No. 24-1068

In the
Supreme Court of the United States

MONSANTO COMPANY,
Petitioner,
v.
JOHN L. DURNELL,
Respondent.

On Writ of Certiorari to the Missouri Court of Appeals

BRIEF FOR PETITIONER

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QUESTION PRESENTED

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") creates a comprehensive regulatory scheme governing the use, sale, and labeling of pesticides. The Act preempts any state "requirement[] for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. §136v(b). For decades, EPA has exercised its authority under FIFRA in determining that Monsanto's Roundup product line and its main active ingredient, glyphosate, do not cause cancer in humans. Consistent with that finding, EPA has repeatedly approved Roundup's label without a cancer warning. Once EPA approves a label, FIFRA prohibits Monsanto from making any substantive change to the label unless it first obtains EPA's permission. Respondent is one of more than 100,000 plaintiffs across the country that have sued Monsanto for not warning users that glyphosate, the active ingredient in Roundup, causes cancer.

The question presented is:

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

PARTIES TO THE PROCEEDING

Petitioner Monsanto Company was the appellant in the Missouri Court of Appeals. Respondent John L. Durnell was the appellee.

CORPORATE DISCLOSURE STATEMENT

Petitioner Monsanto Company is an indirect, wholly owned subsidiary of Bayer AG, a publicly held corporation. No other publicly held corporation owns 10% or more of Monsanto's stock.

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INTRODUCTION

The Environmental Protection Agency ("EPA") has a statutory obligation under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") to evaluate health risks and decline to register pesticides that lack necessary health warnings. In discharging its statutory responsibilities, EPA has exhaustively studied glyphosate—the world's most widely used herbicide—and concluded again and again in registering countless versions of Monsanto's Roundup products that glyphosate does not cause cancer. Consistent with those findings, EPA has approved hundreds of labels bearing no cancer warning for Monsanto's Roundup-branded glyphosate products. In short, EPA has determined that glyphosate and Roundup do not cause cancer and that a warning stating otherwise is neither required nor permitted under FIFRA.

A Missouri jury hearing a state-law failure-to-warn claim had other ideas. While that jury rejected every other one of the plaintiff's state-law claims, it faulted Monsanto for failing to provide precisely the kind of cancer warning on Roundup's label that EPA considered and rejected. That state-law claim is preempted by FIFRA both expressly and impliedly. To ensure "[u]niformity" in pesticide labeling, FIFRA expressly preempts any state-law labeling requirement that is "in addition to or different from those required under" the statute. 7 U.S.C. §136v(b). Congress understood that EPA would have to strike a balance in registering pesticides and deciding what and how many warnings are required. Pesticides by their very nature cannot be rendered entirely risk-free

without rendering them useless in fighting pests, and labels can facilitate safe use. At the same time, over-warning is problematic, as unjustified warnings may discourage use of beneficial pesticides, shift use to less safe or effective alternatives, and distract from warnings that matter. To protect the balance that EPA strikes when registering pesticides and approving their labels, Congress prohibited states from imposing different or additional warnings via tort law or otherwise. The state-court verdict here purported to do just that by requiring warnings that EPA has rejected in its registration decisions. Indeed, under FIFRA, Monsanto could not provide the warnings Missouri law requires without rendering Roundup misbranded under federal law. Accordingly, even in the absence of FIFRA's express preemption clause, respondent's label-based failure-to-warn claim would be preempted because simultaneous compliance with federal and state law would be impossible.

Preemption here comports with both Congress' will and common sense. Pesticides play a critical role in empowering American farmers and protecting the food supply. EPA can strike a balance between those important objectives by ensuring that labels warn against health risks, but neither over-warn nor confuse consumers. But once EPA makes that judgment, the label is the law. It cannot be second-guessed by lay juries applying the law of 50 states without violating Congress' directive, threatening today's food supply and impeding tomorrow's innovation. Indeed, that "crazy-quilt" of conflicting state regulations is exactly what Congress enacted §136v(b) to stamp out. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005). Despite EPA's

considered judgment that Roundup is safe when used in accordance with its EPA-approved label, cascading tort liability has forced Monsanto to remove glyphosate from the residential consumer market while threatening its availability for farmers. In short, the decision below is contrary to the judgments of Congress and EPA, and it poses a real threat to farmers and innovation. This Court should reverse.

OPINIONS BELOW

The Missouri Court of Appeals' opinion, 707 S.W.3d 822 (2025), is reproduced at Pet.App.2-12. The Missouri Supreme Court's order denying Monsanto's application for transfer is unreported but reproduced at Pet.App.1. The opinion of the Missouri trial court denying Monsanto's motion for summary judgment is unreported but reproduced at Pet.App.13-16.

JURISDICTION

The Missouri Court of Appeals issued its opinion on February 11, 2025. The Missouri Supreme Court denied Monsanto's application for transfer on April 1, 2025, and Monsanto filed a timely petition for a writ of certiorari on April 4, 2025. This Court has jurisdiction under 28 U.S.C. §1257(a).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions are reproduced in the appendix to this brief.

STATEMENT OF THE CASE

A. Legal Background

For as long as there have been farms, there have been pests. They include insects, rodents, weeds, fungi, and many, many more. *See, e.g.*, 7 U.S.C.

§136(t). Pests are not mere inconveniences; they cost farmers and the public untold sums of money, can precipitate famines that kill tens of millions of people, and spread diseases that kill hundreds of millions more. Graham A. Matthews, *A History of Pesticides* xiii-xv (2018). To combat those pestilences, humans for centuries have sought to discover or develop pesticides that would enable them to kill pests without damaging crops or human life. *Id.*

With the advent of the Industrial Revolution, farmers began experimenting with newer, more powerful synthetic pesticides, which in turn prompted efforts at regulation. *See, e.g.*, *Stearns Elec. Paste Co. v. EPA*, 461 F.2d 293, 296-97, 299 (7th Cir. 1972). While states initially "provided the primary and possibly the exclusive source of regulatory control over the distribution" of pesticides, in 1910 Congress enacted the first ever national pesticide-regulation legislation. *Bates*, 544 U.S. at 437; *see* Pub. L. No. 61-152, 36 Stat. 331 (1910).

Congress expanded the federal role in 1947 by enacting FIFRA. Pub. L. No. 80-104, 61 Stat. 163. In its original form, FIFRA required pesticide manufacturers to register their products with the Secretary of Agriculture before sale.[1] *Id.* §4, 61 Stat. at 167-68. But the federal-agency role was still limited: Even if the Secretary refused to register a product on the ground that it was misbranded, a manufacturer could "insist[] that … corrections are

[1] Congress later reassigned responsibility for administering FIFRA to EPA. *See* Reorganization Plan No. 3 of 1970, §§1, 2(8), 84 Stat. 2086, 2086-87, 2088; Pub. L. No. 92-516, §25, 86 Stat. 973, 997-998 (1972).

not necessary" and demand "that it be registered" anyway. *Id.* §4(c), 61 Stat. at 168. So while FIFRA originally made it unlawful to sell unregistered pesticides, *id.* §3(a)(1), 61 Stat. at 166, manufacturers could invoke their "absolute right to have [a] product registered under protest." *Stearns*, 461 F.2d at 303. To avoid potential gamesmanship by manufacturers, Congress provided that registration may not serve as a defense in a subsequent misbranding enforcement action brought by the government. FIFRA, §4(c), 61 Stat. at 168.[2]

Over the ensuing decades, Congress strengthened both the federal-agency role and its preemptive effect. By the 1970s, a cacophony of conflicting state pesticide regulations had begun to overwhelm manufacturers. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 990 n.2 (1984). Those "competing state labeling standards" led to "significant inefficiencies." *Bates*, 544 U.S. at 452. Some states wanted chemicals to be labeled as "flammable," while others wanted the same substances labeled as "inflammable"; some states demanded warnings in red, others wanted them in yellow. *See* Federal Pesticide Control Act of 1971: Hearing before the House Comm. on Agric., 92d Cong. 281-83 (1971). Congress stepped in and amended FIFRA to impose nationwide "[u]niformity." Specifically, Congress prohibited states from

[2] In 1964, Congress amended FIFRA to eliminate the registration-under-protest regime. Pub. L. No. 88-305, §3, 78 Stat. 190, 191 (1964). Because registration now represented the government's determination that a pesticide complied with FIFRA, Congress made that registration presumptive proof of compliance in a subsequent misbranding enforcement action. Pub. L. No. 92-516, §3(f)(2), 86 Stat. 973, 982 (1972).

"impos[ing] or continu[ing] in effect" any labeling or packaging requirement "in addition to or different from those required" under FIFRA. Pub. L. No. 92-516, §24, 86 Stat. 973, 997 (1972) (classified to 7 U.S.C. §136v(b)). Through that "[u]niformity" provision, Congress sought to "completely preempt State authority in regard to labeling and packaging," H.R. Rep. No. 92-511, at 16 (1971), and thus eliminate the "crazy-quilt" of conflicting state-level pesticide labeling regimes. *Bates*, 544 U.S. at 448, 453 n.26.

