concludes that a registration no longer complies with FIFRA, it may initiate administrative proceedings to cancel the registration, § 136d(b), although such proceedings are time-consuming, expensive, and thus rare, *see infra* p.23. EPA also may seize, restrict, or prohibit the sale or use of pesticides that violate FIFRA. §§ 136j, 136k; *see also* § 136*l* (authorizing civil and criminal penalties).

None of FIFRA's enforcement mechanisms compensates people injured by an unsafe or mislabeled pesticide. Nor does federal law provide any other damages remedy for those injuries. Historically, then, state-law damages actions have provided the only means of compensating individuals harmed by FIFRA violations. *See Bates*, 544 U.S. at 451; *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1540-41 (D.C. Cir. 1984).

4. FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450; *see Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 613 (1991) ("[T]he statute leaves ample room for States and localities to supplement federal efforts even absent the express regulatory authorization of § 136v(a)."). Indeed, States may ban a federally registered pesticide, even if EPA does not consider it misbranded. *Bates*, 544 U.S. at 446. That authority is reflected in § 136v:

§ 136v. Authority of States

(a) In general

> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by [FIFRA].

The one statutory limit on that traditional state authority is a "narrow" preemption provision, *Bates*, 544 U.S. at 452—§ 136v(b):

(b) Uniformity

> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under [FIFRA].

B. Factual Background

1. Monsanto developed the weedkiller Roundup, whose active ingredient is glyphosate. RA4 (¶ 12); 3 Tr. 1663:23-25. The company long has marketed Roundup as safe for consumer use without personal protective equipment; its consumer labeling does not require a mask, gloves, or other PPE. RA4 (¶ 13), RA45 (¶ 38); 4 Tr. 2509:9-21, 2515:11-2516:11. Farmers, who typically buy Roundup in concentrated form, are warned to wear gloves and to wash their clothes after spraying it. 3 Tr. 2344:10-2347:21.

Roundup contains not only glyphosate but also a surfactant and "[s]everal" cancer-causing contaminants, including "Ethylene oxide and 1,4-Dioxane." 3 Tr. 2007:22-2008:2. The surfactant in the United States is polyethoxylated tallow amine, which helps Roundup penetrate human skin. RA44 (¶ 33); 3 Tr. 1664:3-6, 2008:12-16. POEA makes Roundup more genotoxic and is banned in Europe. RA44 (¶ 34).

Monsanto never has tested whether *formulated* Roundup causes cancer. BIO.App.45a. In 2009, Monsanto's Dr. Farmer wrote "you cannot say that Roundup does not cause cancer. We have not done carcinogenicity studies with 'Roundup.'" JA109 (cleaned up).

Paraquat, a commercial pesticide in use since the 1960s, poses similarly life-threatening risks. Botham. Dep. 96-97. Acutely toxic if ingested, paraquat is a "major suicide agent," particularly in "developing countries." PAN Germany, *Paraquat and Suicide* 2 (2003).

Paraquat is banned in more than 70 countries, including the European Union and China. Botham.Dep. 483-85, 1210-11. It remains in use in the United States as a "restricted-use" pesticide. 43 Fed. Reg. 5782 (Feb. 9, 1978).

Paraquat's acute toxicity is prominently disclosed on its label. Patterson.Dep. 26-29. But the risks from *chronic* exposure are not. Patterson.Dep. 30-32. Even compliant applicators may absorb paraquat through skin contact or inhalation, leading to accumulation in the brain and Parkinson's disease. Botham.Dep. 204-06, 211, 216-17, 251-52. PPE does not eliminate this risk: a 2007 study found 10 of 15 applicators tested positive for paraquat ingestion despite using label-required PPE. Ouzts.Dep. 187-97. There have been "tens of thousands of deaths from paraquat poisoning"—"possibly more than 100,000." Sharon Lerner, *The Paraquat Poisoning Problem* (Mar. 24, 2021).

2. Both pesticides' manufacturers knew of these risks yet suppressed the evidence.

Monsanto registered Roundup products in the mid-1970s by submitting studies from Industrial Bio-Test Laboratories—studies that FDA later discovered were

fraudulent. RA4 (¶ 12), RA39 (¶ 9); RA68; 2 Tr. 1020:8-1022:24. In 1985, EPA classified glyphosate as a possible human carcinogen. RA40 (¶ 15).

