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 FORMER EPA OFFICIALS AND ENVIRONMENTAL PROTECTION NETWORK AS AMICI CURIAE IN SUPPORT OF RESPONDENT

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INTEREST OF AMICI CURIAE[1]

The individual amici are former Environmental Protection Agency (EPA) officials. Collectively, they have 125 years of experience at EPA, spanning from 1974 to 2024, serving across Republican and Democratic administrations.

The Environmental Protection Network (EPN) is made up of over 750 EPA alumni across the country. It harnesses the expertise of former EPA career staff and political appointees from Democratic and Republican administrations who volunteer their time to provide the unique perspective of former regulators with decades of historical knowledge and subject matter expertise.

Amici write to share with the Court their knowledge of the overall pesticide registration and labeling process and the complementary role of states in regulating pesticides. Informed by their deep expertise in EPA's process and procedures, amici share the view that—as the Solicitor General explained to the Court in *Hardeman*—the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) does not preempt label-based state-law failure-to-

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[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than amici curiae, their members, or their counsel made a monetary contribution intended to fund the brief's preparation or submission.

warn claims whenever EPA approves labeling without a warning. These claims are not preempted unless the following criteria are met: the registrant applied to amend its product's labeling to add the warning required by state law, the registrant provided EPA with substantially equivalent information to that to be reviewed by the state court, and EPA denied that precise warning (or EPA has promulgated regulations that prohibit the precise requested warning).

FIFRA requires labeling to include warnings that are necessary and adequate to protect health and the environment. But ample experience shows that EPA's acceptance of particular labeling, based on review of a particular proposal at a certain point in time, is not dispositive of that labeling's FIFRA compliance for all time. Under FIFRA and EPA's procedures, mere one-time acceptance of labeling confers no defense to liability for misbranding. To avoid such liability, the manufacturer must keep both EPA and the product labeling up to date with necessary safety information.

Science evolves, and EPA welcomes labeling amendments to meet state-specific requirements or to reflect updated assessments of pesticide risks. EPA's speedy and informal labeling amendment procedures belie the notion that either EPA or FIFRA should, without consideration of the basis for a state's action, bar a manufacturer from updating its labeling to include a warning that a state court would find necessary and adequate to protect health.

The United States correctly concluded that FIFRA does not broadly preempt state failure-to-warn claims when it first addressed the question in 1999, and again when it responded to a call for the views of the

Solicitor General four years ago in *Hardeman*. Under this correct interpretation of the statute, EPA and states can work together to regulate pesticides in a way that provides needed pest control both effectively and safely, and state failure-to-warn cases are a valuable component of FIFRA's scheme. The United States' recent change in position is contrary to the facts and the law.

Individual amici are:

- Jonathan Cannon, who served as EPA's General Counsel from 1995 to 1998.
- Robert Dreher, who served as EPA's Deputy General Counsel from 1996 to 2000.
- Lynn Goldman, who served as Assistant Administrator, Office of Chemical Safety and Pollution Prevention (then called the Office of Pollution Prevention and Toxic Substances) from 1993 through 1998.
- James Jones, who joined EPA in 1987 and served as Assistant Administrator, Office of Chemical Safety and Pollution Prevention from 2013 to 2017.
- William Jordan, who joined EPA in 1974 and served as Deputy Director for Programs and Senior Policy Advisor, Office of Pesticide Programs before retiring in 2016.
- Jake Li, who served as Deputy Assistant Administrator for Pesticide Programs, Office of Chemical Safety and Pollution Prevention from 2021 to 2024.
- Robert Perlis, who joined EPA's Office of General Counsel in 1987 as an attorney specializing in

pesticide matters, and served as Assistant General Counsel for Pesticides from 2003 to 2020.

- Robert M. Sussman, who served as EPA Deputy Administrator from 1993 to 1994 and as Senior Policy Counsel to EPA Administrator from 2009 to 2013.

INTRODUCTION AND SUMMARY OF ARGUMENT

FIFRA does not preempt state label-based failure-to-warn claims merely because EPA has accepted labeling lacking state-required warnings. When premised on the theory that labeling is "misleading" or warnings are "inadequate," state-law claims are not "'in addition to or different from'" FIFRA's requirements. *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 447 (2005). FIFRA itself requires adequate warnings and labeling that is not misleading. 7 U.S.C. § 136(q)(1)(A), (G); Resp. Br. 3-4, 13, 33. A registrant may sometimes be unable to add warnings to its labeling because EPA refuses to accept them. But without asking EPA, a registrant cannot presume that EPA would reject language that a jury finds necessary to satisfy these requirements.

This is just such a case. Petitioner never proposed to EPA a labeling amendment with a cancer warning. Under the circumstances present here, the fact that EPA approved labeling without a cancer warning cannot be understood as an implicit rejection of such a warning and does not preempt Respondent's label-based failure-to-warn claim.

