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—EASTERN DISTRICT

BRIEF OF CROPLIFE AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER MONSANTO COMPANY

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INTEREST OF AMICUS CURIAE

Established in 1933, CropLife America is the national trade association for the pesticide industry, representing developers, manufacturers, formulators, and distributors of pesticides and plant science solutions. CropLife America's member companies produce, sell, and distribute pesticides, including herbicides, insecticides, and fungicides, which American farmers use to provide consumers with abundant food, fuel, and fiber. CropLife America is committed to safe and responsible use of the industry's products.[1]

CropLife America's members are deeply invested in the discovery and development of new pesticide products and product uses. The U.S. Environmental Protection Agency ("EPA" or "the Agency") makes its pesticide registration decisions based on a thorough review of current scientific and technical information provided by pesticide manufacturers—including many CropLife America member companies—at significant cost to the manufacturers. EPA publishes a list of more than 300 possible scientific tests that may be required as part of a single pesticide's registration, with dozens of those tests each costing in the hundreds of thousands of dollars and some tests costing in

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[1] No counsel for either party authored this brief in whole or in part, nor did such counsel, any party, or other person other than amicus curiae, its members, and its counsel make a monetary contribution intended to fund this brief's preparation or submission. Monsanto Company's ("Monsanto") parent company, Bayer Corp., is a member of CropLife America and pays member dues but did not contribute any money specifically intended to fund preparation or submission of this brief.

the millions.[2] For instance, EPA estimates the average cost of "Combined Chronic Toxicity/ Carcinogenicity Testing of Respirable Fibrous Particles (inhalation route)," just one of the myriad tests that can be required as part of a pesticide registration, to exceed $5 million.[3] Pesticide manufacturers spend, on average, $301 million and more than 12 years on research, development, and registration to bring each new active ingredient for crop protection products to the marketplace.[4]

Given that investment, CropLife America's members are intimately familiar with the comprehensive regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). 7 U.S.C. § 136 *et seq*. CropLife America member companies have a keen interest in FIFRA's legal framework, especially the interrelationship between federal and state pesticide regulation and the statute's application to glyphosate-based products in this and similar cases.

FIFRA preempts any state law requirements that seek to vary an EPA-approved label, especially when, as in this case, EPA has carefully reviewed the science

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[2] U.S. Environmental Protection Agency, "Cost Estimates of Studies Required for Pesticide Registration," April 2025, https://www.epa.gov/system/files/documents/2025-04/test-cost-estimates-2025-04-25.pdf.

[3] *Id.* at 5 (Test Guideline 870.3355).

[4] *See* AgbioInvestor, "Time and Cost of New Agrochemical Product Discovery, Development, and Registration," A Study on Behalf of Crop Life International (Feb. 2024), Executive Summary 5-6, https://tinyurl.com/yu3pjshv.

and determined that the plaintiff's desired health and safety warning is not supported. A state pesticide regulator cannot impose additional or conflicting labeling requirements forcing registrants to warn of health risks that EPA has not itself imposed as part of its registration review and label approval process. For the same reason, a lay jury applying state tort law cannot penalize a registrant for not including a health and safety warning on its label that EPA has affirmatively rejected as part of its federal regulation of that pesticide label.

CropLife America and its members have extensive experience and expertise with respect to FIFRA's labeling regulation. CropLife America files this brief as an *amicus curiae* to assist the Court's understanding of FIFRA's pesticide registration and registration review process and the preemptive effect of EPA's label review determinations. A comprehensive understanding of that process—which, here, has resulted in EPA's repeated determinations that glyphosate-based pesticides are unlikely to cause cancer and that a cancer warning should not be included on the product labels—compels reversal of the Missouri court's preemption holding and the jury verdict against Monsanto.

SUMMARY OF ARGUMENT

This Court should reverse the decision below. The Missouri court's decision—like the Ninth and Eleventh Circuit decisions it follows—is manifestly wrong. Once EPA approves a pesticide label, the label must accompany the pesticide's distribution and sale and cannot be modified without EPA's prior approval. As

EPA has consistently declared, the EPA-approved "label is the law."[5] FIFRA expressly preempts any state law, including state common law, that would modify that EPA-approved label.

FIFRA's statutory and regulatory provisions work together to preempt Missouri's common law duty-to-warn cause of action. First, FIFRA's "Uniformity" provision commands that States "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b). Second, among the "requirements" of federal law promoted and protected by FIFRA's Uniformity provision is EPA's preapproval requirement for label modifications, 40 C.F.R. § 152.44(a) (the "Preapproval Regulation"). Section 152.44(a) provides that, once approved by EPA as part of a pesticide's registration, a pesticide label generally may not be modified without EPA review and approval. *Id.*

Read together, as the Third Circuit correctly did in its recent *Schaffner* decision, FIFRA and its regulatory provisions prohibit a state from imposing liability for a pesticide manufacturer's failure to provide a human health warning different from the label approved by EPA. *See Schaffner* v. *Monsanto Corp.*, 113 F.4th 364, 386-88 (3d Cir. 2024). A lay jury applying Missouri's common law duty-to-warn thus cannot impose liability on a pesticide manufacturer based on its purported failure to provide additional warnings not included within EPA's approved label.

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[5] U.S. Environmental Protection Agency, "Introduction to Pesticide Labels" (April 2025), https://tinyurl.com/5n8kdeh2.

The Missouri jury nevertheless found Monsanto liable under state law for failing to include a cancer warning on its glyphosate-based pesticide that EPA has explicitly and repeatedly found scientifically unsupported and unnecessary. In upholding that verdict, the Missouri Court of Appeals erroneously held that the only relevant federal "requirement" for purposes of FIFRA's Uniformity provision is the statute's command that a pesticide not be misbranded. *See* 7 U.S.C. § 136(q)(1)(G). Under the Missouri court's view, FIFRA's Uniformity provision permits a state labeling requirement where the state law's purpose is also to protect public health and the environment through adequate labeling.

