21-10994

United States Court of Appeals

for the

Eleventh Circuit

JOHN D. CARSON,

Plaintiff/Appellant,

– v. –

MONSANTO COMPANY,

Defendant/Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF GEORGIA
CASE NO: 4:17-cv-00237-RSB-CLR
(Hon. R. Stan Baker)

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE PHAMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLEE

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June 11, 2021

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1 to 26.1-3, counsel for *Amici Curiae* the Chamber of Commerce of the United States of America (the "Chamber") and the Pharmaceutical Research and Manufacturers of America ("PhRMA") hereby certifies that the following persons and entities may have an interest in the outcome of this appeal:

Entities

1. Chamber of Commerce of the United States of America
2. Hughes Hubbard & Reed, LLP, law firm for the Chamber and PhRMA
3. The Pharmaceutical Research and Manufacturers of America

Interested Persons

4. Kimmel, Melissa B., counsel for PhRMA
5. Lee, Thomas H., counsel for the Chamber and PhRMA
6. Lettow, Paul V., counsel for the Chamber
7. Maloney, Stephanie A., counsel for the Chamber
8. Mayer, Theodore V. H., counsel for the Chamber and PhRMA
9. Stansel, James C., counsel for PhRMA
10. Stein, William R., counsel for the Chamber and PhRMA

Pursuant to Federal Rule of Appellate Procedure 26.1, the Chamber states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

PhRMA states that it has no parent corporation and no publicly traded company owns 10% or more of its stock.

Dated: June 11, 2021

Respectfully submitted,

s/ William R. Stein

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Constitutional Provisions

Statutes and Rules

Regulations

Legislative and Administrative Materials

Other Authorities

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

1. Pursuant to Rule 29 of the Federal Rules of Appellate Procedure, this brief is submitted with the consent of Plaintiff-Appellant John D. Carson and Defendant-Appellee Monsanto Company. No party or party's counsel authored this brief in whole or in part. No party, no party's counsel, and no person other than *amici*, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

estimated $83 billion in 2019 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*.

This case implicates core concerns of both the Chamber and PhRMA regarding the proper balance between federal and state regulation of drug labeling. As explained below, the district court's decision correctly interpreted a comprehensive congressionally-enacted regulatory scheme as against a state tort-law challenge and should be affirmed.

STATEMENT OF THE ISSUE

Whether the district court correctly dismissed Plaintiff-Appellant's state-law failure-to-warn claim because it is preempted by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*

SUMMARY OF ARGUMENT

This case presents an issue of vital importance to the United States business community generally, and specifically to companies that operate subject to comprehensive federal regulation in such industries as the food, drug, chemical, and agricultural sectors. Companies subject to these types of comprehensive regulatory regimes depend on the predictability provided by uniform national standards. These

companies 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 Congress assigned to administer the regime 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 Georgia 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 by" the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") itself, and any appropriate actions taken by the Environmental Protection Agency ("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 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 Glyphosate Does Not Cause Cancer and the Product Label May Not Contain Such a Warning.

The modern use of herbicides and pesticides to kill weeds and to protect crops from destruction by insects, animals, and disease has alleviated human suffering and enabled exponential human population growth. Since its discovery by a Monsanto scientist in 1970, glyphosate, the active ingredient in Roundup®, has become the most widely used organic compound in herbicides in the United States and across the globe. 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[2] 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 regulatory scheme

2. Glyphosate is used in herbicides, but the term "pesticide" is often used (as in FIFRA) as an umbrella term to refer to herbicides, pesticides, insecticides, herbicides, and rodenticides.

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. *See* Insecticide Act of 1910, Pub. L. 61-152, 36 Stat 331–35. The statute had the twin aims of checking the efficacy and labeling accuracy of pesticides trafficked through interstate and foreign commerce. To do so, the statute tasked the Department of Agriculture to "examine" specimens of insecticides brought before it, including imports turned over by the Treasury. *Id.* §§ 4, 11. The statute specified that "the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of 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 on farms, gardens, and pastures 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 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 general

guidance for label content on registered products, including: (1) directions for use; (2) risks to persons, plants, and animals; and (3) claims of efficacy. Pub. L. 80-104, 61 Stat. 166–67. The statute authorized the Secretary to request an applicant seeking to register a pesticide to provide data backing up the pesticide's efficacy and risk claims. Pub. L. 80-104, 61 Stat. 167–68. The enactment of FIFRA, and the promulgation of a registration system, represented a significant second step in national regulation of pesticides. However, the States were still the principal regulators and enforcers of the use of pesticides on lands within their respective borders. Indeed, a Uniform State Insecticide, Fungicide, and Rodenticide Act had been drafted in 1946 and was contemplated by several States even after the passage of FIFRA the next year. *See* S. Rep. No. 92-838, at 7 (1972).