This conclusion follows directly from EPA's registration and labeling-amendment procedures. EPA-accepted labeling does not always include all necessary and appropriate warnings. And the registrant plays a key role in drafting and updating labeling language. Properly understood, EPA's process leaves room for registrants to request chronic risk warnings needed to keep people safe. Registrants cannot assume that EPA will refuse these requests for

necessary label amendments. State enforcement, including tort suits, plays an important role in assisting EPA under this statutory scheme.

There are many reasons a pesticide's EPA-accepted labeling may differ from that required by FIFRA. EPA's initial labeling determinations are based on the information available to it only at a particular point in time. But science is constantly evolving. Widespread, long-term use of a pesticide that impacts diverse environments and populations can result in adverse effects that were not predicted by the more limited standard test batteries performed before initial registration. Over 90% of the time, EPA's periodic reviews of previously registered pesticides uncover new information that results in changes to use restrictions on labeling, or even cancellation of registration—yet EPA is required to conduct such reviews only every 15 years. And even that schedule is difficult to meet. (EPA's review of glyphosate—initially due in 2022—is still pending, and EPA decided to reconsider its Interim Decision after the human health portion was vacated.) By itself, EPA cannot keep labeling up to date for every pesticide at every moment. And FIFRA doesn't charge it with that responsibility.

Enter the registrant. FIFRA tasks registrants with keeping EPA and the labeling language up to date. It is the registrant who proposes labeling revisions for EPA's "acceptance" through a relatively fast and informal process. In some areas, EPA regulations constrain the language that the registrants can propose. But where the regulations do not do so—as is the case for chronic risk warnings—EPA's acceptance of certain labeling language does

not equate to a rejection of all other potential language, including warnings, for all time. As EPA's evolving view of glyphosate cancer warnings confirms, a registrant cannot know if EPA will approve particular labeling language unless and until it proposes that language to EPA. And here, Monsanto has not asked to add a cancer warning to its glyphosate products.

Petitioner's contrary arguments ignore both the limitations in EPA's process and the critical role played by the registrant. In Petitioner's telling, EPA's labeling acceptance preserves in amber the pesticide's optimal labeling—one that includes neither too many nor too few warnings—and the registrant is powerless to ask to change it. That account is simply wrong, and inconsistent with agency practice, as the United States repeatedly explained before reversing its position. *See* Brief for the United States as Amicus Curiae at 8-16, 19, *Monsanto Co. v. Hardeman*, No. 21-241 (May 10, 2022) (U.S. Br., *Hardeman*); Brief Amicus Curiae for the United States at 18, *Etcheverry v. Tri-Ag Serv. Inc.*, 22 Cal. 4th 316 (Cal. S. Ct. Mar. 1999) (No. S072524) (U.S. Br., *Etcheverry*).

Nor does EPA have a monopoly on deciding whether a pesticide is misbranded under FIFRA. Not only do states assist with FIFRA enforcement directly, state tort proceedings assist EPA by bringing to light scientific developments for EPA's review. What's more, FIFRA welcomes juries deciding whether its requirements are satisfied; that is precisely what happens with federal misbranding enforcement, which can be a criminal offense tried to a jury. Label-based state tort suits enforcing FIFRA-

parallel requirements aid, not hinder, FIFRA's objectives.

FIFRA's preemptive sweep is important, but narrow. Expanding it to foreclose state label-based failure-to-warn suits for omitting warnings that the registrant never even proposed to EPA would be destructive to FIFRA's aims and its carefully formulated scheme.

ARGUMENT

I. EPA's acceptance of particular labeling does not mean that any other warnings would be "in addition to" FIFRA's labeling requirements.

Petitioner's theory rests on two suppositions: that EPA-accepted labeling represents the optimal labeling for "safe" use of a pesticide and that a registrant has no control over adding language to the labeling. *See, e.g.*, Pet. Br. 25-26. Petitioner is wrong on both counts. EPA labeling "evolve[s]" over time as real-world use data come to light and the registrant fulfills its obligation to share that information with the agency and update its labeling. *Bates*, 544 U.S. at 451. Because the registrant drafts and maintains the labeling, EPA's acceptance of the registrant's proposed labeling does not equate to EPA's rejection of all other possibilities. EPA may say yes to requests to add statements regarding risks from chronic exposure. The registrant has to ask to find out how EPA will respond.

A. EPA's registration decision reflects EPA's acceptance of an applicant's proposed warnings at a specific point in time.

1. FIFRA generally prohibits the distribution or sale of a pesticide "that is not registered" by the EPA. 7 U.S.C. §§ 136a(a), 136j(a)(1)(A).

To apply for registration, an applicant must submit, among other things, the product's "complete formula," "a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use," and a "description of the tests made and the results thereof upon which the claims are based." *Id.* § 136a(c)(1)(C), (D), (F).[2]

Under the statute, EPA "shall register a pesticide" if the agency determines, *inter alia*, that its "labeling … compl[ies] with the requirements of this subchapter"; and that "when used in accordance with widespread and commonly recognized practice[,] it will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(B), (D). "[U]nreasonable adverse effects on the environment" include both an "unreasonable risk to man or the environment" after accounting for a pesticide's risks and benefits and "a human dietary risk from residues

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[2] Under FIFRA, the "label" is the "written, printed, or graphic matter on, or attached to," the pesticide or "any of its containers or wrappers." 7 U.S.C. § 136(p)(1). "Labeling" is a broader category, which includes the actual label and other materials "accompanying the pesticide" or referred to in the label. *Id.* § 136(p)(2). This brief uses the term "labeling" to refer generally to the label and labeling.

that result from" a pesticide's use on food. *Id.* § 136(bb).

