No. 24-1068

In the Supreme Court of the United States

MONSANTO COMPANY, PETITIONER

v.

JOHN L. DURNELL

ON WRIT OF CERTIORARI TO THE MISSOURI COURT OF APPEALS

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

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QUESTION PRESENTED

Whether the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, preempts a label-based failure-to-warn claim where the Environmental Protection Agency has not required the warning.

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INTEREST OF THE UNITED STATES

This case concerns whether the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, preempts respondent's Missouri-law failure-to-warn claim challenging the labeling of petitioner's Roundup products between 1996 and 2018. The United States, through the Environmental Protection Agency (EPA), implements and enforces FIFRA. See 7 U.S.C. 136w. EPA previously reviewed and approved the specific labeling here after confirming that Roundup's active ingredient does not pose an "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits" and that Roundup does "not significantly increase" that risk. 7 U.S.C. 136(bb), 136a(c)(5)(D) and (7)(A). At the Court's invitation, the United States filed an amicus brief at the petition stage of this case.

INTRODUCTION

Under FIFRA, pesticides can generally be distributed or sold in the United States only if EPA decides to register them. And EPA can say yes to registration only if it verifies that the pesticide and its labeling comply with FIFRA's requirements. To do so, EPA reviews extensive data and determines that the pesticide "will not generally cause unreasonable adverse effects on the environment" and that its labeling "compl[ies] with the requirements of" FIFRA. 7 U.S.C. 136a(c)(5)(B) and (D). EPA undertakes a cost-benefit analysis to identify "any unreasonable adverse effects" on humans and the environment. 7 U.S.C. 136(x) and (bb). And EPA must find that the labeling carries all warnings "necessary and * * * adequate to protect health and the environment" against such effects. 7 U.S.C. 136(q)(1)(G). Once a pesticide is registered, EPA has the final word on precautionary warnings, which registrants may not supplement or amend without EPA's review and approval. 40 C.F.R. 152.44(a), 156.70(c).

Respondent's state-law claims second-guess those judgments. Whereas EPA previously determined after reviewing extensive evidence and conducting a cost-benefit analysis that petitioner's labeling adequately protects human health, a Missouri jury determined that the same labeling tortiously failed to warn of cancer risks based on different evidence and different standards. The only way for petitioner to avoid further Missouri-law liability would be to add the very warning to Roundup's labeling that EPA did not require under FIFRA.

The question here is whether FIFRA preempts respondent's Missouri-law failure-to-warn claim. The answer is yes, twice over. First is express preemption. To ensure "[u]niformity," FIFRA expressly preempts all

state-law "requirements for labeling or packaging in addition to or different from those required under this subchapter," *i.e.*, under FIFRA. 7 U.S.C. 136v(b). Section 136v(b) thus "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).

Respondent's state-law claim imposes different labeling requirements than federal law. A state common-law duty to warn on pesticide labeling is undisputedly a "requirement[] for labeling or packaging" under Section 136v(b). Compare that to the federal requirements: Pesticide labeling must carry all "necessary" warnings "adequate to protect health and the environment." 7 U.S.C. 136(q)(1)(G). And EPA "give[s] content to" that criterion, *Bates*, 544 U.S. at 453, by imposing binding, product-specific registration decisions of what warnings each pesticide requires to comply with federal law. Here, EPA determined that Roundup did not need additional warnings to protect human health. Missouri's "additional or different" requirement—that a cancer warning must be included—is therefore preempted.

Ordinary conflict-preemption principles compel the same result. As this Court has explained in the pharmaceutical-labeling context, federal law preempts state-law failure-to-warn claims when federal law bars manufacturers from "independently chang[ing] their labels to satisfy their state-law duty." *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 618 (2011). With exceptions not applicable here, EPA regulations impose the same no-unauthorized-changes requirement for pesticide labeling. 40 C.F.R. 152.44(a). Just as failure-to-warn claims against drug manufacturers are preempted when the

manufacturer needs Food and Drug Administration (FDA) authorization to change the labeling, so too are failure-to-warn claims against pesticide manufacturers preempted when EPA must authorize any labeling changes.

Allowing common-law claims like respondent's would gut the "[u]niformity" essential to FIFRA's labeling scheme. 7 U.S.C. 136v(b). All 50 States could pick their own warning regimes for health concerns, inhalation risks, first-aid procedures, or water quality, either legislatively or via jury trials. Some state legislatures or juries might demand prominent warnings about the threat of blindness or Parkinson's; others might prioritize risks to flora and fauna; yet others might deem such labeling misleading or incomplete. FIFRA rejects that State-by-State cacophony and vests EPA with responsibility to determine what pesticide warnings are necessary to protect human health and the environment.

STATEMENT

A. FIFRA

As enacted in 1947, "FIFRA was primarily a licensing and labeling statute." *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 991 (1984). Congress set "general standards" on the "proper labeling" of pesticides, including "warnings to prevent harm to people, animals, and plants." *Ibid.* Pesticides sold in interstate commerce had to be registered with the Secretary of Agriculture. *Ibid.* But registration did not guarantee that the pesticide or its labeling complied with the Act. The Secretary reviewed FIFRA compliance and could alert an applicant to any concerns but could not refuse registration. See *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 437 n.8 (2005).

In 1972, "growing environmental and safety concerns" led Congress to "'transform[] FIFRA from a labeling law into a comprehensive regulatory statute.'" *Bates*, 544 U.S. at 437 (citation omitted). Congress gave "increased enforcement authority" to EPA and "significantly strengthened FIFRA's registration and labeling standards." *Wisconsin Public Intervenor* v. *Mortier*, 501 U.S. 597, 601 (1991).

Today, that regime generally prohibits the distribution or sale of pesticides not registered by EPA. See 7 U.S.C. 136a(a), 136j(a)(1)(A). FIFRA prohibits the distribution or sale of pesticides with "claims" that "substantially differ" from those approved by EPA or with a "composition" that differs from the one approved by EPA. 7 U.S.C. 136j(a)(1)(B) and (C). FIFRA prohibits using a registered pesticide contrary to its EPA-approved labeling. 7 U.S.C. 136j(a)(2)(G). And EPA regulations bar pesticide registrants from deviating from EPA-approved labeling (with an exception for "minor modifications" not applicable here). 40 C.F.R. 152.44(a), 152.46(a)(1) and (b). If EPA has reason to believe that a pesticide violates FIFRA, EPA may issue a "stop sale, use, or removal" order, 7 U.S.C. 136k(a); seize offending products, 7 U.S.C. 136k(b); or seek civil and criminal penalties, 7 U.S.C. 136*l*.