"Over the years, a complex regulatory scheme has emerged to balance the agricultural and consumer benefits that pesticides can provide against potential risks to human health and the environment." H.R. Rep. No. 104-669(II), at 29-30 (1996). FIFRA strikes a careful balance between ensuring that pesticides are "available to meet pest control needs" and ensuring adequate safety for humans and the environment. S. Rep. No. 95-334, at 3 (1977). "The statute," in other words, "recognizes that there is a degree of risk which must be accepted in order to derive the substantial benefits afforded to society by pesticides." H.R. Rep. No. 94-1105, at 4 (1976). No pesticide—even one that poses zero risk of cancer—can be made entirely free of all risks, given their nature. As EPA noted, a "no-risk concept for pesticide regulation is neither reasonable nor legally tenable. Most pesticides are intended to inflict harm on some form of life, or in some way to modify its structure or development. We thus expect pesticides to impose some degree of hazard; indeed, they would be no good to us if they did not." *Id.*

Today, FIFRA is "a comprehensive regulatory statute" that regulates "the use, as well as the sale and

labeling, of pesticides." *Ruckelshaus*, 467 U.S. at 991-92. No pesticide may be sold or distributed domestically unless it has first been registered with EPA pursuant to FIFRA. 7 U.S.C. §136a(a). EPA may register a pesticide "only if" it determines that the pesticide "will perform its intended function without unreasonable adverse effects on the environment," is "not misbranded," and "its labeling and packaging comply with the applicable requirements" of FIFRA. 40 C.F.R. §152.112(e)-(f); *see* 7 U.S.C. §136a(c)(5)(B)-(D). FIFRA defines the phrase "unreasonable adverse effects on the environment" 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). FIFRA deems a pesticide misbranded if, among other things, the pesticide's label "bears any statement, design, or graphic representation … which is false or misleading in any particular," or if its label "does not contain a warning or caution statement which may be necessary and if complied with[] … is adequate to protect health and the environment." *Id.* §136(q)(1)(A), (G). FIFRA defines the phrase "to protect health and the environment" to mean "protection against any unreasonable adverse effects on the environment." *Id.* §136(x). In other words, "[w]hen EPA determines that a pesticide product can be registered for use, the Agency has concluded that the use of the pesticide product will not cause unreasonable adverse effects to humans or the environment when applied according to the label directions and restrictions." EPA, *Pesticide Registration Manual: Chapter 1* (Oct. 30, 2025), https://perma.cc/GK64-3BUC.

EPA regulations govern the registration process. Under those regulations, pesticide manufacturers submit voluminous scientific and safety data to the agency, alongside proposed labeling that includes any necessary precautionary statements regarding the potential effect of the pesticide on human health. *See* 7 U.S.C. §136a(c); 40 C.F.R. §§156.10(a)(1)(vii), 156.60, 158.500. EPA's regulations specifically instruct EPA to "review all data that are necessary to make the required risk/benefit finding under FIFRA." 40 C.F.R. §152.85(e). EPA reviews the studies and safety data to verify that the pesticide does not create an unreasonable risk of adverse effects on human health, including cancer. It also reviews the proposed label to ensure that it complies with FIFRA's requirements before approval, including that it bears all necessary health warnings. *See id.* §§152.40-.55, 152.112(f). And for pesticides first registered before 1984, EPA conducted a one-time re-registration, which involved a renewed determination by EPA that the pesticide continued to comply with FIFRA's requirements. *See, e.g.*, 7 U.S.C. §136a-1(g). Even after that registration (and re-registration), EPA must review a pesticide's registration every 15 years. *Id.* §136a(g)(1)(A)(iii)(II). This process requires EPA to consider whether any "labeling changes" are necessary given new information and whether the product still meets FIFRA's requirements, including its misbranding prohibition. 40 C.F.R. §155.58(b)(4).

Once EPA approves a label, the "label is the law!" EPA, *Pesticide Registration Manual: Introduction* (May 21, 2025), https://perma.cc/RRQ4-S928. Manufacturers cannot distribute pesticides with labels that differ substantially from the label

approved by EPA. 7 U.S.C. §136j(a)(1)(B). Indeed, manufacturers must seek EPA approval for virtually any substantive change to the label. *See* 40 C.F.R. §§152.44, 152.46. While manufacturers may make some "minor modifications" through a streamlined "notification" process, they may not change any "[p]recautionary [s]tatements" that way. 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; *see* 40 C.F.R. §156.70(c). Instead, for such changes, manufacturers may proceed only by formal amendment requiring agency approval.

If the agency finds that a pesticide does not satisfy FIFRA's standards, it may initiate cancellation proceedings to rescind a pesticide's registration, *see* 7 U.S.C. §§136a(g)(1)(A)(v), 136d(b); 40 C.F.R. §155.40(a)(2), or require mitigation measures to reduce risk to acceptable levels, *see* 40 C.F.R. §155.58. That is a core component of how the agency responds to new information regarding pesticide safety. Manufacturers have a continuing obligation to inform EPA of new information regarding a pesticide's effects on human health and the environment. 7 U.S.C. §136d(a)(2); 40 C.F.R. §159.152. If EPA determines that such information changes its original FIFRA-compliance decision, it can begin cancellation proceedings. But before doing so, EPA must "take[] into account the impact" of the cancellation "on production and prices of agricultural commodities, retail food prices," and the "agricultural economy." 7 U.S.C. §136d(b).

Finally, FIFRA establishes a framework for state-federal cooperation. As a general matter, FIFRA permits states to "regulate the sale or use of any federally registered pesticide," so long as they do not attempt to "permit any sale or use" that is forbidden under federal law. *Id.* §136v(a). States can also grant special, local-use registration to meet unique local needs within the state, so long as EPA has not previously denied a registration for that use. *Id.* §136v(c)(1). But FIFRA expressly cuts states out of some areas of pesticide regulation. In particular, to ensure "[u]niformity" in pesticide labeling, FIFRA makes clear that states cannot "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA. *Id.* §136v(b).

B. Factual Background

Monsanto manufactures and distributes Roundup, a line of herbicides with residential, commercial, and agricultural applications. At all times relevant here, Roundup "employ[ed] glyphosate as its active ingredient." *Schaffner v. Monsanto Corp.*, 113 F.4th 364, 373 (3d Cir. 2024).

Glyphosate is an organophosphorous compound used globally to control pest populations. Matthews, *supra*, at 12-15. Glyphosate-based herbicides are particularly effective (indeed, they are more effective than anything else) because, when applied to a plant, they are "translocated downwards" to the stem and roots, "as well as into the foliage." *Id.* at 103. Glyphosate is so effective as an herbicide that it is estimated to have saved farmers a staggering "$21 billion" annually, while simultaneously allowing them

to use "225 million kg less herbicide" each year. *Id.* at 160; Eva Greenthal et al., *In the Weeds: Understanding the Impact of GE Crops on Pesticide Use* 3 (Apr. 2021), https://perma.cc/3T87-PYWJ. "Glyphosate is appealing to farmers because it is inexpensive, easy to use, kills a broad spectrum of weeds, and breaks down quickly in the environment." *In the Weeds*, *supra*, at 4. At the same time, it "has significantly lower acute and chronic toxicity than many other herbicides on the market." *Id.* In fact, as the President recently concluded, "[t]here is no direct one-for-one chemical alternative to glyphosate-based herbicides." Exec. Order No. 14387, §1 (Feb. 18, 2026). "Lack of access to glyphosate-based herbicides would critically jeopardize agricultural productivity." *Id.*

EPA has registered glyphosate-based pesticides since 1974. *See* EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 12 (Dec. 12, 2017) ("2017 EPA Paper"), https://perma.cc/UWM2-6BHB. Over the ensuing half-century, EPA has repeatedly evaluated (and re-evaluated) whether glyphosate poses adverse health risks for humans, including any risk of cancer. *Id.* For example, in 1986, EPA "requested that the FIFRA Scientific Advisory Panel … evaluate the carcinogenic potential of glyphosate." *Id.* That evaluation revealed no evidence that glyphosate causes cancer in humans, and EPA consequently prescribed "Required Labeling" without any cancer warning. *Id.*; *see also* EPA, *Guidance for the Reregistration of Pesticide Products Containing Glyphosate as the Active Ingredient* 6-8, 20-34 (June 1986), https://perma.cc/DTH7-FR4V. EPA again reviewed the potential health effects of glyphosate in 1991, and its Carcinogenicity Peer Review Committee

found "evidence of non-carcinogenicity for humans." 2017 EPA Paper, *supra*, at 13 (capitalization altered). In 1993, EPA again reviewed glyphosate as a part of the statutory re-registration process and again concluded that "glyphosate products, labeled and used as specified [by EPA], will not pose unreasonable risks or adverse effects to humans." EPA, *Reregistration Eligibility Decision (RED) Glyphosate* 57 (Sept. 1993), https://perma.cc/528H-F4FN. EPA again prescribed "labeling requirements," and those requirements did not include a cancer warning. *Id.* at 71-72.

EPA has come to that same conclusion repeatedly in the years since. *See, e.g.*, 2017 EPA Paper, *supra*, at 12-13; 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (finding glyphosate "not a carcinogen" based on review of an "extensive database" of research). Those conclusions accord with a longstanding global consensus that glyphosate does not cause cancer in humans. *See Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1270-71 (9th Cir. 2023).

In 2015, a working group of the International Agency for Research on Cancer ("IARC") broke from that global consensus by classifying glyphosate as a "Group 2A" agent, meaning that IARC considers it "probably carcinogenic to humans" based on "limited evidence of carcinogenicity." IARC, *Some Organophosphate Insecticides and Herbicides* 398 (2015) ("2015 IARC Paper"), https://perma.cc/9TPL-278R (emphasis omitted). According to IARC, "[l]imited evidence of carcinogenicity" means a "positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered … credible, but chance,

bias or confounding could not be ruled out with reasonable confidence." *Id.* at 27. As context, IARC also views "[n]ight shift work," employment as a "[h]airdresser or barber," and "[v]ery hot beverages" as "[p]robabl[e]" carcinogens. Am. Cancer Soc'y, *Known and Probable Human Carcinogens* (Aug. 1, 2024), https://perma.cc/44M3-2DAP.

