No. 21-10994

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

JOHN D. CARSON, SR.
Plaintiff/Appellant,

v.

MONSANTO COMPANY,
Defendant/Appellee.

Appeal from the United States District Court
for the Southern District of Georgia
No. 4:17-cv-00237 (Hon. R. Stan Baker)

BRIEF FOR AMICUS CURIAE THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF DEFENDANT/APPELLEE'S PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Eleventh Circuit Rule 26.1-1(a)(1) and 26.1-2(d), Amicus Curiae the Chamber of Commerce of the United States of America (the Chamber), through undersigned counsel, hereby submits this Certificate of Interested Parties and Corporate Disclosure Statement.

Following is a complete list of all trial judges, attorneys, persons, associations of person, firms, partnerships, or corporations that have an interest in the outcome of the particular case or appeal, including subsidiaries, conglomerates, affiliates, parent 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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67. Covington & Burling LLP

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89. UFW Foundation

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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.

/s/ *Jennifer B. Dickey*
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STATEMENT OF IDENTITY AND INTEREST OF AMICUS CURIAE

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 briefs in cases, like this one, that raise issues of concern to the nation's business community.*

This case implicates core concerns of the Chamber regarding the proper balance between federal and state regulation of product labeling, including labeling for pesticides and drugs.

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* No counsel for any party authored this brief in whole or in part, and no entity or person — aside from amicus curiae, its members, or its counsel — made any monetary contribution intended to fund the preparation or submission of this brief.

ARGUMENT

This Court has already recognized the exceptionally important issues of federal preemption law presented in this case warranting en banc review. Plaintiff John D. Carson, Sr. claims that Georgia tort law required Defendant Monsanto Company "to warn of [Roundup's] cancerous effects," Panel Opinion at 2 — despite EPA's repeated, authoritative determination that Roundup's active ingredient (glyphosate) does *not* cause cancer. On remand from the en banc Court, the panel ruled that this claim was not preempted, either (1) expressly, by the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 et seq.; or (2) impliedly, by the impossibility of Monsanto's complying both with FIFRA and with Georgia law. As explained below, both of the panel's preemption holdings are erroneous and worthy of the en banc Court's review.

I. The panel misinterpreted FIFRA's preemption provision.

Regarding express preemption, the panel correctly held that —

> FIFRA preempts a state requirement if it (1) is a "requirement '*for labeling or packaging*'"; and (2) that requirement "is '*in addition to or different from* those required under'" FIFRA. In other words, FIFRA preempts any state-law labeling or packaging requirement that is not "fully consistent" with FIFRA's requirements.

Panel Opinion at 11 (citations omitted; quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444, 447 (2005), in turn quoting 7 U.S.C. § 136v(b)). But as elaborated below, the panel erred at step (1), wrongly concluding that labels approved by the Agency as part of the FIFRA registration process do *not* qualify as "requirements" under § 136v(b).

A. Agency-approved labels are "requirements" within the meaning of FIFRA's preemption provision.

Specifically, the panel (again) correctly observed that "FIFRA mandates pesticide registration with the Agency," and as part of that registration, "the manufacturer must submit a proposed label to the Agency along with certain supporting data." Panel Opinion at 12 (citing 7 U.S.C. § 136a(a), (c)(1)(C), (c)(1)(F)). Crucially, once "the Agency approves a label during the registration process, *manufacturers cannot change the label's contents* without the Agency's prior approval and a new registration application, except for 'minor modifications.'" *Id.* (emphasis added; citing 40 C.F.R. §§ 152.44, 152.46).

So far, so good. But when the panel "revisit[ed] FIFRA's 'requirements'" later in its opinion, *id.* at 14, the panel undertook a separate analysis of whether "the Agency's approval of individual pesticide registrations and corresponding labels also qualify as 'requirements' under FIFRA." *Id.* at 16. That was error.

The Supreme Court has made clear that, for purposes of FIFRA's express-preemption provision, a "requirement" is not some esoteric legal construct; rather, it is simply "a rule of law that must be obeyed." *Bates*, 544 U.S. at 445. Agency approvals of pesticide labels under FIFRA have precisely this character: they impose rules that must be obeyed because, as the panel rightly observed, "manufacturers *cannot change* the label's contents without the Agency's prior approval and a new registration application." Panel Opinion at 12 (emphasis added).

For that correct proposition, the panel cited 40 C.F.R. §§ 152.44 and 152.46. Those two provisions mandate that, except for "certain minor modifications," § 152.46(a) — which nobody argues have application here — "*any modification* in the composition, *labeling*, or packaging of a registered product must be submitted with an application for amended registration." § 152.44(a) (emphasis added). That is, any modification of labeling is prohibited unless and until that modification is approved by the Agency. The panel could also have cited 40 C.F.R. § 152.130, which governs "Distribution [of pesticides] under *approved* labeling" (emphasis added); and § 156.70(c), which mandates that "[s]pecific statements pertaining to the hazards of the product and its uses" — of which a cancer warning is a paradigmatic example — "must be approved by the Agency."

