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-RSB-CLR, Hon. R. Stan Baker

SUPPLEMENTAL BRIEF FOR PLAINTIFF-APPELLANT JOHN D. CARSON, SR.

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September 1, 2023

***Carson v. Monsanto Co.*, Case No. 21-10994**

CERTIFICATE OF INTERESTED PERSONS

Under Federal Rule of Civil Procedure 26.1 and Eleventh Circuit Rules 26.1-1, 26.1-2(a), 26.1-2(b), and 28-1(b), undersigned counsel for Appellant John D. Carson, Sr. certifies that the certificate of interested persons provided in his en banc reply brief (Doc.156) is a full and complete list of all persons, firms, associations, partnerships, and corporations, including subsidiaries, conglomerates, affiliates, parent corporations, and other legal entities having an interest in the outcome of this case.

September 1, 2023

/s/ David C. Frederick
David C. Frederick

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INTRODUCTION

Monsanto has known for decades that long-term use of Roundup can cause cancer. But the company never warned Dr. John D. Carson, Sr., about that risk. He used Roundup for nearly 30 years and was diagnosed with cancer as a result.

As this Court correctly concluded, no federal requirement with force of law barred Monsanto from warning Carson of Roundup's cancer risks. The United States and the Environmental Protection Agency agree. And after a year of en banc petitioning, briefing, arguing, and decision, Monsanto still has not convinced a single appellate judge of its preemption position. The company has updated Roundup's labeling 44 times; at any of those times, it could have added a cancer warning.

The en banc court's narrow opinion does nothing to alter that result. The court held that "ordinary principles of statutory interpretation" govern whether courts should undertake a force-of-law analysis. En Banc Op. 10. Under FIFRA, only federal "requirements" may preempt state law. § 136v(b). And "[a] requirement is a rule of law that must be obeyed." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 445 (2005). FIFRA's plain text thus requires the same force-of-law

analysis this Court already conducted. The result on remand should be the same: Carson's claims are not preempted.

ARGUMENT

1. FIFRA preempts only those common-law claims that impose (1) "a requirement 'for labeling or packaging'" (2) "that is 'in addition to or different from'" one of FIFRA's requirements, such as those in the statute's misbranding provisions. *Bates*, 544 U.S. at 444-45 (quoting § 136v(b)).[1] Claims that are "equivalent to" or narrower than those requirements are not preempted. *Id.* at 447 & n.23.

Carson's Georgia-law failure-to-warn claim is narrower than FIFRA's requirements, as this Court correctly held. Op. 9. Georgia requires a warning against known or reasonably knowable risks, *id.*, while FIFRA requires a warning "necessary" and "adequate to protect health," § 136(q)(1)(G). Carson's "claim, if anything, imposes less of a duty on Monsanto than the FIFRA statute." Op. 9. His claim thus is

[1] Citations to provisions of the U.S. Code are to Title 7. "Op." refers to the panel opinion (Doc.104-1), and "En Banc Op." refers to the en banc opinion (Doc.163-1). "Br." refers to Carson's en banc opening brief (Doc.124), and "Reply Br." refers to his reply (Doc.156). References to Monsanto's arguments come from its motion to file a supplemental brief (Doc.165).

"fully consistent" with FIFRA, not preempted. *Bates*, 544 U.S. at 447; *see* Op. 9 ("FIFRA alone does not preempt" Carson's claim).

2. Looking beyond "FIFRA alone" for a source of preemption requires this Court to conduct a force-of-law analysis. This conclusion flows from "ordinary principles of statutory interpretation." En Banc Op. 10. A state law must conflict with one of FIFRA's "requirements" to be preempted. § 136v(b). The Supreme Court has construed the term "requirement" to mean "a rule of law that must be obeyed." *Bates*, 544 U.S. at 445. EPA cannot promulgate "a rule of law that must be obeyed" unless it imposes a legally binding rule. *Cf. Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) ("interpretive rules" lack "the force of law" so cannot "impose any 'legally binding requirements' on private parties"). So Congress's chosen term – "requirements" – functionally imports a force-of-law analysis. *See Hardeman v. Monsanto Co.*, 997 F.3d 941, 956-57 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022).[2]

[2] Monsanto suggests (at 3) that the en banc court rejected this analysis from *Hardeman*. But *Hardeman* applied the plain meaning of the term "requirements" to conclude that "agency action must have the force of law" to "establish requirements that can preempt state law under § 136v(b)." 997 F.3d at 956-57. And the en banc court "express[ed] no opinion" on that issue, leaving it to this Court. En Banc

Bates bolsters that interpretation. The Court identified only two sources of preemptive requirements, both with force of law: "FIFRA's misbranding standards" and "any relevant EPA regulations that give content to" them. 544 U.S. at 453; *see Schoenhofer v. McClaskey*, 861 F.3d 1170, 1175 n.4 (10th Cir. 2017) ("*Bates* . . . identified only two sources of preemption: FIFRA itself and any implementing regulations."); *Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc.*, 617 F.3d 207, 222-23 (3d Cir. 2010) (same); *Hardeman*, 997 F.3d at 957 & n.7 (same).[3]

Op. 11. Further, the en banc court noted that "no circuit split will occur" if this Court concludes Carson's claim is not preempted. *Id.* at 8.