EPA's registration process hinges on robust scientific review. Applicants must submit the product's "complete formula," "claims to be made for it," 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). Applicants must submit extensive data and flag studies related to potential adverse effects. 7 U.S.C. 136a(c)(2); 40 C.F.R. Pts. 152, 158; see 40 C.F.R. 158.34. And applicants must submit

proposed labeling with any required precautionary statements, including for hazards to human health. 7 U.S.C. 136a(c)(1)(C); 40 C.F.R. 156.10(a)(1)(vii), Pt. 156, Subpt. D. To unconditionally register a pesticide, EPA must review those data and conclude that the pesticide "will not generally cause unreasonable adverse effects on the environment," and that its labeling "compl[ies] with the requirements of [FIFRA]." 7 U.S.C. 136a(c)(5)(B) and (D). EPA may also conditionally register certain pesticides with active ingredients that EPA has already registered when they would "not significantly increase the risk of unreasonable adverse effects on the environment" and their labeling complies with FIFRA. 7 U.S.C. 136a(c)(7)(A); see 40 C.F.R. 152.112(f), 152.113.

Critical here, registration reflects EPA's judgment that a pesticide's labeling includes the warnings necessary and adequate to protect human health. In registering a pesticide, EPA must ensure that it would not be "misbranded" with its proposed labeling. 7 U.S.C. 136j(a)(1)(E). A pesticide is misbranded if its labeling is "false or misleading in any particular" or "does not contain a warning or caution statement which may be necessary and * * * is adequate to protect health and the environment." 7 U.S.C. 136(q)(1)(A) and (G). FIFRA defines "'protect health and the environment'" to mean "protection against any unreasonable adverse effects on the environment," which includes "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(x) and (bb). EPA registration thus reflects the agency's view—based on a cost-benefit analysis—that the pesticide

does not pose an unreasonable risk to human health with the approved labeling.

Once EPA registers a pesticide, the registrant may not alter the labeling without EPA approval, other than through "minor modifications." 40 C.F.R. 152.44(a), 152.46(a)(1) and (b). The minor-modifications exception does not apply to "precautionary statements" "pertaining to the hazards of the product"—like a cancer warning—which "must be approved by" EPA. 40 C.F.R. 156.70(c); see EPA, Office of Pesticide Programs, *Pesticide Registration Notice 98-10* (Oct. 22, 1998), https://perma.cc/ZK8Z-2NNM.

EPA's supervision of pesticides and their labeling does not stop with registration. Registrants have an ongoing duty to alert EPA to "additional factual information regarding unreasonable adverse effects." 7 U.S.C. 136d(a)(2). And EPA may cancel or modify a registration if the agency later determines that the pesticide "generally causes unreasonable adverse effects on the environment" or otherwise does not comply with FIFRA. 7 U.S.C. 136d(b). EPA also formally reviews pesticide registrations every 15 years to ensure continued FIFRA compliance. See 7 U.S.C. 136a(g)(1)(A)(iii)(II) and (iv); 40 C.F.R. Pt. 155, Subpt. C. EPA's refusal to cancel a registration or undertake the reregistration process is subject to judicial review. 7 U.S.C. 136a-1(m), 136n; *e.g.*, *Natural Res. Def. Council* v. *EPA*, 31 F.4th 1203 (9th Cir. 2022).

Finally, FIFRA explicitly addresses the "Authority of States," 7 U.S.C. 136v, drawing a bright line between pesticide use—where States have concurrent authority to regulate—and labeling—where EPA is in charge. For pesticide use, FIFRA "preserves a broad role for state regulation." *Bates*, 544 U.S. at 450. States may

generally "regulate the sale or use of any federally registered pesticide," provided they do not authorize sales or uses prohibited by FIFRA (*e.g.*, permitting pesticides that EPA declined to register). 7 U.S.C. 136v(a). And States may, in certain circumstances, register a pesticide "for additional uses" to meet "special local needs" (*e.g.*, on crops that EPA's registration did not address). 7 U.S.C. 136v(c)(1).

But for labeling, Congress prioritized "[u]niformity" with an express-preemption clause. 7 U.S.C. 136v(b). Consistent with EPA's primary role evaluating the content of pesticide labeling, States may "not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter," *i.e.*, under FIFRA. *Ibid.*

B. EPA's Assessment Of Roundup's Cancer Risk

Petitioner is the manufacturer and registrant of various pesticides containing the active ingredient glyphosate that are sold under the Roundup brand name. See Pet. App. 3. Respondent used Roundup products between 1996 and 2018. Tr. 1998, 2004-2005.

EPA first registered glyphosate-based pesticides in 1974 and has since repeatedly evaluated whether glyphosate causes cancer. EPA, Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 12 (Dec. 12, 2017), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0073 (*2017 Issue Paper*). From 1985 to 1986, EPA classified glyphosate as a "Possible Human Carcinogen" after one study reported that three of 50 mice fed extremely high doses of glyphosate developed kidney tumors. *Ibid.*; see *id.* at 85-86. But later rat and mice studies showed no causal link between glyphosate and cancer, and in 1991 EPA classified glyphosate as not likely to cause cancer

in humans. EPA, Office of Pesticides & Toxic Substances, *Second Peer Review of Glyphosate* 1 (Oct. 30, 1991), https://perma.cc/3TU3-Y247; see *id.* at 6-19.

In 1993, EPA reregistered glyphosate, finding that glyphosate is not likely to cause cancer and does "not pose unreasonable risks or adverse effects to humans or the environment." EPA, Office of Prevention, Pesticides & Toxic Substances, *Reregistration Eligibility Decision: Glyphosate* 13 (Sept. 1993), https://perma.cc/528H-F4FN (*1993 Reregistration Decision*).[1] As part of that review, EPA analyzed glyphosate's effects on human health and the environment, considering hundreds of studies on everything from glyphosate's effect on the bluegill sunfish to how much glyphosate lingers on asparagus. See *id.* App. C. On cancer risk, EPA considered multiple long-term studies demonstrating that glyphosate does not cause cancer in rats and mice. See *id.* at 38-39.

EPA identified various warnings that it deemed necessary to protect human health and the environment. EPA determined that some glyphosate products should carry a "Toxic to fish" warning. *1993 Reregistration Decision* 10. EPA determined that other glyphosate products should carry a 12-hour restriction on entering the application area. *Id.* at 12. And EPA decided to retain existing personal-protective-equipment requirements. *Ibid.* But EPA did not require a cancer warning. See *id.* at 11-12. Consistent with that conclusion, EPA has since registered over 100 Roundup products without a cancer warning. See EPA, *Pesticide Product and Label System*, https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1

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[1] The reregistration decision is not consecutively paginated. This brief uses the pagination from the electronic PDF.

(last updated Feb. 28, 2026) (search "Roundup" under "Product or Alternative Brand Name").

