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.)

PETITION FOR REHEARING EN BANC

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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 Interest Persons 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.

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RULE 35-5(C) STATEMENT

I express a belief, based on a reasoned and studied professional judgment, that the panel 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).

I express further a belief, based on a reasoned and studied professional judgment, that this appeal involves a question of exceptional importance: Whether FIFRA preempts a state-law failure-to-warn claim where EPA has exercised its statutory authority to determine that the warning in question would be false and is not required under FIFRA.

/s/ *David M. Zionts*

Attorney of Record for Defendant-Appellee Monsanto Company

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INTRODUCTION

"Federal preemption" may be "a bitter pill," Op.2, but Congress sometimes decides it is necessary medicine. When it does, courts must enforce statutory uniformity provisions as written. The panel decision here, however, effectively nullified such a provision. It reinstated a state-law claim for failure to change a federally-approved label to warn of a safety risk that the responsible federal agency determined does not warrant such a warning. That decision cannot be reconciled with Congress's uniformity command or with Supreme Court precedent.

In the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), Congress dictated that States shall not "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. §136v(b). Because Congress cannot decide the contents of every pesticide label, it delegated authority to experts: the Environmental Protection Agency ("EPA"). Congress prescribed a formal registration process by which EPA exercises that statutory authority. *See id.* §§136a, 136a-1. At points, the statute refers to that process as resulting in "regulatory action." *Id.* §136a-1(b)(5). In that process, EPA "shall" "determine[]" whether a particular label contains all necessary health warnings. *Id*. §§136a(c)(5)(B), 136(q)(1)(G); 40 C.F.R. §152.112(f). EPA does this by notice-and-comment procedures. *See* 40 C.F.R. §§152.102, 155.50, 155.58(a)-(c).

Defendant Monsanto Company manufactures Roundup®, the world's most widely used herbicide, and among the most studied. For decades, EPA has followed congressionally prescribed procedures to conclude that glyphosate, the active ingredient in Roundup®, does not cause cancer. It has thus approved label after label with no cancer warning—necessarily concluding that no such warning is required under FIFRA—and expressly stated that a cancer warning would be false. Given this, any state requirement to warn that glyphosate causes cancer is at least "in addition to" requirements under FIFRA, 7 U.S.C. §136v(b), and thus expressly preempted.

The panel, however, rejected preemption on one ground: it deemed EPA's formal exercise of its labeling authority irrelevant. The panel employed a "force of law" test that the Supreme Court has never applied to statutes expressly preempting state requirements "in addition to or different from" federal requirements. Applying that test anyway, the panel dismissed as inadequate EPA action vastly more formal than what the Supreme Court has considered sufficient to require preemption. The consequences of this approach for pesticide labeling alone would warrant further review. The opinion trivializes EPA's safety determinations about pesticides, as tens of thousands of pending cases seek to impose massive damages for failing to warn of a cancer risk EPA determined does not exist. But the decision sweeps more

broadly still, threatening chaos for settled preemption principles applicable to medicines, food labeling, and more. The full Court's attention is warranted.

ISSUE PRESENTED

Whether FIFRA preempts a state-law failure-to-warn claim where EPA has exercised its statutory authority to determine that the warning in question would be false and is not required under FIFRA.

COURSE OF PROCEEDINGS

Plaintiff John Carson sued Monsanto in the Southern District of Georgia, alleging that glyphosate in Roundup® caused his cancer. Monsanto moved for judgment on the pleadings, which the district court granted in part, concluding that FIFRA expressly preempted Plaintiff's Georgia-law failure-to-warn claim. App.95-96. The parties reached a settlement pursuant to which Plaintiff dismissed his remaining claims and appealed the dismissal of his failure-to-warn claim.[1] On July 12, 2022, a panel reversed.

[1] The parties reached a high-low settlement under which Plaintiff's recovery depends on this appeal. *See Nixon v. Fitzgerald*, 457 U.S. 731, 744 (1982) (jurisdiction continues where settlement leaves "both [parties] with a considerable financial stake in the resolution of the question presented"); Monsanto's Civil Appeal Statement 2-3 (Apr. 5, 2021). Lawyers for other Roundup® plaintiffs moved to file a brief objecting to that settlement, which Monsanto opposed; the panel denied the motion as moot.

STATEMENT

1. FIFRA delegates to EPA the authority to regulate "the use, … sale[,] and labeling[] of pesticides." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 437 (2005). Before EPA registers a pesticide, it must determine that the pesticide will not cause "unreasonable risk to man." 7 U.S.C. §§136(bb), 136a(c)(5)(C). EPA must also "determine[]" that the labeling "compl[ies] with" FIFRA's "requirements," including its prohibition on misbranding. *Id*. §136a(c)(5)(B). Thus, "EPA will approve an application" for registration "only if" "[t]he Agency has determined that the product is not misbranded as that term is defined in FIFRA." 40 C.F.R. §152.112(f). That includes a determination that the labeling contains any "warning or caution statement which may be necessary" to "protect health," and is not "false or misleading in any particular." 7 U.S.C. §136(q)(1)(A), (G). In making these determinations, EPA evaluates cancer risk. *See* EPA, Evaluating Pesticides for Carcinogenic Potential, https://perma.cc/VUH4-2G4U.

Congress prescribed the pesticide registration process in remarkable detail. For example, certain pesticides (including glyphosate) must go through "re-registration," which Congress defined to encompass five phases culminating in "regulatory action." 7 U.S.C. §136a-1. EPA must also review registrations every fifteen years. *See id*. §136a(g)(1)(A)(i), (iv).