Finally, the panel could have looked to the statutory text itself, which confirms that the preemptive "requirements for labeling or packaging," 7 U.S.C. §136v(b), include the Agency's approved labeling for particular products. FIFRA expressly defines "labeling" at the level of the individual pesticide: "The term 'labeling' means all labels and all other written, printed, or graphic matter — (A) accompanying *the* pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying *the* pesticide or device . . . ." *Id.* § 136(p)(2) (emphasis added); *see also id.* § 136(p)(1) (defining "label" as "*the* written, printed, or graphic matter on, or attached to, *the* pesticide or device or any of *its* containers or wrappers" (emphasis added)). And § 136j(a)(2)(A) makes it "unlawful" for any person to "alter . . . , in whole or in part, any labeling required under [FIFRA]."

In sum, the en banc Court held that the question of what qualifies as "requirements for labeling or packaging" under FIFRA's preemption provision "must be answered by recourse to the ordinary principles of statutory interpretation." *Carson v. Monsanto Co.*, 72 F.4th 1261, 1267 (11th Cir. 2023) (*Carson III*). Here, those principles are simple: a "requirement is a rule of law that must be obeyed." *Bates*, 544 U.S. at 445.

Agency approvals of pesticide labels under FIFRA impose such requirements because "manufacturers *cannot change* the label's contents without the Agency's prior approval and a new registration application." Panel Opinion at 12 (emphasis added).

That the Agency's approval of a particular label is only "prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of [FIFRA]," 7 U.S.C. § 136a(f)(2), does not detract from this conclusion. That provision merely emphasizes that in "no event shall registration . . . be construed as a defense for the commission of any offense under [FIFRA]." *Id.* But neither Dr. Carson nor the panel has suggested that Monsanto has committed an "offense" under FIFRA or otherwise failed to "comply" with the statute. Consequently, nothing in § 136a(f)(2) alters the legal effect of the Agency's approved labeling for purposes of the preemption provision.

Therefore, the Agency-approved pesticide label for Roundup is one of "FIFRA's labeling 'requirements' that bear on [the] preemption analysis." Panel Opinion at 12. Any Georgia law requiring an additional warning on that label would impose a labeling requirement "in addition to or different from" those required under FIFRA. 7 U.S.C. § 136v(b));

see also, e.g., Bates, 544 U.S. at 453 (holding that a "claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted"). Any such Georgia-law requirement is expressly preempted.

B. "Force of law" analysis does not alter this conclusion.

Instead of ascertaining the ordinary meaning of "requirements" as used in the statutory scheme, the panel returned to the "force of law" analysis that generated rehearing en banc once before. Thus, the panel opined that to "establish whether a particular Agency action amounts to a 'requirement' under FIFRA, we must determine whether that Agency action carries the force of law." Panel Opinion at 17. And for the panel, that determination "turn[ed] on whether the FIFRA registration process is 'relatively formal.'" *Id.* at 18 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)).

That was the wrong question, and it yielded the wrong answer. As the en banc Court explained, a "'force-of-law' inquiry assesses whether an agency action falls within the scope of the agency's 'congressionally delegated authority.'" *Carson III*, 72 F.4th at 1267 (citing *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019) (*Albrecht*)). That

inquiry "is usually irrelevant where Congress has enacted an express-preemption provision," *id.*, as it has in FIFRA, 7 U.S.C § 136v(b). But if it is relevant, the inquiry is a modest one, grounded in the precept that "pre-emption takes place only when and if 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." *Albrecht*, 139 S. Ct. at 1679 (citing *New York v. FERC*, 535 U.S. 1, 18 (2002). Thus, "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.*

Neither Dr. Carson nor the panel has suggested that the Agency's action here — approval of Roundup's registration, including a label *without* a cancer warning — fell outside the scope of the authority conferred on the Agency by Congress. The same is true of the regulations discussed in the previous section: no one has suggested that these regulations are outside the Agency's congressionally delegated authority.

C. *Riegel v. Medtronic* is not meaningfully distinguishable.

Monsanto has persuasively explained how the panel failed to meaningfully distinguish *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). *See* Petition for Rehearing En Banc at 10–14 (Doc. 180-1) (Petition). We highlight just one aspect of that failure.

The panel observed that under the Medical Device Amendments (MDA) at issue in *Riegel*, once "the FDA has approved a device, manufacturers *cannot change a device's label* (or design, etc.) without the FDA's permission." Panel Opinion at 21 (citing 21 U.S.C. § 360e(d)(5)(A)(i)). That is in supposed "contrast" to FIFRA, *id.*, which "contemplates that pesticide labels will evolve over time," *id.* at 22 (quoting *Bates*, 544 U.S. at 451).

