No. 21-10994

IN THE 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
No. 4:17-cv-00237-RSB-CLR (Baker, J.)

SUPPLEMENTAL BRIEF OF DEFENDANT-APPELLEE MONSANTO COMPANY

Joe G. Hollingsworth
Eric G. Lasker
Martin C. Calhoun
HOLLINGSWORTH LLP
1350 I Street, NW
Washington, DC 20005
(202) 898-5800

David M. Zionts
Michael X. Imbroscio
Emily A. Vernon
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

K. Lee Marshall
BRYAN CAVE LEIGHTON PAISNER LLP
Three Embarcadero Center, 7th Floor
San Francisco, CA 94111
(415) 675-3400

Counsel for Defendant-Appellee Monsanto Company

CERTIFICATE OF INTERESTED PARTIES

Pursuant to Federal Rule of Appellate Procedure 26.1, Eleventh Circuit Rule 26.1-1(a)(1), and Eleventh Circuit Rule 26.1-2(d), Appellee Monsanto Company, through undersigned counsel, hereby submits this Certificate of Interested Parties and Corporate Disclosure Statement.

Below 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, 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.

Interested Persons

1. Andiman, Alexis, Attorney for *Amici* Farmworker Association of Florida, Farmworker Justice, Migrant Clinician Network, Pesticide Action Network, United Farm Workers, and UFW Foundation
2. Andrews, Cory L., Attorney for *Amici* Atlantic Legal Foundation and Washington Legal Foundation

3. Apfel, Carrie, Attorney for *Amici* Farmworker Association of Florida, Farmworker Justice, Migrant Clinician Network, Pesticide Action Network, United Farm Workers, and UFW Foundation
4. Attaway, Scott K., Attorney for Appellant
5. Baker, Hon. R. Stan, United States District Judge
6. Boswell, Chase E., Attorney for Appellee (in the district court)
7. Brueckner, Leslie, Attorney for *Amicus* Public Justice
8. Calhoun, Martin C., Attorney for Appellee
9. Carson, John D., Jr., Attorney for Appellant
10. Carson, John D., Sr., Appellant
11. Coe, Alison, Attorney for *Amici* Farmworker Association of Florida, Farmworker Justice, Migrant Clinician Network, Pesticide Action Network, United Farm Workers, and UFW Foundation
12. Coffin, Shannen W., Attorney for *Amicus* CropLife America
13. Dickey, Jennifer B., Attorney for *Amicus* Chamber of Commerce
14. Ebner, Lawrence S., Attorney for *Amici* Atlantic Legal Foundation and Washington Legal Foundation
15. Farber, Daniel, *Amicus Curiae*

16. Goldman, Patti, Attorney for *Amici* Farmworker Association of Florida, Farmworker Justice, Migrant Clinician Network, Pesticide Action Network, United Farm Workers, and UFW Foundation
17. Hardeman, Edwin M., Plaintiff in *Hardeman v. Monsanto Co.*, No. 3:16-cv-00525-VC (N.D. Cal.)
18. Heinz, Noah, Attorney for *Amici* Daniel Farmer, Thomas O. McGarity, Paul McGreal, and David Rubenstein
19. Hollingsworth, Joe G., Attorney for Appellee
20. Imbroscio, Michael X., Attorney for Appellee
21. Keller, Ashley, Attorney for *Amici* Daniel Farmer, Thomas O. McGarity, Paul McGreal, and David Rubenstein
22. Khayyat, Rund, Attorney for Appellant
23. Kimmel, Melissa B., Attorney for *Amicus* PhRMA
24. Lasker, Eric G., Attorney for Appellee
25. Lazarus, Alan J., Attorney for *Amicus* Products Liability Advisory Council
26. Lee, Thomas H., Attorney for *Amici* Chamber of Commerce, PhRMA, and Products Liability Advisory Council, Inc.