In 2015, a working group at the International Agency for Research on Cancer (IARC) classified glyphosate as "probably carcinogenic to humans." 112 IARC, *Some Organophosphate Insecticides and Herbicides: Glyphosate* 398 (2015) (emphasis omitted). EPA, however, reviewed the same science as part of its periodic reevaluation process and reaffirmed that the "strongest" data support the conclusion that glyphosate is "'not likely to be carcinogenic to humans.'" *2017 Issue Paper* 144. In 2019, EPA stated that IARC's process lacked peer review, ignored key studies, considered "not appropriate" studies involving worms and plants, and has been rejected by other leading international scientific organizations. EPA, *Glyphosate: Proposed Interim Registration Review Decision* 7-8 (Apr. 2019), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-2344; see EPA, Office of Chem. Safety & Pollution Prevention, *Glyphosate: Report of the Cancer Assessment Review Committee* 7-10 (Oct. 1, 2015), https://www.regulations.gov/document/EPA-HQ-OPP-2016-0385-0014. And in 2022, EPA "continue[d] to stand behind its robust scientific evaluation of the carcinogenic potential of glyphosate." Pet. App. 41.

EPA's current reregistration process for glyphosate remains ongoing. In 2022, the Ninth Circuit vacated a 2020 decision reiterating that glyphosate is not likely to cause cancer, and EPA has not issued a new decision. See *Natural Res. Def. Council* v. *EPA*, 38 F.4th 34, 52 (2022). But glyphosate-based Roundup products remain registered without any cancer warning.

C. Procedural History

In 2019, respondent sued petitioner in Missouri Circuit Court, alleging that petitioner failed to warn of Roundup's cancer risks and that he developed non-Hodgkin's lymphoma as a result. Pet. App. 3. The trial court rejected petitioner's argument that FIFRA preempted respondent's claims, and a jury awarded $1.25 million on respondent's failure-to-warn claim. *Id.* at 13-16, 20-21. The court denied petitioner's motion for judgment notwithstanding the verdict. *Id.* at 19.

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 recognized that, as applied here, Missouri common law "effectively imposes a state law requirement for labeling upon [petitioner]." *Id.* at 5-6. But in the court's view, "Missouri's strict liability failure to warn cause of action is fully consistent with federal requirements under [7 U.S.C.] 136(q)(1)(G)" because "both require a pesticide manufacturer to adequately warn users of the potential dangers of using its product." *Id.* at 6-7. The court further held that respondent's claims were not conflict preempted because petitioner had "not met its demanding burden" of offering "evidence" that "EPA would not approve a cancer warning on Roundup's label." *Id.* at 9.

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

SUMMARY OF ARGUMENT

A. FIFRA's express-preemption clause bars respondent's claim.

1. Section 136v(b) preempts state "requirements for labeling or packaging" that are "in addition to or different from those required under" FIFRA. 7 U.S.C.

136v(b). Courts compare the relevant "requirements" under state and federal law to see whether they are "*genuinely* equivalent" or differ in any respect. *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005).

2. State and federal law impose different requirements here. As applied by the Missouri courts, Missouri's common-law duty to warn requires petitioner to add a cancer warning to Roundup's labeling or face additional damages verdicts.

But under FIFRA, federal law requires petitioner to use the existing EPA-approved labeling, without any cancer warning. Section 136v(b) gives preemptive effect to federal requirements "under" FIFRA, 7 U.S.C. 136v(b), recognizing that EPA can "give content to" FIFRA's "broadly phrased" standards, *Bates*, 544 U.S. at 453 & n.28. Here, EPA did so by authorizing Roundup's labeling, balancing costs and benefits as FIFRA requires, and confirming that the labeling contains "necessary" warnings "adequate to protect health and the environment" from which petitioner may not deviate without EPA approval. 7 U.S.C. 136(q)(1)(G); see 40 C.F.R. 152.44(a). Those EPA determinations impose pesticide-specific "requirements" under FIFRA just as FDA's approval of medical devices imposes device-specific "requirements" under a parallel preemption clause in the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539. See *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008); 21 U.S.C. 360k(a)(1).

3. In holding otherwise, the court of appeals considered only FIFRA's general prohibition on misbranding, 7 U.S.C. 136(q)(1)(G), which it understood to track Missouri's duty to warn. That ignores FIFRA's cost-benefit requirement, which Missouri law lacks. And it ignores the preemptive force of EPA's registration decisions

implementing its statutory mandate to ensure that pesticide labeling carries necessary warnings adequate to protect human health.

Respondent claims that a different FIFRA provision, 7 U.S.C. 136a(f)(2), denies preemptive force to EPA's registration decisions. But that "[m]iscellaneous" provision says only that registration is not "a defense" to violating FIFRA, *ibid.*—for example when the labeling violates the terms of EPA's registration or the violation is outside the scope of what EPA considers. Where, as here, EPA passed on the relevant question and determined what labeling is required, States may not impose different requirements based on their disagreement with EPA's scientific judgment.

B. Ordinary conflict-preemption principles also bar respondent's claim. Federal law preempts state laws that "directly conflict." *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 609 (2011). In the generic-drug context, federal law preempts labeling-based failure-to-warn claims when federal law bars manufacturers from "independently" changing their labeling. *Id.* at 620, 624. Even if the federal government might approve a change, the manufacturer cannot comply with its state-law duty (change the labeling) without violating federal law (no unilateral changes). Here, EPA regulations bar registrants from adding warnings about a pesticide's hazards without EPA's permission, 40 C.F.R. 152.44(a), 156.70(c), so respondent's claim is conflict preempted.

C. Respondent's contrary approach risks destroying FIFRA's uniformity with a patchwork of conflicting State-by-State warnings. If States can compel petitioner to add a cancer warning—contrary to EPA's scientific judgments—States could drown EPA's approved warnings in a sea of local health and environmental concerns.

ARGUMENT

Missouri's common-law duty to warn requires petitioner to include on its pesticide labeling a cancer warning that differs from—and, indeed, directly conflicts with—the labeling that EPA requires under FIFRA. That state-law duty is preempted under both FIFRA's express-preemption clause and ordinary conflict-preemption principles.[2]

A. FIFRA Expressly Preempts Respondent's Failure-To-Warn Claim

FIFRA bars States from imposing "any requirements for labeling or packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. 136v(b). Here, Missouri common law imposes a "requirement[] for labeling," *ibid.*, by commanding petitioner to add a cancer warning to Roundup's labeling. That requirement is "in addition to or different from those required under [FIFRA]," *ibid.*, because EPA, in registering Roundup, has evaluated what warnings are necessary to protect health and determined that a cancer warning is not required.

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[2] As explained in our invitation brief (at 10), the United States has been inconsistent about whether FIFRA preempts similar state-law failure-to-warn claims. In court-of appeals-briefing in *Hardeman* v. *Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021), cert. denied, 142 S. Ct. 2834 (2022), the United States argued that FIFRA preempts such claims. But before this Court, the government argued against preemption. See U.S. Amicus Br., *Monsanto Co.* v. *Hardeman*, 142 S. Ct. 2834 (2022) (No. 21-241). Following the change in Administration, the United States has returned to its original view.