Rather than pursue additional testing to resolve those concerns, Monsanto sought to cover them up. In the late 1990s, after four studies concluded glyphosate was possibly genotoxic, RA41 (¶ 22), Monsanto hired Dr. James Parry, who concluded glyphosate could be genotoxic and suggested further tests. BIO.App.1a-8a; 3 Tr. 1702:21-1703:4. Monsanto instead replaced Parry with Dr. Gary Williams, who published an article in 2000 concluding Roundup posed no health risk. RA45 (¶ 39). But Monsanto wrote the article, RA46 (¶ 40), then EPA relied on it when evaluating glyphosate's carcinogenic potential, *id.* (¶ 42). In December 2025, the article was retracted because Monsanto employees' undisclosed involvement "raise[d] serious ethical concerns regarding the independence and accountability of the authors of this article and the academic integrity of the carcinogenicity studies presented."[3]

Syngenta, paraquat's primary producer, likewise long knew paraquat increases the risk of Parkinson's. Botham.Dep. 324, 329, 374, 662. Yet the company assured users that paraquat "does not reach the specific location in the brain necessary to produce Parkinson's symptoms." Botham.Dep. 1072-78. Syngenta directed employees not to measure paraquat in animal brains because any amount "(no matter how small) will not be perceived externally in a positive light."

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[3] Martin van den Berg, Retraction Notice to "Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans" [31 Regul. Toxicol. & Pharm. 117-65 (2000)], published online December 2025, https://bit.ly/4aefz1P.

Botham.Dep. 311-15. From 2008 on, all paraquat research required legal-department approval. Botham. Dep. 1104-06, 1191-93.

Despite these measures, Syngenta's own scientists identified neurological risks. Between 2003 and 2005, scientist Louise Marks found statistically significant neuron loss; Syngenta withheld those findings from EPA until December 2019, after plaintiffs' counsel uncovered them. Botham.Dep. 315-18, 332-34, 363-64, 395-98. A 2010 study found paraquat concentrations in exposed squirrel monkeys' brains did not decline over time. Syngenta chose not to disclose that study. Botham.Dep. 813-14, 826-27. A 2011 NIH-funded study reported a 2.5-fold increase in Parkinson's risk among paraquat-exposed workers. *See* Caroline M. Tanner et al., *Rotenone, Paraquat, and Parkinson's Disease*, 119 Envtl. Health Persp. 866 (June 2011). Syngenta's privately commissioned reanalysis found a comparable increase, but it did not disclose those results. Botham.Dep. 395-403.

3. EPA's regulatory response to both products has been marked by circular reasoning and reliance on manufacturer-controlled evidence.

As to Roundup, EPA has made no findings about whether the formulated product causes cancer. In 2017, the agency determined that it could not reach "a conclusion regarding the association between glyphosate exposure and risk of [non-Hodgkin lymphoma]." Off. of Pesticide Programs, EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 68 (Dec. 12, 2017). The data were uncertain partly because "farmers and other applicators apply *formulations*, *not the active ingredient alone*." *Id.* at 137 (emphasis added). So EPA acknowledged the need for more research "to determine whether formulation

components, such as surfactants, influence the toxicity of glyphosate formulations." *Id.* at 144. Even so, in January 2020, EPA determined that "glyphosate is not likely to be carcinogenic to humans." *NRDC*, 38 F.4th at 43. The Ninth Circuit vacated that conclusion as "the hallmark of arbitrary action." *Id.* at 51.

The agency's treatment of paraquat followed a similar pattern. Paraquat was first registered in 1964, before EPA existed; EPA classified it as a restricted-use pesticide in 1978 but never required neurotoxicity testing—then cited the absence of such testing as proof of safety. Patterson.Dep. 31, 89-90; 43 Fed. Reg. 5782. Successive reevaluations reached the same circular conclusion. *See*, *e.g.*, EPA, *Reregistration Eligibility Decision (RED) Paraquat Dichloride* 33 (Aug. 1997); Shelley DuTeaux et al., Cal. Dep't of Pesticide Regulation, *Preliminary Report of the Potential Human Health Outcomes Resulting from Paraquat Exposure* 16-17 (Dec. 2024) ("DuTeaux, *Preliminary Report*").

Syngenta reinforced that vacuum by keeping critical voices off EPA's Scientific Advisory Panel. In 2005, the company orchestrated opposition to a researcher's nomination "with care" so the effort "cannot be attributed to Syngenta." Botham.Dep. 675-81, 685-89, 696. In 2013, Syngenta told EPA that paraquat-related brain cell loss without disclosing the Marks studies "was not reproducible"; in 2017, it told EPA "There are No Effects of Paraquat in Animal Models"—a statement a corporate designee conceded "would not be correct as written." Dixon.Dep. 208, 211-18, 236-37, 242-44. EPA's 2019 systematic review considered only 11 of 217 identified animal studies, finding "limited, but insufficient epidemiologic evidence." EPA, *Paraquat Dichloride: Systematic Review* 4-5, 89 (June 26, 2019). Its 2021 Interim

Decision imposed new restrictions but again declined to address Parkinson's. EPA, *Paraquat Dichloride: Interim Registration Review Decision* 17-18 (July 2021).

Independent actors have attempted to fill these gaps. In 2015, a working group at the International Agency for Research on Cancer—whose assessments "are generally recognized as authoritative," Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 20, 564 n.46 (3d ed. 2011)—concluded glyphosate probably is carcinogenic to humans. RA48 (¶ 50). California then categorized glyphosate as a chemical known to cause cancer. In April 2022, EPA wrote it "could approve" a California-proposed warning informing consumers that "[IARC] classified glyphosate as probably carcinogenic to humans" while "US EPA has determined that glyphosate is not likely to be carcinogenic to humans." RA57. That letter has been withdrawn.