This myopic reading of FIFRA's regulatory provisions overlooks both the critical scientific determinations made by EPA in approving the contents of a pesticide label and the unalterable nature of the label without prior EPA approval. After extensive study of the relevant science as part of multiple pesticide registrations and registration reviews, EPA has determined that the science does not support a warning that glyphosate causes cancer and has approved a pesticide label that intentionally omits such a warning. Monsanto cannot modify that approved label without EPA's prior approval in an amended registration. 40 C.F.R. § 152.44(a).

Thus, regardless of the purported *purpose* of Missouri's state common law cause of action, a registrant cannot comply with both state and federal *requirements*. That much should be clear when state law purports to require a warning that federal law has explicitly rejected. Here, state law would mandate the

modification of a pesticide label (by imposing monetary liability for failure to provide a state jury's preferred warning) without EPA's mandatory prior approval under 40 C.F.R. § 152.44(a). FIFRA's express preemption provision bars state law from doing so.

This conclusion follows from a pair of this Court's decisions, *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005), and *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008). *Bates* held that, under FIFRA's express preemption provision, state-law requirements must "be measured against any relevant EPA regulations that give content to FIFRA's misbranding standard." *Id*. at 453. As framed there, however, the Court did not consider "any EPA regulations that further refine those general standards." *Id*. at 453 & n.27. Here, by contrast, Monsanto correctly argues that the federal "requirements" protected by express preemption include EPA's labeling regulations implementing EPA's registration scheme and its misbranding prohibition, including 40 C.F.R. § 152.44(a)'s pre-approval requirement.

That difference makes EPA's pesticide labeling decisions here more like the FDA medical device approval process in *Riegel*. In *Riegel*, this Court held that an express preemption provision in the Medical Device Amendments of 1976 preempted state law causes of action challenging the safety of an FDA-approved device. Applying a preemption provision identical in relevant respect to FIFRA's, *Riegel* reasoned that the FDA review and approval process imposed federal "requirements" specific to a particular device that could not be altered or added to by a

state common law. Read together, *Bates* and *Riegel* compel the conclusion that, under FIFRA and its implementing regulations, Missouri state law cannot alter an EPA-approved label omitting a cancer warning for Monsanto's glyphosate-based pesticides.

The lower-court decisions that have rejected FIFRA preemption in this context place undue weight on *Bates*'s remand for further consideration of whether FIFRA preempted a Texas failure-to-warn claim challening a pesticide label's efficacy claims. But there, EPA had expliclity waived review of the pesticide's efficacy claim. Approval of the label therefore 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." 544 U.S. at 440 (citing EPA Pesticide Registration Notice 96-4). Here, by contrast, in registering a glyphosate-based pesticide, EPA has extensively reviewed the relevant science to determine the human health warnings that are required on the product label. That review led EPA to repeatedly reject the need for a cancer warning and approve glyphosate-based pestiside labels that omitted such a warning.

The same decisions that have rejected FIFRA preemption also erroneously rely on 7 U.S.C. § 136a(f)(2), which provides that registration of a pesticide shall not be "construed as a defense for the commission of any offense under" FIFRA. But that provision is not relevant to preemption. It is a vestige of the original 1947 statute, which required the federal government to register a pesticide even when it had concluded that the requirements of FIFRA were

not satisfied. But even if applicable, 7 U.S.C. § 136a(f)(2) does not allow a reviewing court to ignore EPA's labeling determinations made as part of a pesticide registration and registration review.

The Missouri jury's seven-figure verdict is just the tip of the spear threatening the most effective and widely used commercial pesticide in the United States. In a handful of those cases where a jury has been allowed to second-guess EPA's expert science-based labeling judgment, the awards have been staggering—with two recent jury verdicts exceeding $2 billion. Like those decisions, the Missouri jury verdict runs counter to the uniformity required by FIFRA and violates FIFRA's Uniformity provision.

Monsanto makes compelling arguments establishing that Missouri's regulation of its glyphosate-based product labels are also impliedly preempted by FIFRA's regulatory scheme, especially in light of the impossibility of complying with both state and federal labeling requirements. *See* Monsanto Br. at 45–46. CropLife America agrees fully with Monsanto that implied preemption principles require reversal here as well. This brief focuses, however, on express preemption, which is sufficient alone to support reversal. FIFRA's Uniformity provision requires that this Court reverse the Missouri Court of Appeals' decision and hold that Plaintiff's state duty-to-warn claims are preempted.

ARGUMENT

I. FIFRA EXPRESSLY PREEMPTS MISSOURI'S INCONSISTENT STATE LABELING REQUIREMENTS

A. FIFRA's Uniformity Provision Expressly Preempts Inconsistent and Additional State Common Law Duties

State law is expressly preempted when Congress "has prohibited state regulation of the particular aspects of commerce involved in this case." *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977). FIFRA's "Uniformity" provision expressly targets state labeling laws, providing that a State "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" that statute. 7 U.S.C. § 136v(b).

In *Bates*, this Court held that preemption by FIFRA's Uniformity provision "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." 544 U.S. at 443. The Court reasoned that common law causes of action, like Missouri's common law duty to warn, are preempted when they both establish a requirement for labeling or packaging and impose such a requirement that is "in addition to or different from" those required by FIFRA. *Id.* at 444. Whether established by state positive law or common law, FIFRA's Uniformity provision "pre-empts competing state labeling standards—imagine 50 different labeling regimes prescribing the color, font size, and *wording of warnings*—that would create significant inefficiencies for manufacturers." *Id.* at 452 (emphasis added).