1. State-law labeling requirements are preempted if they add to or differ from those required under FIFRA

FIFRA preempts any state-law labeling requirement that is not "*genuinely* equivalent" "to a requirement under FIFRA." *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 453-454 (2005). That preemption standard calls for a matching exercise.

First, the Court identifies the relevant "requirements" under state and federal law. *Bates*, 544 U.S. at 443, 447. "A requirement is a rule of law that must be obeyed," including a "common-law duty." *Id.* at 445. On the state side, the only requirements that may be preempted are "for labeling or packaging." 7 U.S.C. 136v(b). "[R]ules governing the design of a product, for example, are not pre-empted." *Bates*, 544 U.S. at 444. On the federal side, requirements "under" FIFRA extend beyond FIFRA's text. 7 U.S.C. 136v(b). "EPA regulations" with the force of law, for example, may "give content to FIFRA's misbranding standards." *Bates*, 544 U.S. at 453.

Second, the Court "measure[s]" the state requirement against the federal requirements to see whether the state requirement is "in addition to or different from" the federal requirements. *Bates*, 544 U.S. at 453; 7 U.S.C. 136v(b). The question is simply whether state and federal law "require different things"; even "nonconflicting" requirements are preempted so long as state and federal law contain differences. *National Meat Ass'n* v. *Harris*, 565 U.S. 452, 459, 462 (2012) (interpreting similar preemption clause in the Federal Meat Inspection Act, 21 U.S.C. 601 *et seq.*; see 21 U.S.C. 678).

States may therefore enforce FIFRA's requirements with "different or additional *remedies*." *Bates*, 544 U.S. at 447-448 (quoting *Medtronic, Inc.* v. *Lohr*,

518 U.S. 470, 513 (1996) (O'Connor, J., concurring in part and dissenting in part)). For example, if an "EPA regulation" required "the word 'poison' to appear in red letters," a State could also require the word poison to appear in red letters and attach a damages remedy unavailable under federal law. *Id.* at 444. But a State may not require "wording of warnings" different from "those set out in FIFRA and its implementing regulations." *Id.* at 452.

2. As applied, Missouri common law imposes a labeling requirement in addition to or different from those required under FIFRA

Those express-preemption principles foreclose respondent's failure-to-warn claim.

a. Missouri imposes a common-law requirement to place a cancer warning on Roundup

Start with the state-law requirement: In Missouri, a manufacturer is strictly liable for harms caused by a product that a jury deems "unreasonably dangerous" if the manufacturer "did not give adequate warning of the danger." *Moore* v. *Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. 2011); see J.A. 159-160 (jury instruction).

As the Missouri Court of Appeals recognized, that common-law duty "effectively imposes a state law requirement for labeling." Pet. App. 5-6. "[C]ommon-law duties," including those in "[]failure-to-warn claims," are state "'requirements'" under FIFRA. *Bates*, 544 U.S. at 443, 446. And the state requirement here governs "labeling or packaging," 7 U.S.C. 136v(b); respondent's theory is that petitioner failed "'to properly . . . label' Roundup" with "'adequate warnings or instructions'" about cancer risks. Pet. App. 6 n.3; see Cert.

Reply Br., Supp. App. 4 (counsel focusing on labeling in closing argument).

This Court's reformulated question presented therefore presupposes "a label-based failure-to-warn claim." To the extent respondent now contends (Br. in Opp. 17-23; Supp. Br. 2-6, 11-12) that his claim involves advertising, manufacturing, or the failure to alert EPA, those case-specific issues are outside the question presented but may be addressed on remand (if preserved).[3]

b. FIFRA requires no cancer warning on Roundup

The preemption analysis next considers the federal "requirements for labeling or packaging * * * under [FIFRA]." 7 U.S.C. 136v(b).

i. This Court's most recent FIFRA preemption case, *Bates*, *supra*, helps illuminate the relevant federal requirements. To start, those requirements include "FIFRA's misbranding provisions." *Bates*, 544 U.S. at 447. FIFRA requires that pesticide labeling carry "necessary" warnings "adequate to protect health and the environment" to avoid being misbranded. 7 U.S.C. 136(q)(1)(G); see 7 U.S.C. 136j(a)(1)(E). That standard demands a cost-benefit analysis: EPA must identify what warnings are adequate 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 [the] pesticide." 7 U.S.C. 136(bb); see 7 U.S.C. 136(x).

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[3] Respondent's suggestion (Br. in Opp. 20-23; Supp. Br. 2-3, 11-12) that he is challenging the adequacy of petitioner's communications with EPA warrants particular caution given the distinct concerns raised by such fraud-on-the-agency theories. Cf. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-348 (2001).

Bates recognizes that federal-law "requirement[s]" also encompass any "rule of law that must be obeyed," not just FIFRA's statutory terms. 544 U.S. at 445. FIFRA gives preemptive effect to requirements "under" FIFRA—*i.e.*, those "pursuant to" or "by reason of the authority of" FIFRA, see *National Ass'n of Mfrs.* v. *Department of Defense*, 583 U.S. 109, 124 (2018) (citation omitted)—not just those "in" FIFRA itself.

EPA regulations can thus "give content to FIFRA's misbranding standards" by "refin[ing] or elaborat[ing]" FIFRA's "broadly phrased" provisions. *Bates*, 544 U.S. at 453 & n.28. For example, EPA has refined FIFRA's requirement of warnings necessary to protect human health by mandating warnings that escalate from "CAUTION" to "DANGER" based on a pesticide's acute toxicity. 40 C.F.R. 156.64(a)(1). As *Bates* explained, if EPA determines that a mere "CAUTION" is appropriate on "a given pesticide's label," a State's effort to add the more alarming "DANGER" would be preempted. 544 U.S. at 453. Likewise, in applying the Federal Meat Inspection Act's similar preemption clause, this Court has looked to requirements in federal regulations to hold preempted a state law requiring meat labels to accurately state a product's weight. See *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 527-532 (1977) (interpreting 21 U.S.C. 678). Although the federal statute imposed a similar requirement, federal regulations permitted adjustment for moisture loss, while the state law did not, so the state law was preempted. *Id.* at 531-532.

Like regulations, EPA's pesticide-registration decisions carry the force of law and "give content to FIFRA's misbranding standards." *Bates*, 544 U.S. at 453. While the "'DANGER'" language in *Bates*' example comes from a regulation, EPA determines what language is required

for "a given pesticide's label," *ibid.*, only via individual registration decisions. See EPA, Office of Pesticide Programs, *Label Review Manual*, at 7-2 (Dec. 2024), https://perma.cc/9KSZ-KFTP. Otherwise, a plaintiff could claim that a state-law mandate to add "DANGER" was consistent with the federal regulation, even if EPA had determined that "CAUTION" was appropriate.