[3] *Riegel v. Medtronic, Inc.*, built on, but did not alter, *Bates*'s definition of "requirements." There, the Court held that "[p]remarket approval" of the riskiest medical devices "imposes 'requirements'" under the Medical Device Amendments. 552 U.S. 312, 322 (2008). As part of that "formal[]" review process, FDA directly addressed the question at issue in the state-law litigation. *Id.* at 322-23 ("[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness."). And after premarket approval, the statute "forb[ad] 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 (citing § 360e(d)(6)(A)(i)). That formal, inflexible process stands in stark contrast to the regime here. *See infra* pp.7-9.

3. No EPA actions imposed a requirement with force of law barring Monsanto from adding cancer warnings to Roundup's labeling. The United States made this precise point in its brief to the Supreme Court: "EPA could – either through rulemaking or through some other regulatory action carrying the force of law – make a binding determination that the labels of pesticides containing glyphosate should not contain cancer warnings." SG *Hardeman* Br. 13. But EPA has not done so: "neither EPA's repeated statements that glyphosate is unlikely to be carcinogenic to humans, nor its approval of pesticide labeling without cancer warnings, imposes any such prohibition." *Id.* This Court already addressed these actions too, *see* Op. 11-14, concluding that "it isn't" "a close case on whether the EPA has acted with the force of law," *id.* at 11 n.10. The agency has not.[4]

[4] Monsanto's reference (at 2) to EPA's "scientific conclusions" about glyphosate should play no role in this Court's preemption analysis. EPA's conclusion that glyphosate is "not likely to be carcinogenic" lacks any arguable force of law because the Ninth Circuit vacated that conclusion as arbitrary and capricious. *NRDC v. EPA*, 38 F.4th 34, 47 (9th Cir. 2022); *see* Br. 19-22, 37-42; Reply Br. 10-13. Vacated agency conclusions cannot preempt. Further, this case is about formulated Roundup, not just glyphosate. Neither EPA nor Monsanto has studied the cancer risks posed by long-term use of Roundup or the additional risks posed by the surfactant, which makes the pesticide absorb more easily into the skin. *See* Br. 12-15, 54-59; Reply Br. 14-21.

4. Monsanto's remaining arguments lack merit. *First*, the company repeats (at 4-5) its incorrect claim that EPA's decision to register glyphosate products and approve Roundup's labeling has some preemptive effect. As this Court already recognized, EPA's decision to approve a label "serve[s] only as prima facie evidence of compliance with the registration requirements of FIFRA." Op. 10 (citing § 136a(f)(2)); *see id.* at 10 n.9. So registration "at most creates a rebuttable presumption of compliance with FIFRA's registration process." *Id.* at 11. And for that reason, EPA registration "doesn't amount to a sufficiently formal proceeding to carry the force of law." *Id.* The Ninth Circuit thus correctly recognized that "[i]t would defy logic to say a rebuttable presumption carries the force of law necessary to have preemptive effect, as doing so would deny any ability to rebut the presumption." *Hardeman*, 997 F.3d at 957.

Monsanto conflates the duty to register its pesticides (a FIFRA requirement) with the output of those registration decisions (not a FIFRA requirement). Of course, a state law purporting to allow the company to sell an unregistered pesticide would be preempted. FIFRA expressly prohibits the distribution or sale of a pesticide "that is not

registered." § 136a(a). But Congress already addressed the issue Monsanto raises here: Registration provides no immunity from liability under FIFRA or parallel state law. *See* § 136a(f)(2). As *Bates* recognized, "it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded." 544 U.S. at 438-39.

Second, Monsanto suggests (at 5) that manufacturers cannot change EPA-approved labeling because the agency's approval implies that the labeling provides "all necessary health warnings." The United States correctly disagrees, because EPA regulations "do not purport to define the full universe of labeling that might be necessary and adequate 'to protect health and the environment.'" SG *Hardeman* Br. 11 (quoting § 136(q)(1)(G)). Instead, those regulations generally aim elsewhere, focusing on acute health hazards rather than chronic ones. *See id.* at 11 n.2 (citing 40 C.F.R. §§ 156.70(b), 158.130(d)(1)).