Moreover, IARC determined only that glyphosate poses a potential cancer "hazard," as opposed to a cancer "risk." 2015 IARC Paper, *supra*, at 10-11. The "distinction between hazard and risk is significant." *Wheat Growers*, 85 F.4th at 1269. A "hazard indicates that at some theoretical level of exposure, the chemical is capable of causing cancer. Risk, on the other hand, is the likelihood that cancer will occur at a real-world level of exposure." *Id.* And IARC's view was based on exposure of "experimental animals" to glyphosate—even though "[l]aboratory animals are tested with higher rates of pesticides than used by farmers applying them in their fields." Matthews, *supra*, at 104-05; *accord* Michael Grunwald, *Spraying Roundup on Crops is Fine. Really.*, N.Y. Times (Sept. 28, 2025), https://perma.cc/ZY4H-NXNG (noting that IARC studies "exposed rodents to preposterously huge doses [of glyphosate], and even then ignored exculpatory tumor data").[3] And IARC refused to consider multiple studies that directly undermined its carcinogenicity hypothesis. Cancer Assessment Rev. Comm., EPA, *Evaluation of Carcinogenic Potential of*

[3] IARC also deleted evidence from its draft that undermined its conclusion. Kate Kelland, *In Glyphosate Review, WHO Cancer Agency Edited Out "Non-Carcinogenic" Findings*, Reuters (Oct. 19, 2017), https://perma.cc/BB6E-KB65.

Glyphosate 9 (Oct. 1, 2015) ("2015 CARC Report"), https://perma.cc/JXM2-6DCW ("This omission of the negative findings from reliable studies may have had a significant bearing on [IARC's] conclusion."). Moreover, the next year, a different WHO agency found "glyphosate was unlikely to pose a carcinogenic risk to humans from exposure through the diet," 2017 EPA Paper, *supra*, at 13, which was consistent with the earlier findings of two other WHO agencies, WHO & Int'l Programme on Chem. Safety, *Glyphosate* 15 (1994), https://perma.cc/RGZ9-YHV6; WHO, *WHO Guidelines for Drinking Water Quality* 379 (3d ed. 2008), https://perma.cc/89Z2-53FJ.

IARC released its assessment while EPA's statutory registration review was already underway. As part of that review, EPA commissioned multiple reviews to evaluate IARC's findings and assess anew the carcinogenic potential of glyphosate. Those reviews culminated in an 87-page report from EPA's Cancer Assessment Review Committee and a 216-page report from its Office of Pesticide Programs. *See* 2015 CARC Report, *supra*; 2017 EPA Paper, *supra*. To compile those reports, EPA examined all relevant evidence IARC collected, and numerous studies IARC failed to consider—amounting to hundreds of scientific sources and references. 2017 EPA Paper, *supra*, at 21-22; *see also* EPA, *Glyphosate Proposed Interim Registration Review Decision* 7 (Apr. 2019) ("Glyphosate PIRD"), https://perma.cc/8K63-HD36 ("IARC only considered a subset of the studies included in the EPA's evaluation."). EPA also solicited public comments to consider outside views in its evaluation.

Having reviewed all relevant available scientific data, and having reconsidered its own views in light of IARC's findings, EPA concluded that "[t]he strongest support" was for classifying glyphosate as "not likely to be carcinogenic to humans." 2017 EPA Paper, *supra*, at 143. EPA thus rejected IARC's conclusions. Glyphosate PIRD, *supra*, at 7-8. EPA's conclusion was unequivocal. It considered its own review "more robust" than IARC's—after all, IARC considered only half as many "animal carcinogenicity studies." *Id.* at 7. IARC relied on studies about carcinogenicity in worms and plants, which EPA excluded as irrelevant to carcinogenicity in *mammals*. *Id.* And EPA viewed its analyses as "more transparent" than IARC's—EPA's review underwent "external peer review," EPA solicited "public comment," and EPA's deliberations and work product were available for public view. *Id.* at 8. By contrast, IARC held closed deliberations, solicited no public comments, and foreswore outside peer review. *Id.* at 7. Indeed, after its own "robust" and "transparent" review, EPA noted that "*none* of the panelists" on its external peer review committee supported IARC's conclusions. *Id.* (emphasis added); *see also* EPA, Glyphosate (May 9, 2025), https://perma.cc/SXM6-T92Q (explaining that "[t]he Agency concluded that glyphosate is not likely to be carcinogenic to humans," and that "EPA considered a significantly more extensive and relevant dataset than [IARC]").

EPA was hardly the only regulator to reject IARC's consensus-defying views. A "significant number of international regulatory authorities and organizations disagree with IARC's conclusion that glyphosate is a probable carcinogen." *Wheat Growers*,

85 F.4th at 1270. Indeed, "IARC stands essentially alone in its determination that glyphosate is probably carcinogenic to humans." *Id.* at 1278. Canadian regulators, for example, rejected IARC's conclusion and noted that IARC relied heavily on cancer studies in rats with results that were not "reproduced in other chronic studies." Pest Mgmt. Regul. Agency, Health Canada, *Glyphosate: Re-evaluation Decision* 21, 23-24 (Apr. 28, 2017), https://perma.cc/94NF-XBPT. Australian regulators likewise concluded that "the evidence indicates that glyphosate is not carcinogenic in animals." Austl. Pesticides & Veterinary Med. Auth., *Final Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate* 29 (Mar. 2017), https://perma.cc/9HC9-J8G4. The European Union was similarly unmoved by IARC and remained copacetic about glyphosate: It found that IARC's carcinogenicity findings were "not justified," and that "no classification for carcinogenicity is warranted." Comm. for Risk Assessment (RAC), European Chems. Agency, *Proposing Harmonised Classification and Labelling at EU Level of Glyphosate (ISO); N-(phosphonomethyl)glycine* 91-92, 94 (adopted May 30, 2022), https://perma.cc/HR37-3B5J. New Zealand, Japan, and South Korea have also reaffirmed the consensus and rejected IARC's views as well. *See Wheat Growers*, 85 F.4th at 1270.

In August 2019, EPA once more rejected a cancer warning for glyphosate. Pet.App.38-40. As a result of IARC's glyphosate classification, California's Proposition 65 required manufacturers to include a warning that glyphosate is known "to cause cancer" on

their labels. Pet.App.38.[4] In its letter to glyphosate registrants, EPA reiterated that it "disagrees with IARC's assessment," explaining that it had "considered a more extensive dataset than IARC" and determined that glyphosate is "not likely to be carcinogenic to humans." Pet.App.38. Including California's cancer warning, EPA explained, would render a pesticide "misbranded pursuant to section 2(q)(1)(A) of FIFRA." Pet.App.39.

After a second round of public comments, EPA finalized its glyphosate interim registration review in 2020 and again concluded that a cancer warning is not necessary. After various parties brought suit in the Ninth Circuit to challenge that decision, EPA *again* reviewed its decision and reaffirmed that "glyphosate is not likely to be a human carcinogen and … it does not pose human-health risks of concern." EPA.Br.17, *NRDC v. EPA*, Nos. 20-70787, 20-70801 (9th Cir. May 18, 2021), Dkt.80. The Ninth Circuit faulted EPA for failing to offer enough "analysis and explanation," while rejecting the petitioners' "highly disruptive" suggestion that it "order deregistration" of glyphosate. *NRDC v. EPA*, 38 F.4th 34, 52 & n.13 (9th Cir. 2022). In response, EPA announced that it would "revisit and better explain its evaluation of the carcinogenic potential of glyphosate," but that its "underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic

[4] While Proposition 65 might have created a self-executing duty to include the warning based on IARC's finding, California's own Office of Environmental Health Hazard Assessment had concluded that glyphosate is not "carcinogenic to humans." *Wheat Growers*, 85 F.4th at 1278.

to humans," remain unchanged. Memorandum from Cathryn Britton, EPA, to Glyphosate Registration Review Docket (EPA-HQ-OPP-2009-0361) at 5-6 (Sept. 21, 2022), https://perma.cc/3KDJ-JT2N; *see also Wheat Growers*, 85 F.4th at 1280 n.14.

Since then, EPA has continued to approve labels of numerous glyphosate-based pesticide products without cancer warnings. *See* EPA, *Chemical Name: Glyphosate*, https://perma.cc/7PHA-8UXP (last visited Feb. 23, 2026).[5]

C. Proceedings Below

After IARC issued its glyphosate classification, plaintiffs began filing a flood of lawsuits alleging that their use of Roundup caused them to develop non-Hodgkin's lymphoma ("NHL"). Several factors drove the massive number of lawsuits. Roundup is an enormously popular product, *supra*, pp.10-11, meaning that there is an extensive user base of would-be plaintiffs. And NHL is a very common and naturally occurring cancer; "the chance that a man will develop NHL in his lifetime is about 1 in 46; for a woman, the risk is about 1 in 55." Am. Cancer Soc'y, *Key Statistics for Non-Hodgkin Lymphoma* (Jan. 13, 2026), https://perma.cc/G3GM-QZKN. That confluence of factors—plus a more-than-$130-million advertising blitz by plaintiffs' attorneys, *see* Tiger

[5] Approximately a decade ago (and before the Ninth Circuit's decision), EPA approved two labels that included a cancer warning. But EPA has acknowledged that those decisions were the result of an "implementation mistake[]." U.S.Br.17-19 & n.14, *Monsanto Co. v. Hardeman*, No. 19-16636 (9th Cir. filed Dec. 20, 2019), Dkt.32.

Joyce, Am. Tort Reform Ass'n, *When Plaintiffs' Attorneys Mislead the Public*, Bloomberg Law (Sept. 28, 2022), https://perma.cc/SV28-9BFW—resulted in more than 100,000 plaintiffs suing Monsanto alleging that Roundup caused their cancers.