2. Under FIFRA, the applicant drafts the labeling and submits it to EPA as part of the application. 40 C.F.R. §§ 152.42, 152.50(e), (f); *Bates*, 544 U.S. at 438. EPA then decides whether to "accept[]" the labeling. 40 C.F.R. § 156.10(a)(6). In making that decision, EPA assesses whether the labeling "contain[s] the information specified by the Act and the regulations," including, *inter alia*, "[h]azard and precautionary statements as prescribed in subpart D … for human … hazards." *Id.* § 156.10(a)(1)(vii). EPA's human-hazard labeling regulations address:

- Toxicity, for "acute hazards of pesticide products." *Id.* § 156.62; *see also id.* § 156.64 (signal words correlated to acute toxicity, such as DANGER for Toxicity Category I and WARNING for Toxicity Category II); *id.* § 156.70(b) (precautionary statements for "acute hazard[s]").
- Child hazard warnings. *Id.* § 156.66.
- First aid statements. *Id.* § 156.68.
- Physical or chemical hazards related to a pesticide formulation's "flammability or explosive characteristics." *Id.* § 156.78.

EPA has not issued any regulations addressing what FIFRA requires in terms of warnings or other advisory statements for chronic health hazards like carcinogenicity. *See* U.S. Br. at 11, *Hardeman*; *see also* EPA, *Label Review Manual*, Ch. 7 (rev. Mar. 2018), https://tinyurl.com/mm8z67e5.

Neither does FIFRA itself contain any specific standard regarding chronic health risk warnings.

Rather, FIFRA imposes the "general standard[]," *Bates*, 544 U.S. at 453 n.27, that a pesticide cannot be distributed or sold if it is "misbranded." 7 U.S.C. § 136j(a)(1)(E). Among other definitions, a pesticide is deemed "misbranded" if its "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." *Id.* § 136(q)(1)(G). This definition is broad enough to encompass chronic health risks as it means the labeling must "protect[] against any unreasonable adverse effects on the environment," including effects on people. *Id.* § 136(q)(1)(j), (x), (bb). A pesticide is also misbranded if "its labeling bears any statement … which is false or misleading in any particular," including as to safety. *Id.* § 136(q)(1)(A); 40 C.F.R. § 156.10(a)(5)(ix).

3. Because FIFRA and EPA recognize that the understanding of pesticide risks evolves as a pesticide is used, EPA's acceptance of the applicant's proposed labeling is only a starting point, not the end of the road. "FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings." *Bates*, 544 U.S. at 451. Yet EPA ordinarily reviews a pesticide's registration only every 15 years. 7 U.S.C. § 136a(g)(1)(A). The registrant is thus responsible for keeping the labeling up to date and FIFRA-compliant. *Bates*, 544 U.S. at 438-39 (describing manufacturers' "continuing obligation to adhere to FIFRA's labeling requirements").

EPA's registration decision is "prima facie evidence," not conclusive proof, that a pesticide's

"labeling … compl[ies] with the registration provisions" of FIFRA. 7 U.S.C. § 136a(f)(2). Under FIFRA, a pesticide can be "registered but nevertheless misbranded." *Bates*, 544 U.S. at 438. And there are many reasons why that is so, timing principal among them.

B. Pesticides registered by EPA may carry risks that are not adequately addressed by the registration of the EPA-accepted labeling.

Given the Act's structuring of the registration process and EPA's labeling review, already-registered pesticides may present risks requiring warnings that can and should be included in the pesticide's labeling but were not included in the labeling previously accepted by EPA. Evolving science, improved understanding of real-world use of pesticides, and misleading applicant submissions are but some of the reasons for registered labeling that is misbranded.

First, science is constantly evolving. When a pesticide is first registered, the data comes largely from the applicant's laboratory and field research. *See, e.g.*, 40 C.F.R § 158.500(d) (detailing required studies). Because testing pesticides on people is strictly circumscribed, *see* 40 C.F.R. Part 26, toxicity to humans is assessed based on studies that "typically are conducted on animals by pesticide companies in independent laboratories," not human studies. EPA, *Assessing Human Health Risk from Pesticides*, https://perma.cc/DX5E-NWTB (last updated Jan. 23, 2026). EPA sets standards for the applicant's testing, looks at other available data in its possession, and reviews the scientific literature. 40 C.F.R.

§ 152.112(b). But at the time of registration, EPA necessarily has less information than may surface later through incident reports, epidemiological studies, and other real-world data available only after the pesticide comes into widespread use. EPA, *How EPA Receives Data for Pesticide Regulatory Decisions*, https://perma.cc/5RAA-NDMY (last updated Sep. 17, 2025) (*Pesticide Data*). This is especially so for chronic exposure risks where concerns may emerge only after decades of a pesticide's use, science about risks may evolve, and extrapolating results from laboratory animals to human populations involves uncertainty.

