No. 21-10994

United States Court of Appeals

for the

Eleventh Circuit

JOHN D. CARSON,

Plaintiff-Appellant,

– v. –

MONSANTO COMPANY,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF GEORGIA IN CASE NO. 4:17-CV-00237-RSB-CLR (HON. R. STAN BAKER, JUDGE)

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

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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"), The Pharmaceutical Research and Manufacturers of America ("PhRMA"), and the Products Liability Advisory Council, Inc. ("PLAC") hereby certifies that the following persons and entities may have an interest in the outcome of this appeal:

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74. Product Liability Advisory Council, Inc.

75. Public Citizen, Inc.

76. Public Citizen Litigation Group

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80. United Farm Workers

81. UFW Foundation

82. U.S. Chamber Litigation Center

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 and PLAC state that they have no parent corporation and no publicly traded company owns 10% or more of their stock.

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

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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. 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 members have invested nearly $1 trillion searching for new treatments and cures, including an 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

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1. 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.

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 *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, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law affecting product risk management.

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 correctly interpreted a comprehensive,

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

congressionally enacted regulatory scheme as preempting an inconsistent state tort-law claim.

STATEMENT OF THE ISSUE

Whether the district court correctly dismissed Plaintiff-Appellant's state-law failure-to-warn claim as 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 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. Both the public and the economy benefit from consistent, nationwide safety requirements. Compliance with comprehensive regulatory frameworks established by Congress, and with the determinations of the federal agencies to which Congress assigned responsibility to administer those statutes, should not, under the Supremacy Clause, lead to liability under a patchwork of state laws and jury determinations, each establishing different standards.

Appellant's failure-to-warn claim under Georgia common law is expressly preempted by FIFRA §136v(b), which 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. Appellant's claim seeks to require a cancer warning on Roundup® labels that is not required under FIFRA. Congress authorized the Environmental Protection Agency ("EPA") to administer the statutory scheme, and EPA does not require a cancer warning under FIFRA. The statute itself gives EPA's requirements preemptive effect; no "force-of-law" analysis is required.

Appellant's claim is also impliedly preempted. FIFRA prohibits Monsanto from changing the Roundup label in order to comply with Georgia common law without first obtaining EPA approval. EPA, in the exercise of its lawful delegated authority under FIFRA, has consistently determined that a cancer warning should not – indeed, may not lawfully – be placed on glyphosate registered-product labels. For both reasons, it is impossible for a private party to comply with both Georgia common law and FIFRA.

ARGUMENT

I. Express Preemption Requires Only Application of the Preemption Provision, Not a "Force of Law" Inquiry.

This Court asked, "Can an express-preemption provision like [FIFRA] § 136v(b) give preemptive effect to a federal agency action that otherwise lacks the 'force of law'? Or must a reviewing court determine, as a threshold matter, whether federal agency action has the 'force of law'?" Doc.115.

Under the Supremacy Clause, the "Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. Art. VI, cl. 2. The threshold inquiry in a preemption analysis is to identify a "law[] of the United States," that is claimed to supersede a state law. The federal law can be either a statute or agency action. *Louisiana Public Service Com'n v. F.C.C.*, 476 U.S. 355, 369 (1986) ("Pre-emption may result not only from action taken by Congress itself; a federal agency acting within the scope of its congressionally delegated authority may pre-empt state regulation."). Once the federal law is identified, the next inquiry is to determine whether it preempts the state law at issue.

If a preemption claim is based on a federal statute with an express preemption provision, this ends the threshold inquiry. Such a statutory provision unquestionably ***is*** federal law. A separate "force-of-law" inquiry is neither necessary nor relevant. The relevant inquiry is one of statutory interpretation – determining the scope of the preemption provision and its application to the case at hand. *See Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 579 U.S. 115, 116 (2016) ("[when] the [federal] statute 'contains an express pre-emption clause,' we . . . 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" (quoting *Chamber of Commerce v. Whiting*, 563 U.S. 582, 594 (2011))). To understand the scope of a pre-emption statute, the Supreme Court has instructed courts to look both to the text and to "the structure and purpose of the statute as a

whole, 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 v. Lohr*, 518 U.S. 470, 485-86 (1996) (internal citations omitted).