This is one of those cases. In January 2019, respondent John Durnell sued Monsanto in Missouri state court, alleging that he had been exposed to Roundup since 1999 and developed non-Hodgkin's lymphoma as a result. JA.16. He conceded that "Monsanto's glyphosate products are registered in 130 countries and approved for use on over 100 different crops." JA.41. Nevertheless, he alleged, based almost exclusively on the IARC classification, that those 130 countries were wrong, IARC was right, and Roundup had caused his cancer. JA.42, 61-62. He brought multiple state common-law and statutory claims against Monsanto. JA.63-86.

The jury rejected all those claims except a claim for failure to warn consumers of Roundup's alleged carcinogenic potential. The jury awarded Durnell $1.25 million in compensatory damages for that claim. Pet.App.3. Monsanto moved for entry of judgment notwithstanding that verdict on preemption grounds, but the trial court refused. Pet.App.3.

The Missouri Court of Appeals affirmed the trial court's judgment and rejected Monsanto's preemption arguments. The appeals court recognized that "FIFRA will preempt a state law requirement—including a common-law cause of action—that is not fully consistent with FIFRA's requirements." Pet.App.5. Thus, FIFRA would preempt Durnell's claims if prevailing on those claims would hold

Monsanto liable for not carrying a label that is "in addition to or different from" the one FIFRA required. Pet.App.5-6; 7 U.S.C. §136v(b). But the court concluded that a finding of liability would *not* impose such an additional labeling requirement on the theory that the "practical effect" of FIFRA's misbranding prohibition and Durnell's failure-to-warn claim "are the same: both require a pesticide manufacturer to adequately warn users of the potential dangers of using its product." Pet.App.7.

The appeals court likewise rejected Monsanto's implied preemption argument. The court recognized that state tort claims are preempted if it is "impossible to comply with both federal and state law." Pet.App.8. It also recognized that EPA had repeatedly concluded that glyphosate does not cause cancer in humans and approved Roundup labels that did not include a cancer warning. Pet.App.9. And it did not dispute that federal law prohibited Monsanto from unilaterally adding a warning that EPA had not approved. But the court nevertheless rejected Monsanto's implied preemption argument because Monsanto had not affirmatively sought EPA's approval to add a cancer warning and, because Monsanto had never affirmatively asked EPA to approve a cancer warning, the court could not be certain that such a request would be denied. Pet.App.8-9.

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

SUMMARY OF ARGUMENT

FIFRA expressly preempts Durnell's claim. FIFRA preempts state-law "requirements for labeling or packaging in addition to or different from those

required under this subchapter." 7 U.S.C. §136v(b). And FIFRA makes it unlawful to distribute a pesticide with labeling substantially different from the EPA-approved label. *Id.* §136j(a)(1)(B). EPA's pesticide-specific labeling determinations therefore constitute mandates to which a pesticide manufacturer must adhere as a matter of federal law. In other words, they are "requirements for labeling … under this subchapter," i.e., FIFRA, that expressly preempt contrary state-law requirements. *Id.* §136v(b). EPA has determined—repeatedly—that glyphosate does not cause cancer in humans, and it accordingly has approved—repeatedly—Roundup product labels on that basis. EPA thus requires Monsanto to use product labels that do not warn of a supposed link between glyphosate and cancer that EPA has repeatedly evaluated and rejected. Durnell's failure-to-warn claim, by contrast, is premised on the notion that glyphosate *does* cause cancer and that Monsanto was obligated to warn consumers accordingly. His claim quite plainly seeks to impose "requirements for labeling or packaging in addition to or different from those required under [FIFRA]," *id.*, and is therefore expressly preempted.

Durnell's claim is impliedly preempted as well. Federal labeling laws preempt competing state-law regimes when manufacturers cannot unilaterally comply with state requirements. For impossibility preemption, "[t]he question … is whether the private party could *independently* do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) (emphasis added). Here, EPA has approved Roundup labels without a cancer warning. And because "the label is the law," Monsanto is not

free to change its labels without first seeking and obtaining EPA approval. It is thus impossible for the manufacturer of an EPA-registered pesticide to do independently what state law requires. Moreover, even if (contrary to law and reality) Monsanto *could* unilaterally change its label to include a cancer warning, EPA has already shown its hand: It has reviewed the IARC determination and found it wanting; it has stated in no uncertain terms that it will not approve labels that contain glyphosate cancer warnings; and it has made clear that it considers such warnings "false or misleading" statements that render pesticides misbranded under FIFRA. Thus, any unilateral change would be quickly followed by cancellation proceedings and a misbranding enforcement action. In short, Durnell's failure-to-warn claim is preempted twice over.

That conclusion follows directly from Congress' judgment that EPA must strike a balance between eliminating unreasonable risks and ensuring that farmers have the tools they need and companies have incentives to continue to innovate. Allowing lay juries applying the law of 50 states to second-guess EPA's judgments destroys that balance and undermines Congress' goals. Congress protected against such results by preempting claims like Durnell's. This Court should honor Congress' sound judgment and reverse.

ARGUMENT

I. FIFRA Expressly Preempts Durnell's Failure-To-Warn Claim.

FIFRA preempts state-law "requirements for labeling or packaging in addition to or different from

those required under this subchapter." 7 U.S.C. §136v(b). That provision preempts state-law tort suits that seek to impose liability on a pesticide manufacturer for failing to depart from an EPA-approved label to include additional warnings that EPA has specifically determined are unsupported and unnecessary.

A. EPA's Registration of Roundup and Its Labeling Determinations Impose Specific Federal Labeling Requirements Under FIFRA.

1. To register a pesticide, EPA must specifically determine that the pesticide poses no "unreasonable risk to man or the environment." 40 C.F.R. §§152.112(e), 166.3; *see* 7 U.S.C. §§136a(c)(5)(D), 136(bb). And it must specifically determine "that the product is not misbranded" and that "its labeling and packaging comply with the applicable requirements of the Act," including that it contains all warnings adequate to protect human health. 40 C.F.R. §152.112(f); *see* 7 U.S.C. §§136a(c)(5)(B), 136(q)(1)(G), 136(x), 136(bb). In making those determinations, EPA conducts a "rigorous, comprehensive scientific assessment of the product" to "ensure that, when the product is used according to labeled directions, no unreasonable adverse effects on human health or the environment will occur." *Pesticide Registration Manual: Introduction*, *supra*. To facilitate that "rigorous[and] comprehensive scientific assessment," *id.*, FIFRA requires manufacturers to submit voluminous scientific and safety data (including carcinogenicity studies), as well as proposed labeling that includes any precautionary statements regarding

potential effects on human health. *See* 7 U.S.C. §136a(c)(2)(A); 40 C.F.R. §§152.80, 156.10(a)(1)(vii), 156.60, 158.500.

EPA encourages applicants to meet with it before submitting an application so that EPA can provide the applicant with insights about the type of valid scientific data that will be necessary. *See* EPA, *Pesticide Registration Manual: Chapter 2* (Sept. 22, 2025), https://perma.cc/D8KW-AYXK. After an applicant submits the requisite information, EPA may request any additional information needed to determine whether the pesticide is properly labeled and contains all necessary warnings. 7 U.S.C. §136a(c)(2)(B); 40 C.F.R. §152.105. EPA may refer the application to a panel of experts, who will provide "comments, evaluations, and recommendations" to "improve" the "quality of scientific analyses" conducted by EPA personnel. 7 U.S.C. §136w(d); *see* 40 C.F.R. §154.25(d). For example, EPA routinely seeks guidance from its Cancer Assessment Review Committee—an "internal expert consultation committee" that "provides the internal forum for scientists to present and defend their conclusions concerning the carcinogenic potential of a pesticide chemical and interpretation of findings from studies that may inform the carcinogenic risk assessment"—to peer review its conclusions. EPA, *Evaluating Pesticides for Carcinogenic Potential* (Oct. 16, 2025), https://perma.cc/X3CS-RXCD; EPA, *Guidance on Use of Weight of Evidence When Evaluating the Human Carcinogenic Potential of Pesticides* 2 (June 2023), https://perma.cc/MH7X-7K8T. And EPA has published detailed guidelines for assessing cancer risk. *See* EPA, *Guidelines for Carcinogen Risk*

Assessment (Mar. 2005), https://perma.cc/86MQ-MG3W; *Guidance on Use of Weight of Evidence*, *supra*.

EPA's decision to register a pesticide thus signals the agency's pesticide-specific determination that the pesticide is safe when used in accordance with the label approved by EPA during the registration process. "When EPA determines that a pesticide product can be registered for use, the Agency has concluded that the use of the pesticide product will not cause unreasonable adverse effects to humans or the environment when applied according to the label directions and restrictions." *Pesticide Registration Manual: Chapter 1*, *supra*. Given their basic function and nature, almost any pesticide could pose a safety risk if misused. The label is thus critical to EPA's safety determination and its registration decision. Accordingly, once the manufacturer receives approval, it may generally market the pesticide only as labeled in the registration application approved by EPA.

FIFRA makes it illegal to distribute a pesticide with labeling substantially different from the EPA-approved label. 7 U.S.C. §136j(a)(1)(B). And, with minor exceptions not applicable here, a manufacturer 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). In particular, "[s]pecific statements pertaining to the hazards of the product and its uses must be approved by the Agency." *Id.* §156.70(c). The manufacturer may not unilaterally alter a label that EPA has approved, even if it learns of "additional factual information regarding unreasonable adverse effects." 7 U.S.C. §136d(a)(2). Instead, the manufacturer must

"submit such information to" EPA, *id.*, which can then launch cancellation procedures only after "tak[ing] into account the impact" on "food prices" and "the agricultural economy," *id.* §136d(b).