EPA registration embodies additional product-specific judgments. EPA determines, for example, that the required labeling statements are sufficiently conspicuous, that the packaging meets child-safety standards, and—pertinent here—that the pesticide does not risk "unreasonable adverse effects on the environment" and carries "necessary" warnings "adequate to protect health and the environment." 7 U.S.C. 136(q)(1)(G), 136a(c)(5)(B) and (D); see 7 U.S.C. 136(q)(1)(B) and (E); 40 C.F.R. Pt. 156. EPA makes those determinations by considering extensive data, including "long-term carcinogenicity studies." 40 C.F.R. 158.130(d)(3); see 7 U.S.C. 136a(c)(2); 40 C.F.R. Pts. 152, 158. The result is a product-specific judgment of what warnings, including any cancer warnings, are necessary to protect human health and the environment, consistent with FIFRA's misbranding standards.[4]

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[4] The government's invitation brief in *Hardeman*, *supra*, stated (at 11) that "EPA does not typically use the registration process to address [long-term] harms by requiring chronic-risk warnings on a pesticide's labeling." But that is because EPA addresses all unreasonable risks to human health, including chronic risks like cancer, in deciding whether to register a pesticide in the first place and whether to cancel that registration. 7 U.S.C. 136a(c)(5)(D), 136d(b). EPA will also restrict the use of any pesticide that "may cause significant subchronic, chronic or delayed toxic effects on man," 40 C.F.R. 152.170(a) and (b)(1)(vi), and has not done so for Roundup.

EPA's judgments establish "requirements * * * under [FIFRA]," 7 U.S.C. 136v(b), because they are "rule[s] of law that must be obeyed," *Bates*, 544 U.S. at 445. Agencies may issue decisions with the "'force and effect of law'" when they are constitutionally granted such authority by Congress and they comply "with any procedural requirements imposed by Congress." *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 303 (1979) (citation omitted); see *Merck Sharp & Dohme Corp.* v. *Albrecht*, 587 U.S. 299, 321 (2019) (Thomas, J., concurring) (recognizing that agency actions that "necessarily follow from[] the statutory text" can preempt state law) (citation omitted).

Here, Congress has granted EPA the authority to register pesticides. See 7 U.S.C. 136a. And those registration decisions plainly carry the force of law. With limited exceptions, Congress has made it a federal crime to knowingly sell or distribute a pesticide without EPA registration. 7 U.S.C. 136a(a), 136j(a)(1)(A), 136*l*(b). It is likewise a crime to make claims substantially different from those approved by EPA, change a pesticide's composition from that approved by EPA, sell or distribute a restricted-use pesticide for uses not approved by EPA, or use a pesticide in a manner inconsistent with EPA-approved labeling. 7 U.S.C. 136j(a)(1)(B), (1)(C), (2)(F), and (2)(G), 136*l*(b). EPA registration decisions accordingly impose "direct and appreciable legal consequences" and may preempt state law. See *United States Army Corps of Eng'rs* v. *Hawkes*, 578 U.S. 590, 598 (2016) (citation omitted); cf. *Lipschultz* v. *Charter Adv. Servs. (MN), LLC*, 589 U.S. 1038, 1039 (2019) (Thomas, J., concurring in the denial of certiorari) (looking to final-agency-action cases to identify preemptive agency actions).

Additionally, EPA regulations require, with exceptions not applicable here, that EPA approve "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," 40 C.F.R. 156.70(c). If a registrant deviates from the EPA-approved labeling in a way that EPA considers "false or misleading," EPA may seek to cancel the registration, issue a "stop sale" order, seize the product, or seek civil or criminal penalties. 7 U.S.C. 136(q)(1)(A), 136d(b), 136k, 136*l*. EPA registration imposes legally binding requirements that specify what warnings particular pesticides need to comply with FIFRA's misbranding provisions.

ii. That EPA's determinations regarding FIFRA's statutory registration criteria have preemptive effect also flows directly from *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008). *Riegel* concerned the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* Under the MDA, FDA must preapprove certain medical devices and their labeling. See *Riegel*, 552 U.S. at 317-319. Manufacturers may then not make any changes that would affect safety or effectiveness without FDA permission. *Id.* at 319.

Much like FIFRA, the MDA preempts state-law requirements that are "different from, or in addition to, any requirement applicable under this chapter to the device." 21 U.S.C. 360k(a)(1); see *Bates*, 544 U.S. at 447 (observing that the FIFRA and MDA preemption provisions are "similarly worded"). *Riegel* held that FDA's premarket approval creates device-specific preemptive federal "requirement[s]" under the MDA. 552 U.S. at 321-322. FDA reviews safety and effectiveness "specific

to individual devices." *Id.* at 323. And "FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application." *Ibid.* That approval reflects FDA's "determin[ation] that the approved form provides a reasonable assurance of safety and effectiveness," *ibid.*, and preempts inconsistent or supplemental state-law duties, *id.* at 323-325, 330.

Likewise, EPA reviews products individually to determine what warnings are appropriate, consistent with the statutory labeling standards. And just as device makers generally cannot deviate from the FDA-approved device, 21 U.S.C. 360e(d)(5)(A)(i), pesticide registrants generally cannot deviate from EPA-approved labeling. Like FDA, EPA "weigh[s] the competing interests relevant to the particular requirement in question, reache[s] an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implement[s] that conclusion via a specific mandate on manufacturers." See *Lohr*, 518 U.S. at 501. EPA registration decisions thus "require[] labels to take a particular form" and impose "substantive restrictions" akin to those in *Riegel*. *Schaffner* v. *Monsanto Corp.*, 113 F.4th 364, 389 (3d Cir. 2024).

iii. EPA's registration decisions established what warnings Roundup must carry to comply with FIFRA—and a cancer warning is not among them. At trial, respondent testified to using Roundup between 1996 and 2018 and identified four separately registered Roundup products that he used. Tr. 1998-2005. EPA first registered those products using FIFRA's conditional-registration process for pesticides that are "identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not

significantly increase the risk of unreasonable adverse effects on the environment." 7 U.S.C. 136a(c)(7)(A).[5]

In issuing those registrations, EPA necessarily determined that the products were "not misbranded," 40 C.F.R. 152.112(f); see 40 C.F.R. 152.113(a)(3), such that they carried all necessary warnings adequate to protect human health. 7 U.S.C. 136(q)(1)(G). EPA determined that Roundup should carry warnings against being directly applied to bodies of water or one's eyes. *E.g.*, EPA, Office of Pesticide Programs, *Roundup Super Concentrate Weed & Grass Killer 2*, at 8 (Dec. 3, 1999), https://perma.cc/Y495-BUJN; see J.A. 240. But EPA did not require any warning about cancer risk.

c. Missouri's labeling requirement differs from federal requirements

The final question under Section 136v(b) is whether the state requirement is "*in addition to or different from* those required under [FIFRA]." *Bates*, 544 U.S. at 444. Given the relevant requirements above, the answer is obviously yes. Missouri requires petitioner to add a cancer warning to Roundup's labeling. EPA, applying FIFRA's misbranding standards, did not require a cancer warning and forbids petitioner from adding one unilaterally. 40 C.F.R. 152.44(a), 156.70(c). Missouri's effort to change the "wording of warnings" is a paradigmatic case for FIFRA preemption. *Bates*, 544 U.S. at 452.

Moreover, those different bottom-line requirements reflect the different "element[s]" of when state and federal law require a warning. See *Bates*, 544 U.S. at 453.

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[5] EPA pesticide registrations are available at https://ordspub.epa.gov/ords/pesticides/f?p=PPLS. The products respondent identified carry EPA Registration Nos. 71995-25, 71995-29, 71995-33, and 71995-47.

As noted, FIFRA demands a cost-benefit analysis. Pesticide labeling must carry "necessary" warnings "adequate to protect health and the environment." 7 U.S.C. 136(q)(1)(G). And FIFRA includes an "explicit definition," which governs "even if it varies from a term's ordinary meaning." *Van Buren* v. *United States*, 593 U.S. 374, 387 (2021) (citation omitted). To "'protect health and the environment'" means "protection against any unreasonable adverse effects on the environment." 7 U.S.C. 136(x). And "'unreasonable adverse effects on the environment'" includes "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). Under those provisions, pesticide labeling must warn against those risks that are "unreasonable," accounting for costs and benefits. *Ibid.*

Missouri law is different. While Missouri requires a warning on products that are "unreasonably dangerous," Missouri gives different content to that term by giving the jury sole discretion over whether a danger is "unreasonabl[e]." *Moore*, 332 S.W.3d at 756. A defendant is free to argue that "the utility of a design outweighs its risks," *Newman* v. *Ford Motor Co.*, 975 S.W.2d 147, 154 (Mo. 1998)—a formulation that may or may not track FIFRA's cost-benefit analysis. See Restatement (Third) of Torts: Products Liability § 2 cmt. i (1998) (disclaiming any "easy guideline" under a risk-utility approach and identifying "various factors" for evaluating the adequacy of warnings). But the plaintiff is free to respond that "consumer expectations were violated" or that the facts establish "any other theory of unreasonable dangerousness supported by the evidence." *Newman*, 975 S.W.2d at 154. The court may not take sides in that debate, let-

ting jurors give whatever "content" to "the concept of unreasonable danger" "'their collective intelligence and experience'" demands. *Ibid.* (citation omitted). Because Missouri's common-law duty and FIFRA's text are not "*genuinely* equivalent," Missouri's duty is preempted. *Bates*, 544 U.S. at 454.

3. Counterarguments lack merit

a. In declining to find preemption, the Missouri Court of Appeals correctly understood the Missouri-law requirement as one to add a cancer warning to Roundup's labeling. See Pet. App. 5-6. But the court mistakenly thought that the only relevant federal requirement was FIFRA's general mandate for "necessary" warnings "adequate to protect health and the environment." *Id.* at 6 (quoting 7 U.S.C. 136(q)(1)(G)).

As just explained, that reasoning overlooks FIFRA's express definition of "protect health and the environment," which incorporates a cost-benefit requirement absent from Missouri law. 7 U.S.C. 136(x); see 7 U.S.C. 136(bb). And it ignores EPA's role in "giv[ing] content" to FIFRA's general misbranding standards. *Bates*, 544 U.S. at 453. As respondent acknowledges (Br. in Opp. 23, 29), EPA regulations can give content to FIFRA's "requirements." See *Bates*, 544 U.S. at 441, 444, 452-453 & nn.27-28; *id.* at 454 (Breyer, J., concurring). And respondent offers no sound reason to give preemptive effect to EPA's regulations but categorically ignore its registration decisions.

b. Respondent instead invokes (Br. in Opp. 25-28) a different FIFRA provision, 7 U.S.C. 136a(f)(2). Section 136a(f)(2) appears in a "Miscellaneous" subsection of FIFRA's registration section, and it states that registration is "prima facie evidence" that a pesticide complies with FIFRA but is not "a defense for the commis-

sion of any offense under" FIFRA. That provision, respondent contends (Br. in Opp. 26), proves that EPA does not have the last word on whether pesticide labeling complies with FIFRA's misbranding provisions.

But Section 136a(f)(2) does not transform EPA's registration decisions from requirements into friendly suggestions. Rather, Section 136a(f)(2) confirms that a manufacturer can face liability notwithstanding EPA registration—for example, if it uses labeling materially different from the approved labeling or withholds relevant information from EPA. See *Schaffner*, 113 F.4th at 397 n.18; 7 U.S.C. 136d(a)(2). Just as a "valid driver's license" is a requirement to drive, but "is not a defense against a speeding ticket," Section 136a(f)(2) "stands for the unremarkable proposition that a registration is not a defense against an allegation that a product violates the terms of that registration." *Reckitt Benckiser, Inc.* v. *Jackson*, 762 F. Supp. 2d 34, 45 (D.D.C. 2011) (citation omitted). If anything, Section 136a(f)(2) *benefits* registrants by making registration "prima facie evidence" of compliance.

That limited role makes sense given Section 136a(f)(2)'s history. See *Schaffner*, 113 F.4th at 397 n.17. In the original FIFRA, registration could not demonstrate statutory compliance since the government had to register *all* pesticides, even if it thought they violated the Act. Pub. L. No. 80-104, § 4(c), 61 Stat. 168. Like the current Section 136a(f)(2), the original FIFRA thus cautioned that registration not "be construed as a defense." *Ibid.* Congress later deleted the mandatory-registration provision. Act of May 12, 1964, Pub. L. No. 88-305, § 3, 78 Stat. 190-191. And in 1972, Congress "transformed FIFRA * * * into a comprehensive regulatory statute." *Ruckelshaus* v. *Monsanto*

Co., 467 U.S. 986, 991 (1984). Those amendments added the express-preemption clause and the provision that registration is "prima facie evidence" of FIFRA compliance, while retaining the instruction that registration not "be construed as a defense." Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, § 2, 86 Stat. 982, 997. But there is no indication that, in retaining Section 136a(f)(2)'s longstanding miscellaneous provision, Congress intended to radically narrow the new express-preemption clause.

c. Similarly, respondent invokes *Bates* to claim (Br. in Opp. 21, 26) that EPA registration decisions do not impose requirements because a pesticide can be "registered but nevertheless misbranded." *Bates*, 544 U.S. at 438. But a pesticide might be misbranded in a way that deviates from the labeling that EPA approved. Or a pesticide might be misbranded for reasons outside the scope of what EPA assesses during the registration process. For example, in *Bates*, the failure-to-warn claim involved the risk of damage to crops—a question EPA had not "passed on" since FIFRA allows EPA to waive review of a pesticide's efficacy. *Id.* at 440. But when EPA carries out its duties under FIFRA by making a statutorily required determination—here, whether a pesticide contains all warnings necessary and adequate to protect human health—that determination preempts different state-law requirements on the topic.

This Court's subsequent preemption jurisprudence further undercuts respondent's reliance on *Bates*. The Court in *Bates* felt "duty"-bound "to accept the reading [of FIFRA] that disfavors pre-emption." 544 U.S. at 449; but see *id.* at 457 (Thomas, J., concurring in the judgment in part and dissenting in part) (casting doubt on that "presumption against pre-emption"). But since

Bates, this Court has changed course. When a statute "'contains an express pre-emption clause,'" the Court does "not invoke any presumption against preemption but instead 'focus[es] on the plain wording of the clause.'" *Puerto Rico* v. *Franklin Cal. Tax-Free Trust*, 579 U.S. 115, 125 (2016) (citation omitted). Here, Section 136v(b)'s plain text gives preemptive force to the pesticide-specific labeling "requirements" imposed via EPA's registration process.

Respondent also emphasizes (Br. in Opp. 28) States' purportedly "broad power to regulate pesticide products." But States have concurrent authority over pesticide *use*, not labeling. See 7 U.S.C. 136v(a) and (b). States can also help "enforce federal misbranding requirements" by offering "'additional *remedies*'" for FIFRA violations, which may "'give manufacturers an additional cause to comply.'" *Bates*, 544 U.S. at 448, 451 (citation omitted); see *id.* at 455 (Thomas, J., concurring in the judgment in part and dissenting in part) ("Section 136v(b) permits States to add remedies—not to alter or augment the substantive rules governing liability for labeling."). And States may permit *non*-labeling claims like those "governing the design of a product." *Id.* at 444 (majority opinion). But States may not override EPA's judgment of what health-related warnings FIFRA requires for each pesticide's labeling.

d. Finally, respondent claims (Br. in Opp. 24-25) that EPA's registration decisions cannot preempt Missouri law because, in 2022, the Ninth Circuit vacated a 2020 EPA finding that glyphosate is not likely to cause cancer in humans. See *Natural Res. Def. Council* v. *EPA*, 38 F.4th 34, 52 (2022). It is unclear what relevance that subsequent vacatur of a subsequent agency decision could have, given that respondent last used Roundup in

2018. Tr. 2004-2005. The Roundup products petitioner used were properly registered at the time and, as he admits (Br. in Opp. 24), "glyphosate remains registered" today. Those earlier decisions—not the vacated 2020 decision—articulate the relevant requirements.

B. Missouri's Duty To Warn And FIFRA Directly Conflict

Conflict-preemption principles produce the same result: Missouri's duty to warn is preempted. Even when a statute contains an express-preemption clause, ordinary conflict-preemption principles still apply. *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 65 (2002). Under those principles, "[w]hen federal law forbids an action that state law requires, the state law is 'without effect.'" *Mutual Pharm. Co.* v. *Bartlett*, 570 U.S. 472, 486 (2013) (citation omitted); cf. *Merck*, 587 U.S. at 319 (Thomas, J., concurring) (asking whether state and federal law "are in logical contradiction"). Here, Missouri law required petitioner to add a cancer warning that federal law forbade petitioner from adding. The two laws "directly conflict," *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 609 (2011), and Missouri's law is preempted.

1. This Court has often addressed the preemptive effect of federal labeling requirements in the pharmaceutical context. Those cases establish general principles that apply here too.

First, state-law failure-to-warn claims are *not* preempted when federal law permits private parties to add state-mandated warnings unilaterally. That describes the scheme for brand-name drugs, where FDA regulations sometimes allow drugmakers to change their labeling first and seek FDA approval later. See *Wyeth* v. *Levine*, 555 U.S. 555, 568-569 (2009). In those circumstances, labeling-based failure-to-warn claims are not preempted absent "clear evidence" that FDA

would have rejected the proposed change. *Id.* at 571. Because the drugmaker could comply with both state and federal law by unilaterally changing its labeling, there is no "actual conflict between state and federal law" supporting preemption. *Merck*, 587 U.S. at 315.

By contrast, when federal law *forbids* unilateral labeling changes, state-law failure-to-warn claims are preempted—even when private parties can seek federal permission for labeling changes. The fact that "the private party" cannot "independently do under federal law what state law requires of it" establishes impossibility, regardless of any speculation about what might have happened had the party sought federal permission. *PLIVA*, 564 U.S. at 620.

That describes the regime governing generic drugs, where federal law forbids unilateral labeling changes. *PLIVA*, 564 U.S. at 613-615; *Bartlett*, 570 U.S. at 486-487. Generic drugs must bear the same warnings as the brand-name drugs they mimic, so generic drugmakers must work with FDA and brand-name manufacturers to make any labeling changes. *PLIVA*, 564 U.S. at 613, 617. Because generic drugmakers cannot "independently change[] their labels to satisfy their state-law duty" without "violat[ing] federal law," state-law failure-to-warn claims against those drugmakers are preempted. *Id.* at 618. That is true even though generic drugmakers can ask FDA to approve labeling changes. See *id.* at 619. What matters is that the drugmakers cannot "independently" comply with state law, not whether FDA might have hypothetically approved the state-mandated warning. *Id.* at 620, 624. Any other approach "would render conflict pre-emption largely meaningless," since it is often the case "that a third party or the Federal Government *might* do something that makes it

lawful for a private party to accomplish under federal law what state law requires of it." *Id.* at 620.

2. FIFRA's regime establishes clear conflict preemption under those principles. FIFRA's labeling regime for pesticides tracks the generic-drug labeling regime in its critical respect: Manufacturers may not independently add the relevant warnings. They must instead obtain federal agency approval (here, EPA's). State failure-to-warn claims are therefore preempted.

Just as FDA regulations prohibit unilateral labeling changes by generic drugmakers, *PLIVA*, 564 U.S. at 617, EPA regulations require pesticide manufacturers seeking "any modification in the * * * labeling * * * of a registered product" to submit that request to EPA. 40 C.F.R. 152.44(a). EPA may make exceptions for "certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment." 40 C.F.R. 152.46(a)(1) and (b). But no exception is available for "precautionary" "statements pertaining to the hazards of the product"—like a cancer warning—which "must be approved by [EPA]." 40 C.F.R. 156.70(c); see *Schaffner*, 113 F.4th at 382-385; *Pesticide Registration Notice 98-10*, *supra*.

