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)

AMENDED BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, AND THE PRODUCTS LIABILITY ADVISORTY COUNCIL, INC. AS *AMICI CURIAE* IN SUPPORT OF PETITION FOR REHEARING *EN BANC*

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August 10, 2022

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Eleventh Circuit Rule 26.1(a)(1), and Eleventh Circuit Rule 26.1-2(d), 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 Product Liability Advisory Council, Inc. ("PLAC"), through undersigned counsel, hereby submits this Certificate of Interested Persons and Corporate Disclosure Statement.

Below is a complete list of all trial judges, attorneys, persons, associations of persons, firms, partnerships, or corporations that have an interest in the outcome of this particular case or appeal, including subsidiaries, conglomerates, affiliates, part corporations, any publicly held corporations that own 10% or more of the parties' stock, and other identifiable legal entities related to a party. Pursuant to Eleventh Circuit Rule 26.1-2(d), this list also incorporates all persons and entities listed on all CIPs previously filed in this appeal.

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65. Migrant Clinicians Network

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70. The Product Liability Advisory Council, Inc.

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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.

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

RULE 35-5(C) CERTIFICATION

I express a belief, based on a reasoned and studied professional judgment, that the Panel's decision is contrary to the following decisions of the Supreme Court of the United States and that consideration by the full court is necessary to secure and maintain uniformity of decisions in this court:

1. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005);
2. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008);
3. *Merck Sharpe & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668 (2019);
4. *United States v. Mead Corp.*, 533 U.S. 218 (2001).

I express further a belief, based on a reasoned and studied professional judgment, that this appeal involves a question of exceptional importance: whether the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §136 *et seq.*, preempts a state-law failure-to-warn claim where the Environmental Protection Agency ("EPA") has exercised its statutory authority to determine that the warning sought would be false, rendering the product misbranded under FIFRA.

Respectfully submitted,

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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 companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

The 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 more than $1 trillion in the search for new treatments and cures—including $102.3 billion in 2021 alone. PhRMA's mission is to advocate public policies that

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1. No 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.

encourage the discovery of lifesaving 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 non-profit 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 manufacturers of products and companies in the supply chain. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred 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 both state and federal courts, including this Court, on behalf of its members, while presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects 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, including pesticides and drugs.

STATEMENT OF THE ISSUE

Whether FIFRA preempts a state-law failure-to-warn claim where the EPA has exercised its statutory authority to determine that the warning sought would be false, rendering the product misbranded under FIFRA.

ARGUMENT

This Court should rehear this case *en banc*. The Panel's decision contradicts the Supreme Court's interpretation of FIFRA and threatens to upend preemption law and create havoc for manufacturers and distributors of federally-regulated products.

I. The Panel's Preemption Analysis Is Inconsistent with Binding Precedent.

Congress has amended FIFRA since its passage in 1947 to create a "comprehensive regulatory statute" focused on the effects of pesticides and herbicides on human health and the environment. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). As substantially amended in 1972, FIFRA's wide regulatory scope governs "the use, as well as the sale and labeling, of pesticides." *Id.* at 991-92. The EPA may, after reviewing data and a proposed label, register a pesticide that it finds (1) is "efficacious"; (2) "will not cause unreasonable adverse effects on humans and the environment"; and (3) has a label that "complies with the

statute's prohibition on misbranding." *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 438 (2005).

After the EPA raised concerns that it was spending excessive time reviewing efficacy, Congress in 1978 permitted the agency to register pesticides without doing so. *Id.* at 440. In a 180-degree reversal for the federal government from its initial pesticide regulation, Congress directed that the EPA's sole focus in registering a product and approving its label (or labeling changes) is to assess its risks to humans and the environment. After the EPA approves a label, a manufacturer may not revise "mandatory or advisory" labeling statements without EPA approval. Chamber & PhRMA June 11, 2021 Brief ("Am.Br.") 9.

FIFRA's division of authority between states and the EPA strikes a delicate balance. Section 136v provides: 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 [FIFRA]." 7 U.S.C. §136v(a). Yet, to prevent a confusing mosaic of fifty differing regulatory requirements, the next section reads: "Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under [FIFRA]." *Id.* §136v(b). Thus, the statutory text read in context makes clear a state may impose stricter requirements on EPA-approved products (*e.g.*, regarding efficacy, where the EPA conducts no assessment), but not

a labeling or packaging requirement "in addition to or different from" EPA-approved labels (*e.g.*, regarding health risks, where the EPA conducts exhaustive, continuing analysis and has concluded there is no evidence of a given risk to humans).

The question here is whether a state-law tort claim that Monsanto was required to warn Roundup users that its active ingredient, glyphosate, causes cancer was preempted by the EPA's considered and consistent conclusion, following extensive analysis of scientific data, that *it does not*, rendering any such warning federally-prohibited misbranding. The Panel's conclusion that there is no preemption is based on two fundamental errors, with serious implications for the proper development of preemption law and the many industries regulated by FIFRA and similar federal statutes.