2. EPA's decision to register a pesticide thus establishes a set of pesticide-specific labeling mandates that the manufacturer must obey as a matter of federal law. Those mandates plainly qualify as "requirements for labeling … under this subchapter," i.e., FIFRA. 7 U.S.C. §136v(b).

First, they are unquestionably "requirements" within the meaning of §136v(b). As this Court explained in *Bates*, the term "requirements" in §136v(b) encompasses not just obligations "set out in FIFRA and its implementing regulations," 544 U.S. at 452; it reaches beyond "statutes and regulations" to include any "rule of law that must be obeyed," *id.* at 443, 445. The pesticide-specific labeling mandates imposed by EPA through the registration process are plainly "rule[s] of law that must be obeyed." *Id.* at 445. As EPA has explained, once approved, "[t]he pesticide product's label is a legal document." *Pesticide Registration Manual: Introduction*, *supra*. "The label is the law!" *Id.*

Those mandates, moreover, are just as plainly "required *under this subchapter*," i.e., FIFRA, even though they do not appear on the face of the statute. 7 U.S.C. §136v(b) (emphasis added). The phrase "under this subchapter" refers to requirements imposed "through action required or permitted by the" subchapter. Off. of the Legis. Counsel, U.S. House of Reps., *House Legislative Counsel's Manual on Drafting Style* 48 (2022). The pesticide-specific

labeling requirements are imposed by EPA through the pesticide registration process mandated by FIFRA. *Supra*, pp. 8-9. Thus, they plainly qualify as "requirements for labeling … *under*" the statute. 7 U.S.C. §136v(b) (emphasis added); *cf. Ardestani v. INS*, 502 U.S. 129, 135 (1991) (explaining that "'under' means 'subject or pursuant to' or 'by reason of the authority of'").

Statutory context reinforces that conclusion. Had Congress wanted to limit the relevant federal "requirements" in §136v(b) to those imposed on the face of FIFRA, it could have used the phrase "*required by* this subchapter"—as it did elsewhere in the statute. *E.g.*, 7 U.S.C. §136(q)(2)(D) ("other matter required by this subchapter"); *id.* §136h(a) ("data required by this subchapter"); *id.* §136j(a)(2)(N) ("reports required by this subchapter"); *id.* §136k(b) ("information required by this subchapter"). Likewise, had Congress wanted to limit the relevant "requirements" in §136v(b) to those imposed by regulation, *see* BIO.29-30, it could have used the phrase "required by regulation"—as it did elsewhere in the statute. *E.g.*, 7 U.S.C. §136(q)(2)(C)(iv) ("when required by regulation of the Administrator"); *id.* §136a-1(d)(3)(A)(i) ("data that are required by regulation to support the registration of the pesticide"). Instead, Congress made clear that the relevant federal "requirements" in §136v(b) include not just ones imposed *by* FIFRA or *by* regulation; it includes all requirements imposed "*under*" FIFRA—i.e., requirements imposed via agency "action required or permitted by" the statute. U.S. House, *supra*, at 48.

"[W]here Congress includes particular language in one section of a statute but omits it in another

section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983); *see* Antonin Scalia & Bryan A. Garner, *Reading Law* 170 (2012) (instructing that "a material variation in terms suggests a variation in meaning"). Some of FIFRA's provisions, moreover, refer to information "required by *or* under" the statute. *E.g.*, 7 U.S.C. §136j(a)(2)(B)(i) (making it unlawful to refuse to "prepare, maintain, or submit any records *required by or under* section 136c" (emphasis added)); *id.* §136j(a)(2)(B)(ii) (similar); *id.* §136(q)(1)(E) (a pesticide is misbranded if "any word, statement, or other information *required by or under* authority of this subchapter to appear on the label or labeling is not prominently placed thereon" (emphasis added)). The use of the disjunctive in those provisions underscores that "by" and "under" mean different things, and that the latter sweeps more broadly to capture agency requirements imposed under the authority of the statute. *See* Off. of the Legis. Counsel, U.S. Senate, *Legislative Drafting Manual* §304 (1997) ("Use 'by' if the result is achieved by the provision itself. Use 'under' if the result occurs through action required or permitted by the provision.").

Precedent reinforces the conclusion that the pesticide-specific labeling requirements imposed via EPA's pesticide registration process are "requirements for labeling … under" FIFRA. 7 U.S.C. §136v(b). In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), this Court addressed the scope of "a similarly worded" preemption provision in the Medical Device Amendments of 1976 ("MDA"). *Bates*, 544 U.S. at 447 (discussing the MDA). Much like FIFRA, the MDA

prohibits states from imposing any requirement "relat[ing] to the safety or effectiveness" of a medical device that "is different from, or in addition to, any requirement applicable under this chapter," i.e., the MDA. 21 U.S.C. §360k(a). The question in *Riegel* was whether the MDA preempts state tort claims that seek to hold a manufacturer liable for the safety and effectiveness of a medical device marketed in a form that received premarket approval from the Food and Drug Administration ("FDA"). *Riegel*, 552 U.S. at 321-22.

The Court held that FDA's premarket approval process "imposes 'requirements' under the MDA." *Id.* at 322. "Unlike general labeling duties," the Court explained, "premarket approval is specific to individual devices." *Id.* at 322-23. "FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness." *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, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* In other words, 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," it imposes federal "requirements" for purposes of preemption. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996).

For similar reasons, EPA's registration process produces federal "requirements for labeling … under this subchapter" within the meaning of §136v(b). Just as FDA's premarket approval under the MDA "is specific to individual devices," EPA determines on an individual basis what warnings are appropriate and required for a particular pesticide under FIFRA. Just as FDA may grant premarket approval only if it determines that a device is safe and effective, EPA may register a pesticide "only if" it determines that the pesticide does not pose an "unreasonable risk to man or the environment," "is not misbranded as that term is defined in FIFRA," and "its labeling and packaging comply with the applicable requirements of the Act," including that it contains all warnings necessary to protect human health. 40 C.F.R. §§152.40-.55, 152.112(e)-(f), 166.3. And just as the MDA requires a device that has received premarket approval from FDA to be made with almost no deviations, FIFRA makes it illegal to distribute a pesticide with health warnings other than those approved by EPA. *See* 7 U.S.C. §136j(a)(1)(B); 40 C.F.R. §§152.44, 152.46. Thus, EPA determinations made through the registration process impose requirements under FIFRA that bind the manufacturer and specifically identify the "contents required to be included on a pesticide label." *Schaffner*, 113 F.4th at 390.

In light of those precedents and principles, EPA's registration of Monsanto's glyphosate-based Roundup products (including the products at issue in this case) plainly imposes federal labeling "requirements" under FIFRA for purposes of §136v(b). "EPA has repeatedly evaluated the health risks posed by glyphosate," and has repeatedly approved the use of glyphosate as a

pesticide, each time concluding that it is not likely to be carcinogenic to humans. *Id.* at 373.

In 1993, for example, EPA completed glyphosate's statutory re-registration, "determine[d] that glyphosate can be used without resulting in unreasonable adverse effects to man and the environment," and therefore found that "all products containing glyphosate as the active ingredients are eligible for reregistration." *Reregistration Eligibility Decision*, *supra*, at 57. In taking this formal "regulatory action," 7 U.S.C. §136a-1(b)(5), EPA relied on its 1991 decision to "classif[y] glyphosate in Group E (evidence of non-carcinogenicity for humans)." *Reregistration Eligibility Decision*, *supra*, at 14. Similarly, in 2020, EPA issued an interim registration review decision reaffirming its conclusion that glyphosate is not carcinogenic. In doing so, EPA specifically concluded that the substantial "benefits" of glyphosate "outweigh" its risks when "used according to its label instructions." EPA, *Glyphosate Interim Registration Review Decision* 15 (Jan. 2020), https://perma.cc/2YRT-7B6N. While the Ninth Circuit vacated portions of the 2020 interim decision, it emphasized it was not "disrupt[ing] … the status quo," *NRDC*, 38 F.4th at 52, and EPA later reaffirmed, once again, that its "underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic to humans, remain the same." *Supra*, pp.17-18. And EPA has continued to approve glyphosate products without a cancer warning on that basis. *See supra*, p.18.

3. EPA's specific safety determinations that glyphosate does not cause cancer and that a cancer

warning is not necessary suffice to distinguish the unreviewed efficacy statements in *Bates*. In *Bates*, the Court considered whether FIFRA preempted state-law fraud and failure-to-warn claims that were premised on allegedly defective statements about a pesticide's efficacy on its label. The label stated that the pesticide (Strongarm) was "recommended in all areas where peanuts are grown." 544 U.S. at 435. The plaintiffs alleged that when they applied Strongarm to farms with soil having pH levels of 7.2 or higher, the pesticide severely damaged their crops. *Id.* This Court held that the plaintiffs may be able to pursue their claims because (1) their claims concerned the pesticide's efficacy, and EPA "never passed on the accuracy of the statement in Strongarm's original label recommending the product's use 'in all areas where peanuts are grown,'" and (2) the registration did "not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage." *Id.* at 440. In fact, Congress authorized EPA to waive review of pesticide efficacy to focus the agency's efforts on safety and environmental effects. *Id.* So EPA's registration decision did not reflect any Strongarm-specific judgment inconsistent with the plaintiff's state-law claims. *Id.*; *see also Lohr*, 518 U.S. at 498-500.