Second, EPA may grant an application to register a pesticide despite safety concerns for some uses. Contrary to Petitioner's view (Br. 25), registration does not mean a pesticide is "safe when used in accordance with the label approved by EPA." As described above, EPA will register a product if it "will not generally cause *unreasonable* adverse effects" on people or the environment. 7 U.S.C. §§ 136a(c)(5)(D), 136(bb) (emphasis added). In making this determination, EPA looks at the health risk of the pesticide at "high end" expected exposures—generally around the 90% percentile of exposures—rather than the harm at higher, but possible, exposures. EPA, *Conducting a Human Health Risk Assessment*, https://perma.cc/V89N-RUJK (last updated Jan. 13, 2026) (capitalization omitted). EPA then balances the costs of that risk (at expected exposure levels) against the benefits of the pesticide.[3] *See* 7 U.S.C. § 136(bb).

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[3] States may weigh these risks and benefits differently than EPA and can prohibit or restrict the use of EPA-registered pesticides. 7 U.S.C. § 136v(a).

For a widely used pesticide, there may be tens or even hundreds of thousands of people whose exposures exceed the 90th percentile exposure and so are not taken into account in this balancing. Additionally, subsequent real-world use may reveal flaws in EPA's risk-benefit assessment and its estimate of likely exposure levels. If, for example, "widespread and commonly recognized practice," *id.* § 136a(c)(5)(D), does not follow the labeling, exposures may exceed EPA's "high end" exposure assumptions. Additional or different warnings may then be necessary "to protect health." *Id.* § 136(q)(1)(G).[4]

Third, because much of the information EPA relies on in registering a pesticide comes from the applicant, *Pesticide Data*, *supra*, EPA's analysis can be affected by incomplete or misleading submissions. If the applicant provides incorrect information about potential risk—and especially if there is little

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[4] The United States (now) advances the startling proposition (Br. 24) that labeling needs only warn against risks that are "'unreasonable,' accounting for costs and benefits." When EPA determines that the benefits of a pesticide justify registration despite its risks, warnings are not unnecessary; they are more important. The question of whether the balance of risks and benefits militates in favor of registration is different from whether it requires a warning. Failure to warn against a known risk can create "unreasonable risk," and labeling must protect against "unreasonable adverse effects." 7 U.S.C. § 136(q)(1)(G), (x), (bb). Labeling that fails to warn a known risk may also be "misleading" in violation of 7 U.S.C. § 136(g)(A). EPA's long practice bears this out. EPA may, for example, register a pesticide even though it is very dangerous if it gets in the user's eyes, but require the labeling to warn of that risk. *See, e.g.*, Master Label for EPA Reg. No. 524-455, at 5, https://tinyurl.com/43kfuaxv (Master Label for Roundup Original Herbicide).

relevant information in the scientific literature to use as a check—EPA may reach the wrong conclusions. While amici expect that this is a rare occurrence, applicants have provided false data in the past. *See United States v. Craven Lab'ys, Inc.*, No. 93-8100, 1993 U.S. App. LEXIS 39395, at *1-2 (5th Cir. Sep. 9, 1993) (affirming convictions related to "falsification of test data relied upon by the EPA in approving pesticides"); EPA, Off. of Pesticide Programs, *IBT Review Program*, 3-4 (July 1983), https://tinyurl.com/azdyt6w6. And this concern may be more relevant in situations where the registrant faces tort liability. As the United States explained—before its recent change in position—Petitioner's "preemption theory ignores the possibility that the manufacturer's submissions to EPA may be inaccurate or incomplete." U.S. Br. at 12 n.3, *Hardeman*.

Once a pesticide is registered, EPA cannot, independently, quickly review and address potential safety risks. It is required to review registered pesticides only once every 15 years. 7 U.S.C. § 136a(g)(1)(A)(iii)(II), (iv). Even this deadline has proven challenging to meet.[5] There are hundreds of

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[5] Of the 726 pesticide active ingredients that EPA was required by statute to review by 2022, it finished only 21% on time, prompting Congress to extend the deadline. EPA, *Pesticide Registration Review Deadline: Status Update and Plans for Remaining Work* (Sep. 26, 2022), https://perma.cc/CFH6-6C8G (Registration Review Update); EPA, *FY 2024 Pesticide Registration Improvement Act (PRIA) Annual Report*, 5-6, https://tinyurl.com/34sc96d2 (PRIA Annual Report). In 2025, EPA completed only four registration reviews. EPA, *Completed*

pesticide active ingredients that have been registered for more than 15 years for which EPA has not yet completed a single registration review. *PRIA Annual Report*, *supra*, 5-6.

