No. 24-1068

In the Supreme Court of the United States

MONSANTO COMPANY, PETITIONER

v.

JOHN L. DURNELL

ON PETITION FOR A WRIT OF CERTIORARI TO THE MISSOURI COURT OF APPEALS

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, preempts a state-law failure-to-warn claim concerning a pesticide registered by the U.S. Environmental Protection Agency (EPA), where EPA has determined that a particular warning is not required and the warning cannot be added to a product label without EPA approval.

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INTEREST OF THE UNITED STATES

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be granted.

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, prohibits the distribution or sale of a pesticide "that is not registered" by the U.S. Environmental Protection Agency (EPA). 7 U.S.C. 136a(a). To decide whether a pesticide should be registered, EPA must determine whether "its labeling * * * compl[ies] with the requirements of" FIFRA, 7 U.S.C. 136a(c)(5)(B); and whether, "when used in accordance with widespread and commonly recognized practice," the

pesticide "will not generally cause unreasonable adverse effects on the environment," 7 U.S.C. 136a(c)(5)(D). The term "unreasonable adverse effects on the environment" is defined to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb). If a pesticide's label does not contain a warning "necessary and * * * adequate to protect health and the environment," 7 U.S.C. 136(q)(1)(G), the "pesticide is misbranded," 7 U.S.C. 136(q)(1). Once EPA has approved a label, the registrant may not add to or amend the label's precautionary statements without review and approval by the agency. See 40 C.F.R. 152.44(a); see also 40 C.F.R. 156.70(c).

In the interest of "[u]niformity," FIFRA precludes States from imposing any labeling requirements that are "in addition to or different from those required under" FIFRA. 7 U.S.C. 136v(b). Section 136v(b) "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005). Thus, although a State may enforce "rules that are fully consistent with federal requirements," a "manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA." *Id.* at 452, 454.

This case raises an important question about the scope of FIFRA's preemption provision. Since 1974, petitioner Monsanto Company has manufactured the pesticide Roundup with the active ingredient glyphosate.

For decades, EPA has classified glyphosate as a chemical that is not likely to be carcinogenic in humans, and the agency has approved hundreds of labels for Roundup and other glyphosate-based products without requiring a cancer warning. Respondent alleges, however, that petitioner is liable under state law for failure to include such a warning. The court below affirmed a jury verdict against petitioner in respondent's suit, rejecting petitioner's argument that Section 136v(b) preempted respondent's state-law claims.

The decision below is incorrect and implicates a conflict of authorities on the question presented. The Ninth and Eleventh Circuits have allowed similar state-law claims to proceed against petitioner, holding that Section 136v(b) did not preempt state-law requirements to warn of cancer risks purportedly associated with Roundup. See *Hardeman* v. *Monsanto Co.*, 997 F.3d 941, 955-958 (9th Cir. 2021), cert. denied, 142 S. Ct. 2834 (2022); *Carson* v. *Monsanto Co.*, 92 F.4th 980, 989-996 (11th Cir. 2024). More recently, however, the Third Circuit correctly held that EPA's approval of Roundup labels without a cancer warning, combined with regulations requiring the agency's approval before such a warning may be added, precludes imposition of state-law tort liability based on petitioner's failure to warn of cancer risks. See *Schaffner* v. *Monsanto Corp.*, 113 F.4th 364, 399 (2024). The Court should grant certiorari to resolve that circuit conflict and clarify the scope of FIFRA's preemption provision.

STATEMENT

1. a. FIFRA is a "comprehensive regulatory statute" that governs the "use, as well as the sale and labeling, of pesticides." *Bates*, 544 U.S. at 437 (citations omit-

ted). FIFRA prohibits the distribution or sale of a pesticide unless it has been registered by EPA. 7 U.S.C. 136a(a). To apply for registration, a manufacturer must submit, among other things, the product's "complete formula," "claims to be made for it," proposed labeling, and a "full description of the tests made and the results thereof upon which the claims are based." 7 U.S.C. 136a(c)(1)(C), (D), and (F). EPA's implementing regulations impose additional requirements. See 40 C.F.R. Pt. 152. The regulations require manufacturers to submit scientific and safety data, and to flag studies related to potential adverse effects. See 40 C.F.R. Pt. 152, 152.50, Subpt. E, 158.34. The manufacturer must also submit proposed labeling that includes any precautionary statements about potential effects on human health. 40 C.F.R. 156.10(a)(1)(vii), 156.60, 158.500.