A. The Panel misperceives the nature of express preemption.

FIFRA expressly preempts state law if the state-law requirement is: (1) "for labeling or packaging" (of a "federally registered pesticide"), and (2) "in addition to or different from" labeling or packaging requirements under FIFRA. Op.7-8 (citing *Bates*, 544 U.S. at 444); 7 U.S.C. §136v(a)-(b). "A state-law labeling requirement must *in fact* be equivalent to a requirement under FIFRA in order to survive pre-emption. . . . Nominally equivalent labeling requirements [must be] *genuinely* equivalent." *Bates*, 544 U.S. at 453-54 (first emphasis added).

In considering whether Georgia's cancer-warning is "in addition to or different from" the EPA-approved label, the Panel "match[ed] up" the text of FIFRA's labeling provisions with the elements of Georgia'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. Op.10-11. The Panel 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 evaluating 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 ("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.* 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 Food, Drug, and Cosmetic Act ("FDCA")).

The Panel's focus on the abstract for the second part of the FIFRA test was also inconsistent with its approach to the first part, whether the Georgia failure-to-warn claim is a requirement "for labeling or packaging" of a "federally registered pesticide." The Panel found that this element was "clearly" met, Op.10 n.10, even though the Georgia cause of action quoted by the Panel speaks of "chattels," not "pesticides," and of "inform[ing]" users, not "labeling or packaging." *See Greenway v. Peabody Int'l Corp.*, 294 S.E.2d 541, 545-46 (Ga. App. 1982). To interpret "chattels" as "pesticides," and "inform[ing]" as "labeling or packaging," the Panel had to *apply* the Georgia cause of action to the specific facts of plaintiff's claim. Yet the Panel did not conduct the same concrete analysis when assessing whether the Georgia cause of action was "different from" federal requirements. This inconsistent shift in the level of generality at which the Panel examines plaintiff's claim reinforces the problem with the Panel's reasoning.

B. The Panel's force-of-law analysis is irrelevant and, in any event, unrealistically narrow.

The Panel's second fundamental error was assessing whether certain EPA actions had the "force-of-law." "Force-of-law" is a concept used in implied preemption analysis.[3] Here, FIFRA's express preemption provision has the required

3. A statutory provision (including an express preemption provision) unquestionably is federal law. Courts must conduct the "force-of-law" inquiry to determine the implied preemptive effect of *agency* actions. That is the only context where they have done so, including in the case the Panel cited (Op.6).

force-of-law, and the only question thereunder is whether the warning sought by the plaintiff was "in addition to or different from" the EPA-approved label. If it is, no further analysis is required. Indeed, if something more than the agency's ordinary approval process were required to claim protection of this preemption provision, it would deprive the provision of any practical effect.

Even if relevant, the Panel's approach to "force-of-law" is exceedingly narrow and unrealistic. In *Merck Sharp & Dohme Corp. v. Albrecht*, which arose under the FDCA, the Supreme Court outlined three categories of impliedly preemptive 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," and (3) "other agency action carrying the force-of-law," such as notifying a manufacturer of the need to change a label in light of new information. 139 S. Ct. 1668, 1679 (2019) (citations omitted). In another medical safety case, the 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 or adjudication *can* show an agency acted with force-of-law, "the want of that procedure . . . does not decide" the

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See Wyeth v. Levine, 555 U.S. 555, 563-64 (2009) (party made *implied* preemption arguments), 574 (noting the statute did *not* have an express preemption provision).

issue. *United States v. Mead Corp.*, 533 U.S. 218, 230-31 (2001). What's more important is that the agency actions "bind more than the parties to the ruling." *Id.* at 232. The approval of a label indisputably does so, as it takes certain state-law claims associated with the pesticide off the table.

That registration of a label is not a complete defense against a FIFRA violation, Op.9 (citing 7 U.S.C. §136a(f)(2)), is immaterial. Plaintiff's claim arises under state law, not FIFRA. Section 136v(b) is a defense to *state-law* claims; section 136a(f)(2) addresses registration as a defense to *federal-law* violations.

It is also unclear what, if any, agency action could, under the Panel's heightened standard, constitute agency action with the "force-of-law." The Panel acknowledged several EPA actions before dismissing them as lacking required "indicia of formality." Op.11-12. The EPA has conducted two exhaustive and formal examinations of glyphosate, for re-registration in 1993 and registration review in 2020; both concluded that it was not a carcinogen. Am.Br. 21-22. In 2005, the EPA developed—after notice-and-comment—standard hazard descriptions, such as "not likely to be carcinogenic to humans," which it applies to glyphosate. *Id*. 23. The EPA also issued a series of papers confirming that glyphosate is not carcinogenic. Op.12-13. An August 2019 EPA letter to manufacturers stated that a warning that glyphosate causes cancer would be "a false and misleading statement," rendering the product "misbranded" under FIFRA. Supp.App.011. Manufacturers

reasonably would understand these explicit statements to be binding; that is, the EPA would not approve a label containing the warning plaintiff demands.

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 for every action. Requiring such formality would grind federal regulatory processes to a halt. Instead, these agencies act by issuing letters, notices, guidance, and other "informal" means, and sometimes by inaction. As *Merck*, *Riegel*, *Mead*, and other cases recognize, all these forms of action have real and binding consequences on regulated entities—and thus may trigger preemption.