California likewise has regulated paraquat since 1974. *See* DuTeaux, *Preliminary Report* 17. Agricultural use requires a county-issued permit and is subject to restrictions on aerial spraying and use near schools and residences. *See* Cal. Code Regs. tit. 3, §§ 6420(a), 6466, 6470; Cal. Food & Agric. Code §§ 14001-14015. At least 10 States have considered or adopted measures to ban or restrict paraquat. *See* Am. Parkinson Disease Ass'n, *Paraquat is banned in 70+ countries, but still legal in the US* (Feb. 24, 2026).

4. Soon after IARC concluded glyphosate probably causes cancer, thousands of Roundup-exposed plaintiffs brought actions consolidated in a federal MDL.

In 2021, Monsanto's parent company, Bayer, announced that it would discontinue glyphosate-based Roundup products for the residential market. Although farmers continue to use glyphosate-

containing Roundup, Monsanto claims it has used different active ingredients in consumer Roundup since 2023.

In February 2026, Monsanto proposed a nationwide settlement binding all persons who bought, applied, or even *saw* Roundup applied in the United States, but excluding judgments now on appeal. Class Action Settlement Agreement §§ 2.1, 2.1(b)(iii), *King v. Monsanto Co.*, No. 2622-CC00325 (Mo. Cir. Ct. Feb. 17, 2026). After preliminary approval in March, Bayer explained that this Court's review would affect only "outstanding damage awards subject to pending appeals, which are not covered by the settlement."[4] That universe consists of two cases—this one and *Monsanto Co. v. Anderson*, No. 25-1042 (U.S.).

Paraquat applicators have pursued parallel protections through state-law litigation, bringing claims including failure to warn. In 2021, the Judicial Panel on Multidistrict Litigation centralized the federal actions in the Southern District of Illinois. The district court largely has denied defendants' motions to dismiss, including on preemption. On March 3, 2026, Syngenta announced that it would cease global production of paraquat as of June 2026.

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[4] Bayer, *Missouri court grants preliminary approval of Roundup™ class settlement to resolve current and future claims* (Mar. 4, 2026).

ARGUMENT

I. FIFRA DOES NOT EXPRESSLY PREEMPT LABEL-BASED FAILURE-TO-WARN CLAIMS

Express preemption turns primarily on "the language of the pre-emption statute and the statutory framework surrounding it." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996) (cleaned up); *see Carson v. Monsanto Co.*, 72 F.4th 1261, 1267 (11th Cir. 2023) (en banc). FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450. "Most significantly, States may ban or restrict the uses of" EPA-approved pesticides, and they may register pesticides for uses beyond those approved by EPA. *Id.* (citing § 136v(a), (c)); *see also* § 136w-1 (granting States primary enforcement responsibility for use violations).

That framework accommodates state-law failure-to-warn claims based on inadequate labeling, even where EPA has not required the warning. Monsanto's and the government's contrary arguments reflect a misunderstanding of both FIFRA's allocation of regulatory authority and state failure-to-warn law.

A. Failure-To-Warn Claims Like Respondent's Are Consistent With FIFRA, Which Reserves Significant Authority To States

1. FIFRA expressly delegates States "authority" to "regulate" the "sale or use of any federally registered pesticide," except that States may not permit what federal law prohibits. § 136v(a). FIFRA also authorizes State registrations of pesticides to accommodate "special local needs," and such registration "shall authorize distribution and use only within such State." § 136v(c)(1).

That affirmative authorization for States to regulate "use[s]" encompasses state tort claims, which supplement federal and state pesticide regulations. Although FIFRA itself "does not provide a federal remedy to [those] who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements, nothing in § 136v(b) precludes States from providing such a remedy." *Bates*, 544 U.S. at 448. There is a "long history of tort litigation against manufacturers of poisonous substances." *Id.* at 449-51. This Court thus observed that "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder," FIFRA's functioning. *Id.* at 451.

As this Court concluded in *Bates*, § 136v(b) does not expressly preempt state common-law suits. That "narrow" preemption provision, *id.* at 452, "prohibits only state-law labeling and packaging requirements that are '*in addition to or different from*' the labeling and packaging requirements under FIFRA," *id.* at 447 (quoting § 136v(b)) (emphasis in *Bates*). It "calls for an examination of the elements of the common-law duty at issue." *Id.* at 445. For a state tort claim to be preempted, it must set forth (1) "a requirement '*for labeling or packaging*'" (2) "that is '*in addition to or different from*'" one of FIFRA's requirements. *Id.* at 443-44 (quoting § 136v(b)) (emphases in *Bates*).