EPA "shall register a pesticide" if the agency determines, *inter alia*, that "its labeling * * * compl[ies] with the [statute's] requirements," and that "when used in accordance with widespread and commonly recognized practice[,] it will not generally cause unreasonable adverse effects on the environment," 7 U.S.C. 136a(c)(5)(B) and (D), which the statute defines to include unreasonable adverse effects on human health, 7 U.S.C. 136(bb). To verify that the latter requirement is satisfied, EPA reviews scientific studies and safety data. 40 C.F.R. 152.107; 152.112(b),(c),(e), and (f). EPA also reviews the proposed label to ensure that it complies with FIFRA's requirements, including that it contains any warnings necessary to protect human health. See 7 U.S.C. 136(q)(1)(G); see also 40 C.F.R. 152.42, 152.50, Pt. 156.

Once EPA registers a pesticide, the registrant must include all approved precautionary statements on its

product. 40 C.F.R. 156.10(a)(1). A registrant may not alter the label, other than with "minor modifications," without first obtaining EPA's approval. 40 C.F.R. 152.44(a), 152.46(a). As relevant here, registrants may not alter "precautionary statements" without the agency's review and approval. 40 C.F.R. 156.70(c); see Office of Pesticide Programs, EPA, *Pesticide Registration Notice 2000-5* (May 10, 2000), https://perma.cc/ANB4-UGG9; Office of Pesticide Programs, EPA, *Pesticide Registration Notice 98-10* (Oct. 22, 1998), https://perma.cc/ZK8Z-2NNM. A registrant, however, has a continuing obligation to adhere to FIFRA's requirements, including its labeling requirements. See *Bates*, 544 U.S. at 438-439. If a registrant learns at any time of "additional factual information regarding unreasonable adverse effects," it must submit that information for EPA's review. 7 U.S.C. 136d(a)(2).

EPA's obligations also continue after a product's initial review and registration. EPA may initiate the cancellation or modification of a registration if the agency determines that the pesticide "causes unreasonable adverse effects on the environment" or is otherwise misbranded. See 7 U.S.C. 136d(b). EPA also formally reviews each pesticide registration every 15 years. 7 U.S.C. 136a(g)(1)(A)(iii)(II) and (iv). In that review, EPA assesses any new information about risks to human health and the environment to verify that the pesticide continues to satisfy FIFRA's safety standards. See, *e.g.*, 40 C.F.R. 155.40, 155.53(a).

b. FIFRA prohibits the sale or distribution of a pesticide that is "misbranded." 7 U.S.C. 136j(a)(1)(E). A pesticide is misbranded if its labeling "bears any statement * * * which is false or misleading in any particu-

lar." 7 U.S.C. 136(q)(1)(A). A pesticide is also misbranded if it "does not contain a warning or caution statement which may be necessary and if complied with * * * is adequate to protect health and the environment." 7 U.S.C. 136(q)(1)(G). The statute defines "protect health and the environment" to mean "protection against any unreasonable adverse effects on the environment," 7 U.S.C. 136(x). which in turn includes protection against "any unreasonable risk to man or the environment," 7 U.S.C. 136(bb). Taken together, those provisions establish that a pesticide is misbranded under FIFRA if, among other things, its label fails to include information that is "necessary" to protect against "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(q)(1)(G) and (bb).

A breach of these requirements can expose registrants to significant sanctions. An EPA enforcement action premised on such violations may result in an order that the registrant "stop [the] sale, use, or removal" of the pesticide, 7 U.S.C. 136k(a); seizure of offending products, 7 U.S.C. 136k(b); and civil and criminal penalties, 7 U.S.C. 136*l*.

c. FIFRA includes a preemption provision, which bars a State from "impos[ing] or continu[ing] in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. 136v(b). A State may "regulate the sale or use of any federally registered pesticide" within its borders, so long as the State does not permit any sale or use prohibited by FIFRA. 7 U.S.C. 136v(a). In certain circumstances, a State may register a federally approved pesticide for additional uses in order "to meet special local needs" within

the State. 7 U.S.C. 136v(c)(1). But a State may not impose "competing state labeling standards," which "would create significant inefficiencies for manufacturers." *Bates*, 544 U.S. at 452.