EPA's registration review of glyphosate—one of the many pesticide active ingredients for which Congress set a 2022 deadline for registration review—illustrates the challenges. *See NRDC v. EPA*, 38 F.4th 34, 40 (9th Cir. 2022). EPA reached an Interim Decision that glyphosate was not a likely carcinogen in 2020, but that decision was vacated in 2022, prompting EPA to withdraw it. *Id.* at 40; Pet. App. 28-32. EPA has not yet completed its re-review, and shows no signs of doing so any time soon. *See Completed Registration Review Actions, supra* (not listing any actions for glyphosate in 2025 or the first quarter of 2026). And even this much-delayed review is only of glyphosate, the active ingredient, rather than glyphosate in combination with the other ingredients in each glyphosate-based pesticide product. *NRDC*, 38 F.4th at 41 n.2; 7 U.S.C. § 136a(g)(1)(A)(iii). Glyphosate remains registered during the registration review process, consistent with EPA's general policy permitting pesticides to remain on the market until registration review is completed—including an assessment of new evidence. *NRDC*, 38 F.4th at 52 n.13; *Registration Review Update, supra.*

Those registration reviews that EPA has completed demonstrate that scientific developments

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Registration Review Actions for FY 2025 - FY 2026 Quarter 1, https://tinyurl.com/ah7ya4fu (last updated Feb. 10, 2026) (Completed Registration Review Actions) (searching for "Final Decision" and "Case Closure" in 2025).

between reviews can significantly modify EPA's understanding of a pesticide's risks. In over 90% of registration reviews of conventional pesticides completed by the end of the 2024 fiscal year, EPA either canceled all registrations or found additional labeling needed to mitigate risks. *PRIA Annual Report*, *supra*, at 6.

In sum, EPA's understanding of the risks of a pesticide develops over time, just as the science does. A registrant cannot simply assume, based on EPA's past determinations, that it is futile to present EPA with all the necessary data and propose a labeling amendment.

C. The registrant is responsible for maintaining FIFRA-compliant labeling and EPA's amendment process makes it easy to do so.

1. While EPA is required to review registration decisions only once every 15 years, registrants have continuing obligations to keep the labeling up to date and FIFRA-compliant.

FIFRA imposes "a continuing obligation" on manufacturers "to adhere to FIFRA's labeling requirements," including by seeking EPA approval to modify labeling that does not contain all "necessary warnings or cautionary statements." *Bates*, 544 U.S. at 438-39. As described above, EPA's one-off registration decision—including its labeling acceptance—does not mean that a pesticide's labeling forever contains all warnings "which may be necessary and if complied with … [are] adequate to protect health." *See* 7 U.S.C. §§ 136(q)(1)(G), 136a(f)(2). And although EPA "may institute

cancellation proceedings and take other enforcement action if it determines that a registered pesticide is misbranded," *Bates*, 544 U.S. at 439, the Act imposes on the registrant a continuing duty to refrain from selling or distributing misbranded pesticides whether EPA takes these actions or not. 7 U.S.C. § 136j(a)(1)(E).

Nothing in the statute permits a pesticide registrant to sit back and wait for EPA's next 15-year review before addressing information indicating that further warnings are needed. Nor does FIFRA anywhere immunize a manufacturer from liability based on the registrant's reliance on EPA's registration and label-acceptance decisions. *Id.* § 136a(f)(2). EPA's past labeling acceptance is not dispositive proof of continuing FIFRA misbranding compliance; it is only prima facie evidence and can be rebutted. *Id.*

2. Given registrants' ongoing obligation to maintain up-to-date and accurate labeling, the Act makes it straightforward for registrants to amend their labeling with EPA. The fast and simple process for these applicant-requested labeling changes stands in sharp contrast to EPA's review of a pesticide's active ingredients in its initial registration decision or to the extensive and rigorous process governing pre-market approval of a medical device, discussed by the Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-19 (2008).

A registrant requesting a labeling amendment is again in the driver's seat. For changes where EPA acceptance is required, the registrant is responsible for proposing the new labeling language and providing supporting information. 40 C.F.R.

§§ 152.44(a), 152.50(e). EPA then reviews the proposal, and, if it complies with FIFRA, stamps it "'ACCEPTED" and adds it to the pesticide's "official record." EPA, *Label Review Manual*, Ch. 3, at 3-3, https://tinyurl.com/57vd5e54.

EPA's procedures for reviewing proposed labeling amendments are relatively fast and informal. Some types of labeling changes can be made by the registrant unilaterally with notice to the agency. EPA, *Label Review Manual*, Ch. 4, at 4-6–4-7, https://tinyurl.com/absx68jx. Where EPA's acceptance is required, any labeling change "that would not significantly increase the risk of unreasonable adverse effects on the environment" is subject to expedited review. 7 U.S.C. § 136a(c)(3)(B)(i)(I). And even if data review is needed to add a precautionary statement, EPA must process labeling amendments within 4 months, a fraction of the time allotted for registration changes that may increase risk to the environment. *See id*. § 136w-8(b)(3)(B) Tbl. 1, 5. As a practical matter, EPA may accept registrant-proposed labeling changes in a matter of days or weeks. *See, e.g.,* Letter from EPA to Monsanto, Label Amendment / RD 1617 Herbicide (June 28, 2012), https://perma.cc/7BRY-P6MY (accepting Monsanto-proposed labeling update for Roundup Power MAX Herbicides four business days after submission date shown on bottom right of labeling).