That regulatory scheme straightforwardly preempts respondent's failure-to-warn claim. "State law demanded a safer label"—one that warned of Roundup's alleged cancer risks. See *PLIVA*, 565 U.S. at 619. But if petitioner "had independently changed [its] labels to satisfy [its] state-law duty, [it] would have violated federal law"—specifically, EPA's prohibition on unilateral non-minor labeling changes. See *id.* at 618. Because "state law imposed a duty on [petitioner] to take a certain action, and federal law barred [petitioner] from

taking that action," respondent's state-law "tort claims are pre-empted." See *id.* at 624.

3. The court of appeals held otherwise based on an apparent misunderstanding of petitioner's argument and this Court's precedent. The court of appeals would have allowed petitioner to prevail on a conflict-preemption defense only by offering "clear evidence" that EPA would have rejected a cancer warning. Pet. App. 8. But this Court has repudiated the notion that speculation about a federal agency's response to a labeling-change request is relevant when, as here, the manufacturer cannot unilaterally change the labeling. See *PLIVA*, 564 U.S. at 624-626. In that circumstance, there is no need to "speculat[e]" about what the agency might have done. *Id.* at 623 (plurality opinion). The inability to "independently accomplish[] what state law requires * * * establishe[s] pre-emption." *Ibid.* Whether an agency would have approved a labeling change is relevant only when unilateral changes *are* allowed. See *Merck*, 587 U.S. at 312-313.

To be sure, EPA reviewed the evidence and previously declined to require a cancer warning. See pp. 8-10, 22-23, *supra*. Petitioner therefore alternatively argues (Br. 47-50) that respondent's claim would be preempted even under the clear-evidence test. But FIFRA would not allow petitioner to unilaterally add a cancer warning, so this Court need not engage in further "speculation"—and doing so might unnecessarily complicate the preemption question. See *PLIVA*, 564 U.S. at 623 (plurality opinion).

Respondent briefly suggests (Supp. Br. 8 n.6; Br. in Opp. 21 n.13) that petitioner could have added a cancer warning unilaterally using EPA's exception for "minor modifications." 40 C.F.R. 152.46(a)(1). But again, that

exception does not apply to precautionary statements like cancer warnings. 40 C.F.R. 156.70(c); p. 31, *supra*. Petitioner notes that an EPA biologist once permitted a manufacturer to unilaterally add a disclaimer that its product "contain[ed] a chemical" (not glyphosate) "known to the state of California to cause cancer." Br. in Opp. 21 n.13 (citation omitted). Even assuming that decision complied with EPA regulations, an actual cancer warning—like the one respondent seeks—is "readily distinguishable" from a disclaimer about California's beliefs. *Schaffner*, 113 F.4th at 384 n.12. "Specific statements pertaining to the hazards of the product"—like a cancer warning—"*must* be approved by the agency." 40 C.F.R. 156.70(c) (emphasis added).

Respondent also distinguishes (Br. in Opp. 31-32) *PLIVA* on the theory that generic drugmakers must follow brand-name labeling, whereas pesticide manufacturers can seek labeling changes themselves. But *PLIVA*'s "hold[ing]" is that a state-law duty is preempted "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance." 564 U.S. at 623-624. While it might be *easier* for pesticide manufacturers to seek unilateral labeling changes, they cannot add precautionary warnings unilaterally, but instead need EPA's permission. Under *PLIVA*, that suffices for preemption.

C. State-Law Failure-To-Warn Claims Interfere With FIFRA's Uniform Labeling Scheme

FIFRA protects "[u]niformity" in pesticide labeling. 7 U.S.C. 136v(b). The statute "pre-empts competing state labeling standards," guarding against "50 different labeling regimes prescribing the color, font size, and wording of warnings[ ]that would create significant inefficiencies for manufacturers." *Bates*, 544 U.S at 452.

Ordinary conflict-preemption principles serve the same end: When "[f]ederal law requires a very specific label," state law may not "forbid[] the use of that label." *Bartlett*, 570 U.S. at 490. And to the extent legislative history is relevant, the House Report is emphatic: Congress "intended to completely preempt State authority in regard to labeling and packaging." H.R. Rep. No. 511, 92d Cong., 1st Sess. 16 (1971); see *id.* at 1-2 ("State authority to change Federal labeling and packaging is completely preempted.").

Preemption ensures that EPA retains its primary role weighing the costs and benefits of any given pesticide and determining what warnings are necessary to protect health and the environment. See 7 U.S.C. 136(bb), 136a(c)(5)(D). That primacy lets EPA take "the long view," since not every potential risk belongs on labeling. See *Wyeth*, 555 U.S. at 626 (Alito, J., dissenting) (similar in pharmaceutical context). Overloading labeling with warnings about every conceivable risk could "'overshadow' more important information" about more common or serious risks. See *Merck*, 587 U.S. at 304 (citation omitted) (same). And overwarning can "discourage appropriate use of a beneficial [product]." See *ibid.* (citation omitted).

Respondent's approach would replace that uniformity with a free-for-all where individual state legislatures, courts, and juries could impose a bevy of additional, conflicting warnings. State juries in particular are "ill equipped to perform the [agency's] cost-benefit-balancing function." *Wyeth*, 555 U.S. at 626 (Alito, J., dissenting). The jury "sees only the cost of a more dangerous design" because those who benefit from a product "are not represented in court." *Riegel*, 552 U.S. at 325. Even when millions of people benefit from a product that is

safe and effective in 99.99% of uses, those benefits are often deemed not worth the price for the one plaintiff who suffers a rare injury or illness and attributes it to the product.

Manufacturers would face the untenable choice of distributing 50 different versions of labeling—with the risk of liability whenever a pesticide crosses state lines—or overloading the labeling with state-specific concerns. Hawaii might highlight risks to pristine beaches. Oklahoma might warn of harms to horses. Alaska might urge against applications near glaciers. And Maryland might caution against woodland applications that could harm its beloved Baltimore oriole.

Respondent notes (Br. in Opp. 30) that EPA permits some state-specific instructions on pesticide use. Those statements have at least been approved by EPA. And those approvals reflect FIFRA's regime of concurrent authority over pesticide *use*. See 7 U.S.C. 136v(a) and (c). But when it comes to *labeling*, Congress opted for uniformity. There is nothing inherently contradictory or confusing about state-specific uses, like telling sugarcane farmers in Hawaii to spray earlier than farmers in Florida. See Br. in Opp. App. 42a. But if labeling tells users that a pesticide likely causes cancer in Missouri, might cause cancer in Illinois, definitely causes cancer in Tennessee, and is anyone's guess in Iowa, users will not know whom to believe. One State's requirements could even lead to liability in another. If California determines that certain pesticides should warn of the risks of climate change, an Alabama jury might well deem that statement "false or misleading." 7 U.S.C. 136(q)(1)(A). Lost in that noise: EPA's considered judgments about what warnings are actually necessary to protect public health, and any hope of uniformity.

CONCLUSION

The Missouri Court of Appeals' judgment should be reversed.

Respectfully submitted.

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