The Uniformity provision requires the Court to compare the common law cause of action to FIFRA's statutory standards, including the requirement that labels not contain "false or misleading statements." *Id.* at 453 (citing 7 U.S.C. § 136(q)(1)(A)). Critically, the Court emphasized that "[s]tate-law requirements must also be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." *Id.* at 453. The Court provided a telling illustration of such a comparison: "For example, a failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted because it is inconsistent with" FIFRA regulations addressing labeling requirements for pesticide toxicity. *Id.*

Here, FIFRA's Uniformity provision expressly prohibits state requirements for human health warnings on EPA-approved pesticide labels that add to or differ from EPA's approved pesticide label. Because, as described below, Missouri's state duty-to-warn common law tort establishes such an inconsistent state law requirement, Plaintiff's Missouri tort claims are preempted.

B. Under FIFRA, the EPA-Approved Label Is the Law

Monsanto's label—which, as approved by EPA intentionally omits the cancer warning that Plaintiff's lawsuit seeks—establishes a federal "requirement" protected by FIFRA's Uniformity provision. To understand that conclusion, it is helpful to delve into FIFRA's regulation of pesticide labeling, which gives binding legal significance to EPA's approval.

FIFRA is a "comprehensive regulatory statute" governing the sale, use, and labeling of "pesticides." *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 987, 991 (1984). FIFRA defines "pesticide" to include "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest" (7 U.S.C. § 136(u)) and encompasses glyphosate-based herbicides like Monsanto's Roundup® products. *See* 40 C.F.R. § 152.5(c) (defining "pest" to include "any plant growing where not wanted")

FIFRA and its implementing regulations require EPA to review and approve the pesticide label, including necessary human health and safety warnings, and generally prohibit any change to that label without EPA approval. Once approved by EPA, the "label is the law." *See supra* n.5.

1. EPA approves the product label as part of its pesticide registration and registration review processes. FIFRA prohibits the sale of "any pesticide that is not registered." 7 U.S.C. § 136a(a). EPA "shall register a pesticide" only if it determines that, "when considered with any restrictions imposed," the pesticide meets four general requirements: 1) its composition is such as to warrant the proposed claims for it; 2) its labeling complies with FIFRA's requirements; 3) it will perform its intended function without unreasonable adverse effects on the environment; and 4) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment. 7 U.S.C. § 136a(c)(5).

FIFRA defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to

man or the environment," a calculus that requires EPA to balance the "economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb). It also includes consideration of any "human dietary risk from residues that result from a use of a pesticide" on food inconsistent with Federal Food, Drug, and Cosmetic Act safety standards. *See id.*

After a pesticide is registered, EPA must conduct a registration review every 15 years to determine whether the pesticide continues to satisfy registration standards. *See* 7 U.S.C. § 136a(g); 40 C.F.R. §§ 155.40–155.58. This process involves an up-to-date review of the relevant science under notice-and-comment procedures. *See* 40 C.F.R. §§ 155.50(b), (c); *see also* 40 C.F.R. § 155.58(b)(4) (requiring EPA to specify proposed labeling changes as part of registration review).

2. The pesticide label is a central focus of EPA's registration and registration review processes. EPA reviews a pesticide label to ensure that, among other things, it contains warnings and cautionary statements "adequate to protect health and the environment," and that it does not contain any "statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading." 7 U.S.C. §§ 136(q)(1)(A), (G).

"Pesticide product labels provide critical information about how to safely and legally handle and apply pesticides." EPA, Office of Pesticide Programs,

Label Review Manual 1-2.[6] A "critical function of the label is to translate the results of the science evaluations into a set of conditions, directions, precautions, and restrictions that define who may use a pesticide, as well as where, how, how much, and how often it may be used." *Id.* The accuracy of the label is "vital" to EPA's (and other governmental agencies') management and mitigation of pesticide risks; to these agencies' enforcement of pesticide production, distribution-and-sale, and use requirements; to registrants, including manufacturers and distributors; to applicators, who rely on the label for use instructions and hazard and safety information; and to the general public. *Id.*

EPA's regulations govern not only the size, format, and location of the label but also its contents. *See, e.g.*, 40 C.F.R. § 156.10. Pesticide labels convey information such as application rates, application intervals, and required personal protective equipment. Many other details are required, such as the product's contents, the sites of application, the target pests, and the application methods.

The label also contains important health and safety information, such as the applicable acute toxicity category and associated signal word determined by EPA (*see* 40 C.F.R. §§ 156.62, 156.64) and hazard and precautionary statements for humans and domestic animals (40 C.F.R. §§ 156.70–.78) and for the environment, including non-target organisms (40 C.F.R. §§ 156.80–156.85). Hazard and

[6] https://www.epa.gov/system/files/documents/2024-12/label_review_manual_12122024.pdf.

precautionary statements for humans and domestic animals include information on first aid, in case of unintended exposure to the pesticide. *See* 40 C.F.R. § 156.68. The label must also include directions for storage, residue removal, and disposal of the pesticide and its container (*see, e.g.*, 40 C.F.R. §§ 156.140, 156.144, 156.146, 156.156).

EPA will not approve a proposed label or grant a registration if the label is missing any required information. *E.g.*, 40 C.F.R. §§ 156.10(a)(1), 152.112(f). FIFRA explicitly prohibits the distribution and sale of a pesticide with a label that differs from that approved by EPA. A product label that omits these key statements, contains false or misleading statements, or that adds claims, warnings, or uses not approved by EPA, is considered a "misbranded" pesticide, and its distribution and sale are unlawful. 7 U.S.C. §§ 136j(a)(1)(E), 136j(a)(2)(A), 136(q)(1)(A), (G). Distributing or selling a misbranded pesticide may result in civil or criminal penalties as well as stop sale, use, and removal orders and seizure. 7 U.S.C. §§ 136k, 136*l*.