As for chronic risks, like that long-term Roundup use will cause cancer, FIFRA imposes on manufacturers a duty to update their labels and the flexibility to do so. "Because it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded, manufacturers have a continuing obligation to adhere to FIFRA's

labeling requirements," including by seeking EPA approval to amend a label that does not contain all "necessary warnings or cautionary statements." *Bates*, 544 U.S. at 438-39. Manufacturers can also make "minor modifications" to labeling without EPA approval if they notify the agency of the change. *See* 40 C.F.R. § 152.46(a). FIFRA and its regulatory regime thus "contemplate[] that pesticide labels will evolve over time, as manufacturers gain more information." *Bates*, 544 U.S. at 451; *see* SG *Hardeman* Br. 12 n.3.[5]

Manufacturers have seized on that flexibility. "EPA has repeatedly permitted pesticide manufacturers . . . to add notices related to cancer to their products' labels." *Hardeman*, 997 F.3d at 959. For example, under 40 C.F.R. § 152.46(a), "Bayer CropScience notified EPA 'of a minor labeling amendment for LARVIN Technical,' informing EPA

[5] FIFRA's manufacturer-led labeling process distinguishes this case from the scheme involved in *Riegel*. FDA's premarket approval of the riskiest medical devices serves as conclusive evidence that "the approved form [of the devices] provides a reasonable assurance of safety and effectiveness." 552 U.S. at 323. "In the FIFRA registration process, by contrast, EPA neither requires nor precludes any specific chronic-risk warnings, through regulation or otherwise." SG *Hardeman* Br. 19. Rather than provide those warnings, Monsanto ran TV ads showing people spraying Roundup in shorts and without gloves, assuring viewers the pesticide can be used where kids and pets play. *See* Br. 7.

that '[a]s required by California Proposition 65, the following statement has been added to the label, "This product contains a chemical known to the state of California to cause cancer."'" 997 F.3d at 959 n.10. Had Monsanto – now a Bayer subsidiary – taken the same approach here, it could have prevented Carson's injuries.

Third, Monsanto's cases under other statutes do not support its preemption arguments. The company cites (at 4) a case involving food-safety statutes under which the Department of Agriculture's Food Safety and Inspection Service "has issued extensive regulations." *National Meat Ass'n v. Harris*, 565 U.S. 452, 455-56 (2012) (Federal Meat Inspection Act); *Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1286 (9th Cir. 2021) ("poultry products and their labeling are strictly regulated by the Poultry Products Inspection Act"). Because of those many regulatory "requirements," the statutes' preemption provisions "sweep[] widely." *Harris*, 565 U.S. at 459-60. That was the issue in *Kuenzig v. Hormel Foods Corp.*, where the plaintiff's claim would have required the defendants to label the fat percentage of their lunch meat "by calories," not by weight, 505 F. App'x 937, 938 (11th Cir. 2013) (per curiam). That claim was preempted because "[f]ederal regulations

required Defendants to label their percentage fat-free claims based on the number of fat grams compared to the weight of their products." *Id.*

The same reasoning applies to Monsanto's medical-device cases, such as *Riegel*. As then-Judge Gorsuch noted, "the FDA's medical device regulations alone cover 592 pages of eight-point type and the Supreme Court has suggested that in searching for a parallel federal duty a plaintiff may scour them all as well as the statute itself." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1342 (10th Cir. 2015).

EPA, by contrast, has issued "few regulations" under FIFRA, so preemption remains "narrow." *Bates*, 544 U.S. at 452, 453 n.28.

Since Roundup was approved 49 years ago, Monsanto has worked steadily to avoid testing the product and to hide evidence that it may in fact cause cancer. Br. 7-15. But despite that misconduct, the company now seeks "virtual immunity from certain forms of tort liability." *Bates*, 544 U.S. at 450. *Bates* rejected that result; this Court should too.

CONCLUSION

The Court should reverse the judgment of the district court and reaffirm that Carson's state-law failure-to-warn claim is not preempted.

Dated: September 1, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the Court's order that supplemental briefs be limited to 10 pages, excluding the portions of the brief exempted by Federal Rule of Appellate Procedure 32(f). *See* Doc.166.

I further certify that this brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (a)(6) because it has been prepared using Microsoft Word 2016 in a proportionally spaced typeface (Century Schoolbook, 14 point).

/s/ David C. Frederick
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CERTIFICATE OF SERVICE

I hereby certify that on September 1, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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