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 U.S. District Court for the Southern District of Georgia
No. 4:17-cy-00237-RSB-CLR

SUPPLEMENTAL BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF PLAINTIFF-APPELLANT AND REVERSAL

Adina H. Rosenbaum Allison M. Zieve Public Citizen Litigation Group 1600 20th Street NW Washington, DC 20009 (202) 588-1000 arosenbaum@citizen.org

Attorneys for Amicus Curiae Public Citizen

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rules 26.1-1 through 26.1-3, Public Citizen provides the following list of the persons and entities that have or may have an interest in the outcome of this appeal:

Interested Persons

- Andiman, Alexis, Attorney for Amici Farmworker Association of Florida,
 Farmworker Justice, Migrant Clinicians Network, Pesticide Action Network,
 United Farm Workers, and UFW Foundation
- Andrews, Cory L., Attorney for Amici Atlantic Legal Foundation and Washington Legal Foundation
- Apfel, Carrie, Attorney for Amici Farmworker Association of Florida,
 Farmworker Justice, Migrant Clinicians Network, Pesticide Action Network,
 United Farm Workers, and UFW Foundation
- Attaway, Scott K., Attorney for Appellant
- Baker, Hon. R. Stan, United States District Judge
- Bedrosyan, Alexander, Attorney for Amici the Chamber of Commerce of the
 United States of America (Chamber of Commerce), the Pharmaceutical
 Research and Manufacturers of America (PhRMA), and the Product Liability
 Advisory Council, Inc. (PLAC)

- Bernsen, Louis J., Attorney for Amicus Drexel Chemical Co.
- Boswell, Chase E., Attorney for Appellee (in the district court)
- Brueckner, Leslie, Attorney for Amicus Public Justice, PC
- Calhoun, Martin C., Attorney for Appellee
- Carson, John D., Jr., Attorney for Appellant
- Carson, John D., Sr., Appellant
- Coe, Alisa, Attorney for Amici Farmworker Association of Florida,
 Farmworker Justice, Migrant Clinicians Network, Pesticide Action Network,
 United Farm Workers, and UFW Foundation
- Coffin, Shannen W., Attorney for Amicus CropLife America
- Craddock, Joshua J., Attorney for Amicus Retail Litigation Center, Inc.
- Dickey, Jennifer B., Attorney for Amicus Chamber of Commerce
- Ebner, Lawrence S., Attorney for Amici Atlantic Legal Foundation and Washington Legal Foundation
- Farber, Daniel, Amicus Curiae
- Frederick, David C., Attorney for Appellant
- Goldman, Patti, Attorney for Amici Farmworker Association of Florida,
 Farmworker Justice, Migrant Clinicians Network, Pesticide Action Network,
 United Farm Workers, and UFW Foundation

- Hardeman, Edwin M., Plaintiff in *Hardeman v. Monsanto Co.*, No. 3:16-cv-00525-VC (N.D. Cal.)
- Heinz, Noah, Attorney for Amici Public Law Scholars
- Hollingsworth, Joe G., Attorney for Appellee
- Imbroscio, Michael X., Attorney for Appellee
- Keller, Ashley, Attorney for Amici Public Law Scholars
- Khayyat, Rund M., Attorney for Appellant
- Kimmel, Melissa B., Attorney for Amicus PhRMA
- Lasker, Eric G., Attorney for Appellee
- Lazarus, Alan J., Attorney for Amicus PLAC
- Leckner, Travis, Attorney for Amici Public Law Scholars
- Lee, Thomas H., Attorney for Amici Chamber of Commerce, PhRMA, and PLAC
- Lehner, Peter, Attorney for Amici Farmworker Association of Florida,
 Farmworker Justice, Migrant Clinician Networks, Pesticide Action Network,
 United Farm Workers, and UFW Foundation
- Lettow, Paul V., Attorney for Amicus Chamber of Commerce
- Madison, Ashleigh R., Attorney for Appellant
- Maloney, Stephanie A., Attorney for Amicus Chamber of Commerce

- Marshall, K. Lee, Attorney for Appellee
- Martínez Llompart, Patricio G., Attorney for Appellee
- Masslon II, John M., Attorney for Amici Atlantic Legal Foundation and Washington Legal Foundation
- Mayer, Theodore V.H., Attorney for Amici Chamber of Commerce, PhRMA,
 and PLAC
- McGarity, Thomas O., Amicus Curiae
- McGreal, Paul, Amicus Curiae
- Moore, Jennifer A., Attorney for Edwin Hardeman
- Nicholls, Leah M., Attorney for Amicus Public Justice, PC
- Pilliod, Alberta, Plaintiff in *Pilliod v. Monsanto Co.*, No. RG17862702 (Cal. Super. Ct.)
- Pilliod, Alva, Plaintiff in *Pilliod v. Monsanto Co.*, No. RG17862702 (Cal. Super. Ct.)
- Postman, Warren, Attorney for Amici Public Law Scholars
- Quallen, Matthew C., Attorney for Appellee
- Rafferty, Michael F., Attorney for Amicus Drexel Chemical Co.
- Ray, Hon. Christopher L., United States Magistrate Judge
- Reinbold, Derek C., Attorney for Appellant