With narrow exceptions for certain "minor" modifications not relevant here, once the label is approved as part of pesticide registration, "any modification in the . . . labeling . . . of a registered product must be submitted with an application for amended registration . . . [and such] application must be approved by the Agency before the product, as modified, may legally be distributed or sold." 40 C.F.R. § 152.44(a). Changes in precautionary statements are not "minor

modifications" and must be approved in advance by EPA.[7] *See Schaffner*, 113 F.4th at 385, 384 n.11.

C. EPA Thoroughly Reviewed the Health and Safety Effects of Monsanto's Glyphosate Pesticide

1. EPA approves a pesticide label only after exhaustive review of the best available science relating to the pesticide's effects on safety and human health. EPA's Pesticide Registration Manual explains that "[b]efore any pesticide product that EPA has not exempted from registration requirements can be lawfully sold or distributed, EPA performs a rigorous, comprehensive scientific assessment of the product, resulting in a registration decision."[8]

FIFRA and its implementing regulations require registrants to provide substantial scientific data to support a pesticide's safety and health effects. 7 U.S.C. §§ 136a(c)(1)(F) & (c)(2)(A); 40 C.F.R. § 158.500(d) (toxicology data requirements); *see generally* 40 C.F.R. pt. 158. There are substantial data requirements addressing the toxicology of the pesticide, including studies relating to the likelihood that a particular pesticide could cause cancer in laboratory rodents. 40 C.F.R. § 158.500(d). EPA regulations require registrants to satisfy data requirements

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[7] EPA, Office of Pesticide Programs, Pesticide Registration Notice 98-10: Notifications, Non-Notifications and Minor Formulation Amendments at 8 (Oct. 22, 1998), https://tinyurl.com/mtycc4bp.

[8] *See* EPA Pesticide Registration Manual: Introduction, https://www.epa.gov/system/files/documents/2021-08/pesticide-registration-manual-introduction.pdf.

covering a broad range of additional topics, including: the physical and chemical makeup of the pesticide; the acute, sub-chronic, and chronic toxicity of the pesticide; the effect of the pesticide on various plants and animals; the degree to which humans will be exposed to the pesticide during its intended use; whether the pesticide will spread (or "drift") from the area to which it was applied; what happens to the pesticide in the environment (*e.g.*, whether it breaks down quickly and whether it stays in soil or moves to water); and how much of the pesticide remains as a residue in the crops to which it is applied. *See, e.g.*, 40 C.F.R. pt. 158. Registrants are required to follow standardized practices to ensure that registration data are uniform, reproducible, and otherwise have adequate quality and scientific integrity. 40 C.F.R. pt. 160 (prescribing good laboratory practice standards).

EPA uses registration data to identify the potential for various adverse effects such as neurotoxicity, reproductive and developmental toxicity, cancer, and immunotoxicity. *E.g.,* 40 C.F.R. § 158.500(e)(19) (prescribing minimum acceptable study durations for studies that combine chronic oral toxicity and carcinogenicity); 40 C.F.R. §§ 158.1000–1070 (testing for human exposure); *see also, e.g.*, EPA Health Effects test Guideline 870.4200 (Carcinogenicity);[9] EPA, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005).[10] EPA develops dose-response assessments (determining the relationship between the dose and

[9] *See* https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0020.

[10] *See* https://perma.cc/86MQ-MG3W.

potential toxic effects) for a wide variety of species (*e.g.*, humans to fish) and a wide variety of potential responses (*e.g.,* acute effects on skin or eyes, chronic neurological or reproductive effects, and carcinogenicity). *E.g.*, 40 C.F.R. § 158.130 ("Purposes of the registration data requirements"). EPA evaluates effects at potential levels of exposure and models impact on survival, growth, and reproduction of surrogate species. 40 C.F.R. pt. 158, Subpart G (data requirements relating to ecological effects), Subpart K (data requirements relating to human exposure during and after pesticide application).

2. In light of these rigorous standards, EPA's decision *not* to require a cancer warning for glyphosate-based pesticides was no accident. It was the result of decades of evaluation of the relevant scientific evidence. The approved label reflects EPA's repeated conclusion that glyphosate-based pesticides *do not cause cancer*. EPA issued its initial glyphosate registration in 1974 and issued a Reregistration Eligibility Decision for the active ingredient glyphosate in 1993, after a thorough examination of the underlying data.[11] In more than 50 years since the original registration, EPA has concluded again and again that glyphosate does not pose a cancer risk to humans.

Acting on the recommendation of a scientific peer review committee in the early 1990s, EPA found

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[11] *See* EPA, *Ingredients Used in Pesticide Products: Glyphosate*, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate; EPA, *Reregistration Eligibility Decision (RED): Glyphosate* (Sept. 1993), https://tinyurl.com/4rewtdnp.

"evidence of non-carcinogenicity for humans."[12] The Agency reiterated that finding in a formal rule in 1997 and again in subsequent rulemakings.[13]

In 2009, EPA opened its most recent registration review, which has entailed extensive review of glyphosate's environmental safety and toxicology data after numerous rounds of public notice and comment. After review by both EPA's Cancer Assessment Review Committee and a Scientific Advisory Panel, EPA published a Revised Glyphosate Issue Paper evaluating the pesticide's carcinogenic potential.[14] This extensive review of "new science" included assessment of "63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies for the active ingredient glyphosate."[15] EPA concluded that "available data and weight-of-evidence clearly do not support the descriptors 'carcinogenic to humans'" or "'likely to be carcinogenic to humans.'"[16] Instead, the

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[12] *See* EPA, R.E.D. Facts, Glyphosate, at 2 (Sept. 1993), https://tinyurl.com/4rpwv9bz.

[13] Final Rule: Glyphosate; Pesticide Tolerances, 62 Fed. Reg. 17,723, 17,724 (Apr. 11, 1997); *see also* Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,936 (Sept. 27, 2002); Final Rule: Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008).