Further streamlining the process, there is no mandatory public involvement in minor labeling changes. Unlike applications for registrations of new active ingredients, FIFRA and EPA regulations do not provide for public notice and comment or any other

adversarial testing of proposed labeling amendments. *Cf.* 40 C.F.R. § 152.102 (requiring Federal Register notice for registration applications that contain a new active ingredient or propose a new use). Illustrating that registrant-initiated amendments are commonplace, the master labeling of Roundup Original Herbicide has been amended at least 44 times. EPA, *Details for ROUNDUP HERBICIDE*, https://perma.cc/RDC2-8XY6 (listing amendments).[6]

D. EPA's acceptance of proposed labeling lacking certain warnings is not a rejection of missing warnings.

1. Just as EPA's labeling acceptance at a single point in time does not establish that the warnings are forever adequate—*i.e.*, "labeling determinations are not dispositive of FIFRA compliance," U.S. Br. at 8-9, *Hardeman* (internal quotation marks omitted)—that acceptance also is not tantamount to EPA's rejection of any other warning that the registrant never proposed.

Because "pesticide manufacturers are responsible for drafting their own product labels," *Hardeman v. Monsanto Co.*, 997 F.3d 941, 959 (9th Cir. 2021), the failure to include certain information within a pesticide's labeling rarely reflects a considered judgment by EPA that additional information would be prohibited by the Act. Information left out of the labeling may instead be attributed to the registrant's preferences based, for

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[6] Other examples relating to Roundup are available on EPA's website at EPA, *Pesticide Product and Label System*, https://tinyurl.com/3y58e68b.

example, on its marketing strategy. EPA's review of proposed labeling does not purport to consider the universe of FIFRA-compliant additional language that was not presented by the applicant. And, unlike the labels in *PLIVA, Inc. v. Mensing*, on which the government heavily relies (Br. 29-33), nothing "ties" a pesticide's labeling to that proposed by other registrants. *Cf.* 564 U.S. 604, 620 (2011).

EPA's guidance has long indicated that a registrant's requests to add additional warnings within labeling, including warnings mandated by state law, are likely to be approved so long as the warnings do not conflict with specific EPA labeling regulations. And because, as described above, EPA's specific labeling regulations address only acute-exposure toxicity warnings (and other acute risks, like fire or explosion), there is generally no such conflict when chronic-exposure health risks are at issue. This structure fundamentally undercuts Petitioner's argument (Br. 2) that acceptance of labeling that lacks a specific warning means EPA "rejected" a warning that was never proposed, or that FIFRA bars the inclusion of that warning.

All the more so because FIFRA does not prioritize brevity. A review of EPA-accepted labeling illustrates that completeness is EPA's goal. Labeling is often quite long and can be in the form of a booklet or even distributed over the internet. EPA, *Label Review Manual*, Ch. 3, at 3-5, 3-13. The master labeling for food crop uses of Roundup Original Herbicide, for example, is over 80 pages, not including a 23-page supplement, and has numerous state-specific limitations. *See* Master Label for Roundup Original

Herbicide, *supra*, at 15-16, 23, 55, 72-73, 124-27, 133-34, 135.

2. EPA regularly approves a variety of registrant-requested labeling language that involves cautionary statements beyond those specifically addressed in EPA's labeling guidance, including state-specific use restrictions and warnings regarding risks of chronic exposure.

a. While FIFRA preempts state labeling requirements that are "in addition to or different from" FIFRA's, 7 U.S.C. § 136v(b), FIFRA expressly authorizes states to impose more stringent restrictions on sale and use of a pesticide, and even to outright ban EPA-registered pesticides, *id.* § 136v(a). FIFRA does not preempt state-law use or warning requirements that are not label-based.[7] *Id.*; *Bates*, 544 U.S. at 444. EPA thus expects that states may disagree with its risk-benefit assessments and impose their own conditions. EPA does not have the information or ability to consider the wide range of local circumstances—either relating to geography and land use or relating to local demographic characteristics of exposed populations—that may create different risks from the general risks considered as part of the application. *Contra* Pet. Br. 41, 51 (suggesting states' disagreement with EPA's risk-benefit analysis is problematic under FIFRA).

EPA permits registrants to include information about these state-specific use restrictions in labeling.

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[7] Such restrictions could include requiring registrants to warn users about chronic risks using non-labeling methods, such as point-of-sale signage, media advertisements, and training programs.