By contrast, where a party alleges that preemption exists because of federal agency action ***only***, it is necessary as part of the threshold inquiry to determine whether this agency action constitutes federal law. This is where a "force-of-law" analysis comes into play. *See Wyeth v. Levine*, 555 U.S. 555, 577, 580 (2009). The only instance where the Supreme Court has inquired as to whether agency action had the force of law in a preemption case, was where there was no express statutory preemption provision. *Id.* at 574 (noting the deliberate legislative choice not to enact an express preemption provision in the Food, Drug and Cosmetics Act ("FDCA") for prescription drugs). The Supreme Court has ***never*** conducted a "force-of-law" inquiry in cases involving a statutory preemption provision. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

If the court finds that the agency action has the force of federal law, the inquiry turns to whether this federal law preempts the state law (*i.e.*, through field or impossibility preemption).

Section 136v(b) of FIFRA is an express federal preemption statute, so no additional "force-of-law" analysis is necessary. This Court's task is straightforward: apply the statute.

II. FIFRA Expressly Preempts Plaintiff's State-Law Claim.

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 this subchapter [*i.e.*, FIFRA]." 7 U.S.C. §136v(b).

Thus, three elements are necessary for preemption under §136v(b). First, there must be a State "requirement[] for labeling or packaging." Second, there must be a "requirement for labeling or packaging . . . required under [FIFRA]." Third, the State requirement must be "in addition to or different from" that "required" under FIFRA. *Bates v. Dow Agrosciences*, 544 U.S. 431, 443-44 (2005).

All elements are met here. First, it is undisputed that Appellant's failure-to-warn claim under Georgia common law is a State requirement for labeling or packaging. Second and third, Georgia's failure-to-warn cause of action would require a cancer warning where EPA does not, thus imposing a state-law requirement "in addition to or different from" the "requirements" imposed by EPA under FIFRA.

A. FIFRA Empowers and Obligates EPA to Establish Label "Requirements" under "This Subchapter."

Congress empowered EPA to implement and enforce "this subchapter" (FIFRA) by, among other things, regulating the content of the labels and packaging

of registered pesticides – *i.e.*, by determining what the label is required to say regarding human and environmental safety. EPA has approved labels for numerous herbicides containing glyphosate (including Roundup) but has never required that such labels or packaging contain a cancer warning. *See* Monsanto Br.8-13; CropLife Br.11-17, 19-21.

This Court asked, "How should a reviewing court identify the federal 'requirements . . . under this subchapter' to which § 136v(b) refers?" Doc.115. This Court should do so by considering the regulatory scheme established by the statute. Congress set up a comprehensive and relatively formal administrative process, under which EPA undertakes a review of the relevant science and determines whether a pesticide may be and remain "registered" (*i.e.*, safely marketed and sold in interstate commerce), and what its label and packaging must – and may not – contain. 7 U.S.C. §§136a(a), 136a(c)(5)(B). The "requirements under [FIFRA]" within the meaning of §136v(b) are EPA's determinations about the necessary contents of the registered product's labels and packaging. The reviewing court identifies the federal labeling "requirements . . . under this subchapter" by identifying what EPA has determined the label ***must*** say. As long as EPA has acted within its statutory authority under

FIFRA, its labeling determinations are "requirements" under the statute. As EPA puts it, "the label is the law."[3]

Monsanto and *amicus* CropLife have explained in detail the complex regulatory process under FIFRA, and we will not repeat it. *See* Monsanto Br.4-8, 22-24; CropLife Br.3-7 (highlighting the lengthy process of registration, reregistration, registration review, label approval). But a few points deserve emphasis.

FIFRA establishes the overarching statutory requirement: a prohibition on "misbranded" pesticides. 7 U.S.C. §136j(a)(1)(E). The statute also establishes that EPA shall determine whether a pesticide is "misbranded," through the comprehensive process for registering, reregistering, and reviewing registration of pesticides, and approving pesticide labels. EPA's registration and label determinations are based on review of all relevant scientific data, including any studies related to carcinogenicity. *See* 7 U.S.C. §§136(bb), 136a(a), (c)(1)(F), (c)(2)(A); 40 C.F.R. §§152.20, 158.200.40; C.F.R. §158.500(d). EPA will register a pesticide only if it "determines that . . . its labeling and other material comply with the requirements of [FIFRA]." 7 U.S.C. §136a(c)(5)(B); *see also* 40 C.F.R.

3. EPA, Label Review Manual, 1-2 (Dec. 2016), https://www.epa.gov/sites/default/files/2021-02/documents/full-lrm_2-22-21.pdf.