[14] *See* EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017), https://tinyurl.com/56xb5bed.

[15] *Id.* at 144.

[16] *Id.*

scientific evidence most strongly supports the description "not likely to be carcinogenic to humans."[17]

Notably, EPA concluded this assessment *after* the International Agency for Research of Cancer (IARC) announced its view, upon which glyphosate plaintiffs nationwide base their claims, that glyphosate was a probable carcinogen. EPA's scientific review led to its Draft Human Health Risk Assessment, which, after notice and comment, concluded that glyphosate was not likely to cause cancer.[18] After considering thousands of public comments, EPA issued its "Proposed Interim Registration Review Decision," reaffirming that its "independent evaluation of the carcinogenic potential of glyphosate . . . has determined that glyphosate is 'not likely to be carcinogenic to humans.'"[19] EPA expressly rejected IARC's cancer conclusion, explaining that EPA's "cancer evaluation is more robust than IARC's evaluation," which "only considered a subset of the studies included in the EPA's evaluation" and included "some studies that were not appropriate for determining the human carcinogenic potential of glyphosate."[20]

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[17] *Id.*

[18] *See* EPA, Glyphosate: Draft Human Health Risk Assessment in Support of Registration Review, Case No. 0178 (Dec. 12, 2017), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0068.

[19] *See* EPA, Glyphosate: Proposed Interim Registration Review Decision, Case No. 0178, at 7 (Apr. 2019), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2344.

[20] *Id.*

After this extensive process, EPA's Office of Pesticide Programs sent an August 2019 letter to all glyphosate registrants reiterating that it "disagrees with IARC's assessment of glyphosate."[21] EPA noted that its cancer classification is "consistent with other international expert panels and regulatory authorities," including government regulators in Canada, Australia, and New Zealand, as well as the European Food Safety Authority and European Chemicals Agency.[22] EPA notified registrants that glyphosate products that *do* bear a cancer warning would be "misbranded pursuant to" FIFRA.[23]

In January 2020, following another comment period, EPA issued its interim registration review decision, reaffirming its longstanding conclusion that glyphosate does not cause cancer in humans.[24] After that determination was challenged in litigation, the

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[21] EPA, Letter to Glyphosate Registrants on California Proposition 65, at 1 (Aug. 7, 2019) ("EPA Letter"), https://tinyurl.com/53eb7685.

[22] *Id.*; *see, e.g.*, European Food Safety Authority, Glyphosate: no critical areas of concern; data gaps identified (July 6, 2023) (European Chemicals Agency concluding that glyphosate "did not meet the scientific criteria to be classified as a carcinogenic, mutagenic or reprotoxic substance"), https://tinyurl.com/ywbkvdus; European Chemicals Agency, Glyphosate: no change proposed to hazard classification (May 30, 2022) ("classifying glyphosate as a carcinogen is not justified"), https://tinyurl.com/yeywmrfz.

[23] EPA Letter 1.

[24] *See* EPA, Glyphosate: Interim Registration Review Decision, Case No. 0178, at 5 (Jan. 2020), https://tinyurl.com/2s9ht99v.

Ninth Circuit vacated the interim registration review decision, and EPA subsequently withdrew the decision. *See Nat. Res. Def. Council* v. *EPA*, 38 F.4th 34, 52 (9th Cir. 2022). In light of those developments, EPA "is currently updating its evaluation of the carcinogenic potential of glyphosate *to better explain its findings* and include the current relevant scientific information."[25] Even so, EPA has emphasized that its "scientific findings regarding glyphosate, including its longstanding finding that glyphosate is not likely to be carcinogenic to humans" may still be used "as support for a future decision."[26]

Consistent with that view and with its longstanding review of the science, EPA continues to approve glyphosate-based pesticide labels without a cancer warning and has never approved changes to Monsanto's glyphosate product labeling to add a cancer warning.

D. The Jury Verdict Imposes Inconsistent and Additional State Law Requirements in Violation of FIFRA's Uniformity Provision

Measured against this regulatory background and history, Plaintiff's state-law duty-to-warn cause of action is expressly preempted. EPA has repeatedly determined that the specific cancer warning at issue here is not supported by the relevant science. Once approved by EPA, a pesticide label reflecting that

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[25] EPA website "Glyphosate," https://www.epa.gov/ingredients-used-pesticide-products/ glyphosate (emphasis added).

[26] *Id.*

judgment cannot be modified without explicit EPA approval. The Missouri jury based its verdict on such an unapproved modification, finding Monsanto liable under state law for failing to include a cancer warning that EPA has rejected as part of the approved label. FIFRA's Uniformity provision expressly preempts such inconsistent and additional state-law requirements.

The Missouri Court of Appeals reached its contrary conclusion by following the flawed decisions in *Hardeman* v. *Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021), and *Carson* v. *Monsanto Co.,* 92 F.4th 980 (11th Cir. 2024). But *Hardeman* and *Carson* misconstrued *Bates*, which holds that FIFRA "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA *and its implementing regulations*." 544 U.S. at 443–44, 452 (emphasis added).

In *Bates*, the parties did not identify "any EPA regulations that further refine" FIFRA's statutory provisions. *Id.* at 453 n.27. In this case, however, Monsanto has consistently pointed to such regulations. EPA regulations "that give content" to FIFRA's statutory standards include 40 C.F.R. § 152.44. *See Schaffner*, 113 F.4th at 381 (discussing the "Preapproval Regulation").