The same cannot be said about Durnell's claims that Monsanto did not do enough to warn about safety risks to *human health*. EPA is obligated to assess, and has repeatedly assessed, whether glyphosate causes cancer, and its registration of glyphosate products plainly "reflect[s] [a] determination on the part of EPA" that a cancer warning is unnecessary. *Bates*, 544 U.S. at 440. EPA has never required Monsanto to

include a cancer warning on any of its Roundup products, despite numerous registration decisions and repeated evaluations of potential cancer risks. EPA approved hundreds of versions of the label for Monsanto's Roundup-branded products (as well as hundreds of labels for other glyphosate-based herbicides)—without a cancer warning. That includes the labels for the specific Roundup products at issue in this case. JA.186 n.4. EPA's approval of those Roundup labels embodies the agency's substantive judgment that those labels include all warnings "necessary and … adequate to protect health and the environment," and that those products are therefore not "misbranded." 7 U.S.C. §§136(q)(1)(G), 136a(c)(5)(B).

Once EPA approved those labels, FIFRA and EPA regulations precluded Monsanto from making changes without further EPA approval, and prohibited it from distributing the products with a substantially different label. *See supra*, pp.8-9. In fact, EPA specifically confirmed in 2019 that FIFRA not only does not require, but *affirmatively prohibits*, manufacturers from including a state-imposed cancer warning on glyphosate products because such a warning would be "false" and render the products affirmatively "misbranded." *See supra*, pp.16-17. In other words, "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." *Lohr*, 518 U.S. at 501. EPA's registration of Monsanto's glyphosate-based

Roundup products and its approval of their labels thus impose pesticide-specific labeling requirements on Monsanto under FIFRA.

B. Durnell's Failure-to-Warn Claim Imposes State-Law Labeling Requirements That Are in Addition to or Different From Those Required Under FIFRA.

Durnell's failure-to-warn claim imposes state-law labeling requirements that are "in addition to or different from" those imposed under FIFRA. Because the term "requirements" in §136v(b) includes "common-law duties" that "set a standard for a product's labeling," *Bates*, 544 U.S. at 443, 446, Durnell's failure-to-warn claim unquestionably seeks to impose state-law "requirements for labeling." 7 U.S.C. §136v(b).

Those state-law requirements are just as plainly "in addition to or different from" the Roundup-specific labeling requirements imposed under FIFRA. As this Court explained in *Bates*, a state labeling requirement is "in addition to or different from those required under" FIFRA if it "diverges from" those required under FIFRA. 544 U.S. at 452. It is not enough for a state requirement to be "nominally equivalent[]" to a federal requirement or equivalent at some high level of generality. *Id.* at 454. The "state-law labeling requirement must *in fact* be equivalent to a requirement under FIFRA in order to survive pre-emption." *Id.* at 453 (emphasis added). The quintessential example of such a permissible "parallel requirement" is a state-law tort claim that provides a damages remedy for a violation of an existing labeling

requirement imposed under FIFRA. Marketing a product with a label that deviates from the EPA-approved label, for example, violates federal law. *See supra*, pp.8-9. Thus, a state-law tort claim seeking to hold a pesticide manufacturer liable for deviating from the EPA-approved label is fully consistent with §136v(b). Such a claim would not impose an additional or different *requirement*; instead, it would provide a state-law *remedy* for the manufacturer's alleged failure to comply with federal requirements. *Bates*, 544 U.S. at 447-48.

Durnell's failure-to-warn claim, by contrast, is premised on the assertion that Monsanto violated Missouri law by labeling Roundup in conformity with an EPA-approved label. The verdict in Durnell's favor on his failure-to-warn claim necessarily required the jury to find that state law required Monsanto to include in Roundup's label a warning that EPA has deemed unsupported and unnecessary under FIFRA. Such a state-law judgment unquestionably imposes a state-law labeling requirement that is "in addition to or different from" what is "required under" FIFRA. 7 U.S.C. §136v(b). In essence, state law tells the manufacturer to "add this warning," while federal law tells it that it should—indeed, must—stick with the federally required label. Because that verdict requires Monsanto to include a cancer warning that is in addition to those required by the EPA, FIFRA expressly preempts Durnell's failure-to-warn claim.

C. The Missouri Court of Appeals' Contrary Conclusion Cannot be Reconciled With Text or Precedent.

The Missouri Court of Appeals came to a contrary conclusion only by assessing FIFRA's "requirements" at a sky-high level of generality and giving short shrift to Congress' decision to demand uniformity in this vital area. According to the court, Missouri law "is fully consistent with" FIFRA because "both require a pesticide manufacturer to adequately warn users of the potential dangers of using its product." Pet.App.6-7. The court thus viewed the statutory rule requiring manufacturers to include "a warning or caution statement which may be necessary and … adequate to protect health and the environment" as the only relevant "requirement" for purposes of §136v(b). *See* 7 U.S.C. §136(q)(1)(G). That reasoning is flawed from top to bottom.

1. At the outset, assessing FIFRA's requirements at such a high level of generality renders FIFRA's "[u]niformity" provision largely meaningless. Under the court of appeals' approach, virtually all failure-to-warn claims are "consistent" with FIFRA's misbranding provision, because virtually all failure-to-warn claims require (as FIFRA's misbranding provision does) the manufacturer to "adequately warn users of the potential dangers of using its product." Pet.App.7. That approach paves the way for massive variation where Congress demanded uniformity. It allows juries to impose liability for failing to include all manner of warnings, no matter how different they are from what EPA requires. Worse still, different juries in different states would be free to impose

different requirements, thwarting the uniformity Congress sought to achieve. Indeed, many juries have *rejected* materially identical failure-to-warn claims. "State-law duties framed in these vague and broad terms would produce considerable heterogeneity, not uniformity, in the labels that pesticides are required to bear, for different factfinders deciding different individual cases might reasonably disagree about whether a particular warning was necessary to protect health." *Schaffner*, 113 F.4th at 393.

Nothing in FIFRA requires or permits that approach. As explained above, the relevant federal "requirements" are not merely the general misbranding standards set out in FIFRA. They include the Roundup-specific labeling requirements imposed as part of the pesticide registration process. *Supra*, pp.23-34. Durnell resists that conclusion on the ground that "[r]egistration is not even the last word on whether the pesticide's labeling is misbranded," since EPA may institute cancellation proceedings and take enforcement actions if it determines at some point in the future that a registered pesticide is misbranded. BIO.25. But the same could be said about the premarket approval process in *Riegel*. Premarket approval under the MDA does not preclude FDA from later determining that the approved device is not safe and effective. "FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Riegel*, 552 U.S. 319-20. This Court nonetheless held that the premarket approval process

imposes federal "requirements" for purposes of preemption. *Id.* at 322-23. So too here.

If anything, Durnell's argument just underscores that Congress charged EPA, not state juries, with the ongoing responsibility to determine whether a label contains the warnings "necessary … to protect health and the environment," 7 U.S.C. §136(q)(1)(G), and whether "labeling changes" are necessary in light of new information, 40 C.F.R. §155.58(b)(4). FIFRA requires manufacturers to keep EPA up to date on new information "regarding unreasonable adverse effects on the environment." 7 U.S.C. §136d(a)(2); *see also* 40 C.F.R. §159.158(a). And it requires registration review every 15 years. 7 U.S.C. §136a(g)(1)(A)(iii)-(iv). Based on the information it receives, EPA may decline to re-register a pesticide, restrict or revise its application to minimize risk, require changes to the pesticide's label (including by adding new warnings), or initiate cancellation proceedings—though, unlike state juries, EPA is obliged to first consider the implications to food prices and the agricultural economy before cancelling a registration. *Supra*, p.9. But when EPA has done none of the above despite being duly apprised of the relevant information, its registration and label approval decisions—and the federal requirements that flow from those decisions—remain in effect and carry preemptive force.

To be sure, "registration" of a pesticide under FIFRA is not "a defense for the commission of any offense under this subchapter." 7 U.S.C. §136a(f)(2). But it could hardly be otherwise, lest registration preclude a misbranding claim for marketing the product without the EPA-approved label. Indeed,

§136a(f)(2) is not a preemption provision at all; it merely "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). But just because registration is not a defense for the commission of an offense (misbranding or otherwise) under FIFRA does not mean that a state-law failure-to-warn claim like Durnell's can go forward.[6] In *Riegel*, for instance, premarket approval under the MDA did not insulate a manufacturer from agency misbranding charges, *see Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1227 (9th Cir. 2013) (discussing the MDA), yet this Court nevertheless held the approval process imposed specific federal "requirements" for preemption purposes, *see Riegel*, 552 U.S. at 322-23. The same is true under FIFRA. Indeed, this case is more straightforward than *Riegel*, since (unlike the MDA) FIFRA expressly provides that "registration" is "prima facie evidence that [a] pesticide, its labeling and packaging comply with the registration provisions of the subchapter." 7 U.S.C. §136a(f)(2).

In addition to flouting FIFRA's text and structure, the court of appeals' approach cannot be squared with this Court's decisions. This Court has made clear that the question under FIFRA is not whether state and

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[6] Moreover, §136a(f)(2) says only that "registration" itself may not "be construed as a defense." Monsanto does not invoke the bare fact of registration as the basis for its preemption defense. Instead, it relies on both registration *and* EPA's specific determination that a cancer warning for glyphosate-based products is not required under FIFRA.

federal law have "nominally equivalent" labeling standards, but whether the state imposes a labeling requirement for a particular pesticide that is *in fact* different from what EPA requires for that pesticide. *Bates*, 544 U.S. at 453-54. That is why *Bates* explained that FIFRA preempts a state law that requires a "DANGER" label for a particular pesticide when EPA has determined that the label should say "CAUTION" instead. *Id.* If §136a(f)(2) meant that pesticide-specific determinations made during registration cannot support a preemption defense, then the Court's analysis in *Bates* would make no sense. As the Court explained, an EPA regulation "assigns these warnings to particular *classes* of pesticides based on their toxicity." *Id.* (emphasis added). But the regulation does not assign toxicity levels or warning language to any *particular* pesticide; EPA makes that pesticide-specific determination *through the registration process*. *See* 49 Fed. Reg. 37,960, 37,965 (Sept. 26, 1984). Under Durnell's misguided view that §136a(f)(2) makes any agency action done through registration irrelevant for preemption purposes, a state *could* require a "DANGER" warning when EPA requires a "CAUTION" warning, despite this Court's contrary determination in *Bates*.