§152.112(f) (registration will occur "only if," *inter alia*, "[t]he Agency has determined that the product is not misbranded as that term is defined in FIFRA."). "A pesticide is misbranded if its labeling bears any statement . . . which is false or misleading," *id.* §136(q)(1)(A), or "does not contain a warning or caution statement which may be necessary and if complied with . . . is adequate ***to protect health and the environment***." *Id.* §136(q)(1)(G) (emphasis added).

In the 50 years since EPA first registered Roundup and approved a label – throughout reregistration, registration review, and numerous label approvals – the agency has ***never required*** a cancer warning in a glyphosate product. To the contrary, EPA has consistently concluded that glyphosate likely does not cause cancer in humans, including after considering the IARC report and its underlying studies. *See* Monsanto Br.8-13; CropLife Br.11-17.

Once EPA approves a label as part of the registration process, the manufacturer must use it. A pesticide's registration statement includes its label, 7 U.S.C. §136a(c)(1)(C), and it is unlawful to distribute "any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the [registration] statement." *Id.* §136j(a)(1)(B). A registrant may not add to or modify "mandatory or advisory" labeling statements on a registered product 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] The EPA-approved label reflects its determination concerning what information and warnings are required, and not required, on the label.

It is through this regulatory process that EPA establishes labeling "requirements" under FIFRA. Section 136v(b) gives preemptive effect to these EPA determinations.

The Supreme Court and other courts, applying express preemption provisions similarly worded to FIFRA §136v(b), have found that product-specific approvals by federal agencies establish preemptive "requirements" within the meaning of those provisions. For example, the Medical Device Amendments ("MDA") to the FDCA, like FIFRA, bar states from "establish[ing] or continu[ing] in effect . . . any requirement . . . which is different from, or in addition to, any" MDA requirement. 21 U.S.C. §360k(a). Much like EPA under FIFRA, the Food and Drug Administration requires medical devices to undergo a "premarket approval process [that] includes review of the device's proposed labeling." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008). "Once a device has received premarket approval, the

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. Adding a statement that a product poses a cancer risk is not a minor change.

MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319. The Supreme Court has held that "premarket approval . . . imposes 'requirements' under the MDA [preemption provision]," because it "is specific to individual devices" and "*is* federal safety review." *Id.* at 322-23.

The Ninth Circuit has recently applied *Riegel* to the similarly worded preemption provision in the Poultry Products Inspection Act. *See Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1288 (9th Cir. 2021) ("[W]hen the agency reviews and approves a label, the agency is deciding that it is not false or misleading under the PPIA, and thus the agency 'imposes' a federal requirement within the meaning" of the preemption provision).

Riegel also applies here. EPA made a product-specific determination for each glyphosate product's label as a condition for allowing glyphosate products on the market. EPA's determination constituted federal safety review; it reflected and required the warnings that EPA deemed necessary to protect health and the environment in connection with the use of glyphosate products. A cancer warning has ***never*** been one of those requirements. Indeed, echoing *Riegel* (in a non-preemption context), the D.C. Circuit described FIFRA registration as a "***product-specific license*** describing the terms and conditions under which the product can be

legally distributed, sold, and used." *Reckitt Benckiser, Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010) (emphasis added).

B. Georgia's Failure-to-Warn Common-Law Claim Would Impose Label Requirements "In Addition to or Different from" the Label Required under FIFRA.

FIFRA expressly preempts a State "requirement[] for labeling or packaging" that is "in addition to or different from those required" under FIFRA. 7 U.S.C. §136v(b). 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." 544 U.S. at 453 (emphasis added). A State must "ensure that nominally equivalent labeling requirements are *genuinely* equivalent." *Id.* at 454. 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).

In considering whether a state-law cancer-warning is "in addition to or different from" the EPA-approved label, the Ninth Circuit in *Hardeman* (like the panel of this Court in its now vacated opinion) compared the text of FIFRA's labeling provisions with the elements of California's failure-to-warn cause of action

and found that the state requirement is not "different from" the federal one because both generally require a defendant to warn of relevant dangers. *Hardeman v. Monsanto Co.*, 997 F.3d 941, 955-56 (9th Cir. 2021). The court did not analyze how these requirements ***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" based on their text, they are not "in fact" or "genuinely" equivalent, as *Bates* requires.