No less than the regulatory "DANGER" and "CAUTION" labeling requirements discussed in *Bates, see* 544 U.S. at 453, EPA's Preapproval Regulation gives content to FIFRA's misbranding standards. *See Schaffner*, 113 F.4th at 391. That regulation "prohibited Monsanto from modifying Roundup's Preapproved Label" to add a state-compelled cancer

warning because the regulation prohibits modifying the label absent approval by EPA of an amended registration. *Id.* at 381, 382–85. *Bates* requires that FIFRA's express preemption analysis "must involve a comparison [of the state law requirements] to the Preapproval Regulation." *Schaffner*, 113 F.4th at 381–382.

The relevant "requirements" do not end there. 40 C.F.R. § 156.70 sets out requirements for human hazard and related precautionary statement on pesticide labels, prescribing both the content and location for these required statements. "When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect." *Id.* § 156.70(b). As with the label Preapproval Regulation discussed in *Schaffner*, Section 156.70 requires EPA pre-approval of any statement pertaining to the hazards of a product or its uses. 40 C.F.R. § 156.70(c) ("Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency.").

Read together, FIFRA and its regulations make clear that the EPA-approved label *itself* is also a federal "requirement" protected by FIFRA's Uniformity provision. To this day, EPA continues to approve glyphosate-based pesticide labels that deliberately omit cancer warnings. EPA has not approved any relevant amendment to Monsanto's label to accommodate the contrary jury determination applying Missouri law in this case. A Missouri jury,

applying state law, *cannot* require a cancer warning not approved by EPA for inclusion on the label.

This conclusion follows from *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008), where this Court held, under a similarly worded preemption provision, that FDA's premarket approval of medical devices barred state common-law claims challenging the safety or effectiveness of a medical device marketed in a form that received premarket approval from the FDA. Like the FIFRA regime, the FDA regulatory provisions at issue provided that, once a specific device received premarket approval, federal law "forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Instead, FDA must approve any changes to that device's premarket approval. *Id.* This Court reasoned that this premarket review process imposed federal "requirements" specific to individual devices under the relevant preemption provision, which, like FIFRA, prohibited states from imposing additional or conflicting requirements. *Id.* at 324–25. The FDA required approved devices 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* at 323. FDA's premarket approval therefore preempted competing state laws addressed to the product's safety. *Id.* at 323.

The same is true here. *Riegel*'s preemption analysis "carries over to FIFRA" in light of the similarities

between FDA's premarket review and EPA's FIFRA registration process and supports preemption. *Schaffner*, 113 F.4th at 388–89. Like the premarket approval process in *Riegel*, the EPA registration process imposes labeling requirements specific to a particular pesticide. Like the FDA's safety review in *Riegel*, the pesticide label is the result of EPA's careful review of the relevant science. Once approved, the pesticide label is the law and preempts additional or differing state labeling requirements.

The Missouri Court of Appeals' contrary determination that state law survives FIFRA preemption is thus fatally flawed. Its conclusion that state common law is consistent, in a broad general sense, with FIFRA's misbranding provision (Pet. App. 6–7) fails to account for the specific regulations implementing FIFRA. As *Schaffner* correctly reasoned, FIFRA requires an examination of federal requirements at "the more specific level" of its implementing regulations. *Schaffner*, 113 F.4th at 390. "The state-law duty cannot survive preemption simply because its standard of liability is equivalent to the broad statutory definition of misbranding." *Id.*

In adopting the holdings of *Hardeman* and *Carson*, the Missouri Court of Appeals ignored FIFRA's regulatory requirements and disregarded *Bates* admonition that state labeling requirements must "be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." 544 U.S. at 453. Those regulations prohibit a lay jury from modifying an EPA-approved label to add a health warning that EPA deliberately rejected.

II. THE LOWER COURTS' VARIOUS REASONS FOR REJECTING FIFRA PREEMPTION ARE ERRONEOUS

A. The Missouri Court Improperly Read *Bates* to Support Preemption

The lower courts that have reached a different conclusion, including the Missouri Court of Appeals, placed undue weight on *Bates'* remand for further consideration of Texas' duty-to-warn cause of action. Notably, *Bates* did *not* determine that the state law survived preemption; it merely sent the case back to the lower courts to determine whether the Texas cause of action was equivalent to FIFRA's requirement that labels not contain false or misleading statements. *Bates*, 544 U.S. at 453. But the critical regulatory differences between the labeling claims at issue here and in *Bates* require preemption in this case.

The *Bates* plaintiffs challenged certain efficacy statements on the approved label as misleading under Texas law. 544 U.S. at 434–45. But unlike the human health and safety warnings at issue here, EPA explicitly waived review of the efficacy claims in *Bates*, notifying registrants that "EPA's approval of a pesticide label does 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 (quoting EPA Pesticide Registration Notice 96-4). EPA did so pursuant to an express congressional authorization enacted in response to concerns that "evaluation of pesticide efficacy during the registration process devoted too many resources from its task of assessing the environmental and

health dangers posed by pesticides." *Id.* at 440. Thus, in *Bates*, the relevant labeling claims had never been reviewed by EPA, let alone approved. *Id.* ("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.'").

By contrast, a product label "is required to bear hazard and precautionary statements for humans and domestic animals." 40 C.F.R. § 156.60; *id.* § 156.70(b). And critically, any "[s]pecific statements pertaining to the hazards of the product and its uses must be approved" by EPA. *Id.* § 156.70(c). Here, EPA vigorously exercised its authority to "assess[] the environmental and health dangers" that the efficacy review waiver in *Bates* was meant to promote. EPA's exhaustive review of the relevant science was reflected in its determination *not* to require a cancer warning.

This difference is key. EPA's label reflected its scientific determination that glyphosate-based products *do not cause cancer*. *Bates*, by contrast, involved application of state law to a label claim that EPA did not review and specifically warned registrants that they might be held liable if it proved false. *See Bates*, 544 U.S. at 440. *Bates* does not support the Missouri court's conclusion that Missouri law is consistent with FIFRA's Uniformity provision in the different circumstances presented here. A faithful reading of *Bates* mandates preemption.

