MATTHEW V.H. NOLLER (Bar No. 325180)
mnoller@kslaw.com
KING & SPALDING LLP
50 California St., Suite 3300
San Francisco, CA 94111
(415) 318-1200

JEFFREY S. BUCHOLTZ (*pro hac vice* forthcoming)
jbucholtz@kslaw.com
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500

Attorneys for *Amicus Curiae*

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION

This document relates to:

ALL CASES

Case No. 3:16-md-02741-VC

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE WASHINGTON LEGAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS

TABLE OF CONTENTS

INTERESTS OF *AMICI CURIAE* 1
ARGUMENT 1
I. FIFRA preemption turns on the substance of Plaintiffs' claims, not their labels. 2
II. Allowing Plaintiffs to avoid preemption through artful pleading would have harmful consequences. 5
CONCLUSION 8

INTERESTS OF *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business organization. As the nation's leading advocate for business, the Chamber represents companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

The Washington Legal Foundation ("WLF") is a non-profit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as *amicus curiae* in important federal preemption cases, urging courts to ensure that federal law operates efficiently and uniformly—as Congress intended. WLF believes that conflicting federal and state-law duties are not merely inefficient; they are also unfair, making it impossible for regulated parties to comply with both state and federal law without incurring enormous liability.

As the Court's order inviting *amicus* briefs suggests, this is an important case raising many issues of concern to *amici* and their members and supporters. In particular, this case presents a clear example of the troubling phenomenon of plaintiffs using artful pleading to try to avoid federal preemption. Preemption protects national uniformity in important markets and shields defendants from burdensome and improper litigation of state-law claims in circumstances where federal law controls. But, as here, plaintiffs often use pleading labels to avoid preemption defenses in an attempt to force burdensome and expensive litigation and thereby obtain a settlement. *Amici* and their members and supporters have a substantial interest in courts policing the pleading tactics at play in this case.

ARGUMENT

In *Monsanto Company v. Durnell*, 609 U.S. 371 (2026), the Supreme Court held that the

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

Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") expressly preempts state-law claims that Monsanto failed to warn of alleged cancer risks associated with its pesticide Roundup. Throughout this case, Plaintiffs have sought to pursue precisely such failure-to-warn claims against Monsanto. After *Durnell*, there can be no serious dispute that FIFRA preempts those claims. To avoid that result, however, Plaintiffs now argue that they are not alleging failure to warn after all. Plaintiffs contend (for example) that Monsanto falsely advertised Roundup by failing to disclose its cancer risks or that Monsanto defectively designed Roundup. And Plaintiffs argue that these theories survive FIFRA preemption simply because Plaintiffs have rephrased them in a way that does not expressly mention Roundup's label.

This Court should reject Plaintiffs' attempt to "elevate form over substance" in this way. *Aetna Health Inc. v. Davila*, 542 U.S. 200, 214 (2004) (quotation marks omitted). Preemption turns on the substance of a plaintiff's claims, not on "the particular label affixed to them." *Id.* Under *Durnell*, therefore, FIFRA preempts any claim that would have the effect of requiring a manufacturer to give a warning that does not appear on a pesticide's EPA-approved label. 609 U.S. at 390. As Monsanto explains, that is what Plaintiffs' claims would require. FIFRA thus preempts those claims—no matter what Plaintiffs tactically choose to call them.

Allowing such claims to survive would cause multiple undesirable outcomes. First, it would destroy the nationwide uniformity that Congress enacted FIFRA's preemption provision to protect by allowing individual lay juries to override the EPA's expert assessments as to the safety of pesticides sold under an EPA-approved label. Second, it would jeopardize near-identical preemption provisions in a variety of other statutes, leading to a confusing morass of different warnings across several industries in which Congress has tried to ensure nationwide uniformity. Third, it would expose businesses to significantly greater litigation costs, reducing the number of important products available to consumers and increasing the prices of products that remain on the market. The Court should avoid these harms by enforcing FIFRA's preemption provision against Plaintiffs' claims.