- Rosenbaum, Adina H., Attorney for Amicus Public Citizen, Inc.
- Rubenstein, David, Amicus Curiae
- Savignac, Mark C., Attorney for Amicus CropLife America
- Stansel, James C., Attorney for Amicus PhRMA
- Stein, William R., Attorney for Amici Chamber of Commerce, PhRMA, and PLAC
- Thomas, Michael J., Attorney for Appellee (in the district court)
- Varcoe, Andrew R., Attorney for Amicus Chamber of Commerce
- Vernon, Emily A., Attorney for Appellee
- Watson, Sara Beth, Attorney for Amicus CropLife America
- Williamson, Virginia A., Attorney for Appellee (before the panel)
- Wisner, R. Brent, Attorney for Alva & Alberta Pilliod
- Wool, David J., Attorney for Edwin Hardeman & Amicus Public Justice, PC
- Yohalem, Mark R., Attorney for Amicus Retail Litigation Center, Inc.
- Young, Ernest A., Amicus and Attorney for Amici Public Law Scholars
- Zieve, Allison M., Attorney for Amicus Public Citizen, Inc.
- Zionts, David M., Attorney for Appellee

Interested Entities

• Atlantic Legal Foundation

- Bayer AG, BAYRY
- Bryan Cave Leighton Paisner LLP
- Carson, John D., Jr., PC
- Chamber of Commerce of the United States of America
- Covington & Burling LLP
- CropLife America
- Drexel Chemical Co.
- Earthjustice
- Faegre Drinker Biddle & Reath LLP
- Farmworker Association of Florida
- Farmworker Justice
- Harris Shelton Hanover Walsh, PLLC
- Hollingsworth LLP
- Hughes, Hubbard & Reed, LLP
- Keller Lenkner LLC
- Kellogg, Hansen, Todd, Figel & Frederick, PLLC
- Migrant Clinicians Network
- Monsanto Company
- Moore Law Group, PLLC

- Pennington, PA
- Pesticide Action Network
- The Pharmaceutical Research and Manufacturers of America
- Product Liability Advisory Council, Inc.
- Public Citizen, Inc.
- Public Citizen Litigation Group
- Public Justice, PC
- Retail Litigation Center, Inc.
- Southeast Law, LLC
- Steptoe & Johnson LLP
- UFW Foundation
- United Farm Workers
- U.S. Chamber Litigation Center
- Washington Legal Foundation
- Wilson Sonsini Goodrich & Rosati, PC

Pursuant to Federal Rule of Appellate Procedure 26.1, the undersigned counsel certifies that amicus curiae Public Citizen, Inc. is a nonprofit, non-stock

corporation. It has no parent corporation, and no publicly held corporation has an ownership interest in it.

/s/ Adina H. Rosenbaum Adina H. Rosenbaum Attorney for Public Citizen, Inc.

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INTEREST OF AMICUS CURIAE¹

Public Citizen is a nonprofit consumer-advocacy organization that works for the enactment and enforcement of laws protecting consumers, workers, and the public. Public Citizen has a longstanding interest in fighting overly broad claims that federal regulation preempts state laws that protect consumers, and it has appeared as amicus curiae in many cases raising preemption issues, including cases involving preemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

ARGUMENT

A. FIFRA expressly preempts state "requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b). In construing this preemption provision in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 445 (2005), the Supreme Court explained that a "requirement is a rule of law that must be obeyed." Accordingly, to establish a federal "require[ment] under" FIFRA for purposes of section 136v(b), agency action must have the force of law. Agency action that does not establish a "rule of law" does not establish a "requirement" and therefore has no preemptive effect under FIFRA.

¹ Public Citizen has moved for leave to file this brief. No party or party's counsel authored this brief in whole or in part or made a monetary contribution to fund the preparation or submission of this brief. No person or entity other than Public Citizen made a monetary contribution to the preparation or submission of this brief.

B. EPA's registration of a pesticide that does not have a specific warning on its label does not preempt a state-law requirement to provide such a warning. In *Bates*, EPA had registered the pesticide at issue and approved the labeling during the registration. Nonetheless, the Supreme Court held that the plaintiffs' fraud and failure-to-warn claims were not necessarily preempted. Instead, the Court remanded for a determination whether the state requirements were equivalent to FIFRA's requirements. 544 U.S. at 453. *Bates* thus establishes "that mere inconsistency between the duty imposed by state law and the content of a manufacturer's labeling approved by the EPA at registration" does not, on its own, "mean that the state law duty [i]s preempted." *Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc.*, 617 F.3d 207, 222 (3d Cir. 2010).