B. 7 U.S.C. § 136a(f)(2) Does Not Defeat Preemption

In rejecting preemption, *Hardeman* and *Carson* (and the Missouri Court of Appeals in adopting those rulings) also misread 7 U.S.C. § 136a(f)(2), a provision in a subsection entitled ""Miscellaneous," which states: "In no event shall registration of an article be construed as a defense for the commission of any offense under" FIFRA. *See Hardeman*, 997 F.3d at 956–57; *see also Carson,* 92 F.4th at 993. This provision says nothing at all about a pesticide label's impact on *state-law claims*, which is addressed separately in Section 136v(b). Section 136a(f)(2) does not override, *sub silentio*, that express preemption. *See MacDonald* v. *Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994) (provision has "no bearing on [preemption]"); *Schaffner*, 114 F.3d at 396–97.

1. The statutory history of the Section 136a(f)(2) confirms that it has nothing to do with preemption. *See, e.g., BNSF Railway Co.* v. *Loos*, 586 U.S. 310, 329 (2019) (Gorsuch, J., dissenting) (contrasting "statutory history" with "legislative history").

Section 136a(f)(2)'s "no defense" language first appeared in the original enactment of FIFRA in 1947. *See* Pub. L. No. 80-104, § 4(c), 61 Stat. 163, 168 (1947). At that time, the U.S. Department of Agriculture oversaw pesticide registration, and its review of pesticides (and their labeling) was limited. The 1947 Act only required submission of the registrant's name, the pesticide's name, and proposed labeling. *Id.* at 167. While the Secretary of Agriculture had discretion to require disclosure of the pesticide's formulation,

submission of such information was not required as a general matter. *Id.* at 167–168.

Importantly, registration under the 1947 Act did not depend upon agency review and approval, much less agency review and approval of labeling claims regarding a pesticide's health and safety effects. The statute then *required* the Secretary of Agriculture to issue a "protest registration" at the applicant's request even if the agency concluded that the product did not satisfy the statute's requirements. *Id.* § 4. Because a product could be registered over the agency's misgivings, Congress naturally provided that the mere fact that a product was registered did not provide a defense to enforcement.

Only later did Congress strengthen the registration requirements. In 1964, it eliminated "protest registration" and instructed the Department of Agriculture to deny registration if the product did not meet statutory requirements. *See* Pub. L. No. 88-305, § 3, 78 Stat. 190, 190-91 (1964).

Neither the 1947 Act nor the 1964 Amendments included a preemption provision. Then, in 1972, when Congress put EPA in charge of registration, Congress greatly increased the rigor of the registration process through "extensive amendments that 'transformed FIFRA from a labeling law into a comprehensive regulatory statute.'" *Bates*, 544 U.S. at 437. Accordingly, Congress added a proviso to the No-Defense Provision: "as long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the Act." Federal Environmental Pesticide Control Act of 1972,

Pub. L. No. 92-516, § 3(f)(2), 86 Stat. 973, 982 (1972). As protest registration had disappeared, registration now indicated EPA review and approval and therefore was properly prima facie evidence of compliance with registration requirements.

The 1972 Amendments also added the "Uniformity" express preemption provision. Pub. L. No. 92-516, § 24, 86 Stat. 973, 997 (1972). The 1972 Amendment explicitly barred the states from "impos[ing] or continu[ing] in effect any requirements for labeling and packaging in addition to or different from those required pursuant to this Act." *Id.* Emphasizing its preemptive nature, the 1972 Amendments clearly contrasted the "Authority of the States" (defined negatively by what states may *not* do) with the "Authority of Administrator" (defined positively by what EPA *must* do). *Id.*

Today, unlike when the "no defense" language was first enacted in 1947, a pesticide label's human health and safety statements have survived rigorous scientific scrutiny by an expert agency. In contrast to the protest registration included in the 1947 Act, there are no circumstances that compel (or even permit) EPA to approve a pesticide without addressing human health and safety concerns. *See* 7 U.S.C. § 136a(c)(5); 7 U.S.C. § 136(bb).

The relevance of this statutory history was not lost on the Third Circuit in *Schaffner*, which declared that Section 136a(f)(2) was "a vestige of an earlier system," and that Congress retained the provision after later removing the protest registration provisions "perhaps to address non-compliant products already on the market." *Schaffner*, 113 F.4th at 396 n.17. "Given the

passage of time and the introduction of re-registration requirements," however, Section 136a(f)(2) "may have simply lost some vitality." *Id.*

2. In *Hardeman*, the Ninth Circuit nevertheless reasoned that 7 U.S.C. § 136a(f)(2)'s "prima facie" language renders inconclusive EPA's labeling determinations made as part of a pesticide registration. *See* 997 F.3d at 950. But the "prima facie" language has nothing to do with preemption—it was proposed *by the industry*, which explained that it would codify "an unstated premise . . . in the present Act." S. Rep. No. 92-838, at 11-12; Federal Environmental Pesticide Control Act: Hearings before the Subcomm. on Agricultural Research and General Legislation of the S. Comm. on Agriculture and Forestry on H.R. 10729, Part II, 92nd Cong. 263 (1972).

The Ninth Circuit misconstrued Section 136a(f)(2) by ignoring the distinction between the mere fact of the agency's "registration of an article"—that is, EPA's determination that the article may legally be distributed (*see* 7 U.S.C. § 136a(a))—and the authoritative scientific and labeling determinations that the agency makes in the course of a proceeding related to registration. To the extent it applies at all, Section 136a(f)(2) addresses only the former. But no one here contends that EPA's mere registration of glyphosate-based pesticides means that such pesticides are not misbranded under FIFRA.