I. FIFRA preemption turns on the substance of Plaintiffs' claims, not their labels.

FIFRA expressly preempts any state law that "impose[s] or continue[s] in effect any

requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b). Whether that provision applies to a tort claim thus depends on whether it relies on an alleged state-law "requirement[] for labeling or packaging" that is "in addition to or different from" requirements imposed by FIFRA and its implementing regulations. *Durnell*, 609 U.S. at 387-88 (quotation marks omitted). If so, FIFRA expressly preempts the claim. *Id.*; *Taylor AG Indus. v. Pure-Go*, 54 F.3d 555, 560-61 (9th Cir. 1995).[2]

This analysis turns on the *substance*, not the label, of a plaintiff's claim. To be sure, an acknowledged failure-to-warn claim based on a pesticide's label falls within section 136v(b)'s preemptive scope. But that does not mean, as Plaintiffs argue, that FIFRA preemption is *limited* to claims that plaintiffs choose to describe as "label-based failure-to-warn" claims. Dkt. No. 22682-1 at 1. To the contrary, the Supreme Court held in *Durnell* that FIFRA preempts "*any* state tort claim that would require a pesticide manufacturer to use a label" other than "the EPA-approved label." 609 U.S. at 390 (emphasis added); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005) ("The provision also 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." (emphasis added)). So, no matter what a plaintiff chooses to *call* its claim—false advertising, design defect, negligence, implied warranty, or anything else—FIFRA preempts the claim if, *in substance*, it would require a pesticide manufacturer to provide a warning that does not appear on the EPA-approved label. In *Bates*, for instance, the Court held that section 136v(b) could preempt not only the plaintiffs' "negligent failure-to-warn claims," but also fraud claims that were not expressly designated as failure-to-warn claims, because those fraud claims still sought to enforce "a standard for a product's labeling that the [defendant's] label [was] alleged to have violated by containing false statements and inadequate warnings." 544 U.S. at 446; *see also id.* at 456 (Thomas, J., concurring in part) ("A state-law cause of action, even if not specific to labeling, nevertheless

[2] As Monsanto argues, FIFRA also impliedly preempts claims that conflict with FIFRA and its implementing regulations, even if not related to labeling. *E.g.*, Dkt. No. 22735 at 8-12. For example, FIFRA "prohibits selling a pesticide if its 'composition' differs from the composition described at registration." *Durnell*, 609 U.S. at 378 n.1 (quoting 7 U.S.C. § 136j(a)(1)(C)). That prohibition preempts any claim that would require Monsanto to change Roundup's composition in a manner not permitted by FIFRA. *See Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 486 (2013).

imposes a labeling requirement 'in addition to or different from' FIFRA's when it attaches liability to statements on the label that do not produce liability under FIFRA.").[3]

Outside the FIFRA context, the Supreme Court repeatedly has refused to "distinguish[] between pre-empted and non-pre-empted claims based on the particular label affixed to them," which would improperly "elevate form over substance." *Davila*, 542 U.S. at 214 (cleaned up); *cf. Chi. & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981) ("[C]ompliance with the intent of Congress cannot be avoided by mere artful pleading."). The federal courts of appeals thus have rejected attempts, like Plaintiffs' here, to avoid preemption by relabeling what are in essence failure-to-warn claims. *See, e.g.*, *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 394-98 (6th Cir. 2013) (holding that the Food, Drug, and Cosmetic Act preempted warranty, fraud, and design-defect claims that were "essentially failure to warn claims"); *Papas v. Upjohn Co.*, 985 F.2d 516, 519 (11th Cir. 1993) (holding that FIFRA preempted "claims challenging the adequacy of warnings on materials other than the label or package of a product," which "necessarily imply that the labeling and packaging failed to warn the user").

This Court should take the same approach. Whatever state-law causes of action Plaintiffs invoke, Plaintiffs may not enforce any "requirement[] for labeling or packaging" that is "in addition to or different from" FIFRA's requirements. 7 U.S.C. § 136v(b). As Monsanto explains, that is what Plaintiffs are seeking to do. *See, e.g.*, Dkt. No. 22735. For example, Plaintiffs contend that Monsanto should have included cancer warnings in its advertisements, but such an advertising-based claim is preempted because it "necessarily challenge[s] the adequacy of the warnings provided on the product's labeling or packaging." *Taylor*, 54 F.3d at 561 (quotation marks omitted) (quoting *Papas v. Upjohn Co.*, 985 F.2d 516, 519 (11th Cir. 1993)); *see also Yousefzadeh v. Johnson & Johnson Consumer Inc.*, 184 F.4th 130, 150-51 & n.6 (2d Cir. 2026) (holding 21 U.S.C. § 379r(a)(2)'s equivalent preemption provision for non-prescription drugs preempted claim based on "marketing and advertising," and citing cases holding the same under FIFRA). FIFRA thus preempts Plaintiffs' advertising-based claim, as well as any other claim that is substantively a

[3] The Court remanded for the district court to decide in the first instance whether the plaintiffs' claims sought to enforce requirements that "diverge[d] from those set out in FIFRA and its implementing regulations." *Id.* at 452-53.

failure-to-warn claim, no matter what Plaintiffs label those claims.