EPA routinely accepts labeling requested by states indicating that products are not for use in a particular state or locality. EPA, *Pesticide Labeling Questions & Answers*, https://perma.cc/CDB5-DD5B (last updated May 12, 2025). In fact, this language presents so little issue that EPA recently proposed amending its process to allow registrants to add such language to labeling without even notifying EPA. DRAFT Proposed Pesticide Registration Notice 2025-NEW (Revised PRN 98-10), https://tinyurl.com/3ns8c4ua. EPA also does not review "official publications of certain … state agencies and institutions referenced on or accompanying a label." EPA, *Label Review Manual*, Ch. 3, at 3-5; 7 U.S.C. § 136(p)(2)(B). The upshot is that pesticide labeling is often replete with state-specific information—as the master label for Roundup Original Herbicide illustrates. *See, e.g.*, Master Label for Roundup Original Herbicide, *supra*, at 15-16, 23, 55, 72-73, 124-27, 133-34, 135.

b. EPA also routinely approves advisory statements and other warnings needed to comply with state law. EPA guidance provides that registrants have broad latitude to propose "[a]dvisory statements" about "product characteristics and how to maximize safety and efficacy," so long as such statements "do not conflict with mandatory statements, are not false or misleading, and do not otherwise violate statutory or regulatory requirements." *See* EPA, *Label Review Manual*, Ch. 3, at 3-14; *id.* Ch. 7, at 7-4.

EPA guidance informs registrants that labeling may include state-mandated chronic-risk warnings, such as Proposition 65 warnings under California law, so long as the terminology does not conflict with

the "signal word" EPA requires for acute toxicity warnings. *Id.* Ch. 7, at 7-4. EPA has no policy specific to chronic exposure warnings that would create conflicts with state-required chronic-risk warnings. *See supra* Section I.A.2. And EPA has approved the addition of state-required cancer warnings in the past. *See Hardeman*, 997 F.3d at 959 n.10.

In considering glyphosate in particular, EPA's shifting position on chronic risk warnings underscores the variety of possible responses to a registrant's amendment request and the fact that a registrant does not know whether EPA will accept a warning until it asks and provides EPA with all the necessary information. EPA allowed Bayer to add a cancer warning to a glyphosate product by notification, although it subsequently asserted that it had done so in error. *See* Resp. Br. 41-42; Letters between Jennifer Gaines, EPA, Office of Pesticide Programs and Larry Hodges, Bayer CropScience 2, 4 (2012), https://perma.cc/X64N-WX5F. And EPA's nonbinding letters regarding glyphosate cancer warnings—both of which predated EPA's decision to reconsider the human health portion of its glyphosate registration review—indicated that it would reject some language and approve other language. *See* Pet. App. 39 (August 2019 letter stating that "pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded"); Pet. App. 41-43 (April 2022 letter stating that EPA could approve labeling language stating that the International Agency for Research on Cancer "classified glyphosate as probably carcinogenic" to humans but that EPA did not). Those letters are nonbinding, and so not entitled to preemptive effect. *See Merck Sharp & Dohme Corp. v.*

Albrecht, 587 U.S. 299, 315-16 (2019) (actions without force of law are not "clear evidence" of what the agency would do (quoting *Wyeth v. Levine*, 555 U.S. 555, 571 (2009))). But they expressed some openness to a carefully worded label or, at a minimum, point in different directions.

Against this backdrop of frequent acceptance of warnings required by state law, and in the absence of contrary binding regulations, "EPA's approval of pesticide labeling without a chronic-risk warning is not naturally characterized as a FIFRA 'requirement' that no such warning appear." U.S. Br. at 11, *Hardeman* (quoting *Bates*, 544 U.S. at 445).

E. Warnings mandated by FIFRA-parallel state-law label-related standards are fully consistent with the Act.

Where a registrant has never proposed a particular warning for its labeling, and EPA has thus never rejected that warning, it is fully consistent with FIFRA for a state to require labeling that implements the same "general standard[]" as FIFRA's—*i.e.*, requiring warnings that are adequate to protect health. *See Bates*, 544 U.S. at 453 n.27. In any event, state warnings do not have to be identical to those that EPA would have required in a vacuum. FIFRA permits states to place restrictions on pesticide use beyond those required by EPA, and EPA may accept labeling including state-required warnings that EPA might view as unnecessary.

First, such state laws vindicating FIFRA's standards will not create a "crazy-quilt" of state-law requirements that is contrary to the statute. *Contra*

Pet. Br. 2. The Court's rejection of that argument in *Bates* applies just as strongly here.

As EPA's common acceptance of state-specific labeling language indicates, there is no uniformity problem when EPA accepts state-mandated warnings. *Contra* U.S. Br. 33-36. EPA still "approves only one label per pesticide," and "[i]n approving a labeling change, EPA substitutes a new nationally uniform label." U.S. Br. at 17, *Etcheverry*. But such labeling—which is better envisioned as a booklet than as a sticker on a bottle—can encompass plenty of state specifics. The uniformity concern animating the preemption provision is not implicated, because the labeling is still the labeling accepted by EPA rather than different labels for each state with different "color, font size, and wording of warnings." *Bates*, 544 U.S. at 452. And where EPA desires a higher degree of labeling uniformity on a particular topic across products, it can promulgate "regulations that give content to FIFRA's misbranding standards" and thereby preempt contradictory state requirements. *Id.* at 453. For example, a state requirement could be preempted if it specified that a "given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION'" for a certain acute toxicity risk. *Id*. But EPA has adopted no such regulations for chronic-exposure risks like cancer.