The preemption inquiry thus proceeds in two steps. Courts first ask whether a state-law claim imposes any requirement for pesticide labeling or packaging. "A requirement is a rule of law that must be obeyed." *Id.* at 445. Claims that would not require manufacturers to "label or package their products in any particular way" are not preempted. *Id.* at 444; *see id.* ("petitioners' claims for defective design . . . are not

pre-empted"). For example, *Bates* found it "perfectly clear" that common-law claims "that require manufacturers to design reasonably safe products" and "use due care in conducting appropriate testing of their products" are not preempted. *Id.*

Next, courts ask whether the state-law labeling requirement is "in addition to or different from those required under [FIFRA]." § 136v(b). Common-law duties are not preempted if they are "equivalent to, and fully consistent with, FIFRA's misbranding provisions" and the "relatively few regulations that refine or elaborate upon FIFRA's broadly phrased misbranding standards." *Bates*, 544 U.S. at 447, 453 n.28; *see id.* at 454 ("[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."). In other words, FIFRA does not preempt state-law claims that impose "parallel requirements" to those in FIFRA. *Id.* at 447.

2. FIFRA does not expressly preempt state-law failure-to-warn claims where EPA has not imposed specific warnings. *First*, such claims are a permissible exercise of the state authority to regulate pesticide *use* that § 136v(a) preserves. Under FIFRA's decentralized scheme, EPA is not the final arbiter of how pesticides may be used—States are. Section 136v(a) provides that "[a] State may regulate the sale or use of any federally registered pesticide or device in the State." That authority is sweeping: it includes the power to ban a federally registered pesticide outright, even one EPA considers properly labeled. *See Bates*, 544 U.S. at 446. And FIFRA confers on States "primary enforcement responsibility" for pesticide use violations. § 136w-1. Because FIFRA does not dictate how pesticides must be used, state-law requirements

governing use do not impose requirements "in addition to or different from" any federal use requirement.

State failure-to-warn claims operate within that preserved authority, at least where a manufacturer could have satisfied its duty by informing users how to use the product safely. Here, for example, Monsanto could have provided Durnell PPE instructions like those it gives to agricultural users. *See* 5 Tr. 3423:13-15 ("Monsanto gives the most stringent warnings to the most sophisticated users."). Durnell testified he would have heeded them. 4 Tr. 2508:16-2509:19. A warning instructing a consumer to wear gloves when spraying a weedkiller is a use instruction that must, as a practical matter, appear on the label. It thus falls within the state authority § 136v(a) preserves without being negated by the limited carveout of § 136v(b).

This Court confronted a closely related issue in *Bates*, where "Congress [had] amended FIFRA to allow EPA to waive efficacy review of newly registered pesticides." 544 U.S. at 450. The Court held that this gap in federal oversight did not preempt state-law claims, explaining that it was "unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability," including the efficacy-related claims there. *Id.* The same logic applies here: EPA's lack of final authority over use is a reason to preserve state authority, not to preempt it.

Second, nothing in FIFRA prohibits a State from requiring additional warnings to address state or local concerns, so long as those requirements do not result in labeling that is "in addition to or different from" federal requirements. Where a warning requirement

can be implemented through nationally uniform labeling, § 136v(b) is not implicated: "EPA approves only one label per pesticide," and, "[i]n approving a labeling change, EPA substitutes a new nationally uniform label." Brief Amicus Curiae for the United States in Support of Plaintiffs-Appellants 17, *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366 (Cal. 2000) (No. S072524, filed Mar. 1999). Thus, even state-specific instructions are routinely reflected in manufacturers' nationally uniform labeling. *See Bates*, 544 U.S. at 435 (noting supplemental label for Strongarm applicable in New Mexico, Oklahoma, and Texas); *infra* p.27.

Third, even apart from § 136v(a), state-law warning claims are not preempted because—at most—they impose *parallel* requirements to FIFRA's. As the court of appeals observed, "Missouri's strict liability failure to warn cause of action is fully consistent" with FIFRA's requirements. Pet.App.6. The same is true of failure-to-warn causes of action under other States' law. *See*, *e.g.*, *Carson v. Monsanto Co.*, 92 F.4th 980, 992 (11th Cir. 2024) (Georgia); *Hardeman v. Monsanto Co.*, 997 F.3d 941, 955 (9th Cir. 2021) (California). These claims are "equivalent to, and fully consistent with, FIFRA's misbranding provisions," *Bates*, 544 U.S. at 447, not preempted.

Bates instructs that courts weighing claims of parallel requirements examine the elements of the claim. *See id.* at 445; *id.* at 456-57 (Thomas, J., concurring in the judgment in part and dissenting in part). Here, Durnell first had to prove at trial that Monsanto failed to "give an adequate warning of the danger" posed by Roundup. Pet.App.6. That duty tracks § 136(q)(1)(G), which requires a warning "necessary" and "adequate to protect health."