2. In addition, notwithstanding the appeals court's contrary view, Missouri common law is not "fully consistent with" FIFRA's misbranding provision, even at a high level of generality. *See* CVSG.Br.15-16. 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. The "concept of unreasonable danger … is presented to the jury as an ultimate issue without further definition." *Moore*, 332 S.W.3d at 756. In other words, the jury is given a "general instruction" that allows it to "give the concept of unreasonable danger content 'by applying their collective intelligence and experience to the broad evidentiary spectrum of facts and circumstances presented by the parties.'" *Rodriguez v. Suzuki Motor Co.*, 996 S.W.2d 47, 65 (Mo. 1999) (en banc). While litigants are free "to argue that the utility of a design outweighs its risks," the jury is not required to consider a product's benefits. *Id.* Indeed, Missouri has squarely rejected the position that juries must consider the benefits of a product design in assessing "unreasonable danger." *Id.* (explaining that Missouri "rejected the risk-utility approach" to products liability claims).

Under FIFRA, by contrast, a manufacturer is required to add only warnings that are "necessary and … adequate to protect health and the environment." 7 U.S.C. §136(q)(1)(G). And in determining whether a particular pesticide will pose unreasonable risks to "health and the environment," FIFRA requires EPA to "tak[e] into account the economic, social, and environmental costs *and benefits* of the use of [the] pesticide." *Id.* §136(bb) (emphasis added); *see id.* §136(x). Congress did not enact FIFRA with a single-minded focus on achieving "no-risk." H.R. Rep. No. 94-1105, at 4. Indeed, no pesticide—even one that poses zero risk of cancer—can be made

entirely risk-free given the nature of pesticides. No-risk pesticides would often be no-benefit pesticides, and the resulting risks to crops, farmers' livelihoods, and the food supply would be real. Accordingly, FIFRA strikes a careful balance between ensuring that pesticides are "available to meet pest control needs" while ensuring adequate safety for humans and the environment. S. Rep. No. 95-334, at 3. Adding an unjustified warning is hardly costless: Excessive warnings deter the use of critically important products, and the more warnings included on a label, the less effective each warning becomes. *Cf. Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010) ("While it is important for a manufacturer to warn of potential side effects, it is equally important that it not overwarn because overwarning can deter potentially beneficial uses of the drug by making it seem riskier than warranted and can dilute the effectiveness of valid warnings.").

EPA's regulations thus require the agency to consider both costs and benefits at every step. In deciding whether to register a pesticide, EPA may "not approve an application unless there are available to EPA for its review all data that are necessary to make the required risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7)." 40 C.F.R. §152.85(e). In conducting "registration review," EPA must determine "whether any new data or information on the pesticide" warrant "a new risk/benefit assessment." *Id.* §155.53(a). In assessing whether to impose restrictions on a pesticide's use, EPA must find that the "decrease in risks of the pesticide as a result of restriction would exceed the decrease in benefits." *Id.* §152.170(a)(4); *see id.* §152.171(b) (similar). And

in determining whether to "initiate procedures to cancel, deny, or reclassify registration of a pesticide because uses of that product may cause unreasonable adverse effects on the environment," EPA must "assess[] risks that may be posed by pesticides, and the benefits of use of those pesticides," *id.* §154.1(a)—including "social, economic, and environmental benefits that justify initial or continued registration," *id.* §154.7(a)(5).[7]

Because the jury was not instructed to account for such benefits, it did not apply the same substantive standard that FIFRA instructs EPA to apply in determining whether a pesticide is misbranded. While EPA's registration process involves a "cost-benefit analysis," the jury below "s[aw] only the cost of a more dangerous design." *Riegel*, 552 U.S. at 325.

II. FIFRA Impliedly Preempts Durnell's Failure-To-Warn Claim.

While FIFRA's clear text suffices to foreclose Durnell's failure-to-warn claim, Durnell's claim is doubly preempted because it is "impossible" for Monsanto simultaneously "to comply with both state and federal requirements." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013).

1. When it comes to federal labeling regimes, competing state labeling requirements can put a manufacturer between a rock and a hard place. This

[7] To help it make those determinations, EPA requires manufacturers to disclose "data and information" to enable it "to make regulatory judgments under FIFRA … about the risks and benefits of pesticide products." 40 C.F.R. §158.1(a); *id.* §158.45(a) (similar).

Court's decision in *PLIVA* illustrates the point. There, several plaintiffs sued a generic drug manufacturer for failing to warn about the long-term side effects of taking Reglan, a drug used to treat digestive tract problems. 564 U.S. at 609-10. Federal law, however, does not allow generic drug manufacturers to unilaterally change their labels to add additional warnings that deviate from the label for the brand-name drug. While the manufacturer of the brand-name drug may itself change certain safety warnings without first obtaining FDA permission, *see Wyeth v. Levine*, 555 U.S. 555, 572-73 (2009), a *generic* drug manufacturer may not, since federal law requires generic drugs to carry the same label as their brand-name counterparts, *PLIVA*, 564 U.S. at 613. Because "independently chang[ing] their labels to satisfy their state-law duty" would "violate[] federal law," the plaintiffs' failure-to-warn claims were preempted: It "was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same." *Id.* at 618.

Importantly, it did not matter that the generic drug manufacturer might have persuaded the FDA to initiate a label change. Nor did it matter whether the generic drug manufacturers had a "*federal duty* to ask the FDA for help in strengthening the corresponding brand-name label." *Id.* at 619 (emphasis added). "The question for 'impossibility' is whether the private party could *independently* do under federal law what state law requires of it." *Id.* at 620 (emphasis added). And "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of

judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623-24. Simply put, state tort claims that "place a duty on manufacturers to render a [product] safer" by "altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering … labeling." *Bartlett*, 570 U.S. at 490.

FIFRA prohibits unilateral label changes and gives rise to the same impossibility-preemption defense. Once EPA approved the labels for the glyphosate-based Roundup products at issue in this case, Monsanto was forbidden by FIFRA and EPA regulations from "independently chang[ing]" those labels to add the cancer warning that state law requires. *PLIVA*, 564 U.S. at 618. FIFRA makes it "unlawful" to sell a pesticide with labeling that makes "any claims" "substantially differ[ent]" from the EPA-approved labeling. 7 U.S.C. §136j(a)(1)(B), (2)(G); *see also id.* §136a(a); 40 C.F.R. §§152.44, 152.46. And FIFRA prohibits manufacturers from altering approved labels to add "precautionary statements" without first obtaining EPA approval. *See* 40 C.F.R. §156.70(c); *Pesticide Registration Notice 2000-5*, *supra*; *Pesticide Registration Notice 98-10*, *supra*. As EPA puts it: "The label is the law!" *Pesticide Registration Manual: Introduction*, *supra*. To change that label, a manufacturer must submit an amended registration application that includes all data relevant to the change. *See* 40 C.F.R. §§152.44(a), 152.50. "[T]he application must be approved by [EPA] before the product, as modified, may legally be distributed or sold." *Id.* §152.44(a).

Like the manufacturer in *PLIVA*, therefore, Monsanto could not "satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency." 564 U.S. at 623-24. "Federal law requires a very specific label for [Roundup], and state law forbids the use of that label." *Bartlett*, 570 U.S. at 490. Impossibility preemption thus bars Durnell's failure-to-warn claim.

2. The Missouri Court of Appeals distinguished *PLIVA* on the ground that *PLIVA* interpreted a different statute. Pet.App.11. That is a non sequitur. Precisely because it was an implied-preemption case, *PLIVA* was not narrowly interpreting distinct statutory text, but was articulating general principles that apply whenever a regulated party faces competing state and federal commands that cannot be simultaneously satisfied by the regulated party's own unilateral actions. *See PLIVA*, 564 U.S. at 618-19. That is why the *PLIVA* opinion cites a case arising under a completely different federal statute to articulate the basic standard for impossibility preemption. *See id.* at 618 (citing *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)). Indeed, this Court has recognized in numerous contexts that "[w]hen federal law forbids an action that state law requires, the state law is 'without effect.'" *Bartlett*, 570 U.S. at 486.

Instead of applying *PLIVA*, the Missouri Court of Appeals relied on *Wyeth*. That is ironic because *Wyeth* too arose under a different statute, not FIFRA. And that statute, unlike FIFRA and the provisions governing generic drug manufacturers, "*permits* a

[brand-name] manufacturer to make certain changes to its label *before receiving the agency's approval*." 555 U.S. at 568 (emphasis added). As this Court explained in *PLIVA*, that allowance made all the difference. 564 U.S. at 624. The "federal regulations applicable to Wyeth allowed the company, *of its own volition*, to strengthen its label in compliance with its state tort duty." *Id.* (emphasis added). But when a "private party" may not "*independently* do under federal law what state law requires of it," it is "impossible" for that party "to comply with both state and federal requirements." *Id.* at 618, 620. That is this case. FIFRA prohibits Monsanto from *independently* altering its label to include a cancer warning, as Missouri law would require. Durnell's failure-to-warn claim is thus preempted.