As the Tenth Circuit recently explained in finding preemption under a similarly-worded statute, this abstract approach 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). If a label is permitted under a federal law prohibiting deceptive labelling but not state law, the assertion that the two laws "require[] exactly the same thing . . . plainly fails." *Id.* A plaintiff making this assertion "misses the points of preemption," because its "claims are 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 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 Federal Meat Inspection Act (21 U.S.C. §678), the PPIA (21 U.S.C. §467e; *see Webb v. Trader Joe's Co.*, 999 F.3d 1196, 1201-02 (9th Cir. 2021)), and others. *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 approach deprives these preemption clauses of their full effect.

It 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 pesticide-specific requirements as established by EPA. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 529-30 n.27 (1992) ("To analyze failure-to-warn claims at the highest level of generality . . . would render the [express preemption provision] almost meaningless."). EPA's determinations about glyphosate products, which are based on the agency's thorough, decades-long review of scientific evidence, 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 reviewable agency action. But the United States has not waived its sovereign immunity for such challenges to be brought in state court, and the express preemption provision indicates strongly that Congress would not have wanted multiple judges and juries in a ***state***-law tort action to serve as *ad hoc* review of the EPA's considered and evidence-based determinations on these matters, unconstrained by the statutory limitations on judicial review of federal agency action. 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 U.S. Supreme Court.

Congress's purpose in adopting Section 136v(b) of FIFRA was to achieve national uniformity for manufacturers' and distributors' labeling and packaging obligations; this is why it added a heading to Section 136v(b) titled, "Uniformity." 7 U.S.C. §136v(b). The Ninth Circuit's approach would abolish such uniformity. Manufacturers and distributors of products regulated by these statutes would have to canvas failure-to-warn tort litigation in all fifty states, and infer requirements based on the outcomes of these litigations. One impractical option for companies

would be to design fifty different labels – and try to ensure that a product labelled for one state (*e.g.*, Texas), does not end up in another with a different labeling requirement (*e.g.*, Georgia). This would entail enormous costs, not to mention burdens on interstate commerce. Furthermore, it would confuse consumers who encounter the same product in multiple states and find that the product's label warns of different dangers at each encounter.

A second undesirable alternative would be for companies to try to design a label that complies with all fifty sets of state requirements. This would create its own danger of "overwarning." The label would be so long and cumbersome that some customers would ignore it or find it too confusing to be useful. Health, safety, and environmental standards promulgated by expert federal regulators like EPA carefully balance the need to inform users of significant risks while avoiding such "overwarnings." This balance must not be eviscerated by the decision of a lay jury under a generic state common-law cause of action.

The *Hardeman* court's reasoning, urged by Appellant, is wrong. The Georgia cause of action in this case imposes a requirement for labeling or packaging ***with respect to glyphosate*** that is different from or in addition to the label requirements under FIFRA, and is therefore preempted.

C. The "Miscellaneous" Provision in FIFRA Is Irrelevant to Preemption.

Like the Ninth Circuit in *Hardeman*, Appellant places great reliance on 7 U.S.C. §136a(f)(2), which provides that registration of a pesticide is not a defense to violations under FIFRA, and serves only as *prima facie* evidence that the pesticide and its labeling and packaging comply with the statute's registration requirements. *Hardeman*, 997 F.3d at 956; Appellant Br.42-43, 45-46 (Doc.124). Monsanto and CropLife have demonstrated the errors of this argument, and *amici* agree with their position. *See* Monsanto Br.36-42; CropLife Br.22-25. We add one point.

This "Miscellaneous" provision does not change the character of the EPA-approved label as a "requirement" with preemptive effect under §136v(b). Section 136a(f)(2) merely states that registration does not, by itself, prove compliance with ***all*** provisions of FIFRA. But this does not mean that registration is not ***necessary*** to comply with the statue. Clearly registration and use of the approved label are ***necessary, but not sufficient***, to comply fully with the statute. There are many ways a manufacturer or distributor may violate the statute despite having properly registered the product and used the approved label. For example, a manufacturer may fail to comply with EPA regulations requiring that a pesticide be colored or discolored, 7 U.S.C. §§136j(a)(1)(D), 136w(c)(5), may distribute an "adulterated" pesticide, *id.* §§136j(a)(1)(E), 136(c), or may fail to file reports required by the statute, *id.* §136j(a)(2)(N). This means that use of the EPA-approved label is not the

only "requirement" under FIFRA, but it is still a "requirement." And one with preemptive effect under §136v(b).