Durnell's claim also requires warnings in narrower circumstances than FIFRA does.[5] FIFRA requires adequate safety warnings no matter the consumer's knowledge. § 136(q)(1)(G). Missouri requires a warning only if the product is "unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics." 5 Tr. 3378:19-21; *see Moore v. Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. 2011); JA159-60 (jury instruction).

Durnell's failure-to-warn claim thus functionally enforces FIFRA's misbranding prohibition. "[A] state cause of action that seeks to enforce" FIFRA "'does not impose a requirement that is "different from, or in addition to," requirements under federal law,'" and so is not preempted. *Bates*, 544 U.S. at 447-48 (quoting *Lohr*, 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part)).

B. Monsanto's Express-Preemption Arguments Lack Merit

Monsanto's cornerstone argument is that EPA's decision to register a pesticide and approve its label imposes a preemptive "requirement" under FIFRA. That argument always has been incorrect, but it is even less persuasive now that the Ninth Circuit has vacated the reasoning EPA used when registering glyphosate and EPA has not challenged that vacatur.

1. After an 11-year re-registration process that began in 2009, EPA failed to sustain its initial view that glyphosate was not likely to cause cancer. The Ninth Circuit held that EPA lacked substantial evidence for that position and that its reasoning was "the hallmark of arbitrary action." *NRDC*, 38 F.4th at 51.

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[5] FIFRA does not expressly preempt "narrower" state requirements. *Bates*, 544 U.S. at 447 n.23.

Although glyphosate remains registered, any preemptive effect of registration is nil. A vacated agency decision has no legal effect. "In essence, a vacatur order takes the unlawful agency action off the books, which is an entirely appropriate response when a plaintiff successfully establishes that the agency's conduct violates the law." *Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 50 (D.D.C. 2020) (Jackson, J.) (cleaned up). The D.C. Circuit therefore has vacated an agency order because it "relied not only on [an already-vacated order] but also on its defective reasoning." *WorldCom, Inc. v. FCC*, 246 F.3d 690, 696 (D.C. Cir. 2001).

EPA's registration of glyphosate cannot support preemption because its "defective reasoning" about carcinogenicity has been vacated. Even so, Monsanto cites (at 17, 31, 49) EPA's statement that its "underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic in humans, remain the same." EPA, *EPA Withdraws Glyphosate Interim Decision* (Sept. 23, 2022). That bare statement has no legal effect, much less a preemptive one.

2. Even apart from the glyphosate-specific vacatur, EPA's registration and approval of labeling cannot immunize a manufacturer from tort liability. That conclusion flows from FIFRA's text, structure, and Monsanto's own labeling practices.

Text. FIFRA provides explicitly in § 136a(f)(2) that registration is only "prima facie evidence" that a pesticide complies with the statute—that is, they are "not final" but may be rebutted. *United States v. ICC*, 337 U.S. 426, 435 (1949). Registration thus is not "a defense for the commission of any offense under [FIFRA]." § 136a(f)(2).

Section 136a(f)(2) provides in full:

> **(2) Registration not a defense**
>
> In no event shall registration of an article be construed as a defense for the commission of any offense under [FIFRA]. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of [FIFRA].

Three conclusions follow. *First*, a pesticide can be "registered but nevertheless misbranded." *Bates*, 544 U.S. at 438. *Second*, EPA is not the ultimate arbiter of whether labeling is adequate: even if the agency approved a label, "a judge or jury" could "find that [the] same label violates FIFRA." *Hardeman*, 997 F.3d at 956; *see Bates*, 544 U.S. at 452 ("lay juries are in no sense anathema to FIFRA's scheme"). *Third*, manufacturers have a continuing duty to update labeling that is misbranded—retaining an EPA-approved but misbranded label is not a "requirement" of FIFRA; it is a violation. *Bates*, 544 U.S. at 438. A jury's conclusion that an EPA-approved label inadequately warned an injured plaintiff of the risks is perfectly consistent with that scheme.

Structure. Statutory context reinforces that conclusion. *First*, the statute requires EPA to determine whether manufacturer-drafted warnings are "necessary" and "adequate to protect [public] health" based on manufacturer-submitted material. § 136(q)(1)(G); *see* § 136a(c)(2), (c)(5)(B)-(D). Monsanto's position grants manufacturers immunity when *labels they draft* are approved by EPA based on *science they submit*. No rational Congress would enact such a statute.

Second, as the United States previously informed this Court, "EPA does not typically use the registra-

tion process to address [long-term] harms by requiring chronic-risk warnings on a pesticide's labeling." U.S. *Hardeman* Br. 11. The government now contends (at 19 n.4) that EPA addresses chronic risks through cancellation proceedings, but that is no answer. For one thing, cancellation is rare: from 2010 to 2018, EPA involuntarily cancelled just one pesticide registration. *See* Nathan Donley, *The USA lags behind other agricultural nations in banning harmful pesticides*, 18 Envtl. Health #44, at 5-6 (2019).