Second, for all the reasons discussed above, EPA's acceptance of certain labeling does not mean that any other labeling warnings are "in addition" to those required under FIFRA, and thereby preempted. 7 U.S.C. § 136v(b). Which warnings "may be necessary and … adequate to protect health," *id.* § 136(q)(1)(G), can change as the science develops over time.

Necessary warnings can also vary from state to state depending on typical uses and conditions in that state. Contrary to Petitioner's argument (Br. 2, 42), EPA's labeling acceptance is not a judgment that any additional statements about chronic risk would mislead or over-warn a pesticide's users. *See supra* Section I.D.1.

Ultimately, EPA acceptance of labeling is only the beginning, not the end, of the story. The registrant is responsible for ongoing compliance with FIFRA's misbranding requirements and cannot rely on EPA's acceptance of its labeling. The registrant can propose to EPA any labeling needed to satisfy this legal requirement—including labeling needed to comply with state-law standards that parallel FIFRA's. And such compliance with state-law standards is in the typical case fully consistent with FIFRA, not obligating the registrant to comply with any "requirements … in addition to or different from" FIFRA's, and so is not preempted. 7 U.S.C. § 136v(b).

II. State tort suits can complement EPA's process without interfering with EPA's authority.

Label-related state-law requirements that parallel FIFRA's standards are also not impliedly preempted. Far from it. In amici's experience, state efforts to address risks aid EPA's work and further FIFRA's goals.

A. States may be able to respond to scientific developments more quickly than EPA.

State tort suits do not impede EPA's efforts. On the contrary, they often support EPA's work by ventilating the latest scientific research and providing a catalyst for registrants to provide the latest information to EPA and update their labeling.

EPA recognizes that "science is constantly evolving, and new scientific information can come to light at any time and change our understanding of potential risks from pesticides." EPA, *Upcoming Registration Review Actions*, https://perma.cc/5NSD-MDEP (last updated Aug. 26, 2025). But EPA's periodic pesticide registration reviews cannot quickly keep up with changing science. *See supra* Section I.B.

By contrast, states often have information about what is happening in the field before EPA, enabling a faster response to new scientific developments. Especially where registrants are reticent to inform EPA of safety concerns, state tort suits can also bring information about the adverse effects of a pesticide to light. And the risk of state-law liability can encourage registrants to quickly report any safety concerns to EPA and request revised labeling. As this Court has noted, "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA." *Bates*, 544 U.S. at 451.

B. State jury decision-making is consistent with FIFRA's enforcement scheme.

State tort suits are also compatible with FIFRA's "relatively decentralized scheme" for enforcement. *Bates*, 544 U.S. at 450. The statute does not anoint EPA as the sole decisionmaker or enforcer.

EPA has long partnered with states to enforce FIFRA in ways that give state decisionmakers a role in evaluating compliance. EPA can, for example, "enter into cooperative agreements with States and Indian tribes … to delegate … the authority to cooperate in the enforcement of this Act," 7 U.S.C. § 136u(a). States also review labeling for FIFRA compliance, as EPA has long recognized. *Bates*, 544 U.S. at 442 n.14 (quoting EPA's website, circa 2005, explaining that "[m]ost states conduct a review of the pesticide label …").[8]

FIFRA also contemplates that crucial decisions—including, as relevant here, whether labeling contains adequate warnings—would be decided by juries. As this Court previously explained, "lay juries are in no

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[8] State expertise plays an important role in ensuring the accuracy of efficacy claims on labeling. *See Bates*, 544 U.S. at 440. EPA does not determine whether pesticides are effective, instead leaving evaluation of claims of effectiveness—including claims made in labeling—to states to review. *Id.* (describing how Congress authorized EPA "to register a pesticide without confirming the efficacy claims made on its label"). At least for tort actions alleging failure to warn about lack of efficacy, Petitioner appears to recognize the complementarity of state law. Pet. Br. 31-32. The same should hold true for other types of warnings unless EPA has evaluated all relevant information and made a labeling decision that directly conflicts with state requirements.

sense anathema to FIFRA's scheme." *Bates*, 544 U.S. at 452. Knowing sale of a misbranded pesticide is a criminal offense, *see* 7 U.S.C. § 136*l*(b)(1)(A), giving juries an important role in determining whether labeling includes necessary and adequate information. As even Petitioner acknowledges (Br. 35), "a state-law tort claim seeking to hold a pesticide manufacturer liable for deviating from the EPA-approved labeling is fully consistent with § 136v(b)." The same goes for a state-law tort claim seeking to hold a registrant liable for deviating from FIFRA's adequate-warning standards. *Cf. Riegel*, 552 U.S. at 330.

Ultimately, elevating EPA as the only relevant decision-maker regarding the adequacy of pesticide warnings fundamentally misunderstands FIFRA's statutory and regulatory scheme. Far from hindering the objectives of the Act, label-based state failure-to-warn suits applying standards that parallel FIFRA's help EPA to better do its job of protecting public safety.

CONCLUSION

The judgment should be affirmed.

Respectfully submitted,

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