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
Court of Appeals of Missouri, Eastern District

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AMERICAN CHEMISTRY COUNCIL, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PRODUCT LIABILITY ADVISORY COUNCIL, AND WASHINGTON LEGAL FOUNDATION AS *AMICI CURIAE* SUPPORTING PETITIONER

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INTEREST OF *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America is the world's largest business federation. The Chamber represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

The American Chemistry Council (ACC) is a trade association representing leading companies engaged in the multibillion-dollar business of chemistry. ACC members apply the science of chemistry to make innovative products, technologies, and services that make people's lives better, healthier, and safer. ACC is committed to improved environmental, health, safety, and security performance through Responsible Care®; common-sense advocacy addressing major public policy issues; and health and environmental research and product testing. ACC members and chemistry companies are among the largest investors in research and development, and are advancing products, processes, and technologies to address climate change, enhance

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and no entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

air and water quality, and progress toward a more sustainable, circular economy.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, PhRMA's members are fighting for solutions to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

The Product Liability Advisory Council, Inc. (PLAC) is a nonprofit professional association of corporate members representing a broad cross-section of product manufacturers. PLAC contributes to the improvement and reform of the law, with emphasis on the law governing the liability of manufacturers of products and those in the supply chain. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred leading product litigation defense attorneys are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed over 1,100 *amicus curiae* briefs on behalf of its members, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product risk management.

The Washington Legal Foundation (WLF) is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of

law. It often appears as *amicus curiae* in important federal preemption cases, urging courts to ensure that federal law operates efficiently and uniformly—as Congress intended. WLF believes that conflicting federal and state-law duties are not merely inefficient; they make it impossible for regulated parties to comply with both state and federal law without incurring enormous liability.

Amici have a strong interest in ensuring that the preemptive force of federal laws is fully recognized—thus alleviating the need for businesses to navigate a patchwork of inconsistent state regulations.

INTRODUCTION AND SUMMARY OF ARGUMENT

Respondent's theory of preemption disregards this Court's precedent, nullifies an express federal preemption provision, and allows juries to impose massive liability on businesses *for adhering to federal law*. Adopting this theory would subject regulated businesses to a patchwork of different state labeling requirements—despite Congress's explicit determination that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, provides a ceiling, not just a floor, for labeling requirements. Respondent's theory could infect labeling laws across many industries, leaving businesses scrambling to comply.

Under respondent's misguided approach, state labeling laws governing pesticides (no matter how disparate) would survive preemption so long as they share FIFRA's *general* purpose of ensuring adequate warnings. That is wrong. Preemption does not turn on whether state law has its heart in the right place; it turns on what, specifically, the state law requires.

Rewriting FIFRA's preemption provision to look at nothing but the most general purpose would destroy it—and similar preemption provisions across other federal statutes. Regulated businesses must follow federal labeling law; state labeling requirements must yield.

Respondent's theory of preemption would undermine basic principles of both express and implied preemption in a variety of areas. This Court should reject it.

I. A state may not adopt labeling requirements that are "in addition to or different from those required under" FIFRA's regulatory framework. 7 U.S.C. § 136v(b). That language "sweeps widely." *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 459 (2012) (considering materially identical preemption language in the Federal Meat Inspection Act). It gives express preemptive force not only to the text of FIFRA itself, but also to the contents of a label that the Environmental Protection Agency (EPA) approves for a pesticide "under" FIFRA's mandatory registration process. As the EPA has therefore made clear, "[t]he label is the law," EPA, *Pesticide Registration Manual* at 3 (last updated May 21, 2025), https://perma.cc/QG93-V9GJ. A pesticide manufacturer may not depart from it by altering the warnings or adding warnings that the EPA has not endorsed—such as the carcinogen warning for glyphosate that respondent and a Missouri jury insist petitioner's Roundup label must include.

Respondent's theory of preemption circumvents the clear language of FIFRA's express preemption provision by defining the federal labeling "requirements" at an absurdly high level of generality. Respondent insists that state-law labeling requirements are permitted as long as they are generally directed to adequately warning a product's users. But that reasoning zooms

out so far that the federal preemption provision disappears. This approach would strip FIFRA's preemption provision, and this Court's preemption precedent, of any force.

II. Even setting aside FIFRA's express preemption provision, respondent's state failure-to-warn claim is preempted for the independent reason that it requires what federal law prohibits—making this a clear case in which compliance with both regimes is an impossibility. This Court has confirmed that a state labeling requirement is impliedly preempted if federal law prohibits the regulated entity from unilaterally altering its label to conform to a state requirement. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617-19 (2011). That is exactly the case here, as the EPA's regulations make abundantly clear. *See* pp. 11-12, *infra*. It is simply impossible for manufacturers to adhere to the EPA-approved label, as required, *and* to add the warning that respondent argues state law requires. In that scenario, federal law prevails. That is even plainer in this situation, where the EPA has taken the additional step of informing registrants that it would consider a carcinogen warning to be misbranding.