For another, when EPA does act, the protracted process is no substitute for adequate labeling. When environmental groups petitioned EPA to cancel chlorpyrifos's registration in 2007, for example, EPA "spent more than a decade" assembling a record and employed "one delaying tactic after another." *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 678 (9th Cir. 2021). Only after a Ninth Circuit-imposed deadline did EPA ban chlorpyrifos on food crops—and the Eighth Circuit then vacated that ban as arbitrary and capricious. *See Red River Valley Sugarbeet Growers Ass'n v. Regan*, 85 F.4th 881, 883 (8th Cir. 2023). After all that, *chlorpyrifos remains on the market*.

Practice. If Monsanto were right (at 32-33) that EPA-approved labels say exactly what is necessary to protect human health—no more, no less—its own conduct would be inexplicable. The company has revised Roundup's labeling *hundreds* of times, including more than 50 changes to the four products Durnell used.[6]

3. Monsanto's counterarguments lack merit. *First*, the company contends (at 38-39) that § 136a(f)(2) "is not a preemption provision at all."

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[6] 4 Tr. 2470:14-23, 2471:7-18, 2472:16-23, 2473:6-13; *see* JA234-240.

But express preemption turns on "the language of the pre-emption statute *and* the statutory framework surrounding it." *Lohr*, 518 U.S. at 486 (cleaned up, emphasis added). Section 136a(f)(2)'s placement outside § 136v(b) is no reason to disregard it.

Because "EPA's labeling determinations are not dispositive of FIFRA compliance," Monsanto offers no basis to treat those determinations as any more "conclusive as to which common law requirements are 'in addition to or different from' the requirements imposed by FIFRA." *Hardeman*, 997 F.3d at 956. Just as a manufacturer with a registered pesticide still may be liable for misbranding under FIFRA, it likewise may be subject to parallel liability under state law. *See Bates*, 544 U.S. at 451 (discussing "[p]rivate remedies that enforce federal misbranding requirements").

Second, Monsanto leans heavily (at 39-40) on *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). But *Riegel* involved the Medical Device Amendments ("MDAs"), which operate differently from FIFRA.

The MDAs contain no provision like § 136a(f)(2), which provides that registration is only "prima facie evidence" of compliance, not proof that labeling is "adequate to protect health," § 136(q)(1)(F), (G). *See* U.S. *Hardeman* Br. 18-19. The MDAs also reserve far less power for States. Under FIFRA, States may *ban the sale or use of a pesticide outright*. *See* § 136v(a). The MDAs have no analogue.

More generally, the statutory schemes differ. The MDAs "swept back" "state obligations" and "imposed a regime of detailed federal oversight," limiting States from imposing nearly any condition "'which relates to . . . safety or effectiveness.'" *Riegel*, 552 U.S. at 316 (quoting 21 U.S.C. § 360k(a)(2)). FIFRA, by contrast,

"authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450 (citing § 136v(a)); *see also* § 136w-1 (conferring on States "primary enforcement responsibility"). Thus, "different federal statutes and regulations may . . . lead to different pre-emption results." *PLIVA*, 564 U.S. at 626.

Federal product review likewise differs. For medical devices, "premarket approval is specific to individual devices" and requires FDA to determine that the device "offers a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 322-23. By contrast, FIFRA's misbranding provisions impose only "general standards." *Bates*, 544 U.S. at 453 n.27; *see Lohr*, 518 U.S. at 501 (no preemption where federal requirements "reflect[ed] important but entirely generic concerns"). And EPA has acknowledged that it has not evaluated glyphosate "formulations" like Roundup and that, "if at any time[] information becomes available that indicates adverse human health effects of concern for exposure to glyphosate or its formulations, EPA intends to review it and determine the appropriate regulatory action." *Hardeman*, 997 F.3d at 952 (cleaned up). EPA similarly has not evaluated paraquat's Parkinson's risks.

Third, Monsanto and the United States focus on a "cancer warning." That framing misapprehends state failure-to-warn law and state use restrictions, which do not turn on whether a manufacturer used a particular phrase. To avoid liability, Monsanto need not have adopted a specific "cancer warning," just as Syngenta need not adopt a specific "Parkinson's disease warning." Rather, state law requires manufacturers to provide "adequate instructions" and warnings to reduce or avoid risks. Restatement (Third) of Torts: Products Liability § 2 cmt. i (1998).

Here, the record reflects multiple ways Monsanto could have satisfied that obligation. It could have provided consumers like Durnell a PPE warning. Or it could have added "links to relevant scientific evidence and materials related to whether exposure to Roundup Products causes [non-Hodgkin lymphoma]." Class Action Settlement Agreement at PDF p.167, *In re Roundup Prods. Liab. Litig.*, No. 3:16-md-2741-VC, ECF #12509-2 (N.D. Cal. Feb. 3, 2021).[7] Monsanto and the government ignore these options.