27. Lehner, Peter, Attorney for *Amici* Farmworker Association of Florida, Farmworker Justice, Migrant Clinician Network, Pesticide Action Network, United Farm Workers, and UFW Foundation
28. Lenkner, Travis, Attorney for *Amici Curiae* Daniel Farmer, Thomas O. McGarity, Paul McGreal, and David Rubenstein
29. Lettow, Paul V., Attorney for *Amicus* Chamber of Commerce
30. Madison, Ashleigh Ruth, Attorney for Appellant
31. Maloney, Stephanie A., Attorney for *Amicus* Chamber of Commerce
32. Marshall, K. Lee, Attorney for Appellee
33. Martínez Llompart, Patricio G., Attorney for Appellee*
34. Masslon II, John M., Attorney for *Amici* Atlantic Legal Foundation and Washington Legal Foundation
35. Mayer, Theodore V.H., Attorney for *Amici* Chamber of Commerce, PhRMA, and Products Liability Advisory Council, Inc.
36. McGarity, Thomas O., *Amicus Curiae*
37. McGreal, Paul, *Amicus Curiae*
38. Moore, Jennifer A., Attorney for Edwin Hardeman
39. Nicholls, Leah M., Attorney for *Amicus* Public Justice

* Patricio G. Martínez Llompart is no longer employed at Covington & Burling LLP.

40. Pilliod, Alberta, Plaintiff in *Pilliod v. Monsanto Co*. No. RG17862702 (Cal. Super. Ct.)
41. Pilliod, Alva, Plaintiff in *Pilliod v. Monsanto Co*. No. RG17862702 (Cal. Super. Ct.)
42. Postman, Warren, Attorney for *Amici* Daniel Farmer, Thomas O. McGarity, Paul McGreal, and David Rubenstein
43. Quallen, Matthew C., Attorney for Appellee*
44. Ray, Hon. Christopher L., United States Magistrate Judge
45. Reinbold, Derek C., Attorney for Appellant
46. Rosenbaum, Adina H., Attorney for *Amicus* Public Citizen, Inc.
47. Rubenstein, David, *Amicus Curiae*
48. Savignac, Mark C., Attorney for *Amicus* CropLife America
49. Stein, William R., Attorney for *Amici* Chamber of Commerce, PhRMA, and Products Liability Advisory Council, Inc.
50. Stansel, James C., Attorney for *Amicus* PhRMA
51. Thomas, Michael J., Attorney for Appellee (in the district court)
52. Varcoe, Andrew R., Attorney for *Amicus* Chamber of Commerce
53. Vernon, Emily A., Attorney for Appellee

* Matthew C. Quallen is no longer employed at Covington & Burling LLP.

54. Watson, Sara Beth, Attorney for *Amicus* CropLife America
55. Williamson, Virginia A., Attorney for Appellee (before the panel)[*]
56. Wisner, R. Brent, Attorney for Alva Pilliod & Alberta Pilliod
57. Wool, David J., Attorney for Edwin Hardeman & *Amicus* Public Justice
58. Young, Ernest A., Attorney for *Amici Curiae* Daniel Farmer, Thomas O. McGarity, Paul McGreal, and David Rubenstein
59. Zieve, Allison M., Attorney for *Amicus* Public Citizen, Inc.
60. Zionts, David M., Attorney for Appellee

Entities

61. Atlantic Legal Foundation
62. Bayer AG, BAYRY
63. Bryan Cave Leighton Paisner LLP
64. Carson, John D., Jr., P.C.
65. Chamber of Commerce of the United States of America
66. Covington & Burling LLP
67. CropLife America
68. Earthjustice
69. Faegre Drinker Biddle & Reath LLP

[*] Virginia A. Williamson is no longer employed at Covington & Burling LLP.