2. Petitioner is the manufacturer and registrant of the pesticide Roundup with the active ingredient glyphosate. See Pet. App. 3. In 1985, EPA classified glyphosate as a possible human carcinogen, but a scientific advisory panel determined the following year that glyphosate's human carcinogenicity "could not yet be classified." *Schaffner* v. *Monsanto Corp.*, 113 F.4th 364, 373 (3d Cir. 2024). Since 1991, and after reviewing additional data, EPA has classified glyphosate as a chemical not likely to be carcinogenic in humans. *Ibid.* In its 2020 interim registration-review decision, EPA reaffirmed that assessment, after a decade-long review in which the agency considered more than 238,000 public comments. Pet App. 35; *Natural Res. Def. Council* v. *EPA*, 38 F.4th 34, 43 (9th Cir. 2022).[1] EPA has consistently approved Roundup labels without a cancer warning, see Pet. 7 n.1, 16, based on the agency's conclusion that glyphosate is not likely to be carcinogenic in humans, see EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 12-13 (Dec. 12, 2017).

In 2015, a working group at the International Agency for Research on Cancer (IARC) classified glyphosate as a

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[1] The Ninth Circuit vacated the human-health portion of the 2020 interim registration-review decision and remanded to EPA for "further analysis and explanation." *Natural Res. Def. Council*, 38 F.4th at 52. In response, EPA withdrew the interim decision, while explaining that its withdrawal "does not automatically mean that EPA's underlying scientific findings, including its finding that glyphosate is not likely to be carcinogenic to humans," are incorrect. Pet. App. 30-31.

possible human carcinogen. IARC, 112 *Some Organophosphate Insecticides and Herbicides: Glyphosate* at 398 (2015). EPA has since taken different positions as to whether it would approve labels that reflected that development. In 2019, the Director of the Registration Division of EPA's Office of Pesticide Programs issued a letter to registrants of products that contain glyphosate. Pet. App. 38-40. The letter stated that, because EPA had determined that glyphosate is "'not likely to be carcinogenic to humans,'" pesticide products that contained a "warning statement due to the presence of glyphosate are misbranded" under FIFRA. *Id.* at 39. In 2022, in response to a request from California, EPA stated that the agency would approve a warning label that both (a) recited the IARC's conclusion about glyphosate's probable carcinogenic effect and (b) explained that "EPA has determined that glyphosate is not likely to be carcinogenic to humans." *Id.* at 42; see *id.* at 41-43. EPA noted at that time that the agency "continue[d] to stand behind its robust scientific evaluation of the carcinogenic potential of glyphosate." *Id.* at 41.[2]

3. In 2019 respondent sued petitioner in Missouri Circuit Court, alleging that respondent's use of Roundup until 2012 had caused him to develop non-Hodgkin's lymphoma. Pet. App. 3. Respondent alleged, *inter alia*, that petitioner had tortiously failed to warn of cancer risks posed by Roundup. See *ibid.*

The trial court rejected petitioner's argument that FIFRA preempted respondent's claims. Pet. App. 13-

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[2] EPA later withdrew the 2022 letter in light of a Ninth Circuit decision that enjoined the enforcement of the California law that had precipitated the request for the warning. See *National Ass'n of Wheat Growers* v. *Bonta*, 85 F.4th 1263, 1266-1267 (2023).

16. The case proceeded to trial, where a jury awarded respondent $1.25 million based on his failure-to-warn claim. *Id.* at 20-21. Petitioner sought a judgment notwithstanding the verdict, which the court denied. *Id.* at 19.

4. The Missouri Court of Appeals affirmed. Pet. App. 2-12. The court held that FIFRA does not expressly preempt respondent's failure-to-warn claim. *Id.* at 5-7. The court explained that "[t]he 'practical effect' of both FIFRA's prohibition on misbranding under [7 U.S.C.] 136(q)(1)(G) and a strict liability failure to warn claim in Missouri are the same: both require a pesticide manufacturer to adequately warn users of the potential dangers of using its product." *Id.* at 7. The court concluded on that basis that, for purposes of Section 136v(b), Missouri law does not impose a requirement "in addition to or different from" FIFRA's misbranding prohibition. *Ibid.*

The Missouri Court of Appeals acknowledged that the Third Circuit had found similar state-law claims to be preempted. Pet. App. 10 (citing *Schaffner*, 113 F.4th at 370-399). The court did "not find *Schaffner* persuasive," however, and it chose instead to follow decisions in which the Ninth and Eleventh Circuits had rejected petitioner's express-preemption arguments. *Id.* at 10-11. The court also held that respondent's claims were not impliedly preempted. *Id.* at 8-9. The court explained that "[t]he record contains no evidence that [petitioner] either informed the EPA of the justifications for a change to its warning label or that the EPA has informed [petitioner] it would not approve such a warning." *Id.* at 9.