II. Allowing Plaintiffs to avoid preemption through artful pleading would have harmful consequences.

If approved, Plaintiffs' attempt to avoid FIFRA preemption by relabeling their claims "would nullify FIFRA's preemption clause." *Durnell*, 609 U.S. at 388. It is hard to imagine a failure-to-warn claim that any clever lawyer could not redescribe as, for example, a false-advertising or design-defect claim: Instead of openly characterizing the allegedly tortious conduct as a failure to warn, a plaintiff's lawyer easily could allege that an advertisement was "false" because it did not include a given warning or that the product was defectively designed because it posed an alleged risk that the company did not warn about. *See* Restatement (Third) of Torts: Prod. Liab. § 2 (1998) (explaining that "inadequate instructions or warnings" are a category of "[p]roduct [d]efect"); W. Page Keeton, *Products Liability-Inadequacy of Information*, 48 Tex. L. Rev. 398, 403 (1970) ("[T]he question whether a product was properly designed is inseparable from the question whether adequate instructions are provided to [e]nsure safe usage."). Allowing section 136v(b) to be so easily evaded would "expose manufacturers to potentially massive tort liability for doing what EPA required them to do and eviscerate the uniformity of EPA's labeling determinations." *Id.* at 392 (cleaned up).

That result, which is forbidden by FIFRA, would threaten nationwide markets and the agricultural industry more broadly. FIFRA allows the best-equipped decisionmakers—the EPA in consultation with the Department of Agriculture—to make a single nationwide judgment as to whether a pesticide is safe and accompanied by appropriate warnings. Plaintiffs' claims would instead transfer that power to local juries who lack the same economic and scientific resources, undermining Congress's careful regulatory scheme. Congress recognized that removing pesticides from the market can have major effects on the availability of important crops and food prices. Congress therefore included layers of protections in the pesticide cancellation process to prevent economic disruption. *See* 7 U.S.C. § 136d (requiring, among other things, consideration of economic effects of cancellation, evidentiary hearings upon request, and judicial review of cancellation decision). Plaintiffs here seek the same practical outcome as cancellation—removing

Roundup from shelves—without any of the same protections. Indeed, Plaintiffs' claims would allow a jury in a single jurisdiction to second-guess whether a pesticide can remain on shelves, no matter its importance to the broader agricultural industry, food prices, and the national economy.

These consequences would not be limited to pesticides and agriculture. As the Supreme Court recognized in *Durnell*, allowing claims like Plaintiffs' "to overcome preemption would affect more than FIFRA" because numerous other "federal statutes across a range of industries contain similar or identical labeling preemption provisions." 609 U.S. at 387.[4] For example, the Medical Device Amendments bar states from "establish[ing] or continu[ing] in effect … any requirement … which is different from, or in addition to, any requirement" under that law. 21 U.S.C. § 360k(a). Similarly, the Federal Meat Inspection Act prohibits states from imposing any "[m]arking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this [Act]." 21 U.S.C. § 678 (emphasis added). Other examples abound. *See, e.g.*, *id.* § 1052(b) (egg labeling); *id.* § 467e (labeling poultry and poultry products); *id.* § 379s(a) (cosmetic labeling); *id.* § 379r(a)(2) (non-prescription drug labeling); *id.* § 387p(a)(2)(A) (tobacco product labeling); *id.* § 343-1(a)(2)-(4) (food labeling). If this Court were to hold that FIFRA's preemption provision could be avoided merely by relabeling a failure-to-warn claim, then other courts could be led to transplant the same misguided reasoning into all these other provisions, disrupting "the uniformity that Congress sought." *Durnell*, 609 U.S. at 388.