The 1960s and 1970s witnessed a sea change in U.S. popular opinions 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 to human health. These concerns spurred the creation of a new federal administrative agency, the Environmental Protection Agency (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) (citing H.R. Rep. No. 92-511, at 1 (1971)). 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 to FIFRA, which remain the core of FIFRA today, was a recalibration of 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. 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 laws. 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 arguably lesser power to subject products within its territory to its own labeling requirements.[3]

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

- its efficacy, *id.* § 136a(c)(5)(A);

3. The next section of FIFRA permits a state to "provide registration for additional uses of federally registered pesticides" within the State for "special local needs" but for "distribution and use only within such State." 7 U.S.C. §136v(c)(1).

- that it will have no 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.*, "false or misleading in any particular," supplies adequate instructions for use, and contains all necessary warnings, *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 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 of pesticides during the registration process. Pub. L. 95-396, 92 Stat. 819, 820–22. The agency was expending too much time and resources churning

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, 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.

through massive amounts of data to gauge the efficacy of pesticides, 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.* (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 any scientific or other confirmation of the efficacy claims asserted on its label, although efficacy is still a requirement of FIFRA, as is the manufacturer's obligation to be accurate in its claims about efficacy. 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 in the pesticide space over seven decades. Congress enacted the Insecticide Act of 1910 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. 5, *supra*. By 1979, efficacy ("adulterated") was no longer a part of EPA's active monitoring mission. *See Bates*, 544 U.S. at 440 (citations omitted). The misbranding mission to police labels for false or misleading information, adequate use instructions, and necessary warnings, still endures. But EPA's primary mission under FIFRA has changed: its principal role now is to assess the health and environment risks of registered pesticides and ensure that labels accurately reflect this assessment.

This evolution in the federal regulatory regime illuminates 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 uniformity and authorized EPA to assess the health and environmental dangers of registered products and ensure their proper labeling instead. Close consideration of Congress's goals with regard to the effects of federal regulation on business and consumers 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 and effort to performing the mission of investigating and ascertaining the safety to environment and humans of pesticides and prescribing labels that accurately reflect its assessments. States retain regulatory powers with respect to the use of pesticides within their borders, but Congress has

preempted their power to regulate 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 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.*, 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Commerce v. Whiting*, 563 U.S. 582, 594 (2011)).

Congress has written an express preemption clause into FIFRA. 7 U.S.C §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 this subchapter." Thus, whether the statute precludes a tort action under state law turns on two elements: (1) whether the state law is a requirement "for labeling or packaging," and, if so, (2) whether the state-law requirement is "in addition to or different from" labeling or packaging requirements "required" under FIFRA. *Bates*, 544 U.S. at 444. The first part of the *Bates* test is easily satisfied in this case.

Plaintiff's claim is that Monsanto has failed to warn about glyphosate's cancer risks in its labeling or packaging for Roundup, as Georgia tort law requires.[5]

As to 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 requirement under FIFRA in order to survive preemption." *Id.* at 453. Put another way, to escape an 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 federal law. *See Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011).

If a federal court in diversity found that Georgia tort law *required* Monsanto to state that Roundup "may cause cancer" on its product label or packaging, then Georgia law would be expressly preempted because there is no parallel federal law requirement under FIFRA to do so. That is the case here. In fact, as discussed

5. FIFRA defines "labeling" broadly. 7 U.S.C. § 136(p)(2); *see* Br. of Def.-Appellee Monsanto Co. ("Monsanto Br."), *Carson v. Monsanto Co.*, No. 21-10994 (11th Cir. June 4, 2021).

below, EPA has determined that the Roundup label and packaging may *not* include such a warning. *See* pp. 23–24, *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 reasoned that FIFRA did not prohibit a glyphosate registrant like Monsanto from unilaterally adding a cancer warning to its approved label, as required by California. *See Hardeman*, 997 F.3d at 954. But FIFRA requires Monsanto to obtain EPA's approval before making such a major label change. *See* p. 9 & n.4, *supra*. 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).

The Ninth Circuit panel's reliance in *Hardeman* on 7 U.S.C. § 136a(f)(2) to override the clear preemptive effect of Section 136v(b) is also mistaken. 997 F.3d at 956. Section 136a(f)(2) provides that registration of a product is not to "be construed as a defense for the commission of any offense under" FIFRA but is instead "prima facie evidence" of compliance with the statute. The Ninth Circuit read this provision to mean that "even though EPA approved Roundup's label, a

judge or jury could disagree and find that same label violates FIFRA" because it does not say "may cause cancer." *Hardeman*, 997 F.3d at 956. But Section 136a(f)(2) has "no bearing" on preemption. *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994). As Monsanto explains, the provision clarifies that the mere fact of registration is no defense to a claim that a product or label is a violation of FIFRA (*e.g.*, the product label omits an EPA-required warning). Monsanto Br. at 36–38. The Ninth Circuit cannot be right that, simply because state tort law and FIFRA misbranding requirements are 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 requests that differ from, EPA's requirements. EPA's determinations, which are based on the agency's thorough, decades-long review of scientific evidence and studies, *see* § II, *infra*, are agency actions that FIFRA commands and authorizes.