EPA's registration of a pesticide does not preempt state failure-to-warn claims because the registration process does not conclusively establish what FIFRA requires as to labeling. As the Supreme Court recognized in *Bates*, a pesticide can be "registered but nevertheless misbranded." 544 U.S. at 438. Although registration is generally prima facie evidence that the pesticide and its labeling comply with FIFRA's registration provisions, FIFRA specifies that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under" FIFRA. 7 U.S.C. § 136a(f)(2). "The Act thus makes clear that a particular pesticide may be found to violate FIFRA's misbranding prohibition even though

EPA approved the labeling when registering the pesticide." Br. for U.S. as Amicus Curiae at 8, *Monsanto Co. v. Hardeman*, No. 21-241 (U.S., filed May 10, 2022) (hereafter, "U.S. Br., *Hardeman*"). That is, EPA's approval of the label in the registration process "is not conclusive of FIFRA compliance." *Hardeman v. Monsanto Co.*, 997 F.3d 941, 956 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022). "And because EPA's labeling determinations are not dispositive of FIFRA compliance, they similarly are not conclusive as to which common law requirements are 'in addition to or different from' the requirements imposed by FIFRA." *Id.*

Stated differently, under section 136a(f)(2), "EPA's decision to approve a label during the registration process raises only a rebuttable presumption that the pesticide and its label comply with FIFRA," and it "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." *Id.* at 957.²

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² In its motion for supplemental briefing, Monsanto suggested that section 136a(f)(2) might affect the meaning of the term "requirements" in section 136v(b). Monsanto Mot. 4. Although section 136a(f)(2) does not affect the meaning of "requirements," it does bear on whether registration determines what is "required under" FIFRA, 7 U.S.C. § 136v(b), demonstrating that the registration process does not conclusively establish what FIFRA "require[s]" with respect to labeling. Because of the existence or absence of provisions such as section 136a(f)(2) in different statutory schemes—and because of other differences between different statutory and regulatory schemes—federal actions that establish "requirements" under one statute might not establish "requirements" under other statutes that use that term. *See Hardeman*, 997 F.3d at 956 n.6 (explaining that section 136a(f)(2) distinguishes cases such as this (continued)

C. Attempting to avoid the clear import of the remand in *Bates*, Monsanto has contended that its preemption argument does not rely on the "bare fact of registration" but on "EPA's regulatory determinations that glyphosate does not cause cancer and that a cancer warning for glyphosate products is not required under FIFRA." Monsanto En Banc Br. 15. EPA's determinations, however, do not impose "rule[s] of law that must be obeyed," *Bates*, 544 U.S. at 445, and thus do not impose requirements under FIFRA. See U.S. Br., Hardeman, at 13 n.4 (noting that although the process that led to EPA's interim registration review decision for glyphosate "could have culminated in binding requirements or prohibitions governing chronichazard warnings for glyphosate, it did not"). And although EPA cannot register a pesticide without first determining that its labeling complies with FIFRA and that the product will not have unreasonable adverse effects on the environment, FIFRA's specification that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under" FIFRA, 7 U.S.C. § 136a(f)(2) (emphasis added), makes clear that the assessments EPA makes in the registration process are not dispositive of whether the pesticide's labeling complies with FIFRA's requirements and do not conclusively establish what FIFRA requires. See, e.g., Hardeman, 997 F.3d at 957 n.8 (explaining that a determination that glyphosate

from *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which involved the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act).

is not carcinogenic made as part of an EPA registration decision "is not necessarily at odds with [a] future failure-to-warn claim," because the registration decision "only supports presumptive (not conclusive) compliance with FIFRA").

Moreover, the Ninth Circuit has held that EPA's determination in its registration review of glyphosate that glyphosate is not likely to be carcinogenic to humans was not supported by substantial evidence, and it vacated the human-health portion of the agency's 2020 interim registration review decision. *Nat. Res. Def. Council v. EPA*, 38 F.4th 34, 51 (9th Cir. 2022). The court's conclusion that EPA's determination that glyphosate is not likely to be carcinogenic to humans was not supported by substantial evidence provides a further reason why that determination does not preempt state law.³

CONCLUSION

The Court should reverse the judgment of the district court.

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³ Monsanto has also pointed to an August 2019 letter sent by the director of EPA's pesticide registration division to certain pesticide registrants stating that a California Proposition 65 warning about glyphosate would "constitute a false and misleading statement" and render a pesticide "misbranded." *See*, *e.g.*, Monsanto En Banc Br. 47. EPA, however, "did not follow any 'formal administrative procedure' that would give the letter the force of law," and the letter thus did not establish any requirements under FIFRA. *Hardeman*, 997 F.3d at 957 (citation omitted); *see also* U.S. Br., *Hardeman*, at 13 (explaining that "[n]o FIFRA provision or EPA regulation authorizes that agency official to impose binding FIFRA 'requirements' on manufacturers through an informal letter").

Respectfully submitted,

/s/ Adina H. Rosenbaum
Adina H. Rosenbaum
Allison M. Zieve
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
arosenbaum@citizen.org

Attorneys for Amicus Curiae Public Citizen

September 1, 2023

CERTIFICATE OF SERVICE

I hereby certify that this brief has been served through the Court's ECF system on counsel for all parties required to be served on September 1, 2023.

/s/ Adina H. Rosenbaum Adina H. Rosenbaum