As *Schaffner* reasoned, "while section 136a(f)(2) indicates that registration cannot itself be a defense to a charge of misbranding, we do not understand it to indicate that the registration process cannot play any role in determining the content of a requirement

imposed under FIFRA." *Schaffner*, 113 F.4th at 396-97. What matters is not the registration itself but that EPA has made a specific determination that glyphosate does not cause cancer and that no cancer warning is required. That labeling determination cannot be overridden by a jury applying Missouri's duty-to-warn common law cause of action, regardless of Section 136a(f)(2).

III. PREEMPTION PROMOTES MUCH-NEEDED CERTAINTY FOR THE INDUSTRY AND CONSUMERS BY ENFORCING EPA'S EXPERT NO-CANCER DETERMINATION

The jury in this case awarded $1.25 million in damages, but that award is eclipsed by massive jury awards in other glyphosate cases. In the last several years, two different plaintiffs have been awarded more than $2 billion in compensatory and punitive damages.[27] Though Monsanto has prevailed in the majority of cases that have gone to trial, it does not take many multi-billion-dollar awards to endanger a company's—and an industry's—existence.

The threat of such immense liability multiplied across the many pending cases could easily drive an economically vital product off the market, despite

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[27] *See, e.g.*, Associated Press, "Georgia jury orders Monsanto parent to pay nearly $2.1 billion in Roundup weedkiller lawsuit," (Mar. 27, 2025) (compensatory damages of $65 million and punitive damages of $2 billion), https://tinyurl.com/n5fx57y9; CNN.com, "Bayer ordered to pay $2.25 billion after jury concludes Roundup weed killer caused a man's cancer, attorneys say," (Jan. 30, 2024) (award included $2 billion in punitive damages), https://tinyurl.com/yc6x867r.

EPA's repeated findings that it poses no cancer risk as part of FIFRA's registration and registration review process. Indeed, Bayer has already removed its glyphosate-based products from residential lawn and garden applications.

Should the continued risk of large verdicts based on flawed legal theories lead to similar decisions for commercial applications, the result would be devastating to U.S. agricultural production. Glyphosate is a highly effective herbicide with a broad spectrum of "use in agriculture, including horticulture, viticulture, and silviculture, as well as non-agricultural sites including commercial, industrial and residential areas."[28] Increased agricultural use has resulted in corresponding increases in crop yield. Glyphosate is also the leading active ingredient used to control noxious and invasive weeds in aquatic systems, pastures and range lands, forestry, and rights of way.[29] These applications are "critical to maintaining vital infrastructure and safety for transportation, distribution of goods and services (railways and roadways) and utilities (electric and gas)."[30]

Imposing a state-law warning requirement where EPA has found that glyphosate does not cause cancer discourages these socially and economically useful

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[28] *See* U.S. EPA, Office of Chem. Safety & Pollution Prevention, "Glyphosate: Response to Comments, Usage, and Benefits," at 2 (April 18, 2019), https://www.epa.gov/sites/default/files/2019-04/documents/ glyphosate-response-comments-usage-benefits-final.pdf.

[29] *Id.*

[30] *Id.*

applications. Unsupported warnings may lead consumers to avoid buying useful products that do not pose a risk.[31] A cancer risk warning would discourage the widespread use of glyphosate with a resulting loss of crop yields and other benefits from use.

And, despite the tendency to think "better safe than sorry," unnecessary and unsupported warnings "are not innocuous. If warnings indicate a high relative risk when there is none, they will distort relative product comparisons, thus compromising credibility."[32] A farmer faced with unnecessary warnings will be unable to make meaningful decisions between products and could lose confidence in the robust scientific basis of EPA's registration process. [33] In short,

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[31] This concern often arises under California's Proposition 65, which requires widespread cancer warnings on many everyday items. *See, e.g., Post Foods, LLC* v. *Superior Court of Los Angeles Cty.*, 235 Cal. Rptr.3d 641, 649 n.5 (Ct. App. 2018) ("[W]hether a Proposition 65 warning on whole grain cereals would lead to labels on otherwise healthful foods . . . presents a concern."). For similar reasons, the Ninth Circuit has rejected such warnings for glyphosate-based pesticides as inconsistent with the First Amendment. *See Wheat Growers* v. *Bonta*, 85 F.4th 1263 (9th Cir. 2023).

[32] *See* W. Kip Viscusi, Individual Rationality, Hazard Warnings, and the Foundations of Tort Law, 48 RUTGERS L. REV. 625, 665 (1996).

[33] *See*, *e.g.*, *Dowhal* v. *Smithkline Beecham Consumer Healthcare*, 12 Cal. Rptr. 3d 262, 274 (2004) (accepting FDA's determination that placing Proposition 65 warnings on nicotine patch packaging "might lead pregnant women to believe that NRT products were as dangerous as smoking, or nearly so, and thus discourage the women from stopping smoking").

there is a real-world cost, both economic and in terms of human health, to "crying wolf."[34]

Finally, dissonant state and federal requirements place manufacturers in an untenable position. It is difficult to imagine, for instance, how a manufacturer could thread the needle between EPA's and Missouri's warning requirements, given that EPA has specifically rejected any cancer warning for glyphosate as mislabeling. The impossibility of dual compliance supports Monsanto's implied preemption arguments. *See* Monsanto Br. at 45–46. Congress designed FIFRA's Uniformity provision to guard against "50 different labeling regimes" and to avoid conflicting state and federal labeling standards. *See Bates*, 544 U.S. at 452. The holding below frustrates the uniformity that Congress has explicitly prescribed.

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[34] *See Wheat Growers,* 85 F.4th at 1276-77 (citing, with approval, Judge Friedland's partial dissent in *Am. Beverage Ass'n* v. *City & Cnty. of San Francisco*, 916 F.3d 749, 755–56 (9th Cir. 2019) (en banc)).

CONCLUSION

For these reasons, this Court should reverse.

Respectfully submitted,

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FEBRUARY 2026