EPA's assessment, and the basis for its conclusions, may be challenged in proceedings under the Administrative Procedure Act, wherever 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 the exceedingly remote prospect of the Supreme Court's certiorari jurisdiction 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*. There, the Court remanded for consideration of whether mislabeling claims under Texas law were preempted by FIFRA. *Bates*, 544 U.S. at 435–36. But unlike here, *Bates* concerned the *efficacy* of the pesticide at issue (Strongarm®). *See* 544 U.S. at 438 (citing 7 U.S.C. § 136a(c)(5)(A)). As noted above, EPA stopped conducting efficacy analysis in registration in 1979. *See* pp. 9–10, *supra*. Consequently, EPA's registration of Strongarm did not entail a review of 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" to the requirements of Texas state law. *Bates*, 544 U.S. at 447, 453.

By contrast, EPA's principal gatekeeping mission since 1979 has been precisely to focus on potential "adverse effects." *See* Monsanto Br. at 6. EPA's registration, re-registration, label approval, and ongoing registration review of Roundup have entailed exhaustive examination of glyphosate's possible "unreasonable adverse effects" on humans. *See* 7 U.S.C. §§ 136(bb), 136a(c)(5)(C).

Thus, in December 2017, EPA announced its proposed conclusion that the "strongest support" for a characterization of the carcinogenic potential of glyphosate is "not likely to be carcinogenic to humans." Supp. App. 179–80 (EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017) ("Revised Glyphosate Issue Paper")).[6] EPA reached this conclusion that the data and evidence did not support alternative descriptors after comprehensive and considered reason of all the scientific evidence and studies, including the IARC study at the heart of plaintiff's case. Supp. App. 311 (Revised Glyphosate Issue Paper). EPA reached the same conclusion in April 2019 in its Proposed Interim Registration Review Decision. Supp. App. 056–57 (EPA, Glyphosate — Proposed Interim Registration Review Decision Case Number 0178 (Apr. 2019) ("2019 Proposed Interim Registration Review Decision")). And in an August 2019 letter to Registrants ("2019 Letter to Registrants"), EPA put glyphosate registrants on notice that placing a cancer warning on glyphosate-based products would be "false and misleading" and would render the product "misbranded" under FIFRA. Supp. App. 011*; see* Monsanto Br. at 9–14.

FIFRA's express preemption provision applies because Georgia tort law purportedly requires a label with a cancer warning on glyphosate products, which is

6. Supp. App. refers to the Supplemental Appendix of Defendant-Appellee Monsanto Company, filed on June 7, 2021.

"in addition to or different from," 7 U.S.C. § 136v(b), what FIFRA requires, as determined by EPA pursuant to its authority under the statute's "comprehensive regulatory" regime, *Ruckelshaus*, 467 U.S. at 991 (1984).

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

In addition to being expressly preempted under 7 U.S.C. § 136v(b), plaintiff's state-law failure to warn claim 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). The Supremacy Clause of the Constitution provides that: "The Constitution, and Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S Const., art. VI, cl. 2. The plain import of the Supremacy Clause is that when the "Laws of the United States" command a private party like Monsanto 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. "[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).

A situation in which Congress passes a statute that tells private parties "Don't do X" and a state legislature enacts a law saying "Do X" is the most straightforward case of impossibility preemption. In the present case, it is not Congress but EPA, a federal agency acting pursuant to authority expressly conferred under FIFRA, that has framed the federal-law duty. Consequently, preemption occurs when the agency ''is acting within the scope of its congressionally delegated authority, for an agency literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019) (alteration incorporated) (quoting *New York v. FERC*, 535 U.S. 1, 18 (2002)). Likewise, it is not the state legislature but state common law that is alleged to provide the basis for the plaintiff to assert a state-law duty to warn.

By way of comparison, in the context of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, the Supreme Court has 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." *Id.* at 1678–79. The Court advised that the judge conclude that "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.

The *Albrecht* Court went on to enumerate three categories of "appropriate" agency action: (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." *Id.* at 1679 (citations omitted). The Court explicitly noted that "[t]he question of disapproval 'method' is not now before us." *Id.* 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 indicated a flexible view of the types of agency action that counted as "carrying the force of law" for impossibility preemption purposes.