The asserted contrast is illusory: the fact that pesticide manufacturers "cannot change" agency-approved labels is an *identical* feature of the two statutory schemes, not a distinguishing one. *Compare* Panel Opinion at 12 (FIFRA) *with id.* at 22 (MDA); *see also supra* pp. 4–6. The Supreme Court's estimation that pesticide labels will "evolve over time" is true only so far as it goes. Unless those labels evolve within FIFRA's framework — with "the Agency's prior approval and a new registration

application," Panel Opinion at 12, or by a judicial determination (under the substantial-evidence standard) that an approved label fails to satisfy FIFRA's standards, *see* 7 U.S.C. § 136n(b) — the labels cannot be changed by state-law requirements like a common-law duty to warn. Indeed, it is "unlawful" to alter an Agency-approved label. *Id.* § 136j(a)(2)(A).

II. The panel erred in denying impossibility preemption.

The panel correctly observed that preemption also "occurs when 'it is impossible for a private party to comply with both state and federal requirements.'" Panel Opinion at 26 (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011)). According to the panel, such impossibility can be shown only by "clear evidence" that —

> (1) Monsanto fully informed the Agency of the justifications for the warning that Georgia state law would impose;
>
> (2) the Agency informed Monsanto that it would not approve changing the label to include that warning; and
>
> (3) the Agency undertook its action pursuant to congressionally delegated authority in a way that carries the force of law.

Id. at 26–27 (cleaned up; citing *Albrecht*, 139 S. Ct. at 1678–79). The panel erred in applying all three of these elements.

First, the panel ruled that the "fully informed" element could not be satisfied because "Monsanto did not request . . . a cancer warning at all."

Panel Opinion at 28. But as Monsanto has persuasively demonstrated, other courts of appeals have rejected this narrow reading, and it would create a circuit split if it were permitted to stand. *See* Petition at 15–16; *cf. Albrecht*, 139 S. Ct. at 1684 (Alito, J., concurring) (noting that agency knowledge "does not depend on whether the relevant drug manufacturer, as opposed to some other entity or individual, brought the new information to the [agency's] attention").

Second, the panel essentially ruled that the "would not approve" element could not be satisfied unless a manufacturer shows some *express* rejection of an *express* request for a warning required by state law. That narrow reading is unjustified: evidence may be "clear" even if it is circumstantial. And the undisputed circumstances here are compelling:

- EPA has long concluded that "glyphosate is . . . not a carcinogen," Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008); *accord, e.g.*, Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,935–43 (Sept. 27, 2002);

- EPA adheres to that conclusion to this day, *see* App.119–20; and

- EPA in 2019 explicitly cautioned that a warning on glyphosate-based herbicides to the effect that glyphosate may cause cancer would be "false and misleading," and such a warning would render any product so labeled "misbranded pursuant to section 2(q)(1)(A) of FIFRA," Supp.App.11 (citing 7 U.S.C. §136(q)(1)(A)).

Accordingly, the evidence is indeed "clear" that EPA would not approve the warning that Dr. Carson contends is required by Georgia law.

Third, in asking whether EPA undertook its action pursuant to congressionally delegated authority "in a way that carries the force of law," Panel Opinion at 27, the panel again misconceived the requisite inquiry. As noted above, the en banc Court made clear that the "'force-of-law' inquiry assesses whether an agency action falls within the scope of the agency's 'congressionally delegated authority.'" *Carson III*, 72 F.4th at 1267. If agency action falls within such authority, *it has the force of law*; no additional inquiry is necessary. As discussed above (pp. 7–8), no one disputes that EPA's approval of Roundup's registration (including a label *without* a cancer warning) or EPA's other actions described above fell within the scope of the agency's congressionally delegated authority.

In sum, it was impossible for Monsanto to comply *both* with the requirements of FIFRA as imposed by EPA pursuant to its congressionally delegated authority *and* with the requirements of Georgia law as claimed by Dr. Carson. Consequently, Dr. Carson's failure-to-warn claim was preempted for that reason as well.

III. The panel's errors are exceptionally important and warrant en banc review.

Here, the panel's errors in applying both express and implied preemption are not only incorrect under the ordinary meaning of the statutory text and governing case law, but they are also errors of exceptional importance that warrant the en banc Court's correction. As the Chamber explained in detail in its earlier amicus brief supporting rehearing en banc, FIFRA's preemption provision is paralleled in numerous statutes, including the MDA, 21 U.S.C. § 360k(a); the Federal Meat Inspection Act, 21 U.S.C. § 678; and the Egg Products Inspection Act, 21 U.S.C. § 1052(b). *See* Amended Brief of Chamber, et al. (Doc. 98-1, filed Aug. 10, 2022). The panel's crabbed interpretation of that provision could subject manufacturers under all of these schemes to intolerable uncertainty and potential liability regarding their products. And it could quickly spiral into precisely the type of 50-state labeling scheme that Congress expressly sought to avoid by enacting these express-preemption provisions.

CONCLUSION

For the foregoing reasons, Monsanto's petition for rehearing en banc should be granted.

Dated: March 4, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Federal Rule of Appellate Procedure 29(b)(4) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) and Eleventh Circuit Rule 29-3, this document contains 2,598 words.

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