Appellant's argument that EPA's label determinations with respect to glyphosate are not "requirements" under FIFRA contradicts the common-sense reading of the statute, ignores reality, and undermines legal predictability. Manufacturers like *amici*'s members look to their regulators – the agencies that Congress tasked to carry out a regulatory scheme – and to their regulators' actions in respect of their specific products to determine their federal obligations. In the case of FIFRA, this includes the labels that EPA approves during registration, re-registration, and registration review of a pesticide. Where an agency that is charged with implementing a statute repeatedly makes determinations concerning a product falling under that statute, and those determinations remain consistent over decades, businesses rely on those determinations to know what is expected of them under federal law. If Appellant's argument were correct, the EPA determinations would be little more than advisory opinions regarding manufacturers' and distributors' statutory obligations – a result that would raise questions about why Congress involved EPA in the process at all, and why it bothered enacting an express preemption provision. Moreover, it would undermine the very uniformity and predictability that Congress sought to achieve.

III. Appellant's Claim Is Also Impliedly Preempted.

Appellant's state-law failure-to-warn claim is also 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).

The Supreme 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." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019). In this case, it is not even the state legislature but state common law that is alleged to provide the basis for Appellant to assert a state-law duty to warn.

Appellant inaccurately argues that implied preemption arises ***only*** "when a statute contains no express-preemption provision." Appellant Br.59 (Doc.124). The Supreme Court has repeatedly held that the presence of an express preemption provision in a statute "does *not* bar the ordinary working of conflict pre-emption principles." *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 869 (2000); *see also Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995).

Two types of impossibility preemption apply here.

A. Monsanto Could Not Have Added a Cancer Warning Without EPA Approval.

Under FIFRA, Monsanto could not have lawfully added a cancer warning to the Roundup label to comply with Georgia common law because EPA had not approved such a label change. "The question for 'impossibility' is whether the private party could ***independently*** do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) (emphasis added). In *PLIVA* the Supreme Court held that a state-law claim that would require the private party to change a label on a drug was preempted, because an FDA regulation required that the agency approve any label change; "conjectures" that the FDA would approve the label change were irrelevant. *Id.* at 621. Here, as shown above (pp. 10-11, n.4), except for "minor" changes, FIFRA prohibits a registrant from adding to or modifying "mandatory or advisory" labeling statements on a registered product unless EPA approves the proposed change. A cancer warning would be an "advisory" warning requiring EPA pre-approval, and certainly not a "minor" change that could be unilaterally added.

B. There is Clear Evidence that EPA Would Reject the Cancer Warning Supposedly Required by Georgia Common Law.

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). "[C]lear evidence" exists if the agency (1) was "fully informed" of "the justifications for the warning" the plaintiff alleges state tort law requires; (2) has "informed the . . . manufacturer that [it] would not approve changing the . . . label to include that warning;" and (3) acts with "the force of law." *Id.* at 1678-79.

1. EPA is "fully informed" of the alleged reason for a state-mandated glyphosate warning.

EPA is "fully informed" of Appellant'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, it has gathered, assessed, and reassessed copious scientific evidence and medical studies as to whether the compound causes cancer in humans, and has consistently concluded that it likely does not. *See* Monsanto Br.8-13. In fact, in its reregistration for glyphosate completed in 1993, EPA designated glyphosate a Group E carcinogen, denoting "evidence of ***non-carcinogenicity*** in humans." Supp.App.127 (Excerpts from EPA, Reregistration Eligibility Decision (RED) Glyphosate (1993)) (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." Supp.App.56-57 (2019 Proposed Interim Registration Review Decision). *See* Monsanto Br.11.[5]

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 (2020 Interim Registration Review Decision). EPA has continued to stand by that position after the transition to the administration of President Biden. Supp.App.613 (Br. of U.S. EPA, *Nat'l Res. Def. Council v. EPA*, No. 20-70787 (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

5. Regulatory agencies in 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. Supp.App.11 (2019 Letter).

provide further explanation for its decision. Supp.App.624 (2022 Interim Decision Withdrawal); *see* Monsanto Br.12-13.

2. EPA clearly informed registrants that it would not approve adding a cancer warning to the label.

EPA has been clear in informing Monsanto and other glyphosate product 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 discussed above (pp. 21-23), EPA has consistently concluded that glyphosate "does not pose a cancer risk to humans."[6] EPA adheres to this conclusion to this very day. App.119-120.