The Missouri Supreme Court denied petitioner's application for transfer. See Pet. App. 1.

DISCUSSION

In *Monsanto Co.* v. *Hardeman*, 142 S. Ct. 707 (2021), this Court invited the Solicitor General to file a petition-stage brief addressing substantially the same preemption question as is presented here. The government's amicus brief argued that FIFRA did not preempt the state-law failure-to-warn claim asserted in that case, see U.S. Amicus Br. at 6-16, *Monsanto*, *supra*, No. 21-241, and that the preemption question would not warrant review "unless and until a conflict in authority emerge[d]," *id.* at 17-20. That amicus brief acknowledged that, in a prior court of appeals brief filed in the same case, the government had argued that the failure-to-warn claim *was* preempted. See *id.* at 6. This Court denied certiorari. *Monsanto Co.* v. *Hardeman*, 142 S. Ct. 2834 (2022).

Since that time, a conflict has developed among the courts of appeals on the question whether FIFRA expressly preempts state-law tort claims premised on petitioner's failure to warn its customers about potential cancer risks created by use of Roundup. See *Schaffner* v. *Monsanto Corp.*, 113 F.4th 364, 382-385 (3d Cir. 2024). In light of the Third Circuit's intervening decision in *Schaffner* and the change in Administration, the United States has reexamined the arguments it pressed before this Court in *Hardeman* and has returned to its previous position as to the scope of FIFRA preemption. Under that approach, EPA's approval of Roundup labels without a cancer warning, combined with an EPA regulation that prohibits petitioner from adding such a warning without agency approval, preempts respondent's failure-to-warn claim. The Missouri Court of Ap-

peals' contrary holding is incorrect. Review is now warranted to resolve the conflict on an important question of federal law.

A. The Decision Below Is Incorrect.

FIFRA "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005). Because Missouri's failure-to-warn cause of action imposes a "labeling or packaging requirement that is 'in addition to or different from those required under [FIFRA],'" *id.* at 443-444 (quoting 7 U.S.C. 136v(b)) (emphasis omitted), the federal law preempts respondent's failure-to-warn claim to the extent of the difference.

1. a. Under FIFRA, a pesticide is "misbranded" if, among other things, its label omits "a warning or caution statement which may be necessary and if complied with * * * is adequate to protect health and the environment." 7 U.S.C. 136(q)(1)(G). Through its registration process, EPA "give[s] content to" FIFRA's misbranding standards as they apply to particular pesticides. *Bates*, 544 U.S. at 543. Before approving a registration request, EPA extensively reviews a manufacturer's science and safety data, as well as publicly available science and data, to determine whether the pesticide will pose any "unreasonable adverse effects on the environment," 7 U.S.C. 136a(c)(5)(C), (D), with the term "unreasonable adverse effects on the environment" defined to include any "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide," 7 U.S.C. 136(bb); see p. 6, *supra*. The agency approves the registration only if it concludes that the

label contains all warnings that are necessary to satisfy that standard.

Once EPA has registered a pesticide, the agency's regulations limit a registrant's ability to change its label without EPA's express approval. A registrant must apply for permission to make "any modification in the composition, labeling, or packaging of a registered product," 40 C.F.R. 152.44(a), including any "[s]pecific statements pertaining to the hazards of the product and its uses," 40 C.F.R. 156.70(c). The manufacturer may not unilaterally alter a label that EPA has approved, even if the registrant learns of "additional factual information regarding unreasonable adverse effects." 7 U.S.C. 136d(a)(2). Instead, the registrant must "submit such information to" EPA. See *ibid.*[3]

b. As applied to this case, the labeling requirements imposed by Missouri's failure-to-warn law are preempted by FIFRA.

i. Although a State may permissibly impose "parallel" requirements on a manufacturer, preemption is appropriate where the "Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 501 (1996). In *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312

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[3] EPA regulations allow registrants to make "certain minor modifications to registration" by notifying the agency, without waiting for agency approval. 40 C.F.R. 152.46(a). A registrant could not unilaterally amend its label, however, to include the type of precautionary statements about health risks that are at issue here. See 40 C.F.R. 156.70(c); *Schaffner*, 113 F.4th at 382-385.