The plaintiff has never argued in this case that EPA exceeded the scope of its congressional authorization under FIFRA or that Congress in FIFRA has unconstitutionally delegated authority to that agency.

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 plaintiff's 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 9–10. In fact, in its FIFRA reregistration for glyphosate completed in 1993, EPA designated glyphosate a Group E carcinogen, denoting "evidence of *non-carcinogenicity* in humans." Supp. App. 069 (EPA, Reregistration Eligibility Decision (RED) – Glyphosate (Sept. 1993) ("1993 Reregistration Eligibility Decision")) (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 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." Supp. App. 056–57 (2019 Proposed Interim Registration Review Decision).[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 humans." Supp. App. 395 (EPA, Glyphosate: Interim Registration Review Decision Case No. 0178 (Jan. 2020) ("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 the U.S. EPA 1, *Nat'l Res. Def. Council v. U.S. Env't Prot. Agency*, Nos. 20-70787, 20-70801, Dkt. 80 (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").

7. Regulatory agencies in the European Union, Australia, Canada, Germany, Japan, New Zealand, and other countries have also concluded that scientific evidence does not support a finding that glyphosate causes cancer in humans. Supp. App. 011 (2019 Letter to Registrants).

B. There is clear evidence that EPA informed registrants 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. As already noted, EPA in its 1993 FIFRA reregistration for glyphosate, officially designated it a Group E carcinogen, indicating "evidence of non-carcinogenicity in humans." Supp. App. 084 (1993 Reregistration Eligibility Decision). In 2005, EPA stopped using hierarchical categories, such as Group E. Notice of Availability of the Document Entitled Guidelines for Carcinogenic Risk Assessment, 70 Fed. Reg. 17,765–17,817 (Apr. 7, 2005). Instead, EPA now uses standard hazard descriptors, including "not likely to be carcinogenic to humans," *id.* at 17,772, and as recently as January 2020 has used that very descriptor for glyphosate, *see* § I.B, *supra*. It would therefore constitute misbranding to have registrants include a cancer warning when EPA has itself consistently reported 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 ordinance mandating a cancer warning on labels of Roundup and other glyphosate products in the wake of the 2015 IARC report. *See* Supp. App. 011 (2019 Letter to Registrants). EPA explained that it "disagrees with IARC's assessment," because "EPA scientists have performed an

independent evaluation of available data since the IARC classification" and determined that glyphosate is "not likely to be carcinogenic to humans." *Id.* EPA 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)).

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

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

As explained above, the Supreme Court in *Albrecht* articulated a flexible understanding of what constitutes "appropriate" agency action that counts as federal law preempting state law in the drug approval context when "it is 'impossible for a private party to comply with both state and federal requirements.'" 139 S. Ct. at 1672 (quoting *Bartlett*, 570 U.S. at 480 (citation omitted)). The more important, "obvious" point, according to the Court in *Albrecht*, was that "whatever the means the [agency] uses to exercise its authority, those means must lie within the scope of the authority Congress has lawfully delegated." *Id.* at 1679.

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 carcinogen 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). Supp. App. 386–421 (2020 Interim Registration Review Decision); Supp. App. 061–144 (1993 Reregistration Eligibility Decision); *see also* Monsanto Br. at 50. EPA has also routinely approved the registration of individual pesticides containing glyphosate and approved labels without a cancer warning. Supp. App. 045 (Br. of United States as Amicus Curiae in Support of Monsanto, *Hardeman v. Monsanto Co.*, No. 19-16636 (9th Cir. Dec. 20, 2019)). 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. 7 U.S.C. §§ 136a(c)(5)(C), (D); *id.* § 136(bb). Moreover, as noted above, EPA notified glyphosate registrants concerned about a 2017 California ordinance requiring cancer warnings that it would *not* approve labels adding the warning because the product would then be misbranded. Supp. App. 011 (2019 Letter to Registrants). The Ninth Circuit in *Hardeman* focused unduly on the 2019 Letter without properly acknowledging the unbroken, decades-long pattern of legally binding 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* appears to have presumed that the *Albrecht* Court's use of the word "formally" meant a "formal proceeding" akin to rulemaking. But that is belied by the example 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 Food, Drug and Cosmetic Act 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 on the carcinogenicity of glyphosate it received and considered—surely count too.

* * *

Health, safety, and environmental standards promulgated by regulators such as EPA represent a measured balancing of interests and weighing of acceptable risks in the marketplace. Companies that operate in good-faith 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 affirm the judgment of the district court.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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CERTIFICATE OF SERVICE

I hereby certify that on June 11, 2021, I electronically filed the foregoing brief with the Clerk of Court for the United States Court of Appeals for the eleventh 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 June 11, 2021 /s/ William R. Stein