Furthermore, on August 7, 2019, EPA sent a letter to glyphosate product registrants in response to a March 2017 California requirement mandating a cancer warning on labels of Roundup and other glyphosate products based on the 2015 IARC report. *See* Supp.App.11 (2019 Letter). EPA explained that it "disagrees with IARC's assessment," and cautioned that a warning on glyphosate-based herbicides to the effect that glyphosate may cause cancer would be "false and misleading," and

6. *See, e.g.*, Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,935-60,943 (Sept. 27, 2002); Final Rule: Glyphosate, Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008).

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)).[7]

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

3. EPA has engaged in a decades-long, consistent pattern of congressionally authorized "appropriate" agency actions carrying the "force of law" for preemption purposes.

It is only in the context of implied preemption that a "force-of-law" inquiry is required. 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

7. 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." App.119. The federal EPA, however, reaffirmed its position that an unqualified warning that glyphosate causes cancer would be false and misleading. *Id.* In this case, Appellant claims that Georgia law requires an unqualified warning. App.31-36 (Compl. ¶¶81-101).

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).

Here, it is undisputed 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 classified glyphosate herbicides as not likely to cause cancer in humans in connection with formal registration, re-registration, and registration review processes mandated by FIFRA, as well as in various rulemakings and other regulatory actions, in each instance subject to extensive notice and comment (and judicial review under the APA). *See. e.g.*, Supp.App.395 (2020 Interim Registration Review Decision); Supp.App.127 (1993 RED); n.6, *supra*; Monsanto Br.43-49. EPA has also routinely approved the registration of individual pesticide products containing glyphosate and has consistently approved labels without a cancer warning. Supp.App.32-46 (Br. of U.S. as Amicus Curiae, *Hardeman v. Monsanto Co.*, No. 19-16636 (9th Cir. Dec. 20, 2019)); Monsanto Br.8-13. 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 registration/label approval/reregistration/registration review process were required to establish agency action with the "force-of-law" for impossibility preemption purposes, no agency action would be impliedly preemptive. That is precisely because these processes are the principal means by which EPA exercises its statutory authority.

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. Supp.App.11 (2019 Letter). The Ninth Circuit in *Hardeman* found that the 2019 Letter, by itself, lacked force of law, but mistakenly failed to place the letter 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.

Even without this context, the 2019 Letter had force of law, similar to the response letter cited by the *Albrecht* Court. The Ninth Circuit in *Hardeman* (and the Panel in its now vacated opinion) appear to have presumed that the *Albrecht* Court's use of the word "formally" meant notice-and-comment rulemaking. This "force-of-

law" approach is exceedingly narrow and unrealistic. And it is belied by the example that the *Albrecht* Court itself cited. The *Albrect* Court cited FDA regulations 21 C.F.R. §§314.110(a), 314.125(b)(6), which refer to various ways that the agency may "communicate its disapproval" of a proposed labeling change. 139 S. Ct. at 1679. One of these ways is a "complete response letter to [an] applicant." 21 C.F.R. §110. EPA's 2019 Letter to all registrants of a class of products definitively indicating that EPA would reject a state-law mandated label change containing a specific warning is functionally no different.

Moreover, when *Albrecht* 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 carcinogenicity that EPA received and considered – surely count too.

Agencies such as 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. Instead, where appropriate to the statutory scheme, these agencies act by issuing letters, notices, and other means, and sometimes by determining that no change is required in the face of new information – all of which are considerably less formal than EPA's registration, reregistration, registration review, and label approval process under FIFRA. Yet as *Albrecht*, *Riegel*, and other cases recognize, these forms of action nonetheless have real and binding consequences on regulated entities – and thus may trigger preemption.

Appellant's position on implied preemption would expose manufacturers and distributors to conflicting obligations under federal and state law. They could risk violating their obligations under federal statutes by adopting the state-law warning. Or they could face heightened products-liability risk in the states for complying with federal law. Complying with one regime would violate (or pose a substantial risk of

being held to have violated) the other one. This is the exact Catch-22 that preemption seeks to prevent.

CONCLUSION

Amici respectfully ask that the Court affirm the judgment below.

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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 Eleventh Circuit Rule 32-4. This document contains 6,497 words.

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Dated March 15, 2023 /s/ William R. Stein

CERTIFICATE OF SERVICE

I hereby certify that on March 15, 2023, 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 March 15, 2023 /s/ William R. Stein