(2008), this Court considered the preemption provision in the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, to the Federal Food, Drug, and Cosmetics Act, ch. 675, 52 Stat. 1040 (21 U.S.C. 301 *et seq.*). Similar to FIFRA's express-preemption provision, the MDA preempts state-law requirements that are "different from, or in addition to, any requirement applicable under this chapter to the [medical] device." 21 U.S.C. 360k(a)(1); see *Riegel*, 552 U.S. at 316; *Bates*, 544 U.S. at 447 (observing that the two statutes' preemption provisions are "similarly worded").

The Court in *Riegel* held that the medical-device premarket-approval process conducted by the Food and Drug Administration (FDA) created federal-law "requirement[s]" within the meaning of Section 360k(a)(1). See 552 U.S. at 321-322. The Court explained that FDA "premarket approval is specific to individual devices," *id.* at 323, and that "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness," *ibid.* The Court further held that the federal-law requirements imposed on specific devices by the FDA's premarket-approval process preempt any inconsistent duties imposed by state tort law. See *id.* at 323-325, 330.

For substantially the same reasons, EPA's pesticide-registration process produces "requirements for labeling" within the meaning of 7 U.S.C. 136v(b). Just as FDA "premarket approval is specific to individual devices," *Riegel*, 552 U.S. at 323, EPA determines on an individualized basis what warnings are appropriate for particular pesticides. And once EPA has registered a particular

pesticide, the agency allows "almost no deviations from the" approved labeling without express EPA approval. *Ibid.*; see 40 C.F.R. 152.44(a). EPA determinations made in the course of the registration process thus are binding and identify more specifically the "contents required to be included on a pesticide label." See *Schaffner*, 113 F.4th at 390.

ii. The Missouri Court of Appeals described "the dispositive question" before it as "whether [respondent's] failure to warn claim imposes a requirement that is 'in addition to or different from' FIFRA's labeling requirements." Pet. App. 6. The court concluded that the relevant federal- and state-law requirements were equivalent because "[t]he practical effect of both FIFRA's prohibition on misbranding under section 136(q)(1)(G) and a strict liability failure to warn claim in Missouri are the same: both require a pesticide manufacturer to adequately warn users of the potential dangers of using its product." *Id.* at 7 (internal quotation marks omitted). The court thus viewed the general rule set forth in 7 U.S.C. 136(q)(1)(G), which requires each pesticide label to contain whatever warnings are "necessary and * * * adequate to protect health and the environment," as the *only* federal labeling "requirement[]" relevant to the preemption inquiry. The court did not consider, as potentially preemptive federal "requirements for labeling" within the meaning of Section 136v(b), the Roundup-specific labeling requirements to which petitioner is subject as a result of the EPA registration process.

That approach reflects an unduly parsimonious reading of FIFRA's preemption provision. Section 136v(b) bars States from enforcing "any requirements for labeling or packaging in addition to or different from those

required *under* this subchapter [*i.e.*, FIFRA]." 7 U.S.C. 136v(b) (emphasis added). The current federal-law requirements specifying what warnings must appear on Roundup labels result in part from EPA's approval (after a substantial scientific review) of a Roundup label that contains certain warnings but not warnings about cancer risk, and in part from EPA regulations that prohibit registrants from significantly changing their pesticide labels without the agency's approval. See *Schaffner*, 113 F.4th at 393 (explaining that EPA's regulations "give[] content to the broad [FIFRA] misbranding standard by specifically requiring a pesticide's label to bear the particular precautionary statements on" the label approved by EPA during the registration process); *id.* at 390-393.

The specific labeling mandates that identify the prescribed contents of Roundup labels thus result from EPA actions implementing FIFRA's more general provisions. The mandates therefore are naturally characterized as being "required under" FIFRA, even though they do not appear on the face of the statute. That reading is strongly supported by *Riegel*, in which the Court held that FDA premarket approval of a specific medical device "imposes 'requirements' *under the MDA*." 552 U.S. at 322 (emphasis added); see 21 U.S.C. 360k(a)(1) (giving preemptive effect to "any requirement applicable *under this chapter* to the device") (emphasis added); *Schaffner*, 113 F.4th at 388 ("The analysis of 'requirements' adopted in *Riegel* carries over to FIFRA."); *id.* at 388-389.