II. The Panel's Decision Has Adverse Implications for Preemption Law Generally, Across Many Federally Regulated Industries.

The Panel's decision introduces dramatic uncertainty for other federal regulatory schemes governing the labeling of thousands of products sold throughout the country. The Panel's reliance on the abstract "matching" of state and federal requirements, as a practical matter, risks reading express preemption out of such statutes. And introducing "force-of-law" analysis—especially the Panel's impossibly narrow version—sows even greater confusion.

Statutes containing similar preemption clauses abound. The Panel's decision risks confusing manufacturers and exposing them to heightened products liability risk for following federal rules—or inexplicably regulating pesticide manufacturers in a unique way. For example, the Medical Device Amendments ("MDA") to the

FDCA, like FIFRA, bars 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 the EPA under FIFRA (*see* 40 C.F.R. §§152.44, 152.46; Pet.5), "once the [agency] approves a device's label . . . the manufacturer usually may not alter the label's warnings without prior agency approval." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1341 (10th Cir. 2015) (Gorsuch, J.) (state-law claims preempted); *see also Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 38 (2d Cir. 2020) (same, FDCA cosmetics provisions). The MDA's preemption clause bars challenges to the marketing of a device that received federal premarket approval. *Riegel*, 552 U.S. at 322-23.

The FMIA contains similar preemptive language, 21 U.S.C. §678, and manufacturers must "obtain preapproval of labels" from the relevant agency to avoid "false or misleading labeling." *Thornton*, 28 F.4th at 1021. Guidance is found in regulations and a policy book containing information not in "applicable regulations or inspection manuals." *Id.* at 1021-22. Nonetheless, "because defendants' origin labels were federally approved, plaintiffs' claims of misleading labels [were] preempted." *Id.* at 1025.

The Federal Poultry Products Inspection Act parallels the FMIA. *See Webb v. Trader Joe's Co.*, 999 F.3d 1196, 1201-02 (9th Cir. 2021) (state-law labeling claims preempted). 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 Panel's decision implies that manufacturers and distributors of a host of products nationwide must now ask whether they should update labels to reflect a dizzying number of state laws and tort theories—thereby violating federal law. It risks rendering express preemption a dead letter, since states could avoid preemption by phrasing requirements in terms similar to federal ones, even if they have diametrically opposite consequences in application.

To overcome the Panel's two errors, federal statutes themselves would need to contain most specific determinations that are entrusted to expert agencies, and their express preemption provisions would need to anticipate all specific scenarios where a state law (or lawsuit) might apply. This is untenable. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 548 (1992) (Scalia, J., concurring and dissenting in part) (criticizing interpretation under which "[t]he statute that says *anything* about pre-emption must say *everything*; and it must do so with great exactitude, as any ambiguity concerning its scope will be read in favor of preserving state power"); *Critcher*, 959 F.3d at 38 ("[S]uch additional labeling requirements, . . . would be construing state law to impose many 'requirements' that are not contained in the federal statute, or in the regulations issued thereunder, and . . . disrupt what Congress intended to be a uniform—and federally-led—regulatory scheme.").

Equally important, the Panel's decision will upend implied preemption analysis—under which "force-of-law" *is* relevant—in this Circuit, limiting its application to an impossibly narrow category of agency actions. Op.13. In the pharmaceutical industry, for example, implied preemption is key in determining the permissibility of state warning requirements. The Supreme Court in *Merck* and other courts have found preemptive many forms of FDA disapproval of drug warnings that are considerably less formal than the EPA processes under FIFRA, let alone notice-and-comment rulemaking as now seemingly required by this Circuit (Op.7). *See, e.g.*, *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 809-10, 813-15 (7th Cir. 2018), *reaffirmed after Merck*, 951 F.3d 882, 891 (7th Cir. 2020) (state-law failure-to-warn claim preempted because of FDA requirement for uniform label for all drugs in same class and rejection—in emails, letters and other informal ways—of manufacturer's subsequent label-change requests); *Lyons v. Boehringer Ingelheim Pharms., Inc.*, 491 F. Supp. 3d 1350, 1357-58, 1367 (N.D. Ga. 2020) (failure-to-warn claim preempted where FDA re-approved label without the warning on nineteen occasions and (in letters and website statements) twice rejected attempts to add warning because of concerns it would make label "too long to be useful"). The Panel's approach creates real danger, since the FDA's disapprovals reflect a careful balancing of the need to inform users of significant risks yet avoid "overwarnings" that discourage the use of life-saving medicines.

* * *

In amending FIFRA, Congress sought to provide predictable and clear guidance for companies. It did so largely by giving the EPA primacy over health-and-safety warnings where it brings the federal government's scientific resources to bear on assessments that states do not have the resources to conduct independently. Misreading governing precedent, the Panel's decision forces manufacturers to keep up with a patchwork of state laws and tort theories, and, in doing so, to risk violating federal law, thus thwarting Congress's intent.

CONCLUSION

Amici suggest that the Eleventh Circuit rehear the argument *en banc* and affirm the district court's judgment.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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CERTIFICATE OF SERVICE

I hereby certify that on 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.

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