70. Farmworker Association of Florida

71. Farmworker Justice

72. Hollingsworth LLP

73. Hughes, Hubbard & Reed, LLP

74. Keller Lenkner LLC

75. Migrant Clinicians Network

76. Monsanto Company

77. Pennington, P.A.

78. Pesticide Action Network

79. The Pharmaceutical Research and Manufacturers of America

80. Product Liability Advisory Council, Inc.

81. Public Citizen, Inc.

82. Public Citizen Litigation Group

83. Public Justice, P.C.

84. Southeast Law, LLC

85. Steptoe & Johnson LLP

86. United Farm Workers

87. UFW Foundation

88. U.S. Chamber Litigation Center

89. Washington Legal Foundation

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Carson En Banc Reply Br.	En Banc Reply Brief for Plaintiff-Appellant (Apr. 5, 2023), ECF No. 156
Monsanto En Banc Br.	En Banc Brief of Defendant-Appellee (Mar. 15, 2023), ECF No. 140
En Banc Oral Arg. Recording	Recording of En Banc Oral Argument (June 13, 2023), https://www.ca11.uscourts.gov/system/files_force/oral_argument_recordings/21-10994_0.mp3
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FMIA	Federal Meat Inspection Act
PPIA	Poultry Products Inspection Act
1986 Registration Standard	EPA, Guidance for the Reregistration of Pesticide Products Containing Glyphosate as the Active Ingredient (June 1986) (Supp.App. 443-469)
1993 Reregistration Eligibility Decision	EPA, Reregistration Eligibility Decision (RED) – Glyphosate (Sept. 1993) (Supp.App. 59-144)
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INTRODUCTION

EPA has long determined that FIFRA does not require a warning that glyphosate causes cancer—because in EPA's scientific judgment, glyphosate is *not* likely to cause cancer. Before Plaintiff John Carson used Roundup®, EPA weighed cancer risk and imposed "REQUIRED LABELING" for glyphosate products *without* a cancer warning. Supp.App. 456, 462-469. During Carson's use, EPA took "regulatory action" through the statutory re-registration process, 7 U.S.C. § 136a-1(b)(5), determined that glyphosate is not likely to cause cancer, Supp.App. 69, and again imposed "Labeling Requirements" with no cancer warning, Supp.App. 142-143.[1] Last year, long after Carson stopped using Roundup®, EPA reaffirmed "its finding that glyphosate is not likely to be carcinogenic to humans." Supp.App. 624. Throughout, EPA repeatedly approved Roundup® labels with no cancer warning.

The premise of Carson's case is that EPA is wrong. He claims that Georgia law required Monsanto to provide the very warning EPA concluded is neither justified nor required: that glyphosate causes cancer. That claim is preempted.

FIFRA preempts state-law "requirements for labeling or packaging" that are "in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b). The en banc Court identified the key question: whether, "by recourse to the ordinary

[1] EPA further instructed: "Do not add any additional personal protective equipment requirements to the labels of glyphosate end-use products." Supp.App. 143. *Compare* En Banc Oral Arg. Recording at 43:52-54 (counsel for Carson faulting Monsanto for not "telling people to wear protective gear").

principles of statutory interpretation," EPA's "decision to register Roundup as an approved pesticide without a cancer warning, along with the Agency's repeated scientific conclusions about its active ingredient, glyphosate, establish that the 'requirements … required under' the Act do not include a warning about Roundup's cancer risk." *Carson v. Monsanto Co.*, 72 F.4th 1261, 1267 (11th Cir. 2023) (en banc). The answer: EPA's actions *do* establish that the "requirements …. required under [FIFRA]" do not include a cancer warning. The reason: FIFRA requires a registrant to provide the safety warnings *that EPA determines* are required under FIFRA, and requires a registrant not to deviate from the EPA-approved labeling.

The Supreme Court has held, under a materially identical preemption provision, that an agency's product approval "imposes 'requirements' under [the statute]." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008). Following the same ordinary principles of statutory interpretation, EPA's consistent approvals of Roundup® labels—after specifically considering cancer risk and making a statutory determination that no warning is required—impose requirements under FIFRA. States cannot impose an additional requirement to provide a cancer warning.

ARGUMENT

I. The Statute's Reference To "Requirements" Does Not Compel A Force-Of-Law Inquiry As A Matter Of Statutory Interpretation.

The en banc Court rejected "Carson's argument that the Supremacy Clause … mandates a force-of-law analysis when interpreting any express-preemption

provision," noting that he "relies on inapposite implied-preemption decisions." 72 F.4th at 1267. The Court did not resolve "Carson's argument that section 136v(b)'s reference to 'requirements' compels a force-of-law inquiry." *Id.* It does not.

"Congress is entitled to know what meaning [courts] will assign to terms regularly used in its enactments." *Riegel*, 552 U.S. at 324. For decades, it has used the term "requirements" in express-preemption provisions. *See, e.g.*, 21 U.S.C. § 343-1(a)(1) (food labeling); *id*. § 379r(a) (over-the-counter drug labeling); *id*. § 379s(a) (cosmetic labeling); *id*. § 360k(a) (medical devices); *id*. § 467e (poultry); *id*. § 678 (meat); 49 U.S.C. § 30103(b) (motor vehicles). If the word "requirements" compelled a force-of-law analysis for FIFRA, it would compel the same analysis for each of these many other statutes. Yet courts do not apply a force-of-law inquiry to these other preemption statutes. If an express-preemption provision's reference to "requirements" compelled a force-of-law analysis, such an analysis would be routine—not "usually irrelevant." *Carson*, 72 F.4th at 1267.

Carson's argument is thus foreclosed by precedent. In *Riegel*, the Supreme Court held that "premarket approval … imposes 'requirements' under the MDA [Medical Device Amendments]." 552 U.S. at 322. It does so not because premarket approval itself has the force of law, but because it gives content to the statute's own requirements: under the MDA, "FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness,"

and "FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application." *Id*. at 323; *see Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340-41 (10th Cir. 2015) (Gorsuch, J.) (claims preempted because "once the FDA approves a device's label as part of the premarket approval process …, the manufacturer usually may not alter the label's warnings without prior agency approval").

This Court has interpreted the preemption provisions of the FMIA and PPIA the same way. In *Kuenzig v. Hormel Foods Corp.*, the plaintiffs alleged that a federally-approved meat label was misleading. But FMIA and PPIA regulations "required" defendants to "submit their labels to the Food Safety and Inspection Service (FSIS) for approval prior to using the labels on their … products." 505 F. App'x 937, 938 (11th Cir. 2013). Accordingly, the plaintiff's state-law claim that the label was misleading "would impose requirements 'in addition to, or different than' federal law." *Id*. This Court did not ask whether the agency acted with the force of law.

The Tenth Circuit similarly found preemption where FSIS had "approved defendants' labels" as "not deceptive or misleading under the FMIA." *Thornton v. Tyson Foods*, 28 F.4th 1016, 1024 (2022). The plaintiffs alleged that beef products were misleadingly labeled "Product of the U.S.A." *Id.* at 1020. They argued that "the FMIA prohibits false or misleading labeling"; since they "alleged misbranding,

their claims are not preempted." *Id.* at 1021, 1025. That argument failed: through the statutorily required "preapproval" process, "FSIS ha[d] already determined that defendants' labels are not … misleading under federal law." *Id.* at 1025. Notably, no statute or regulation resolved whether and when "Product of the U.S.A." was misleading. The agency recorded that decision in its "Food Standards and Labeling Policy Book"—"a composite of policy and day-to-day labeling decisions, many of which do not appear in the applicable regulations or inspection manuals." *Id.* at 1022 (cleaned up). Although this type of agency document generally lacks the force of law, *see United States v. Mead Corp.*, 533 U.S. 218, 234 (2001), the Tenth Circuit conducted no force-of-law analysis. It recognized that day-to-day labeling decisions, memorialized in a policy book, "determined" the label was not misbranded. Preemption applied because the state-law claim imposed a "different requirement than what the FSIS already approved." *Thornton*, 28 F.4th at 1026.

Carson errs in asking this Court to interpret FIFRA differently based on the observation that a "requirement is a rule of law that must be obeyed." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 445 (2005). *Bates* was distinguishing a legal "requirement" from "an event, such as a jury verdict, that merely motivates an optional decision." *Id*. A defective design verdict might prompt an ingredient change, which would "induce a manufacturer to alter its label to reflect [that] change," but would not be "a rule of law that must be obeyed" compelling the label

change. *Id.* In making this point, the Court neither said nor suggested anything about the role of agency action in establishing the "requirements … required under [FIFRA]." 7 U.S.C. § 136v(b). Indeed, the Court highlighted that in *Bates*, EPA had *not* made "any determination" about the specific warning the plaintiffs claimed was required, *i.e.*, that the product at issue would "damage crops." 544 U.S. at 440.

As with the similar statutes discussed above, FIFRA itself creates the "rule of law that must be obeyed." *Bates*, 544 U.S. at 445. And as with these similar statutes, the application of FIFRA's requirements to particular products depends on agency determinations: the statute prescribes the rules of law that must be obeyed, and charges EPA with "giv[ing] content" to those rules. *Id.* at 453.

II. Where EPA Considers A Safety Issue and Determines No Warning Is Necessary, It Establishes "Requirements Under FIFRA."

FIFRA's Uniformity provision cannot be interpreted differently than the corresponding provisions of similar statutes. For instance, FDA premarket approval establishes "requirements" under the MDA—not because the approvals have the force of law, but because *the statute requires* the manufacturer to use without deviation a label that the FDA determined included all necessary warnings, after reviewing the device for safety. Similarly, FSIS label approvals establish "requirements" under the FMIA and PPIA—not because they have the force of law, but because *the statutes require* the manufacturer to sell a product only after the agency has approved its label as not false or misleading. And for the same reasons,

EPA label approvals establish "requirements" under FIFRA—not because registration has the force of law, but because *the statute requires* the registrant to use without deviation a label that EPA determined includes all warnings necessary to protect health. Whether these approvals themselves have the force of law is beside the point. FIFRA has the force of law, and FIFRA assigns a key role to EPA.

Regulations are just one way that Congress authorized the agency to give content to the Act's requirements—not the only way. Congress also authorized, indeed required, EPA to determine the pesticide-specific application of FIFRA's requirements via the registration process. *See* 7 U.S.C. § 136a(c)(5)(B).

Bates illustrates how agency decisions made through the registration process give content to requirements under FIFRA. A federal requirement to use a "CAUTION" warning preempts a state requirement to use a "DANGER" warning. *Bates*, 544 U.S. at 453. Which warning to give depends in part on a regulation, which "assigns these warnings to particular *classes* of pesticides based on their toxicity." *Id.* (emphasis added). But no regulation assigns any specific pesticide to any particular "class." EPA makes that scientific determination—with consequences for preemption—as part of the statutory registration decision.

As relevant here, EPA's labeling determinations give content to the "requirements … required under [FIFRA]" because FIFRA *requires* a registrant to provide the warnings *that EPA determines* are necessary to protect health:

- FIFRA *requires* a pesticide to include warnings "necessary and … adequate to protect health." 7 U.S.C. §§ 136j(a)(1)(E), 136(q)(1)(F).
- FIFRA *requires* EPA to "determine[]" whether product labeling complies with this requirement. *Id.* § 136a(c)(5)(B).
- And FIFRA *requires* the registrant not to deviate from the EPA-approved label. *Id.* § 136j(a)(1)(B).

This is precisely the type of statutory framework that led the Supreme Court to conclude in *Riegel* that a product-specific agency action shapes the product-specific content of "'requirements' under [the statute]." 552 U.S. at 322-23. Where EPA has reviewed a specific safety question—here, whether the product causes cancer—and determined that no safety warning is required, "[EPA] requires a [pesticide] that has received [labeling] approval to be made with almost no deviations from the [approved label], for the reason that the [EPA] has determined that the approved [label] provides" all necessary health warnings. *Id*. at 323.

Consistent with this framework, EPA imposes "Required Labeling" for glyphosate-based pesticides. *E.g.*, Supp.App. 142, 456. Consider a hypothetical scenario where EPA concluded during the registration process that glyphosate *does* cause cancer, and prescribed "REQUIRED LABELING: Glyphosate causes cancer." If EPA had issued this edict, no one would doubt this agency action established a "requirement … required under" FIFRA, and a state-law requirement *not* to include a warning that glyphosate causes cancer would be preempted.

Preemption must also apply where the agency determined what safety warnings are required under FIFRA, and decided that a cancer warning is *not* required.

In short, EPA imposed required labeling *not* including a cancer warning; EPA considered cancer risk and determined that a cancer warning is *not* required; and FIFRA *requires* registrants to use the EPA-approved label with the EPA-required safety warnings. That "establish[es] that the 'requirements … required under' the Act do not include a warning about Roundup's cancer risk." *Carson*, 72 F.4th at 1267. A state-law labeling requirement to warn that glyphosate causes cancer is thus "in addition" to the labeling "requirements … required under [FIFRA]."

III. FIFRA's "Miscellaneous" Provision Does Not Change The Analysis.

A provision of FIFRA titled "Miscellaneous" provides that registration is prima facie evidence of compliance with FIFRA, and not a defense to commission of an offense under that statute. 7 U.S.C. § 136a(f)(2). From this, the Ninth Circuit infers that because registration creates a "rebuttable presumption," it does not "carr[y] the force of law necessary to have preemptive effect." *Hardeman v. Monsanto Co.*, 997 F.3d 941, 957 (9th Cir. 2021).

Under the en banc Court's decision, *Hardeman* is wrong. *Hardeman* treated § 136a(f)(2) as relevant to whether EPA's actions carry the force of law. Since "force of law" is irrelevant to express preemption, that provision is also irrelevant.

The Miscellaneous provision confirms an unremarkable point: a duly registered pesticide can in some circumstances still violate FIFRA. Thus, in an EPA enforcement action, "a manufacturer with a registered product still could be liable for misbranding." Carson En Banc Reply Br. 28. EPA could charge a registrant with selling a pesticide without EPA-approved labeling,[2] or not filing adverse event reports[3]—and the fact of registration would be no defense. Critically, though, the exact same thing is true under the MDA: FDA can charge a manufacturer of an approved device with misbranding—for example, based on not filing adverse event reports—and premarket approval would be no defense. 21 U.S.C. § 352(t)(2).[4]

The fact that premarket approval is not a conclusive defense to an FDA misbranding charge does not defeat MDA preemption. Under *Riegel*, if FDA considered the safety of a device and approved it, state law cannot compel the manufacturer to give a warning FDA decided not to require. Likewise, the fact that registration is not a conclusive defense to a misbranding charge does not defeat FIFRA preemption. As in *Riegel*, if EPA considered a specific safety issue, state law cannot compel the registrant to give a warning EPA decided not to require.

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[2] *See* EPA, *Settlement with Reckitt Benckiser Resolves Violations Related to Sales of Mislabeled Rodenticides* (Oct. 7, 2021), https://tinyurl.com/3a5v4hma.
[3] *See* Consent Agreement & Final Order, *In re E.I. du Pont de Nemours & Co.*, No. FIFRA-03-2014-0217 (Sept. 15, 2014), https://tinyurl.com/mvuwetb6 (pesticide misbranded where registrant failed to disclose adverse environmental reports).
[4] *See* FDA, *Reporting Allegations of Regulatory Misconduct*, https://tinyurl.com/yt8ujrt5.

Respectfully submitted,

Dated: September 1, 2023

/s/ *David M. Zionts*

Joe G. Hollingsworth
Eric G. Lasker
Martin C. Calhoun
HOLLINGSWORTH LLP
1350 I Street, NW
Washington, DC 20005
(202) 898-5800

David M. Zionts
Michael X. Imbroscio
Emily A. Vernon
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

K. Lee Marshall
BRYAN CAVE LEIGHTON PAISNER LLP
Three Embarcadero Center, 7th Floor
San Francisco, CA 94111
(415) 675-3400

Counsel for Defendant-Appellee Monsanto Company

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1. This brief complies with the page limitation set by this Court's order of August 2, 2023, because, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), it is no more than 10 pages.

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point, Times New Roman font.

/s/ *David M. Zionts*

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I hereby certify that on September 1, 2023, I caused the foregoing document to be electronically filed with the United States Court of Appeals for the Eleventh Circuit using the appellate CM/ECF System for filing and transmittal of a Notice of Electronic Filing to counsel of record.

/s/ *David M. Zionts*