iii. The Missouri Court of Appeals also erred in treating FIFRA's prohibition on misbranding under section 136(q)(1)(G) as substantively equivalent to a state failure-to-warn claim. See Pet. App. 7. Under Missouri

law, a manufacturer is strictly liable for harms caused by an "unreasonably dangerous" product if the manufacturer "did not give adequate warning of the danger." *Moore* v. *Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. 2011) (en banc); Pet. App. 6-7. In determining whether a particular product is unreasonably dangerous, a Missouri jury need not consider the product's economic and social benefits, as the "concept of unreasonable danger . . . is presented to the jury as an ultimate issue without further definition." *Moore*, 332 S.W.3d at 756 (citation omitted). Under FIFRA, by contrast, a manufacturer is required to add only such warnings as are "necessary and * * * adequate to protect human health and the environment." 7 U.S.C. 136(q)(1)(G). And in determining whether a particular pesticide will pose an "unreasonable risk to man or the environment," EPA "tak[es] into account the economic, social, and environmental costs *and benefits* of the use of [the] pesticide." 7 U.S.C. 136(bb) (emphasis added). Because the jury below was not instructed to account for such benefits, the jury did not apply the same substantive standard that FIFRA instructs EPA to apply in determining whether a pesticide is misbranded. Cf. *Riegel*, 552 U.S. at 325 (noting that, while the FDA's premarket-approval process involves a "cost-benefit analysis," the jury in a tort suit "sees only the cost of a more dangerous design").

2. Respondent's contrary arguments are unavailing.

a. Respondent relies in part on this Court's decision in *Bates*. There, the Court considered whether FIFRA preempted state-law fraud and failure-to-warn causes of action that were premised on allegedly deceptive statements on a pesticide's label. The defendant manufacturer's label stated that its pesticide (Strongarm) was "recommended in all areas where peanuts are

grown." *Bates*, 544 U.S. at 435 (citation omitted). The plaintiffs alleged, however, that "[w]hen [they] applied Strongarm on their farms—whose soils have pH levels of 7.2 or higher, as is typical in western Texas—the pesticide severely damaged their peanut crops while failing to control the growth of weeds." *Ibid.* EPA subsequently approved a "supplemental" label, authorized for use only in New Mexico, Oklahoma, and Texas, that "contained the following warning: 'Do not apply Strongarm to soils with a pH of 7.2 or greater.'" *Ibid.* (citation omitted).

The *Bates* Court explained that plaintiffs could pursue their claims if the state-law requirements were "fully consistent with federal requirements," but that FIFRA would preempt "any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." 544 U.S. at 452. The Court did not decide whether the state-law requirements at issue in *Bates* were "in fact * * * equivalent to a requirement under FIFRA," *id.* at 453, and it remanded with instructions that, if the case proceeded to trial, "the court's jury instructions must ensure that nominally equivalent labeling requirements are *genuinely* equivalent," *id.* at 454.

Respondent emphasizes (Br. in Opp. 26) that, in *Bates*, the Court noted the possibility that a pesticide might be "registered but nevertheless misbranded." 544 U.S. at 438. In *Bates*, however, the plaintiffs did not allege that the defendant had failed to warn about risks to human health; they alleged that Strongarm had damaged their crops and had not controlled the growth of weeds. *Id.* at 435. The Court explained that, when EPA registered the pesticide at issue, it was not required to confirm claims

on the proposed label about the product's efficacy. See *id.* at 440; *id.* at 450 ("Congress amended FIFRA to allow EPA to waive efficacy review of newly registered pesticides."). Because EPA had never "passed on the accuracy of the statements in Strongarm's original label recommending the product's use 'in all areas where peanuts are grown,'" *id.* at 440, EPA's registration of the pesticide did not reflect any Strongarm-specific judgment that was inconsistent with the plaintiffs' state-law claims.