III. Respondent's rationale would dangerously undermine Congress's repeated decisions to require nationwide uniformity in major areas of economic regulation. Many federal statutes that create labeling standards for varied industries—from medical devices and cosmetics to pork and dairy—employ the same express preemption language used in FIFRA, or an indistinguishable variant. Should respondent's approach prevail, courts throughout the nation could gut statutory preemption across several other federal regulatory regimes. And if federal preemption is discarded in cases

like this one, state-court juries could impose potentially crushing liability on manufacturers under *state* law for failing to give warnings that *federal* law forbids.

This Court should reverse the decision of the Missouri Court of Appeals and preserve the efficacy of federal preemption in this and other contexts.

ARGUMENT

I. FIFRA expressly preempts the imposition of liability based on state labeling requirements that differ from federal law.

FIFRA should be read to mean what it says: states cannot impose labeling requirements that are "in addition to or different from those required under" FIFRA's regulatory framework, 7 U.S.C. § 136v(b), which mandates that a pesticide manufacturer adhere to the label that the EPA approves for a given pesticide. "[T]he label," in other words, "is the law." *Pesticide Registration Manual* at 3, *supra*. A state failure-to-warn claim requiring petitioner to add a carcinogen warning to the Roundup label that the EPA has declined to require is the paradigmatic example of a state labeling requirement that is "in addition to or different from" the federal requirement. 7 U.S.C. § 136v(b). Respondent's misguided theory demanding such a conflicting state labeling requirement is contrary to the plain language of FIFRA's express preemption provision and disregards this Court's case law.

A. The express preemption provisions in FIFRA and similar statutes must be given their plain meaning.

FIFRA imposes several levels of preemption, and the one governing labeling is the most stringent. State-by-state labeling variation is a major impediment to a na-

tional market—and if localities join in with their own requirements, there might be thousands of different labeling mandates rather than 50. So, to prevent a confusing and unworkable patchwork, FIFRA does what other federal labeling statutes do: it "sweeps widely," *Nat'l Meat Ass'n*, 565 U.S. at 459, to preempt divergent state-law labeling requirements. Specifically:

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

7 U.S.C. § 136v(b). Contrast that preemption provision with the one allowing states to continue to "regulate the *sale or use* of any federally registered pesticide or device in the State," subject to any prohibitions on sale or use imposed by FIFRA itself. 7 U.S.C. § 136v(a) (emphasis added). The difference is stark. "We must presume that Congress 'says in a statute what it means and means in a statute what it says there.'" *Rotkiske v. Klemm*, 589 U.S. 8, 13-14 (2019) (citation omitted).

In applying the labeling-specific preemption provision, the plain text controls: a state's "requirement[] for labeling" that is "in addition to or different from" a "requirement[] for labeling" under FIFRA is preempted—period. 7 U.S.C. § 136v(b). Under this straightforward standard, state requirements that are only "nominally equivalent" or that merely share the same general purpose are preempted. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005). This Court explained in *Bates*, which concerned FIFRA, that states may adopt labeling requirements only if they are "*genuinely* equivalent" to the federal labeling requirements under

FIFRA's regulatory framework. *Id.* For example, a state "failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted" if the EPA regulations mandated the more subdued label, some other warning(s), or even no warning at all. *Id.* at 453. It is not necessary that "the federal Act requires what the state law forbids (or forbids what the state law requires)"; mere difference suffices. *Nat'l Meat Ass'n*, 565 U.S. at 460-61.

Indeed, subsequent cases from this Court have made clear that express preemption clauses like the one at issue here are, if anything, even weightier than some language in the *Bates* opinion suggested. In one paragraph (that was not necessary to the Court's reasoning), the Court suggested that it had "a duty to accept the reading [of FIFRA] that disfavors pre-emption." 544 U.S. at 449. But this Court has since held that any "presumption against pre-emption," *id.*, is inapplicable when a "statute 'contains an express pre-emption clause,'" *Puerto Rico v. Franklin Cal. Tax-free Tr.*, 579 U.S. 115, 125 (2016) (quoting *Chamber of Commerce v. Whiting*, 563 U.S. 582, 594 (2011)). Instead, courts must "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Id.* (quoting *Whiting*, 563 U.S. at 594); *accord Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part) ("[O]ur task is to determine which state-law claims § 136v(b) pre-empts, without slanting the inquiry in favor of either the Federal Government or the States."). In short, it makes no sense to presume against preemption in interpreting *an express preemption clause*: there is no risk that Congress "cavalierly" wrote such a statute without realizing it would be

preemptive. *Bates*, 544 U.S. at 449 (citation omitted). In interpreting that statute, the courts' task is to adhere faithfully to the preemption provision Congress wrote.

That is especially true of a multi-tiered preemption provision like FIFRA's. Congress could have drawn FIFRA's and other similar preemption provisions more narrowly if it had intended to allow state labeling regulations that were not "*genuinely* equivalent." *Bates*, 544 U.S. at 454. Or it could have adopted an express rule of narrow construction. For example, on the other end of the spectrum from FIFRA, the McCarran-Ferguson Act explicitly provides for inferences against preemption of state insurance law where a federal law does not "specifically relate[] to the business of insurance." 15 U.S.C. § 1012(b); *see, e.g.*, *Barnett Bank of Marion Cnty., N.A. v. Nelson*, 517 U.S. 25, 37-38 (1996). There is no such rule of narrow construction in FIFRA, and it would be "particularly inappropriate" to read it as if there were. *See Rotkiske*, 589 U.S. at 14 ("Atextual judicial supplementation is particularly inappropriate when, as here, Congress has shown that it knows how to adopt the omitted language or provision.").

That methodological point—that express preemption provisions should be construed faithfully, not narrowly—warrants reiteration by this Court. Although most lower courts have seamlessly incorporated the principle,[2] the Third Circuit has affirmatively held that the

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[2] *See, e.g.*, *Medicaid & Medicare Advantage Prods. Ass'n, Inc. v. Hernandez*, 58 F.4th 5, 11-12 & n.5 (1st Cir. 2023) (collecting cases); *Young Conservatives of Tex. Found. v. Smatresk*, 73 F.4th 304, 311 (5th Cir. 2023).

presumption of preemption continues to apply to express preemption provisions post-*Franklin*. *See Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 n.9 (3d Cir. 2018). That error did not affect the Third Circuit's interpretation of FIFRA, in which it did not apply any presumption against preemption. *See Schaffner v. Monsanto Corp.*, 113 F.4th 364, 379-93 (3d Cir. 2024). But this Court should remind lower courts not to give any residual weight to this anti-preemption presumption in statutory interpretation.

Certainly, a plain reading of FIFRA's preemption provision cannot be any *narrower* than what this Court said in *Bates:* states cannot impose labeling requirements "in addition to or different from" the requirements "under" FIFRA's regulatory framework but must limit themselves to requirements that are "*genuinely* equivalent." 7 U.S.C. § 136v(b); 544 U.S. at 454. And asking only whether a state requirement is "functionally" similar, Resp. Br. in Opp. 23, would not be a narrow construction: it would be a wholesale abandonment of the preemptive scope that Congress selected for this statute and many others.

B. An EPA-approved pesticide label imposes "requirements" for labeling that have preemptive force under FIFRA's preemption provision.

1. FIFRA's preemption provision grants preemptive force to federal labeling requirements "under" FIFRA—not only requirements that appear in the statute itself, but also requirements resulting from FIFRA's regulatory regime. No one would dispute that, if the contents of the EPA's currently approved label for Roundup were written word-for-word into FIFRA, a lawsuit identical to this one plainly would be

preempted. A Missouri-law duty to add a carcinogen warning to the Roundup label would indisputably be "in addition to or different from" a "requirement[] for labeling … required under [FIFRA]," 7 U.S.C. § 136v(b), and therefore preempted. Requirements resulting from actions taken by the EPA under FIFRA's regulatory regime carry the same preemptive force: they are "required under" FIFRA even if not set out verbatim *in* FIFRA.

"[A] requirement" encompasses any "rule of law that must be obeyed." *Bates*, 544 U.S. at 445. A pesticide label approved by the EPA, as part of the registration process that FIFRA requires for every pesticide, easily satisfies this definition. *See* Pet. 4-6 (explaining registration process); 7 U.S.C. § 136a(a). The warnings on such a label are based on EPA-directed testing requirements, *see* 40 C.F.R. pt. 158, and although applicants propose labeling consistent with the test results, it is the EPA that determines the appropriate warnings. The crucial point is that the EPA may approve the proposed labeling (and may grant registration) only if the labeling "compl[ies] with the requirements" of FIFRA, 7 U.S.C. § 136a(c)(5)(B), (c)(9)—including the requirement that the proposed labeling not omit "warning or caution statement[s] which may be necessary and … adequate to protect health and the environment," *id.* § 136(q)(1)(A), (G); *id.* § 136j(a)(1)(B), (E); *accord* 40 C.F.R. § 152.112(f). Once the EPA has approved proposed labeling, the manufacturer cannot depart from it. 7 U.S.C. § 136j(a)(1)(B); 40 C.F.R. §§ 152.44, 152.46, 156.70(c); *accord id.* § 152.130(a).[3]

[3] FIFRA does allow manufacturers to alter certain aspects of pesticide labeling without prior agency approval (and subject to agency reapproval), *see* 7 U.S.C. § 136a(c)(9)(C), but this exception

At that point, "[t]he label is the law," *Pesticide Registration Manual* at 3, *supra*—it sets the "rule of law that must be obeyed," *Bates*, 544 U.S. at 445. Thus, a state-law failure-to-warn claim that requires pesticide manufacturers to include a particular warning that the EPA has declined to require would necessarily impose a requirement that is "in addition to or different from" the federal requirement. *Bates*, 544 U.S. at 447 (emphasis omitted) (quoting 7 U.S.C. § 136v(b)).

2. This Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), all but decides this case. There, the Court considered whether the preemption provision in the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (FDCA) barred state-law strict-liability and negligence claims based on, among other things, a medical device's labeling. *Id.* at 315-16, 320-21. The relevant preemption provision in the FDCA closely resembles the FIFRA provision at issue here; it prohibits states from imposing "any requirement—' … which is different from, or in addition to, any requirement applicable under [the FDCA] to the device.'" *Id.* at 316 (quoting 21 U.S.C. § 360k(a)(1)). The Court concluded that the FDCA's extensive premarket review process for medical devices, which included review of a device's proposed labeling, "imposed … 'requirements'" for purposes of the

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is not relevant here. Under this exception, manufacturers may add information on "product efficacy, product composition, container composition or design, or other characteristics," but only if that information "do[es] not relate to any pesticidal claim or pesticidal activity." *Id.*; *see also* EPA, *Pesticide Regulation (PR) Notice 98-10: Notifications, Non-Notifications and Minor Formulation Amendments* at 1 (Oct. 22, 1998), https://perma.cc/JG7C-HK3K (describing this exception as applying to "minor, low risk" information).

preemption provision. *Id.* at 318, 322. In particular, the Court explained that "[o]nce a device has received premarket approval, the [statute] forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute." *Id.* at 319; *see id.* at 323 ("[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application ...."); *accord Altria Grp., Inc. v. Good*, 555 U.S. 70, 86 (2008) ("The plaintiffs' products [in *Riegel*] fell within the core of the [statute's] pre-emption provision because they sought to impose different requirements on precisely those aspects of the device that the FDA had approved.").

The same is true here. A company may market a pesticide only upon completing a thorough registration process and obtaining the EPA's approval of, among other things, the pesticide's label. *See* pp. 11-12, *supra*. And the company is forbidden by law from altering that label without EPA approval, except in circumstances not present here. *See Schaffner*, 113 F.4th at 382-85; note 3, *supra*. The fact that *the EPA* has authority to approve changes to a pesticide's label does not make the existing label any less a "requirement" for purposes of FIFRA. After all, the statute in *Riegel* allowed for post-approval labeling changes to be made with FDA approval, but the Court still held that "[p]remarket approval … impose[d] 'requirements'" for purposes of preemption. 552 U.S. at 322-23.

C. Respondent's theory disregards both this Court's precedent and the EPA-approved labels that manufacturers are compelled by law to follow.

Respondent insists that his state-law failure-to-warn claim is not preempted by § 136v(b), but only by ignoring this Court's precedent and the compulsory nature of the EPA-approved label. Respondent compares the requirements his state failure-to-warn claim would impose only with FIFRA's broad prohibition on marketing misbranded pesticides, and blithely concludes that the two are "functionally" identical because they both require that a label include any "warning 'necessary' and 'adequate to protect health.'" Resp. Br. in Opp. 23 (quoting 7 U.S.C. § 136(q)(1)(G)).

That mile-high approach defies this Court's direction in *Bates*, and adopting it would nullify Congress's decision to bar state-law labeling requirements that are additional or different. "[A] state-law labeling requirement must *in fact* be equivalent to a requirement under FIFRA in order to survive pre-emption." *Bates*, 544 U.S. at 453 (emphasis added). It is not enough that federal and state requirements share the same general purpose. What matters is that the two be "*genuinely* equivalent," *id.* at 454—a standard that must factor in *all* the "requirements for labeling or packaging" that are imposed "*under*" FIFRA (not just "by" FIFRA), including its regulatory regime. *See, e.g.*, *Nat'l Meat Ass'n*, 565 U.S. at 460 (recognizing that requirements "under" the relevant statute include those imposed by both "the [Federal Meat Inspection Act] and its regulations"). Thus, the Court made clear in *Bates* that the preemption analysis must consider "the relevant FIFRA misbranding standards, *as well as any*

regulations that add content to those standards." 544 U.S. at 454 (emphasis added); *see also id.* at 453 (in preemption analysis, "[s]tate-law requirements must … be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards"). A state law that imposes labeling requirements on a pesticide manufacturer that differ in any way from those imposed by the EPA-approved label cannot plausibly be said to be "genuinely" equivalent to labeling "requirements" under FIFRA.

Accepting respondent's suggested rewriting of *Bates* would render FIFRA's preemption provision a dead letter. Indeed, taken to its logical endpoint, respondent's approach would uphold a state failure-to-warn claim seeking warnings different from the federal labeling requirements for any registered pesticide even if those federal requirements were explicitly written into an EPA regulation. In those circumstances, FIFRA and Missouri's state-law claim would still be "equivalent" in the only sense that matters to respondent: they would both "require[] a warning 'necessary' and 'adequate to protect health.'" Resp. Br. in Opp. 23 (citations omitted); *see also* Pet. App. 7. But that broad alignment cannot be enough to deem the requirements the same. As the Tenth Circuit explained in finding preemption under a similarly worded statute (the same one that was at issue in this Court's decision in *National Meat Ass'n*), framing the preemption analysis at such a high level of generality misses that analysis's "critical feature"—how both requirements apply in a particular case. *Thornton v. Tyson Foods, Inc.*, 28 F.4th 1016, 1025 (10th Cir. 2022). If a label is permitted under a federal law prohibiting deceptive labeling but prohibited under state law, the assertion that the

two laws "require[] exactly the same thing … plainly fails." *Id.* (citation omitted).

Respondent cannot escape this result by relying on a "Miscellaneous" subsection of FIFRA's registration provision that has no bearing on preemption. The subsection, entitled "Miscellaneous," includes the following provision:

> 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].

7 U.S.C. § 136a(f)(2) (emphasis added). This provision is irrelevant to the preemption analysis. Respondent rightly does not suggest that petitioner committed an "offense" *under FIFRA*. *See id.* §§ 136j, 136*l* (setting out offenses under FIFRA and the criminal and civil penalties for committing them). And there is no dispute here regarding whether petitioner otherwise "complied" with "the registration provisions of" FIFRA. Rather, the sole question in this case is whether petitioner may be held liable under *state law* because it did not add a warning to its EPA-approved label. As the Third Circuit correctly recognized, the fact that "section 136a(f)(2) indicates that registration cannot itself be a defense to a charge of misbranding" does not mean "that the registration process cannot play any role in determining the content of a requirement imposed under FIFRA." *Schaffner*, 113 F.4th at 397.

Respondent's theory of preemption is wrong. This Court should not countenance respondent's attempt to

rewrite the text of FIFRA and ignore this Court's precedent.

II. A state-law claim is impliedly preempted if the regulated party cannot simultaneously comply with both federal and state law.

Respondent's failure-to-warn claim is preempted twice over. Even absent express preemption, a state-law claim is impliedly preempted if, as here, "it is impossible for a private party to comply with both state and federal requirements." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (citation and internal quotation marks omitted); *see Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000) (holding that neither an express preemption provision nor a saving clause limiting express preemption "bar[s] the ordinary working of conflict pre-emption principles").

A. This Court's decision in *PLIVA*, 564 U.S. 604, resolves the implied preemption question against respondent. In *PLIVA*, this Court held that a state-law failure-to-warn claim against a generic drug manufacturer was impliedly preempted by the FDCA's provisions governing the approval and marketing of generic drugs. *Id.* at 610-11. The Court explained that generic manufacturers cannot simply change their labels at will: the FDCA requires generic labels to be "the same as" the FDA-approved label for the brand-name drug. *Id.* at 612-13 (citing 21 U.S.C. § 355(j)(2)(A)). Although the Court assumed that federal law requires generic manufacturers "that become aware of safety problems [to] ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug[s]," the FDCA still "prevented [generic m]anufacturers from *independently* changing their generic drugs' safety labels." *Id.* at 616-17 (emphasis

added). This, the Court held, was sufficient for implied preemption:

> [S]tate law imposed on the [generic] Manufacturers a duty to attach a safer label to their generic [drug]. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same.

Id. at 618 (citation omitted).

That reasoning applies with full force here. FIFRA and its implementing regulations forbid pesticide manufacturers like petitioner from "independently" changing the content of the EPA-approved label for a registered pesticide. Pet. 29-30; *see also* pp. 11-12, *supra*. Instead, "any modification in the … labeling … of a registered product must be submitted with an application for amended registration" to the EPA, and "the application must be approved by the Agency before the product, as modified, may legally be distributed or sold." 40 C.F.R. § 152.44(a); *see also id.* § 156.70(c) ("Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency."); *Schaffner*, 113 F.4th at 382-85. Nor can pesticide manufacturers "independently" add any claims or warnings to their television advertisements that "substantially differ" from the EPA-approved label. 7 U.S.C. § 136j(a)(1)(B); *see* pp. 11-12, *supra*. In either circumstance, a pesticide manufacturer could not simultaneously comply with the EPA-approved label and with the state tort-law duty that is the basis of the jury verdict here.

Respondent dismisses *PLIVA* as distinguishable because it involved generic-drug manufacturers, who must "keep the [generic] label the same" as the brand-name drug label, whereas "pesticide manufacturers 'have a continuing obligation to adhere to FIFRA's labeling requirements.'" Resp. Br. in Opp. 31 (quoting *Bates*, 544 U.S. at 438). But that is no answer to the key similarity between the FIFRA regulatory regime and that in *PLIVA*: under both regimes, manufacturers cannot "independently chang[e]" their labels. *PLIVA*, 564 U.S. at 617. They cannot sell their products with any label other than the federally approved one. State law, therefore, may not require manufacturers to stop selling the product due to concerns with the federally approved label. *Mut. Pharm. Co.*, 570 U.S. at 488 ("[A]n actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" (quoting *PLIVA*, 564 U.S. at 621)).

It makes no difference that pesticide manufacturers can *ask* the EPA to approve a new label. That exact argument was made in *PLIVA* and this Court "reject[ed] it," because accepting it would "make most conflicts between state and federal law illusory." 564 U.S. at 620-21. It is "certainly possible" that a manufacturer could obtain approval for a new label, just as it is *possible* that a manufacturer could convince the EPA "to rewrite" its regulations to allow unilateral label changes, or "talk[] Congress into amending" FIFRA to allow the same. *Id.* But those far-flung "conjectures" do not preclude implied preemption, because the relevant inquiry is whether the regulated party *can now*

"independently do under federal law what state law requires of it." *Id.*

B. Even if FIFRA and its regulations allowed pesticide manufacturers to unilaterally alter the content of an EPA-approved label to add a carcinogen warning, that still would not defeat implied preemption, because the EPA has been "fully informed" of the claimed reasons for adding a carcinogen warning to the Roundup label, and "there is 'clear evidence'" that the agency would reject such a warning. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 310, 313-14 (2019) (citation omitted). More than that: the EPA has rejected such a warning explicitly, concluding that it would be false and misleading.

Since the EPA originally registered glyphosate under FIFRA in 1974, the agency has gathered, assessed, and reassessed copious scientific evidence and studies as to whether the compound is likely to cause cancer in humans and has consistently concluded that it is not. *See* Pet. Br. 10-18. For example, in its 1993 FIFRA reregistration for glyphosate, the EPA designated glyphosate a Group E carcinogen, denoting "evidence of non-carcinogenicity in humans." EPA, *Reregistration Eligibility Decision (RED) – Glyphosate* at viii (Sept. 1993), https://perma.cc/GZM7-4696. More than two decades later—after the International Agency for Research on Cancer (IARC) released its 2015 report asserting that glyphosate may cause cancer in humans—the EPA completed another exhaustive reexamination of all then-current data, research, and literature as part of its FIFRA registration review of the compound. Again, the EPA concluded that glyphosate was likely not a human carcinogen, noting that its review was "more robust" and "more transparent" than IARC's,

and that its conclusion was "consistent with other regulatory authorities and international organizations." EPA, *Glyphosate: Proposed Interim Registration Review Decision Case Number 0178* at 7-8 (Apr. 2019).[4]

Consistent with these conclusions, the EPA has stated that it would not approve a label for glyphosate warning that it is a carcinogen. In August 2019, the EPA sent a letter to glyphosate registrants in response to a March 2017 California action mandating a cancer warning on labels of Roundup and other glyphosate products in the wake of IARC's 2015 report asserting that glyphosate may cause cancer in humans. *See* Letter from Michael L. Goodis, EPA, Office of Pesticide Programs, to Registrant at 1-2 (Aug. 7, 2019), https://perma.cc/TK6P-KJ6X. In that letter, the EPA explained that it "disagrees with IARC's assessment," because "EPA scientists have performed an independent evaluation of available data since the IARC classification" and determined that glyphosate is "not likely to be carcinogenic to humans." *Id.* And that position was consistent with "other international expert panels and regulatory authorities." *Id.* The EPA explicitly cautioned that a warning on glyphosate-based herbicides suggesting that glyphosate may cause cancer would be "false and misleading," and would render any product so labeled "misbranded pursuant to section 2(q)(1)(A) of FIFRA." *Id.* (citing 7 U.S.C. § 136(q)(1)(A)).

To be sure, the EPA suggested in a 2022 letter that it might approve a label that includes a statement that IARC "classified glyphosate as probably carcinogenic to

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[4] https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-2344 (select "Download" to view).

humans." Letter from Michal Freedhoff, EPA, Office of Chemical Safety and Pollution Prevention, to Dr. Lauren Zeise, California EPA at 1 (Apr. 8, 2022), https://perma.cc/LRD4-XWG4. But the EPA did not retract its established position that glyphosate is not a carcinogen; rather, it said that the warning might be approved because it does not actually represent that glyphosate *is* a carcinogen and also includes the statement that the "US EPA has determined that glyphosate is not likely to be carcinogenic to humans." *Id.* And the EPA later withdrew that 2022 letter, *see id.* (noting "[w]ithdrawn"), following the Ninth Circuit's decision enjoining California from enforcing its labeling requirements with respect to glyphosate, *see Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1283 (9th Cir. 2023).

The EPA's message is unmistakably clear: it will not approve a change to labels for FIFRA-covered glyphosate herbicides to warn that they are carcinogenic to humans. *Cf.* 40 C.F.R. § 152.112(f) (prohibiting the EPA from approving a label that it views as false or misleading). This is far more than the mere "possibility of impossibility" that does not suffice for implied preemption. *PLIVA*, 564 U.S. at 624 n.8 (emphasis omitted). It is impossible for pesticide manufacturers to both comply with federal law and avoid state-law liability under respondent's theory.

C. The EPA monitors existing registrations, and periodically must re-review them, to ensure the statutory requirements continue to be met. *See* 7 U.S.C. § 136a(g) (re-registration); 40 C.F.R. § 155.40. The EPA requires registrants to report adverse effects of registered products, 7 U.S.C. § 136d(a)(2); 40 C.F.R. pt. 159, and can also determine that additional data must

be submitted in order to maintain an existing registration, 7 U.S.C. § 136a(c)(2)(B)(1). When as part of this continual reevaluation the EPA maintains its approvals without changes to hazard warnings, that judgment is "highly relevant" to the implied preemption analysis. *Merck*, 587 U.S. at 325 (Alito, J., concurring in the judgment). As this Court reiterated in *Merck*, the preemption analysis accounts for any "agency action carrying the force of law." 587 U.S. at 316. And as Justice Alito explained in concurrence, agency action includes agency *inaction* where the agency would have a statutory duty to act. *See id.* at 324-25 (Alito, J., concurring in the judgment). Thus, "if the [agency] declines to" act where it would have a statutory obligation to do so, "the logical conclusion is that the [agency] determined that" such action "was unjustified." *Id.* at 324.

As discussed, *see* pp. 11-12, *supra*, the EPA may grant registration only if the proposed labeling "compl[ies] with the requirements" of FIFRA, 7 U.S.C. § 136a(c)(5)(B), (c)(9)—including the requirement that the proposed labeling not be "false or misleading" and not omit "warning or caution statement[s] which may be necessary and … adequate to protect health and the environment," *id.* § 136(q)(1)(A), (G); *id.* § 136j(a)(1)(B), (E); *accord* 40 C.F.R. § 152.112(f). The EPA's decisions to re-register pesticides without requiring label changes, including the labels of numerous glyphosate-based pesticide products, *see* Pet. Br. 8, 12; EPA, *Chemical Name: Glyphosate*, https://tinyurl.com/yc6cczyw, thus necessarily show that the EPA has repeatedly determined that the federally approved labeling complies with FIFRA.

Similarly, the EPA may initiate proceedings to cancel the registration for a pesticide when "it appears to the Administrator [of the EPA] that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of [FIFRA]." 7 U.S.C. § 136d(b). The EPA has declined to initiate any proceedings to cancel the registration for Roundup or any other products containing glyphosate. That decision by the EPA is "highly relevant to the pre-emption analysis," just as Justice Alito explained of comparable declinations by the FDA in *Merck*. 587 U.S. at 325 (Alito, J., concurring in the judgment) (discussing 21 U.S.C. § 355(o)(4)(A), which obliges the FDA to initiate a label change if it becomes aware of new information that should be included in the labeling). The Court likewise cited 21 U.S.C. § 355(o)(4)(A) as an example of agency action "carrying the force of law." 587 U.S. at 316. The EPA's decision not to initiate cancellation proceedings confirms its position that FIFRA does not require a carcinogenic warning for glyphosate.

It would be impossible to comply simultaneously with the EPA's interpretation of FIFRA and with the state common-law duty to give a different warning that the Missouri courts accepted. Respondent's primary submission is that this Court—and any state court considering imposing a state-law duty to adopt a different label—must assume there is no conflict unless the agency has formally said there would be. Resp. Br. in Opp. 32-33. In other words, respondent asks the Court to ignore the responsible agency's *decades* of reaffirming glyphosate labels' registration. Repeated decisions *not* to bring enforcement action cannot be brushed aside as inertia or indolence: regulators are presumed to be walking their beat rather than idling at the precinct.

III. Respondent's position threatens to undermine several important federal statutes and would allow for crushing liability against businesses that comply with federal law.

Not only is respondent's rationale patently incorrect, it also presents a genuine threat to nationwide markets, and to the agricultural economy more broadly. FIFRA and other federal labeling requirements emphasize the importance of uniformity in labeling: a different labeling requirement for every state (or worse, every locality) would make nationwide marketing impossible. Statutes like FIFRA allow the best-equipped decisionmakers—here, the EPA and the Department of Agriculture—to evaluate whether to remove a pesticide from the national market and make a single nationwide judgment. Respondent's rationale would put those nationwide economic decisions in the hands of state juries who lack the same economic and scientific resources. These real-world harms threaten not only individual businesses, but the national economy.

A. Respondent's rationale undermines Congress's careful attention to the effects of pesticide registration and cancellation on the economy. Congress recognized that removing pesticides from the market can have major effects on the availability of important crops, agriculture more generally, and food prices. It therefore included layers of protections in the pesticide cancellation process to prevent economic upset. Respondent here seeks the same practical result of cancellation—removing Roundup from shelves—yet without any of the same regulatory protections against economic upset. Indeed, respondent's theory of preemption would allow a jury in a single jurisdiction to second-guess

whether a pesticide can remain on shelves, no matter its importance to the broader agricultural industry, food prices, and the national economy. That cannot be accurate.

FIFRA's intricate regulatory framework includes procedures for canceling the registration for a pesticide when "it appears to the Administrator [of the EPA] that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of [FIFRA]." 7 U.S.C. § 136d(b). Congress included explicit protections for the economy in those procedures. Before even commencing a cancellation proceeding, the Administrator must "take[] into account the impact … on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." *Id.* The Administrator must also consult the Secretary of Agriculture about "such impact." *Id.* And the Administrator must consider "restricting a pesticide's use or uses as an alternative to cancellation," again "tak[ing] into account the impact … on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." *Id.*

Once the Administrator considers the economic implications of cancellation, consults the Secretary of Agriculture, and considers possible alternatives to cancellation, the Administrator may issue intent to cancel the registration, *see id.*, and—upon party request—may proceed with a cancellation hearing, *see id.* § 136d(d). The hearing itself includes procedures to ensure that the result is based on impartial scientific evidence. The parties may engage in discovery, and all parties and the presiding hearing examiner may refer "questions of scientific fact" to the National Academy of

Sciences. *Id.* The hearing culminates in an order that (as relevant here) may cancel the registration, "requir[e] modification of the labeling," or withdraw the Administrator's notice of intent to cancel. *Id.* That order must be accompanied by "detailed findings of fact," *id.*, and is subject to judicial review, *id.* §§ 136d(h), 136n.

Any state-law rule declaring that petitioner may no longer market Roundup with its federally approved label—that it must instead add a carcinogen warning that the EPA regards as false and misleading—would in practice be equivalent to cancellation of Roundup's registration. Yet a single state jury can reach that decision and effectively bar Roundup from shelves, without any obligation to consider the effects on the national agricultural economy. *See* Pet. 12-13 (highlighting the importance of Roundup to American farmers). Juries make decisions about compensating a single plaintiff, not about feeding a nation or the world.

B. In zones of regulation like this one—for which Congress has specified that states cannot impose different or additional labeling requirements—federal law is not just a floor. Federal law is also a ceiling, the authoritative measure of a regulated business's labeling obligations. Respondent's rationale, by contrast, threatens to leave federal requirements as merely the first hurdle that a regulated business must clear. Every state could have its own requirements—meaning that juries, or other authorities, in every jurisdiction could set their own standards, after the fact, on a case-by-case basis. Failing to anticipate the preferred standards of just one jury could result in crippling liability.

Businesses are already subject to comprehensive

regulatory schemes under both federal and state law, which impose significant costs on their operations to the tune of hundreds of billions of dollars annually. *See, e.g.*, U.S. Chamber of Commerce Found., *The Regulatory Impact on Small Business: Complex. Cumbersome. Costly*. at 4 (Mar. 2017), https://perma.cc/6DVW-8MY3; Nicole V. Crain & W. Mark Crain, Nat'l Ass'n of Mfrs., *The Cost of Federal Regulation to the U.S. Economy, Manufacturing & Small Business* at 4-5 (Oct. 2023), https://perma.cc/88NS-KNAT. Allowing each of the 50 states to adopt its own unique rulebook for pesticide labeling promises to compound those existing burdens by subjecting businesses to a thicket of different state common-law labeling requirements. As this Court recognized, allowing "50 different labeling regimes prescribing the color, font size, and wording of warnings … would create significant inefficiencies for manufacturers" and deprive them of the "uniformity" they "need" to operate. *Bates*, 544 U.S. at 452 & n.26 (citation omitted). The inevitable consequence of that regulatory morass would be to drive up the cost of operations, stifle competition, and constrain employment opportunities—with severe impacts on downstream business enterprises and ordinary consumers, who would face higher prices and have access to fewer valuable goods and services.

The harmful effects of denying preemption here would not be confined to FIFRA. Many federal statutes employ express preemption language that is identical (or virtually identical) to the operative language in FIFRA, preempting state-law labeling requirements in a host of industries precisely because Congress recognized that the ability to market a product throughout the country with a single label is essential to maintaining an efficient nationwide market. For example,

the Medical Device Amendments bar states from "establish[ing] or continu[ing] in effect … any requirement … which *is different from, or in addition to*, any requirement" under that law. 21 U.S.C. § 360k(a) (emphasis added). Once the FDA "approves a device's label," "the manufacturer usually may not alter the label's warnings without prior agency approval." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1341 (10th Cir. 2015) (citing 21 U.S.C. § 360e(d)). Similarly, the Federal Meat Inspection Act prohibits states from imposing any "[m]arking, *labeling*, packaging, or ingredient requirements *in addition to, or different than*, those made under this [Act]." 21 U.S.C. § 678 (emphasis added). Other examples abound. *See, e.g.*, *id.* § 1052(b) (for egg products, prohibiting "[l]abeling … requirements, in addition to or different than those made under [the Egg Products Inspection Act], the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act"); *id.* § 467e (same for labeling of poultry and poultry products); *id.* § 379s(a) (prohibiting states from "establish[ing] or continu[ing] in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with" federal labeling standards); *id.* § 379r(a)(2) (similar for non-prescription drug labeling); *id.* § 387p(a)(2)(A) (same for tobacco products); *id.* § 343-1(a)(2)-(4) (prohibiting states from imposing "any requirement" for nutrition labeling on certain foods that "is not identical" to those required by the Nutrition Labeling and Education Act).[5] Adopting

[5] While labeling is one particularly important area in which Congress has repeatedly acted to ensure that products can be marketed nationwide with a single label, other federal statutes use the same preemption language for state requirements outside the labeling context. 21 U.S.C. § 379aa(h) (serious adverse event

respondent's improper interpretation of FIFRA could well lead courts to transplant the same misguided reasoning into many other similarly worded preemption provisions—neutering their preemptive force.

This Court should prevent such results. Ignoring the preemptive force of federal labeling requirements would force the businesses that comply with them into a vise, requiring them to adhere to the federally approved label while facing crippling liability from state failure-to-warn claims for doing so, in at least 50 different ways. Preventing that from happening is exactly why Congress wrote an express preemption provision into this statute and others, barring any state law that imposes obligations different from federal law. This Court should remove the threat and follow Congress's clear directive: differing state laws are preempted.

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reports for non-prescription drugs); *id.* § 379aa-1(h) (serious adverse event reports for dietary supplements); 7 U.S.C. § 4817(b) (promotion and consumer education regarding pork); 15 U.S.C. § 78o(i) (regulation of brokers and dealers).

CONCLUSION

The Court should reverse the judgment of the Missouri Court of Appeals.

Respectfully submitted.

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