That, in turn, would "work against our national marketplace, confuse consumers, raise prices, undermine public confidence in our regulatory system and in products important to the public health, and result in divergent public health protection throughout the country." FDA Modernization and Accountability Act, S. Rep. No. 105-43, at 64 (1997). In the context of non-prescription drugs, for example, FDA has sought to ensure that warning labels are clear and readable and contain "the least amount of information possible to assure proper self-selection and use." FDA, Over-the-Counter Human Drugs; Labeling Requirements, 64 Fed. Reg. 13,254, 13,269

[4] In addition, other federal statutes use the same preemption language for state requirements outside the labeling context. *See, e.g.*, 21 U.S.C. § 379aa(h) (serious adverse event reports for non-prescription drugs); *id.* § 379aa-1(h) (serious adverse event reports for dietary supplements); 7 U.S.C. § 4817(b) (promotion and consumer education regarding pork); 15 U.S.C. § 78o(i) (regulation of brokers and dealers).

(Mar. 17, 1999). Jumbled warnings that change from brand to brand and state to state would undermine that goal. Moreover, if labels were overloaded with disclaimers to avoid potential litigation, consumers may discount all the warnings as equally unimportant. FDA has long sought to prevent such "overwarning" by designing labels "so that less important information does not overshadow more important information." *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 304 (2019) (quotation marks omitted) (quoting FDA, Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,605-49,606 (Aug. 22, 2008)). FDA further seeks to ensure that labels "exclude exaggeration of risk, or inclusion of speculative or hypothetical risks, that could discourage appropriate use of a beneficial drug." *Id.* (cleaned up) (quoting FDA, Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008)). Preemption could not protect any of these important goals if plaintiffs could avoid preemption through the mere contrivance of labeling their claims something other than "failure to warn."

Allowing idiosyncratic labeling requirements under state law would also increase regulatory compliance and litigation costs. Businesses already are subject to comprehensive regulatory schemes under both federal and state law, which cost hundreds of billions of dollars annually. *See, e.g.*, U.S. Chamber of Commerce Found., *The Regulatory Impact on Small Business: Complex. Cumbersome. Costly*. at 4 (Mar. 2017), https://perma.cc/6DVW-8MY3; Nicole V. Crain & W. Mark Crain, Nat'l Ass'n of Mfrs., *The Cost of Federal Regulation to the U.S. Economy, Manufacturing & Small Business* at 4-5 (Oct. 2023), https://perma.cc/88NS-KNAT. Allowing each of the 50 states to adopt its own unique rulebook for labels and warnings across a variety of industries would compound those existing burdens by subjecting businesses to a thicket of different state requirements. As the Supreme Court has recognized, allowing "50 different labeling regimes prescribing the color, font size, and wording of warnings … would create significant inefficiencies for manufacturers" and deprive them of the "uniformity" they "need" to operate. *Bates*, 544 U.S. at 452 & n.26. The flood of different (and perhaps conflicting) warnings would also "driv[e] consumers who buy … products in more than one state crazy." *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011).

Opening the door to state-law litigation over requirements that Congress and federal agencies chose not to impose would also force manufacturers and retailers to engage in costly legal battles to defend against state-specific claims that may differ from jurisdiction to jurisdiction. This is no small risk. The U.S. tort system's commercial liability costs totaled $367 billion in 2022, an increase of 13.3 percent over the year before. *See* U.S. Chamber of Com. Inst. for Legal Reform, Tort Costs in America 7 (3d ed. Nov. 2024).[5] Those costs can dissuade manufacturers from investing the vast sums necessary to develop their important products in the first place. *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1346–47 (10th Cir. 2015) (Gorsuch, J.) (discussing medical devices). At a minimum, increasing litigation costs lead to higher prices, as manufacturers are forced to recover the costs through their sales. *See* Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & Econ. 203, 227 (1997) (finding that "a substantial premium exists in U.S. pharmaceutical prices, strongly related to the prospective costs of litigation, which is absent in the Canadian prices").

Such an approach would increase costs for all manufacturers, large and small, as well as downstream business enterprises and ordinary consumers, who would face higher prices and have access to fewer valuable goods and services. Avoiding that outcome is a worthwhile goal that Congress properly pursued through preemption provisions like FIFRA's. Plaintiffs should not be able to avoid those provisions—and impose the very harms Congress sought to prevent—through the sort of artful pleading that Plaintiffs are attempting in this case.

CONCLUSION

The Court should hold that Plaintiffs' claims are preempted by FIFRA.

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KING & SPALDING LLP

By: *Matthew V.H. Noller*
MATTHEW V.H. NOLLER
(Bar No. 325180)
JEFFREY S. BUCHOLTZ
(*pro hac vice* forthcoming)

[5] https://www.uschamber.com/assets/documents/ilr/2024_ILR_USTorts-CostStudy-FINAL.pdf