By contrast, EPA carefully evaluates the "particular requirement in question" here, *Riegel*, 518 U.S. at 501—*i.e.* that a pesticide's label must contain warnings sufficient to prevent unreasonable risks to human health—when it approves a pesticide label. See pp. 11-12, *supra*. Through that process, EPA has identified more specifically the health-based warnings that a Roundup label must include to avoid misbranding liability. With respect to the ingredient (glyphosate) that respondent views as hazardous, EPA has made specific and consistent factual findings, and the agency has repeatedly approved Roundup labels that did not contain cancer warnings. See p. 7, *supra*. By imposing liability for petitioner's failure to include such a warning, the state-court judgment subjected petitioner to a "requirement[] for labeling" that is "in addition to or different from those required under" FIFRA. 7 U.S.C. 136v(b).

b. Respondent's reliance (Br. in Opp. 25-28) on 7 U.S.C. 136a(f)(2) is likewise misplaced. Section 136a(f)(2) states that registration is "prima facie evidence" that a pesticide complies with FIFRA's requirements, but that registration is not "a defense for the commission of any offense under" FIFRA, including misbranding offenses. *Ibid.* Registration, for instance,

may not protect a registrant from federal liability if the label that appears on a product in distribution differs materially from the label the agency approved. See *Schaffner*, 113 F.4th at 397 n.18. The registrant might also face liability under FIFRA if it fails to include in its registration application "factual information of which [it was] aware regarding unreasonable adverse effects of the pesticide," 40 C.F.R. 152.50(f)(3), or fails to inform EPA when the registrant learns of "additional factual information regarding unreasonable adverse effects," 7 U.S.C. 136d(a)(2); see 7 U.S.C. 136j(a)(2)(S).

Even if a manufacturer's failure to submit accurate and timely information to EPA could subject it to liability under federal law (either for misbranding or other offenses), it would not necessarily follow that state-law failure-to-warn claims could go forward. The viability of such claims would still depend on whether imposition of state-law liability would impose labeling requirements "in addition to or different from those required under" FIFRA. 7 U.S.C. 136v(b). And any private suit that asked a court or jury to assess the adequacy of a manufacturer's disclosures to EPA would raise distinct concerns. Cf. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-348 (2001) (holding that so-called "fraud-on-the-FDA" claims are impliedly preempted because the federal-law obligation to inform the FDA of any safety concerns regarding a medical device is not privately enforceable).

In any event, respondent's approach to FIFRA preemption would allow state-law liability well beyond the circumstances described above. Respondent suggests (Br. in Opp. 26) that pesticide manufacturers' submissions to EPA may sometimes be "inaccurate, incomplete, or proven inadequate based on later research." But

neither the Missouri Court of Appeals' opinion nor the jury instructions in this case required a finding to that effect as a prerequisite to liability. Instead, the state court's approach would allow a jury to evaluate the same information that EPA had evaluated and reach a determination that conflicts with the agency's findings, thus undermining the interest in "[u]niformity" that FIFRA's preemption provision is intended to protect. 7 U.S.C. 136v(b).[4]

B. The Acknowledged Circuit Conflict Warrants This Court's Review

1. The court below acknowledged that its decision conflicts with the Third Circuit's decision in *Schaffner*. There, the Third Circuit held that FIFRA preempted similar state-law claims based on respondent's failure to warn of cancer risks allegedly posed by Roundup. *Schaffner*, 113 F.4th at 370-399. The *Schaffner* court concluded that, because EPA had registered the pesticide and approved a label that omits a particular health warning, FIFRA expressly preempted a state-law duty to include that warning on the product's label. *Id.* at 370-371. In particular, the *Schaffner* court explained that EPA's regulations require "pesticide labels to conform to the EPA's opinion as to whether specific labels would constitute misbranding, and thus each 'give[s] content to' the broad requirement that such labels not be misbranded." *Id.* at 391 (quoting *Bates*, 544 U.S. at 453) (brackets in original). The court further held that,

[4] Petitioner also contends that FIFRA impliedly preempts respondent's failure-to-warn claim because it is "impossible" for petitioner to comply with both federal- and state-law requirements. Pet. 28 (citation omitted). Because FIFRA expressly preempts the claim at issue, this Court need not decide whether FIFRA impliedly preempts respondent's claims.

in determining whether enforcement of a state-law duty to warn would impose labeling requirements "in addition to or different from those required under" FIFRA, 7 U.S.C. 136v(b), the court should take into account EPA's regulatory requirement that manufacturers adhere to EPA-approved labels. *Schaffner*, 113 F.4th at 390-393. Based on that comparison between state and relevant federal requirements, the Third Circuit held that the plaintiffs' claims were preempted. *Id.* at 399.

The Ninth and Eleventh Circuits have reached a contrary conclusion. Those courts have allowed similar state-law failure-to-warn claims against petitioner to proceed, notwithstanding EPA's registration of the pesticide and its approval of Roundup labels that do not contain cancer warnings. See *Hardeman* v. *Monsanto Co.*, 997 F.3d 941, 955-958 (9th Cir. 2021); *Carson* v. *Monsanto*, 92 F.4th 980, 989-996 (11th Cir. 2024). Several state courts have reached similar conclusions. See, *e.g.*, *Johnson* v. *Monsanto Co.*, 554 P.3d 290, 306-307 (Or. Ct. App. 2024), petition for cert. pending, No. 24-1098 (filed Apr. 18, 2025); *Pilliod* v. *Monsanto Co.*, 282 Cal. Rptr. 3d 679, 698 (Cal. Ct. App. 2021), cert. denied, 142 S. Ct. 2870 (2022); *Caranci* v. *Monsanto Co.*, 338 A.3d 151, 167-170 (Pa. Super. Ct. 2025).

2. Respondent maintains (Br. in Opp. 22) that no conflict is implicated here because the Third Circuit in *Schaffner* relied on the assumption that "Monsanto had no option to update Roundup's labeling." Respondent observes (*ibid.*) that EPA regulations did not prevent petitioner from seeking EPA approval to add a cancer warning to its label. In fact, the *Schaffner* court noted the possibility of a hypothetical state-law tort suit alleging that FIFRA required petitioner to request EPA approval to add a cancer warning to its label. 113 F.4th at 386 n.13.

The court "express[ed] no opinion" about such a claim's potential merits, however, because the plaintiffs in that case had not advanced such a claim. *Ibid.*; but cf. p. 19, *supra* (citing *Buckman*, *supra*).

Similarly here, the jury's liability determination was not premised on any finding that petitioner was remiss in failing to request approval to add a cancer warning to the Roundup label. Rather, the jury was instructed to find petitioner liable so long as Roundup was sold without an adequate cancer warning. See Cert. Reply Br., Supp. App. 4. That instruction left the jury no room to consider whether petitioner could or should have provided updated information to the agency.

Respondent also contends (Br. in Opp. 16-20) that his claims do not depend on Roundup's labeling, which is subject to Section 136v(b)'s preemption rule, but instead turned on television advertisements, which are beyond Section 136v(b)'s reach. The court below, however, characterized respondent's failure-to-warn claim as a "common-law action which effectively imposes a state law requirement for labeling." Pet. App. 5-6. Indeed, respondent's failure-to-warn count alleged that "Monsanto had a duty to properly . . . label" Roundup products. *Id.* at 6 n.3. The decision below therefore turned on whether respondent's "failure to warn claim impose[d] a requirement that is 'in addition to or different from' FIFRA's labeling requirements"—the question that has divided the federal courts of appeals. *Id.* at 6 (citation omitted).

3. The circuit conflict warrants this Court's review. FIFRA's preemption provision is entitled "[u]niformity." 7 U.S.C. 136v(b). The Third Circuit's approach correctly allows EPA to determine on a nationwide ba-

sis what warnings must appear on a particular pesticide's label to avoid an unreasonable risk to human health. Under the Ninth and Eleventh Circuits' approach, by contrast, "different factfinders deciding different individual cases" might reach conflicting determinations as to "whether a particular warning was necessary to protect health." *Schaffner*, 113 F.4th at 393. That risk goes beyond the concern that "properly instructed juries" will reach differing conclusions from each other. *Bates*, 544 U.S. at 452. Rather, the approach that respondent advocates, and that the Ninth and Eleventh Circuits have adopted, allows juries to reach different determinations than EPA itself.

This is a case in point. After careful scientific review and an assessment of hundreds of thousands of public comments, EPA has repeatedly determined that glyphosate is not likely to be carcinogenic in humans, and the agency has repeatedly approved Roundup labels that did not contain cancer warnings. See p. 7, *supra*. Under respondent's approach, however, a jury may second-guess the agency's science-based judgments and hold petitioner liable for failing to provide warnings "in addition to or different from those required under" FIFRA. 7 U.S.C. 136v(b).

Section 136v(b) was meant to prevent that sort of inconsistency and patchwork results. Where, as here, EPA has specified the health warnings that should appear on a particular pesticide's label, a manufacturer should not be left subject to "50 different labeling regimes prescribing" different requirements. *Bates*, 544 U.S. at 452. This Court's intervention is warranted to give FIFRA's preemption provision its proper force.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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