Even if (contrary to fact) agency regulations allowed Monsanto to unilaterally add a cancer warning without prior EPA approval, Durnell's claim would *still* be preempted because Monsanto has put forth "clear evidence" that EPA would ultimately require Monsanto to rescind that warning. *Wyeth*, 555 U.S. at 571; *see also Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 313 (2019). In *Wyeth*, the regulations applicable to brand-name drug manufacturers gave FDA the "authority to eventually rescind Wyeth's unilateral CBE changes," *PLIVA*, 564 U.S. at 624 n.8, "even after the manufacturer has made them," *Merck*, 587 U.S. at 315. As a result, *Wyeth* made clear that notwithstanding the ability of brand-name drug manufacturers to make unilateral label changes, they could still show impossibility preemption if they could muster "clear evidence" that "FDA would have rescinded any change in the label

and thereby demonstrate that it would in fact have been impossible to do under federal law what state law required." *PLIVA*, 564 U.S. at 624 n.8 (discussing *Wyeth*).

Monsanto has mustered more than "clear evidence" here that EPA was "fully informed" of the "justifications for the warning required by state law," and that EPA nevertheless "informed the [pesticide] manufacturer that the [EPA] would not approve changing the [pesticide's] label to include that warning." *Merck*, 587 U.S. at 314. EPA has already made clear how it would "exercise" its "judgment" on the issue. *PLIVA*, 564 U.S. at 624. For decades, EPA has assessed the carcinogenic potential of glyphosate and consistently approved both glyphosate and Roundup's labeling without a cancer warning. *See supra*, pp.11-12. The IARC working group's "hazard identification" prompted further review, but not a change of EPA's considered view (or the views of most nations' regulators, for that matter). *Supra*, pp.14-15. EPA eliminated any possible doubt in 2019 when it informed all glyphosate registrants that, "[g]iven EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,'" EPA considers any warning that glyphosate is carcinogenic "to constitute a false and misleading statement" that violates FIFRA's prohibition against "misbranded" substances. Pet.App.39.[8] And in its 2020 interim registration

[8] EPA suggested in 2022 that it might approve language advising consumers both of California's determination, based solely on IARC, that Roundup poses cancer risks, and of EPA's disagreement with that determination. But EPA subsequently

review decision, EPA reaffirmed its view that glyphosate is not likely to be a human carcinogen, such that a cancer warning was not necessary. While the Ninth Circuit vacated that decision after concluding that EPA failed to offer enough "analysis and explanation" for its conclusion, *NRDC*, 38 F.4th at 52, EPA once again reaffirmed that its "underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic to humans," remain the same. *See supra*, pp.17-18.

The court of appeals insisted that none of EPA's actions carried the "force of law." Pet.App.9-10. But that misses the point, as clear evidence that the agency would have rejected any effort to revise the label can come from materials that do not independently have the force of law. That is particularly true here, when any effort to revise the label to account for IARC conclusions that EPA has already rejected would come in an adjudicatory proceeding that would have the force of law. Regardless, EPA has already taken multiple actions with the force of law that make clear that it would not allow the warnings Missouri law demanded.

First, in conducting its statutorily required re-registration in 1993, EPA engaged in formal statutory

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withdrew that 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* EPA, *Letter to California's Office of Environmental Health Hazard Assessment on California Proposition 65* (last updated May 9, 2025), https://perma.cc/4UFP-Q9MQ. Even if EPA had not withdrawn that letter, it would not help Durnell. He sought a warning that glyphosate would cause cancer, not one explaining the (lopsided) scientific debate over glyphosate.

procedures, *see* 7 U.S.C. §136a-1, and went through the notice-and-comment process before reaffirming its conclusion that "glyphosate products, labeled and used as specified [by EPA], will not pose unreasonable risks or adverse effects to humans." *Reregistration Eligibility Decision*, *supra*, at 57. Second, EPA has notified glyphosate registrants in a letter that it would not approve glyphosate labeling containing a warning that glyphosate causes cancer. Pet.App.38-40. Third, EPA has declined to require a cancer warning through its registration review process or its approval of individual labels—a process that (like the FDA notification requirement discussed in *Merck*) requires EPA to propose "labeling changes" when necessary, 40 C.F.R. §155.58(b)(4), and requires EPA to determine that the label contains all necessary health warnings.

III. Preemption Of Durnell's Claims Is Critical To American Agriculture And Innovation.

Through enactment of FIFRA, Congress established a uniform federal regulatory framework for pesticide labeling designed to promote the development and availability of safe and effective pesticides that are vital to American agriculture and innovation. Allowing a patchwork of state regulatory regimes and empowering state-court juries to second-guess the balance struck by EPA in registering pesticides undermines those critical congressional objectives.

FIFRA precludes registering pesticides that pose "any unreasonable risk to man or the environment." 7 U.S.C. §136(bb). But the key word is "unreasonable." Congress recognized that the very

nature of pesticides means that "there is a degree of risk which must be accepted in order to derive the substantial benefits afforded to society by pesticides." H.R. Rep. No. 94-1105, at 4. Imposing overly stringent regulatory requirements on pesticide manufacturers is not cost-free. It could severely restrict the ability of farmers to combat pests that could threaten both the food supply and the economic viability of American agriculture. Moreover, farmers will not unilaterally disarm in the fight against pests. Accordingly, keeping efficacious pesticides off the market based on purported risks that EPA has determined are unfounded, or based on risks that are real but reasonable, will cause farmers to resort to products that may create equal (or worse) health and environmental risks, while providing inferior protection for crops. Congress therefore crafted FIFRA to strike a careful balance between ensuring that pesticides are available to meet the country's pest control needs and ensuring adequate safety for humans and the environment. *See supra*, pp.6, 22.

Preemption (whether express or implied) of state-law tort suits like Durnell's is essential to protecting that judgment and achieving that balance. Subjecting manufacturers to a patchwork of overlapping and potentially inconsistent state-law labeling requirements imposed on a case-by-case basis by lay juries would substantially complicate manufacturers' efforts to market effective pesticides. The Roundup litigation is a case in point. Despite consistent findings by EPA and worldwide regulators that glyphosate does not pose a cancer risk, and EPA's express rejection of IARC's contrary view, plaintiffs have parlayed that IARC finding into over one

hundred thousand lawsuits seeking billions and billions in liability.[9] The kind of unnecessary excess warning they seek has real costs. An oversaturation of warnings for minor or non-existent risks will deter beneficial uses of the pesticide and "diminish the believability and credibility of warnings in general, [as] such warnings are tantamount to 'crying wolf.'" *Wheat Growers*, 85 F.4th at 1277 (quoting *CTIA v. City of Berkeley*, 928 F.3d 832, 854-55 (9th Cir. 2019) (Friedland, J., dissenting in part)).

Worse still, lay juries are ill-equipped to understand the limitations in the official-sounding IARC hazard determination, such as the absence of peer review and the failure to consider countless studies included in EPA's far more comprehensive review. Moreover, a lay jury sees only an injured plaintiff suffering an awful disease, albeit one that befalls countless Americans with no exposure to glyphosate. That jury does not see the countless farmers who benefit from using Roundup and desperately want it to remain available. *See* Am.Farm.Bureau.Fed'n.Br.14-17.

The costs in the case of Roundup are real. The retail version of the glyphosate-based product has

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[9] Despite EPA's consistent registration of Roundup and rejection of the need for cancer warnings, Monsanto has faced billions of dollars in potential Roundup-related liabilities, as dramatically illustrated by a recently announced proposed class settlement for a subset of Roundup claims totaling up to $7.25 billion. The settlement does not affect this case or resolve nearly $1 billion in liability for pending appeals and other claims falling outside the settlement. Resolution of this case remains critical for those unresolved cases, for any opt-out cases, and for the future of the pesticides as commercially viable products.

been removed from shelves because as long as state-law liability looms, selling is not commercially viable. The commercial and agricultural versions remain available for the time being, but the economics of continuing to market the product remain in substantial doubt, despite the EPA's repeated examination and rejection of claimed cancer risks. The elimination of glyphosate-based herbicides from the market would be devastating for the agricultural economy. Indeed, just recently, the President underscored that the "reduction or the cessation of domestic production" of "glyphosate-based herbicides would … hav[e] a debilitating impact on domestic agricultural capabilities." Exec. Order No. 14387, *supra*, §1.

The threat is not just to existing products, but to the incentives to develop the next generation of even better pesticides. Given the nature of pesticides, there is no such thing as a no-risk pesticide. And if the ultimate result of exhaustive research-and-development efforts is equally exhaustive state-court litigation under the varying laws of 50 states, then the whole game is not worth the candle. Congress created the right incentives by empowering EPA to strike a balance between meeting the needs of farmers and managing inevitable (but not unreasonable) risks, including through labels that neither under- nor over-warn. Congress then protected the balance struck by EPA by including an express preemption provision and a regime that does not place manufacturers of EPA-registered pesticides between a rock and a hard place. This Court should vindicate Congress' judgment and reverse the judgment below.

CONCLUSION

This Court should reverse.

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STATUTORY APPENDIX

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7 U.S.C. §136. Definitions

For purposes of this subchapter—

* * *

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under

customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter—

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

* * *

(x) Protect health and the environment

The terms "protect health and the environment" and "protection of health and the environment" mean protection against any unreasonable adverse effects on the environment.

* * *

(bb) Unreasonable adverse effects on the environment

The term "unreasonable adverse effects on the environment" means (1) 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, or (2) a human dietary risk from

residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

* * *

7 U.S.C. §136v. Authority of States

(a) In general

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

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

(c) Additional uses

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration

under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State.

(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.

(3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal Food, Drug, and Cosmetic Act that permits the residues of the pesticides on the food or feed. If the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of, a pesticide under a registration issued by a State constitutes an imminent hazard, the Administrator may immediately disapprove the registration.

(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 136w of this title, that a State is not

capable of exercising adequate controls to assure that State registration under this section will be in accord with the purposes of this subchapter or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond.