United States Court of Appeals

for the

Third Circuit

Case No. 22-3075

DAVID SCHAFFNER, JR.; THERESA SUE SCHAFFNER,

Plaintiffs-Appellees,

– v. –

MONSANTO CORPORATION,

Defendant-Appellant.

ON APPEAL FROM AN ORDER OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA IN CASE NO. 2-19-CV-01270
HONORABLE CYNTHIA R. EDDY

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE PRODUCTS LIABILITY ADVISORY COUNCIL, INC. AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLANT

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February 15, 2023

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third Circuit Local Appellate Rule 26.1.1(b), *amici* disclose that:

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The Pharmaceutical Research and Manufacturers of America has no parent corporation and no publicly traded company owns 10% or more of its stock.

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STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America (the "Chamber") is the world's largest business federation. The Chamber represents approximately 300,000 direct members and indirectly represents the interests of more than three million businesses 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 Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies research, develop, and manufacture medicines that allow patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an

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1. Pursuant to Rule 29 of the Federal Rules of Appellate Procedure, this brief is submitted with the consent of Plaintiffs-Appellees David Schaffner, Jr. and Theresa Sue Schaffner and Defendant-Appellant Monsanto Company. No party or counsel for any party authored this brief in whole or in part. No entity or person, other than *amici*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

estimated $102.3 billion in 2021 alone – more R&D investment than any other industry in America. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates in such cases as an *amicus curiae*.

The Product Liability Advisory Council, Inc. ("PLAC") is a nonprofit professional association of corporate members representing a broad cross-section of American and international product manufacturers.[2] These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of product manufacturers and companies in the supply chain. PLAC's perspective derives from the experiences of a corporate membership spanning many industries and manufacturing sectors. In addition, hundreds of the leading product litigation defense attorneys are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed more than 1,200 briefs as *amicus curiae* in state and federal courts, including this Court, on behalf of its members, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law affecting product risk management.

2. *See* https://plac.com/PLAC/About_Us/Amicus/PLAC/Amicus.aspx.

This case implicates core concerns of the Chamber, PhRMA, and PLAC regarding the proper balance between federal and state regulation of product labeling. The district court's decision incorrectly interpreted a comprehensive congressionally enacted regulatory scheme as not preempting a state tort-law challenge and should be reversed.

STATEMENT OF THE ISSUE

1. Whether a state-law requirement of a cancer warning is expressly preempted because it is "in addition to or different from" labeling requirements approved under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b), where the Environmental Protection Agency ("EPA") has determined, after repeated and thorough assessment of the scientific evidence, that such a cancer warning is not required under FIFRA.

2. Whether impossibility preemption bars a state-law-mandated warning because the manufacturer cannot provide the proposed warning without EPA approval, and EPA has determined that the warning is false and thus prohibited by federal law.

SUMMARY OF ARGUMENT

This case presents an issue of vital importance to the United States business community generally, and specifically to companies subject to comprehensive federal regulation in such industries as the food, drug, chemical, and agricultural

sectors. Companies operating under such comprehensive regulatory regimes depend on the predictability provided by uniform national standards. These businesses cannot, consistent with the Supremacy Clause of the U.S. Constitution, be subject to different states' laws imposing liability for conduct required by uniform federal law. Both the public and the economy benefit from consistent, nationwide safety and quality protections. Compliance with the comprehensive regulatory framework established by Congress and with the directions of the federal agency to which Congress assigned responsibility to administer the statute should not give rise to liability under a patchwork of state laws and jury determinations, each establishing different standards.

The failure-to-warn claim brought under Pennsylvania common law in this diversity case is both expressly preempted by 7 U.S.C. § 136v(b) and impliedly preempted. First, Section 136v(b) provides 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" FIFRA by the EPA, the federal agency that Congress authorized to administer the statutory scheme. Second, any state law requiring a warning that EPA, in the exercise of its lawful delegated authority under FIFRA, has consistently determined should not – indeed, may not lawfully – be placed on registered-product labels, is impliedly preempted because "it is impossible for a

private party to comply with both state and federal requirements." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (citation and internal quotation marks omitted).

ARGUMENT

I. FIFRA Expressly Preempts a State Common-Law Duty to Warn that Glyphosate Causes Cancer When EPA Has Determined that Such a Warning is not Required – Indeed is Prohibited – Under FIFRA.

The modern use of herbicides and other pesticides to kill weeds and to protect crops from destruction by insects, animals, and disease has dramatically alleviated human suffering and improved human health and lifespan. *See* S. Rep. No. 92-838, at 3 (1972). Since its discovery in 1970, glyphosate, the active ingredient in Roundup®, has become one of the most widely used organic compounds in herbicides across the globe by sales volume. Appx0041, 0045 (Plaintiffs' Complaint ¶¶ 38, 55-56).[3] It has been an essential enabler of the world's food supply.

A. The history of pesticide regulation shows that current State authority does not extend to labeling requirements that run contrary to EPA determinations.

Regulation of pesticides has evolved significantly over the last 100 years. Where States were once the exclusive regulators of pesticides within their respective territories, the twentieth century saw the rise of a comprehensive federal regulatory

3. Appx refers to the Appendix filed by Monsanto Co. in this appeal on February 9, 2023.

scheme that focuses principally on human health and environmental risks and that displaces much of what States may regulate.

In 1910, Congress took its first step in the federal regulation of pesticides by passing the Insecticide Act, "preventing the manufacture, sale, or transportation of adulterated or misbranded" insecticides or fungicides across state borders or into the United States. Insecticide Act of 1910, Pub. L. 61-152, 36 Stat 331-35. The statute had the aims of verifying both the efficacy and the labeling accuracy of pesticides sold in interstate and foreign commerce. To accomplish this, the statute tasked the Department of Agriculture to "examin[e]" specimens of pesticides brought before it, including imports turned over by the Treasury Department. *Id.* §§ 4, 11. The statute specified that the Secretaries of the Treasury, Agriculture, and Commerce and Labor "shall make uniform rules and regulations for carrying out the provisions of this Act[.]" *Id.* § 3. State governments retained their prime role in regulating the use of pesticides within their territories, including for health and safety.

In 1947, Congress repealed the Insecticide Act and enacted FIFRA, launching a registration system to better advance the twin aims of ensuring pesticide efficacy and ensuring proper labeling. Pub. L. 80-104, 61 Stat. 163 *et seq.* Manufacturers now bore the burden of registering their pesticides with the Department of Agriculture for approval before sale in interstate commerce. The statute also introduced guidance for label content on registered products, including:

(1) directions for use; (2) risks to persons, plants, and animals; and (3) claims of efficacy. *Id.*, 61 Stat. 167-68. The statute authorized the Secretary to request an applicant seeking to register a pesticide to provide data supporting the pesticide's efficacy and risk claims. *Id.* The enactment of FIFRA, and the promulgation of a registration system, represented a significant second step in the national regulation of pesticides. However, the States were still the principal regulators and enforcers of the use of pesticides on lands within their borders. Indeed, a Uniform State Insecticide, Fungicide, and Rodenticide Act had been drafted in 1946 and adopted by several States by the time of the passage of FIFRA in 1947. *See* S. Rep. No. 92-838, at 7 (1972).

The 1960s and 1970s witnessed a sea change in U.S. popular opinion regarding pesticides and the perceived benefits of technologies that swelled agricultural output ever higher. Famine became virtually extinct in industrialized nations like the United States. Overpopulation and depletion or spoliation of natural resources became significant concerns. Most relevant for present purposes, manmade pesticides, formerly viewed as unalloyed goods, were increasingly perceived as potential dangers to the environment and human health. *See Id.* at 8-9. These concerns spurred the creation of a new federal agency, the EPA, which, in 1970, took over the Department of Agriculture's FIFRA duties. *See* Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15,623 (Oct. 6, 1970).

Two years later, Congress effected a dramatic overhaul of FIFRA by enacting the Federal Environmental Pesticide Control Act of 1972, Pub. L. 92-516, 86 Stat. 973. "The amendments transformed FIFRA from a labeling law into a comprehensive regulatory statute." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). FIFRA now "regulated the use, as well as the sale and labeling, of pesticides; regulated pesticides produced and sold in both intrastate and interstate commerce; provided for review, cancellation, and suspension of registration; . . . gave EPA greater enforcement authority[; and] added a new criterion for registration: that EPA determine that the pesticide will not cause 'unreasonable adverse effects on the environment.'" *Id.* at 991-92 (citation omitted).

An important feature of the landmark 1972 amendments, which remain in effect today, was to recalibrate the balance of regulatory power between State governments and the federal government (acting through EPA) with respect to pesticide regulation. *See* 7 U.S.C. §§ 136-136y. Section 136v is the relevant provision in this case. It begins: "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." *Id.* § 136v(a). Congress thus recognized the States' continuing police power over their respective territories: California, for example, could ban the sale or use of any pesticide within its borders for any reason.

But, at the same time, Congress recognized the importance of "uniformity," and thus preempted all State laws having to do with labeling or packaging: "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." *Id.* § 136v(b). This is the express preemption provision at the heart of this case. Congress enacted it to ensure that manufacturers would not be burdened by a mosaic of divergent state labeling requirements. Accordingly, while a State may have the power to ban the use or sale of a product within its sovereign territory, it does not have the power to subject products within its territory to its own labeling (*i.e.*, warning) requirements.

As amended in 1972, FIFRA directed EPA to register a pesticide upon confirming:

- its efficacy, *id*. § 136a(c)(5)(A);
- its lack of unreasonable adverse effects on humans and the environment, *id*. §§ 136a(c)(5)(C), (D), 136(bb); and
- that the proposed label is not "misbranded," *i.e.*, is not "false or misleading in any particular," supplies adequate instructions for use, and contains all necessary warnings "adequate to protect health and the environment," *id*. §§ 136(q)(1)(A), (F), (G); *see* § 136a(c)(5)(B).

To register a pesticide, a manufacturer submits a proposed label to EPA, along with test data regarding its efficacy and safety. *Id.* §§ 136a(c)(1)(C), (F). Because FIFRA prohibits any sale of a registered pesticide that is misbranded, manufacturers must use the EPA-approved label and continue to adhere to FIFRA's labeling requirements after registration. *See id*. § 136j(a)(1)(E). A registrant may not add to or modify "mandatory or advisory" labeling statements on a registered product – such as a statement that a product poses a cancer risk – unless EPA approves the proposed change. 40 C.F.R. § 152.44; EPA P.R. Notice 2000-5, Guidance for Mandatory and Advisory Labeling Statements.[4]

In 1978, Congress revised FIFRA to authorize EPA to waive data submissions for efficacy during the registration process. Pub. L. 95-396, 92 Stat. 819, 820–22. The agency was expending too much time and resources churning through massive amounts of data to gauge pesticide efficacy, at the cost of effective assessment of their potential harm to the environment and human health. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 440 (2005). The next year, EPA availed itself of this congressional authorization to issue a general waiver of efficacy review. *Id.*

4. A registrant may make minor changes (such as changes to brand name, changes in packaging, use of symbols and graphics, warranty statements) by notification to EPA, and very minor changes (such as typographical and printing errors, changes in package size and net contents) without notification. *See* 40 C.F.R. §152.46; EPA P.R. Notice 98-10, Notifications, Non-Notifications, and Minor Formulation Amendments.

(citing 44 Fed. Reg. 27,932 (Nov. 26, 1979); 40 C.F.R. §158.640(b)). The upshot is that EPA now registers a pesticide without first independently confirming the efficacy claims asserted on its label. Nevertheless, because efficacy is still a requirement of FIFRA, the manufacturer remains obligated to be accurate in its efficacy claims. 7 U.S.C. § 136a(c)(5).

It is important to step back and take stock of the evolution in congressional enactments and federal agency missions concerning pesticide regulation over seven decades. Congress enacted the 1910 Insecticide Act to task the Department of Agriculture with "preventing the manufacture, sale, or transportation of adulterated or misbranded" pesticides in interstate and foreign commerce. *See* p. 6, *supra*. By 1979, EPA had assumed Agriculture's former role, and efficacy ("adulteration") was no longer a part of EPA's active monitoring mission. *See Bates*, 544 U.S. at 440. EPA's primary mission under FIFRA changed: its principal role now is to assess the health and environmental risks of registered pesticides and ensure that labels accurately reflect this assessment.

This evolution in the federal regulatory regime informs the preemption analysis. In assessing a claim of express preemption, courts should analyze "the language of the pre-emption statute and the 'statutory framework' surrounding it[,] . . . as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding

regulatory scheme to affect business, consumers, and the law." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996) (citation omitted). As a survey of the history of pesticide regulation shows, Congress gradually displaced State regulatory power over the labeling of pesticides for the sake of national uniformity; instead, Congress empowered EPA to assess the health and environmental dangers of registered products and ensure their proper labeling in accordance with that assessment. Close consideration of Congress's goals regarding the effects of federal regulation is particularly important when considering an express preemption clause in a comprehensive regulatory scheme such as FIFRA. Courts are not at liberty to cast aside an explicit Congressional statement preempting state law.

EPA today commits substantial resources to its mission of investigating and ascertaining the safety of pesticides to humans and the environment and of prescribing labels that accurately reflect its assessments. States retain regulatory powers with respect to the use of pesticides within their borders, but in order to ensure the national uniformity, Congress has preempted their power to regulate the accuracy of labels or warnings regarding the health and environmental risks posed by FIFRA-registered pesticides.

B. 7 U.S.C. §136v(b) expressly preempts state law requiring a cancer warning on a FIFRA registrant's product label when EPA has determined that a warning is not required because the product does not cause cancer.

When Congress acts affirmatively under one of its Article I powers to displace State law by writing an express preemption clause into a federal statute, the courts must give it full effect. The Supreme Court has explained that when a federal "statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 579 U.S. 115, 125 (2016) (quoting *Chamber of Commerce v. Whiting*, 563 U.S. 582, 594 (2011)). A preemption provision in a federal statute *is* the law; no further "force-of-law" analysis is necessary. *See* Br. of Def.-Appellant Monsanto Co. ("Monsanto Br.") at 40-41, *Schaffner v. Monsanto Co.*, No. 22-03075 (3rd Cir. Feb. 8, 2023) (Dkt 15).

In FIFRA, Congress has included an express preemption clause that provides a "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." 7 U.S.C §136v(b). Thus, whether the statute precludes a state-law tort action turns on two elements: (1) whether state law imposes a requirement "for labeling or packaging," and, if so, (2) whether the state-law requirement is "in addition to or different from those required" under FIFRA. *Bates*, 544 U.S. at 444. The first part

of the *Bates* test is easily satisfied in this case. Plaintiffs' claim is that Monsanto failed to warn about glyphosate's cancer risks in its labeling or packaging for Roundup, as Pennsylvania tort law purportedly requires.[5]

Under the second step of the *Bates* test, "a state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447. The Supreme Court in *Bates* emphasized that "a state-law labeling requirement must in fact be equivalent to a [labeling] requirement under FIFRA in order to survive preemption." *Id.* at 453. A State must "ensure that nominally equivalent labeling requirements are *genuinely* equivalent." *Id.* at 454 (emphasis in original). Put another way, to escape this express preemption provision, state law must impose "parallel requirements" to those that FIFRA imposes – such that a violation of the state law is a violation of the federal law. *Id.* at 447. Under FIFRA, State and federal labeling requirements "are not genuinely equivalent if a manufacturer could be held liable under state law without having violated the federal law." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (citation omitted).

If a federal court in diversity found that Pennsylvania tort law *required* Monsanto to state that Roundup "may cause cancer" on its product label or

5. FIFRA defines "labeling" broadly. 7 U.S.C. §136(p)(2); *see* Monsanto Br. at 25.

packaging, then Pennsylvania law would be expressly preempted because there is no parallel federal law requirement under FIFRA to do so. EPA has not imposed any such requirement; to the contrary, EPA has determined that the Roundup label and packaging may *not* include such a warning. *See* pp. 23-25, *infra.* Indeed, inclusion of such a warning would be unlawful misbranding under FIFRA.

In its recent decision in *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021) – the first federal Roundup appeal – the Ninth Circuit misapplied *Bates* on this critical issue. It held that FIFRA did not prohibit a glyphosate warning required by a California jury. *Id.* at 954. But FIFRA requires Monsanto to obtain EPA's approval before making such a major label change (*see* p. 10 & n. 4, *supra*), which EPA has never given. Even assuming, *arguendo*, that FIFRA *permitted* Monsanto to add a cancer warning on its approved label, that is different from proving that FIFRA *required* the warning label. And *Bates* mandates that "a state-law labeling requirement must in fact be equivalent to a *requirement* under FIFRA in order to survive pre-emption." 544 U.S. at 453 (emphasis added).

Hardeman and the MDL district court decision at issue in this case, *In re: Roundup Products Liab. Litig.*, 364 F.Supp.3d 1085 (N.D. Cal. 2019), suffer from the same fundamental error. In considering whether a state-mandated cancer-warning is "in addition to or different from" the EPA-approved label "required under" FIFRA, the courts "match[ed] up" the broadly worded text of FIFRA's

labeling provisions with the broadly worded elements of a state-law failure-to-warn cause of action and found that the state requirement is not "different from" the federal one because both generally require a manufacturer to warn of relevant known or knowable dangers. *Hardeman*, 997 F.3d at 955-56; *Roundup*, 364 F.Supp.3d at 1087. These courts did not analyze how these elements *apply* to glyphosate, but simply compared them in the abstract. But if the requirements produce different results as applied, although they may be "nominally equivalent" at a high and abstract level of generality, they are not "in fact" or "genuinely" equivalent, as *Bates* requires.[6]

As the Tenth Circuit recently explained in evaluating preemption under a similarly-worded statute, the abstract approach taken in *Hardeman* misses the "critical feature" – how both requirements apply in a particular case. *Thornton v. Tyson Foods, Inc.*, 28 F.4th 1016, 1025 (10th Cir. 2022) (construing Federal Meat Inspection Act ("FMIA")). If a label is permitted under federal but not state law prohibiting deceptive labelling, the assertion that the two laws "require[] exactly the same thing . . . plainly fails." *Id.* (internal quotation marks omitted). A plaintiff making such an assertion "misses the points of preemption," because its "claims are

6. The same flawed reasoning was adopted by a panel of the Eleventh Circuit in *Carson v. Monsanto Co.*, 51 F.4th 1358, 1363 (11th Cir. 2022). However, that opinion has been vacated pending *en banc* consideration. *See* 2022 WL 17813843 (11th Cir. Dec. 19, 2022).

based on the labeling of the products themselves, not on a legal theory." *Harris v. Topco Assocs., LLC*, 538 F.Supp.3d 826, 831 (N.D. Ill. 2021) (construing Food, Drug, and Cosmetic Act ("FDCA")).

Under the abstract approach deployed in *Hardeman*, to have preemptive effect, the text of the federal statutes would need to address all the very specific determinations that comprehensive regulatory schemes typically entrust to agencies, and their express preemption provisions would need to anticipate all specific scenarios where a State law (or lawsuit) might apply. This is untenable.

Statutes containing preemption clauses similar to the one in FIFRA abound, such as the Medical Device Amendments to the FDCA (21 U.S.C. §360k(a)), the FMIA (21 U.S.C. §678; *see Thornton,* 28 F.4th at 1021), the Poultry Products Inspection Act (21 U.S.C. §467e; *see Webb v. Trader Joe's Co.*, 999 F.3d 1196, 1201-02 (9th Cir. 2021)). Many other examples exist. *See, e.g.*, 21 U.S.C. §1052(b) (Egg Products Inspection Act); 21 U.S.C. §379s(a) (National Uniformity for Nonprescription Drugs). The Ninth Circuit's and the MDL court's approach risks depriving these statutes of any effect and exposing manufacturers to heightened products-liability risk for complying with federal law.

The Ninth Circuit and the MDL court thus cannot be right that, simply because state tort law and FIFRA misbranding requirements seem consistent at a very high level of generality (*i.e.*, protecting against unreasonable adverse effects on health

and the environment), States are free to ignore, or impose labeling requirements that differ from, FIFRA's requirements as established by the EPA. EPA's determinations about glyphosate, which are based on the agency's thorough, decades-long review of scientific evidence and studies, are agency actions that FIFRA commands and authorizes and that establish what is required under FIFRA.

EPA's assessment, and the basis for its conclusions, may be challenged in proceedings under the Administrative Procedure Act by an appropriate plaintiff, whenever there is appropriate reviewable agency action. But a judge or jury in a *state*-law tort action has no special license to challenge or contradict the agency's considered and evidence-based opinion of what *federal* law (which Congress has lawfully authorized only EPA to enforce) requires for the purpose of express preemption analysis. If that were so, express preemption would be rendered impotent. Both *Hardeman* and this case were litigated in federal district courts under diversity jurisdiction, but plaintiffs litigating in State court could make the same specious argument nullifying an express preemption clause, subject to correction only by a difficult-to-obtain writ of certiorari by the Supreme Court under 28 U.S.C. § 1257.

Bates itself is illustrative of how express preemption analysis works and exposes how far afield the Ninth Circuit went in *Hardeman* and the MDL court went in this case. In *Bates*, the Supreme Court remanded for consideration of whether

mislabeling claims under Texas law were preempted by FIFRA. *Bates*, 544 U.S. at 435-36, 454. But unlike here, *Bates* concerned the *efficacy* of the pesticide at issue (Strongarm®). *Id.* at 438 (citing 7 U.S.C. § 136a(c)(5)(A)). As noted above (pp. 10-11), EPA stopped conducting efficacy analysis in registration in 1979. Consequently, EPA's registration of Strongarm did not entail a review of, or determination regarding, the efficacy claims on the pesticide label. As a result, it was entirely possible that FIFRA's general requirements for accurate labeling and packaging with respect to efficacy were "parallel" and "genuinely equivalent" to the requirements of Texas state law. *Bates*, 544 U.S. at 447, 454.

By contrast, EPA's principal gatekeeping mission since 1979 has been precisely to focus on potential "adverse effects" to health and environment and the corresponding need for adequate warnings on labels and packaging of dangers to health and safety. *See supra* at 10-11. As explained in detail in Monsanto's brief (at 11-16), EPA's registration, re-registration, multiple label approvals, and ongoing registration review of Roundup have entailed – for over 50 years since its initial registration in 1974 – exhaustive and continuous examination of glyphosate's possible "unreasonable adverse effects" on humans. *See* 7 U.S.C. §§ 136(bb), 136a(c)(5)(C). In each instance EPA determined that there is no basis to conclude that glyphosate causes cancer in humans, and that there is no need for a cancer warning on its label or otherwise – including after reviewing and rejecting

the IARC study (and its underlying data) at the heart of Plaintiffs' case. *See* Monsanto Br. at 13-16.

If Pennsylvania tort law requires a cancer warning on glyphosate products, that requirement is expressly preempted because it would be "in addition to or different from" the label "required" under FIFRA, since EPA, pursuant to its authority under the statute's "comprehensive regulatory" regime, *Ruckelshaus*, 467 U.S. at 991, does not require a cancer warning. To the contrary, EPA has determined that such a warning would be misleading. *See* pp. 22-25, *infra*. To find against preemption in these circumstances would contravene not only the statutory text, but the congressional goal underlying § 136v(b) – subjecting manufacturers of federally regulated pesticides to nationally uniform labeling requirements, rather than a patchwork of different, conflicting, and confusing state requirements, potentially requiring manufacturers "to print 50 different labels" and "driving consumers who buy [pesticide] products in more than one state crazy." *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011). Moreover, manufacturers that ship product to a State with labels designed to meet that State's requirements have no way of controlling where the product with these state-specific labels end up, and thus may become subject to liability in another State with conflicting requirements. This cannot be what Congress intended in enacting § 136v(b).

II. The Plaintiff's Claim is Also Impliedly Preempted Because Registrants Cannot Simultaneously Comply with EPA's Command that Glyphosate is Not a Carcinogen and a State-Law Duty to Say that it is.

Plaintiffs' state-law failure-to-warn claim also is impliedly preempted because "it is impossible for a private party to comply with both state and federal requirements." *Bartlett*, 570 U.S. at 480 (citation and internal quotation marks omitted). Under the Supremacy Clause, U.S. Const., art. VI, cl. 2, when the "Laws of the United States" command a private party like Monsanto not to do something – "don't label a product as causing cancer" – and "the Laws of any State" tell it to do the exact opposite – "label the product as causing cancer" – the private party must follow the federal law. This situation is the most straightforward case of impossibility preemption. "[I]t has long been settled that state laws that conflict with federal law are without effect.'' *Bartlett*, 570 U.S. at 479-80 (citations and internal quotation marks omitted).

In the present case, it is EPA, a federal agency acting pursuant to authority expressly conferred by Congress in FIFRA, that has framed the federal-law duty. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019). The Court in *Albrecht* held that a federal agency has the power to preempt "the validly enacted legislation of a sovereign State" when the agency is "acting within the scope of its congressionally delegated authority." *Id.* In this case, it is not even the state

legislature but state common law that is alleged to provide the basis for Plaintiffs to assert a state-law duty to warn.

In the analogous context of the FDCA, 21 U.S.C. §§ 301 *et seq.*, the Supreme Court clarified that a judge should decide as a matter of law that "state law failure-to-warn claims are pre-empted" by a federal statute and "related labeling regulations when there is clear evidence that the [agency] would not have approved the warning that state law requires." *Albrecht*, 139 S. Ct. at 1676 (citation and internal quotation marks omitted). The requisite "clear evidence" has three elements: (1) the agency was "fully informed" of "the justifications for the warning" the plaintiff alleges state tort law requires; (2) the agency has "informed the . . . manufacturer that [it] would not approve changing the . . . label to include that warning;" and (3) the agency's action "carr[ies] the force of law." *See id.* at 1678-79. The Court described "the underlying question" as "whether federal law (including appropriate FDA actions) prohibited the drug manufacturer from adding any and all warnings to the drug label that would satisfy state law." *Id.* at 1678.

A. There is clear evidence that EPA is "fully informed" of the alleged reason for a state-mandated glyphosate warning.

There is no question that EPA is "fully informed" of plaintiffs' asserted justification for the alleged state-law duty to warn that glyphosate causes cancer in humans. Since EPA originally registered glyphosate under FIFRA in 1974, the agency has gathered, assessed, and reassessed copious scientific evidence and

studies as to whether the compound causes cancer in humans, and has consistently concluded that it likely does not. *See* Monsanto Br. at 11-16. In fact, in its reregistration for glyphosate completed in 1993, EPA designated glyphosate a Group E carcinogen, denoting "evidence of *non-carcinogenicity* in humans." Appx0874 (Excerpts from EPA, Reregistration Eligibility Decision (RED) Glyphosate (1993), Dkt. 19) (emphasis added). More than two decades later – after IARC released the 2015 report asserting that glyphosate may cause cancer in humans – EPA completed another exhaustive multi-year reexamination of all then-current data, research, and literature as part of its FIFRA registration review of the compound. And again, EPA concluded that glyphosate was likely not a human carcinogen, noting that its study was "more robust" and "more transparent" than IARC's, and "consistent with other regulatory authorities and international organizations." Appx0178-0179, 0184 (2019 Proposed Interim Registration Review Decision). *See* Monsanto Br. at 14.[7]

In January 2020, EPA reiterated after notice and comment that it had "thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to

7. Regulatory agencies including the European Union, Australia, Canada, Germany, Japan, and New Zealand have also concluded that scientific evidence does not support a finding that glyphosate causes cancer in humans. Appx0192-0193 (2019 Letter to Registrants).

humans." Appx0235 (2020 Interim Registration Review Decision). EPA has continued to stand by that position after the transition to the administration of President Biden. *See* Br. of U.S. EPA, *Nat'l Res. Def. Council v. U.S. Env't Prot. Agency* 1, Nos. 20-70787, 20-70801 (9th Cir. May 18, 2021) ("glyphosate is not likely to be a human carcinogen and poses no human-health risks of concern," and "[t]he record underlying these conclusions is robust, reflecting more than a decade of analysis and thorough review of the scientific literature"). EPA adhered to this conclusion even after the Ninth Circuit vacated the 2020 Interim Decision requiring the agency to provide further explanation for its decision. Appx1091 (2022 Interim Decision Withdrawal); *see* Monsanto Br. at 16.

B. EPA clearly informed registrants that it would not approve a label change to add a cancer warning.

EPA has been clear in informing Monsanto and other glyphosate registrants that it would not "approve changing the . . . label to include" the warning that glyphosate may cause cancer in humans. *See Albrecht*, 139 S. Ct. at 1678. In its 1993 FIFRA reregistration for glyphosate, EPA officially designated it a Group E carcinogen, indicating "evidence of non-carcinogenicity in humans." Appx0874 (1993 RED). EPA has since switched to using standard hazard descriptors, including "not likely to be carcinogenic to humans," Appx0967 (2017 Revised Glyphosate Issue Paper), and has been using that very descriptor for glyphosate consistently since 2005, including as recently as September 2022. Appx1091 (EPA Withdraws

Glyphosate Interim Decision). It would therefore constitute misbranding to have registrants include a cancer warning when EPA has itself consistently concluded that glyphosate is "not likely to be carcinogenic to humans."

Furthermore, on August 7, 2019, EPA sent a letter to glyphosate registrants in response to a March 2017 California requirement mandating a cancer warning on labels of Roundup and other glyphosate products on the basis of the 2015 IARC report. *See* Appx0192 (2019 Letter to Registrants). EPA explained that it "disagrees with IARC's assessment," and explicitly cautioned that a warning on glyphosate-based herbicides to the effect that glyphosate may cause cancer would be "false and misleading," and would render any product so labeled "misbranded pursuant to section 2(q)(1)(A) of FIFRA." *Id.* (citing 7 U.S.C. § 136(q)(1)(A)).[8]

EPA thus has been unmistakably clear in its message to registrants that it will not accept Plaintiffs' requested change to the label on FIFRA-registered glyphosate herbicides to warn that they are carcinogenic to humans.

8. On April 8, 2022, in response to a question from the California EPA, the (federal) EPA advised that it could approve a label statement stating: "The [IARC] classified glyphosate as probably carcinogenic to humans. U.S. EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations." Appx1045. The federal EPA, however, reaffirmed its position that an unqualified warning that glyphosate causes cancer would be false and misleading. *Id.* In this case, Plaintiffs claim that Pennsylvania law requires an unqualified warning. Appx0075-0076 (Compl. ¶¶ 164-65).

C. There is clear evidence that EPA has engaged in a decades-long, consistent pattern of Congressionally authorized "appropriate" agency actions carrying the "force of law" for preemption purposes.

In *Albrecht,* the Supreme Court enumerated three categories of "appropriate" agency action that have the "force-of-law": (1) "notice-and-comment rulemaking setting forth labeling standards"; (2) "formally rejecting a warning label that would have been adequate under state law"; or (3) "other agency action carrying the force of law." 139 S. Ct. at 1679 (citations omitted). It then reemphasized "the obvious point that, whatever the means the FDA uses to exercise its authority, those means must lie within the scope of the authority Congress has lawfully delegated." *Id.* The Court thus articulated a flexible understanding of what constitutes "appropriate" federal agency action that counts as "carrying the force of law" and preempts state law when "it is 'impossible for a private party to comply with both state and federal requirements.'" *Id.* at 1672 (quoting *Bartlett*, 570 U.S. at 480 (citation omitted)).

Here, it is undisputed (and cannot be disputed) that EPA has acted within the scope of its congressional authorization under FIFRA. There is abundant "clear evidence" that EPA has for decades, and through multiple actions authorized under FIFRA, adopted the position that it would *not* approve a cancer warning label for registered uses of glyphosate. Most notably, EPA has rendered cancer classifications as part of formal registration, re-registration, and registration review processes mandated by FIFRA, subject to extensive notice and comment (and

judicial review under the APA). *See. e.g.*, Appx0234-235 (2020 Interim Registration Review Decision); Appx0882 (1993 RED); *see also* Monsanto Br. at 50-51. EPA has also routinely approved the registration of individual pesticides containing glyphosate and has consistently approved labels without a cancer warning. Appx0215-0216, 0218, 0224 (Br. of U.S. as Amicus Curiae, *Hardeman v. Monsanto Co.*, No. 19-16636 (9th Cir. Dec. 20, 2019)); *see* Monsanto Br. at 11-16. In so doing, EPA necessarily made statutorily prescribed findings that the glyphosate-based pesticide would have no "unreasonable adverse effects" on humans and the environment, and thus found not only that cancer warnings were not "required under" FIFRA, but that such warnings would be false and misleading, 7 U.S.C. §§ 136a(c)(5)(C)-(D), 136(bb). If something more than the agency's ordinary registration/label approval/reregistration/registration review process were required to establish agency action with the "force-of-law" for impossibility preemption purposes, it is hard to imagine what would do so (and in any event such an approach would deprive the express preemption provision of any practical effect).

Moreover, as noted above, EPA notified glyphosate registrants concerning a 2017 California requirement for cancer warnings and stated that it would *not* approve labels adding the warning because the product would then be misbranded. Appx0192-0193 (2019 Letter to Registrants). The Ninth Circuit in *Hardeman* found that the 2019 Letter, by itself, lacked force of law, without situating it within the

context of the unbroken, decades-long pattern of legally binding formal agency actions constituting clear evidence that EPA would not approve a cancer warning label on glyphosate products. *See Hardeman*, 997 F.3d at 957.

The Ninth Circuit in *Hardeman* and the MDL district court appear to have presumed that the *Albrecht* Court's use of the word "formally" meant notice-or-comment rulemaking. This approach to "force-of-law" is exceedingly narrow and unrealistic. And it is belied by the example that the *Albrecht* Court itself cited. The FDA regulations which the *Albrecht* Court cited – 21 C.F.R. §§ 314.110(a), 314.125(b)(6) – refer to various ways that the agency may "communicate its disapproval" of a proposed labeling change, including a letter to an applicant. EPA's August 2019 Letter to all registrants of a class of products definitively and unambiguously indicating that EPA would reject a state-law mandate label change containing a specific warning is functionally no different.

In any event, when the *Albrecht* Court indicated that "other agency action carrying the force of law" counted as appropriate agency action for preemption purposes, it cited 21 U.S.C. § 355(o)(4)(A). 139 S. Ct. at 1679. That provision of the FDCA requires the Secretary of Health and Human Services to notify the responsible person if the Secretary "becomes aware of new information, including any new safety information" relating to an approved drug that "should be included in the labeling of the drug." 21 U.S.C. § 355(o)(4)(A). As Justice Alito explained

in his concurrence, that provision is "highly relevant" to implied preemption analysis because "if the FDA declines to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified." *Albrecht*, 139 S. Ct. at 1684-85 (citations omitted). If such an *implicit* failure to update a label in light of new safety information counts as appropriate agency action with the force of federal law in impossibility preemption, then EPA's multiple *explicit* refusals to update – after review of all the studies and data relevant to the carcinogenicity of glyphosate it received and considered – surely count too.

In another medical safety case, the Supreme Court found that an agency's "[p]remarket approval . . . imposes requirements [because it is] specific to individual devices." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-23 (2008). Thus, while formal notice-and-comment rulemaking or adjudication *can* show that an agency acted with force of law, it is not required for such a determination.

Agencies like the EPA or FDA, with broad responsibilities governing thousands of products and their labels, do not and cannot act through notice-and-comment rulemaking, or even formal adjudication, for every action. Requiring such formality would grind federal regulatory processes to a halt. Instead, these agencies act by issuing letters, notices, and other means, and sometimes by failing to require change in the face of new information – all of which are entirely less formal than

EPA's registration, reregistration, and registration review process under FIFRA. Yet as *Albrecht*, *Riegel*, and other cases recognize, these forms of action nonetheless can have real and binding consequences on regulated entities – and thus may trigger preemption.

* * *

Health, safety, and environmental standards promulgated by regulators like EPA carefully balance the need to inform users of significant risks while avoiding "overwarnings" that discourage the use of vital products. Companies that operate in compliance within such a regulatory framework should not be concurrently subject to divergent and unpredictable jury verdicts under differing State tort laws in irreconcilable conflict with federal law and administrative actions.

CONCLUSION

For the reasons stated above, *amici* respectfully suggest that the Court should reverse the judgment of the district court.

Dated: February 15, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This document complies with the word limit of Fed. R. App. P. 29(a)(5), excluding the parts of the document exempted by Fed. R. App. P. 32(f) and Third Circuit Local Appellate Rule 29.1(b).* This document contains 6,406 words.

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Dated: February 15, 2023 /s/ William R. Stein

∗ . Third Circuit Local Appellate Rule 29.1(b) provides, "The statement required by FRAP 29(c)(4) does not count toward the word limitations of FRAP 32(a)(7)." The current version of FRAP 29 does not contain a sub-section (c)(4). However, the version of the Federal Rules in effect as of December 1, 2010 – when the Third Circuit Local Appellate Rules were last updated – contained a provision 29(c)(4), which referred to the "concise statement of the identity of the amicus curiae, its interest in the case, and the source of its authority to file." Therefore, as confirmed to us by the Third Circuit Clerk's Office, the corresponding statement in this document, *see supra* p. 1, has been excluded from the word count. (In the current version of the FRAP, the statement of identity and interest of the amicus curiae is covered in Rule 29(a)(4)(D)).

CERTIFICATE OF BAR MEMBERSHIP

Pursuant to Third Circuit Local Appellate Rule 28.3(d), I certify that the following attorneys whose names appear on the brief are members of the bar of this Court or have filed an application for admission pursuant to Third Circuit Local Appellate Rule 46.1:

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CERTIFICATE OF SERVICE

I hereby certify that on February 15, 2023, I electronically filed the foregoing brief with the Clerk of Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. I certify that the foregoing document is being served this day on all counsel of record, and that service will be accomplished by the appellate CM/ECF system.

Dated: February 15, 2023 /s/ William R. Stein