Fourth, Monsanto argues (at 36-38) that state-law warnings would undermine national "uniformity." But *Bates* cautioned against "overstat[ing] the degree of uniformity and centralization that characterizes FIFRA," explaining that the statute "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." 544 U.S. at 450.

To be sure, FIFRA's preemption provision plays "a narrow, but still important, role": It promotes uniformity in the presentation of labels—ensuring that they use the same font, font size, color, and similar features nationwide. It also bars state-law requirements that conflict with the few specifically listed federal ones. *Id.* at 452. Thus, a claim that a label should have said "DANGER" rather than "CAUTION" would be preempted where federal regulations specify those terms. *Id.* at 453 (citing 40 C.F.R. § 156.64).

No such federal requirement exists here. EPA has not mandated or prohibited warnings about glyphosate's chronic risks, just as it has not addressed paraquat's long-term neurotoxicity. FIFRA's "narrow" preemption provision therefore does not apply.

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[7] The district court rejected that settlement on other grounds, and Monsanto never made that request of EPA.

Nor does real-world practice support Monsanto's uniformity concerns. Labels already incorporate state-specific instructions. Roundup's label directs users to "requirements specific to your State or Tribe" and to consult state regulators. BIO.App.30a. It also includes aerial spraying restrictions in California and Arkansas, BIO.App.35a-40a, and differing application rates for sugarcane in Florida, Hawaii, Louisiana, and Texas, BIO.App.42a-43a. Paraquat also is subject to longstanding state-specific regulation. *Supra* p.13. Monsanto complains (at 36-38) about 50 different state labeling regimes, but never explains why it poses a "uniformity" problem to offer state-specific instructions for sugarcane but not cancer on one label.

Finally, the government's overwarning concern has no merit. U.S. Br. 34 (citing *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 304 (2019)). *Merck* addressed prescription drugs—products whose therapeutic benefits patients may need, and where excessive warnings might deter necessary treatment. No comparable concern exists here. A Roundup consumer or paraquat applicator who chooses to wear gloves or PPE, switch products, or pull weeds by hand suffers no adverse health effect. The government thus imports a concern about patients forgoing medication into a context where the consequence is a change in weed-management practices.

II. FIFRA DOES NOT IMPLICITLY PREEMPT LABEL-BASED FAILURE-TO-WARN CLAIMS

The court of appeals also correctly held Monsanto cannot show implied preemption. That "is a demanding defense." *Wyeth*, 555 U.S. at 573. Before the court below, the company did not even try to carry its heavy burden: "The record contains no evidence that Monsanto either informed the EPA of the justifications

for a change to its warning label or that the EPA has informed Monsanto it would not approve such a warning." Pet.App.9.

Here, Monsanto draws its implied-preemption arguments from prescription-drug cases under the Federal Food, Drug, and Cosmetic Act. This Court conducts an implied-preemption analysis in such cases because Congress has "declined to enact [an express-preemption] provision for prescription drugs." *Wyeth*, 555 U.S. at 567. Those cases have dubious relevance here because FIFRA has an express-preemption provision. *See Bates*, 544 U.S. at 459 (Thomas, J., concurring in judgment in part and dissenting in part) (favorably noting "this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption"). On their own terms, Monsanto's implied-preemption arguments lack merit.

1. Monsanto's first implied-preemption theory (at 43-47) rests on the premise that it could not add a cancer warning to Roundup's labeling without EPA's approval. That premise is false, and the arguments that flow from it misread *PLIVA*.

In *PLIVA*, the Court addressed implied preemption in the generic-drug context, where federal law imposes a "duty of sameness" requiring generic labels to match their brand-name counterparts. 564 U.S. at 616. Because of that duty, generic manufacturers cannot unilaterally change their labels—they only may "ask the agency to work toward strengthening the label" for both generic and brand-name drugs. *Id.* Absent "the Federal Government's special permission and assistance" with the brand-name companies, they cannot independently satisfy state-law duties to provide adequate warnings. *Id.* at 623-24. That constraint drove the Court's holding: when federal

law affirmatively prohibits a manufacturer from acting independently, state-law duties requiring such action are preempted.

FIFRA could hardly be more different. *First*, it places primary responsibility for labeling on the manufacturer, not the agency. § 136a(c)(1)(C). When label changes are necessary, the registrant drafts and submits revised labeling to EPA, which "shall" approve the change if it complies with FIFRA. § 136a(f)(1); 40 C.F.R. § 152.50(e). That process bears little resemblance to the regime in *PLIVA*, which depended on "a Mouse Trap game" of coordination with brand-name manufacturers and afforded no unilateral authority to the regulated party. 564 U.S. at 619.

Second, pesticide registrants are not bound by generic drugmakers' "duty to keep the label the same." *Id.* at 618. Instead, they must abide by FIFRA's duty to keep the label current—that is, the "continuing obligation to adhere to FIFRA's labeling requirements." *Bates*, 544 U.S. at 438.

Third, FIFRA differs further by permitting certain label changes without prior EPA approval. Under EPA regulations, registrants may implement specified modifications through a notification process, subject to later agency review. *See* 40 C.F.R. § 152.46(a); Off. of Pesticide Programs, EPA, Pesticide Registration Notice 98-10 (Oct. 22, 1998). Although Monsanto responds (at 31) that adding a cancer warning would not qualify for such treatment, "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. For example, "Bayer CropScience notified EPA 'of a minor labeling amendment for LARVIN Technical,' inform-

ing EPA that 'as required by California Proposition 65, the following statement has been added to the label, "This product contains a chemical known to the state of California to cause cancer."'" *Id.* at 959 n.10 (cleaned up). Had Monsanto—now a Bayer subsidiary—taken the same approach here, it could have prevented Durnell's injuries.

2. Monsanto's second theory (at 47) is that it cannot add a "cancer warning" to Roundup labels because EPA would not accept it. Again under the FDCA, failure-to-warn claims are preempted when there is "clear evidence" that FDA would not have approved the warning that state law requires. *Wyeth*, 555 U.S. at 571. But "clear evidence" rests on "agency actions taken pursuant to the [agency's] congressionally delegated authority": "notice-and-comment rulemaking," an order "formally rejecting a warning label," or "other agency action carrying the force of law." *Merck*, 587 U.S. at 315-16.

There is no "clear evidence" showing Durnell's failure-to-warn claim is preempted. *First*, EPA has promulgated no notice-and-comment-based regulation requiring certain warnings on glyphosate-based product labels and barring others. Monsanto instead points (at 49-50) to EPA's 1993 *Reregistration Eligibility Decision*. EPA, *Reregistration Eligibility Decision (RED) Glyphosate* (Sept. 1993). But that decision imposed labeling requirements only with respect to water contamination and workplace safety; it did not forbid the warnings at issue here. *Id.* at 72-73.

Second, EPA has taken no formal action rejecting a warning adequate to prevent Roundup-caused harms, and Monsanto never has asked for such a warning.

Third, EPA has taken no other action with the force of law disapproving a state-law-required warning.

Monsanto cites (at 50) a 2019 letter from an EPA employee concluding that glyphosate is "not likely to be carcinogenic to humans" and that California's warning of glyphosate's potential carcinogenic effects was "false or misleading." Pet.App.38-39. But the company neglects to mention that every court to consider this letter has held that it "did not carry the force of law because it neither reflected sufficient formality nor created a rule of law that must be obeyed." *Carson*, 92 F.4th at 996 (citation omitted); *see Hardeman*, 997 F.3d at 957 (same).

Monsanto also says (at 50) that EPA's decisions declining to require a cancer warning—whether through its registration review process or its approval of individual labels—carry impossibility-preemptive force. But this Court never has held that agency silence can speak that loudly. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 67-68 (2002) (agency decision not to regulate does not preempt state common-law claims).

III. MONSANTO'S POSITION WOULD HAVE SUBSTANTIAL NEGATIVE EFFECTS

Monsanto's position would bar essentially all failure-to-warn claims based on a pesticide's "labeling." Such immunity for pesticide manufacturers would hinder FIFRA itself. As this Court observed in *Bates*, state-law tort actions "may aid in the exposure of new dangers associated with pesticides," giving manufacturers "added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement." 544 U.S. at 451. That's true for consumers who have used Roundup products for decades around their homes and neighborhoods. And the same is true for plaintiffs in the *Paraquat* MDL,

whose lengthy exposure to small doses of the pesticide left them with Parkinson's. Their extended exposure can help inform EPA about the long-term effects of pesticides and aid the agency in carrying out "its task of assessing the environmental and health dangers posed by" poisonous substances. *Id*. at 440.

That task is exceptionally important. Rather than test formulated Roundup for long-term cancer risks or provide warnings, Monsanto instead has waged a decades-long campaign to mislead the scientific community and the public about the weedkiller's cancer risks. Syngenta likewise carried out a protracted campaign of misinformation—one deliberately aimed at influencing EPA itself. *Supra* pp.9-11. Those efforts came to light through litigation, not EPA's oversight.

These companies' practice of hiding their products' defects shows why the proper scope of FIFRA preemption matters. As the United States once informed this Court, there is "the possibility that the manufacturer's submissions to EPA may be inaccurate or incomplete, or that evolving science will cast doubt on the adequacy of approved labeling." U.S. *Hardeman* Br. 12 n.3. If FIFRA preempted the very suits that expose those deficiencies, manufacturers could profit from their own nondisclosure. Regulatory silence—some of it of their own making—would become a shield against accountability.

Bates rejected that result, and rightly so. Congress has not disturbed *Bates*, and Monsanto does not ask this Court to overrule it. If FIFRA does not preempt state-law suits for crop damage, it surely does not preempt suits for grievous injury and death.

CONCLUSION

The state court of appeals' judgment should be affirmed.

Respectfully submitted,

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