Manufacturers may not deviate from EPA-approved labeling. 7 U.S.C. §136j(a)(1)(B). And new health warnings may not be added without EPA approval. 40 C.F.R. §§152.44, 152.46; Pesticide Registration Notice 98-10, at 8, https://perma.cc/AKK3-WB33.

2. "EPA has repeatedly approved the use of glyphosate as a pesticide, each time concluding that it is not likely to be carcinogenic to humans." *Hardeman v. Monsanto Co.*, 997 F.3d 941, 951 (9th Cir. 2021), *cert denied*, 142 S.Ct. 2384 (2022). "[F]orty-four versions of the label for the original formulation of Roundup have been accepted by EPA since 1991," with no cancer warning. Supp.App.45 (*Hardeman* U.S. CA9 Br.).

In 1993, EPA completed glyphosate's statutory re-registration, reaching the "Regulatory Conclusion" that all registered glyphosate products "will not pose unreasonable risks or adverse effects to humans." *EPA R.E.D* [Reregistration Eligibility Decision] *Facts*, *Glyphosate* 7 (Sept. 1993), https://perma.cc/C8V2-ECAC. That agency action included notice-and-comment, and incorporated EPA's 1991 "classifi[cation]" of glyphosate as showing "evidence of non-carcinogenicity for humans." *Id*. at 2, 7.

EPA continued to evaluate whether glyphosate is carcinogenic, including as part of statutory registration review procedures. And through those ongoing evaluations, it repeatedly reaffirmed that glyphosate is "Not Likely to be

Carcinogenic to Humans." Supp.App.179-80 (2017 Revised Glyphosate Issue Paper); *see* Final Rule: Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) ("extensive database available on glyphosate" "indicate[s] that glyphosate is … not a carcinogen"). In 2018 and 2019, EPA twice sought public comment on its "human health … risk assessment[]." Supp.App.54. In 2020, EPA issued a final Interim Registration Review Decision, concluding that "EPA thoroughly assessed risks to humans from exposure to glyphosate from all registered uses and all routes of exposure and did not identify any risks of concern." Supp.App.394. That same review updated the labeling required for glyphosate products—without adding a cancer warning. Supp.App.407-412.[2]

EPA notified glyphosate registrants in 2019 that warning glyphosate causes cancer would "constitute a false and misleading statement," rendering pesticides "misbranded" under "FIFRA." Supp.App.11 (2019 EPA Letter). In 2022, EPA notified California authorities that it could approve labeling stating that an international agency has determined that glyphosate causes cancer and that EPA has determined it does not. EPA's new letter did not disavow its prior conclusion that a

[2] Following an administration change, EPA reaffirmed that conclusion. EPA Br. *NRDC v. EPA,* Nos. 20-70787, 20-70801, 2021 WL 2170531, at *1 (9th Cir. May 18, 2021). The Ninth Circuit recently vacated the human-health effects conclusions of EPA's interim registration review for lack of adequate explanation. 2022 WL 2184936 (9th Cir. Jun. 17, 2022). The court explained that its decision "simply maintained the status quo," acknowledging that "EPA could come to the same human-health conclusion on remand." *Id.* at *13.

warning that glyphosate causes cancer would make a product misbranded. Letter (Apr. 8, 2022), https://perma.cc/GPS5-72SZ.

3. In 2015, a working group at the International Agency for Research on Cancer ("IARC") classified glyphosate as "probably carcinogenic to humans." IARC's "hazard" assessment does not consider whether there is actual risk at real-world exposure levels. Regulators worldwide, including EPA, disagree with IARC. Supp.App.11 (2019 EPA Letter).

Nonetheless, Monsanto has faced more than 100,000 personal injury actions alleging glyphosate causes cancer. Most concern non-Hodgkins lymphoma, and all such federal cases were centralized in a multi-district litigation in the Northern District of California. Following a trial, the Ninth Circuit affirmed a verdict for the plaintiff, rejecting preemption. *Hardeman*, 997 F.3d at 954-60.

4. Plaintiff here had a different cancer, so the case proceeded separately, presenting the first opportunity for a federal appeals court other than the Ninth Circuit to address the preemption question. Without citing express preemption authority, the panel concluded that "any preemption analysis in the FIFRA context first requires us to do a *Mead* analysis," asking if "EPA has acted with the force of law." Op.6-7. The panel acknowledged "there is something akin to a notice and comment requirement in the registration process," but decided that "registration itself does not lead to any formal agency action, like a rule." Op.13 n.12. Deeming

EPA's determinations irrelevant, the panel compared Georgia's requirement to warn of "dangerous condition[s]" with FIFRA's requirement to warn when "necessary to protect health and the environment." Op.11. At that high level of abstraction, the panel concluded Georgia "imposes less of a duty on Monsanto than the FIFRA statute does," so Georgia law "is not expressly preempted." Op.10-11. The panel likewise rejected implied preemption because "EPA has not acted with the force of law." Opp.11 n.11.

ARGUMENT

I. The Panel's Refusal to Treat EPA Labeling Determinations As Relevant to Express Preemption Conflicts With Decisions of the Supreme Court and Other Circuits.

FIFRA preempts state labeling requirements that are "in addition to" or "different from" those "required under [FIFRA]." 7 U.S.C. §136v(b). Although the Supreme Court has construed both FIFRA and other statutes with materially identical preemption language, it has *never* asked whether agency action has the "force of law." That is undoubtedly because, unlike with implied preemption, there is no question what "law" does the preempting: the preemption provision. Here, Congress preempted labeling requirements in addition to what is "required under FIFRA," and directed EPA to determine what is "required under FIFRA" for particular pesticides. EPA "shall" register a pesticide if it "determines" the labeling "compl[ies] with the requirements of [FIFRA]." 7 U.S.C. §136a(c)(5)(B).

Following that instruction, EPA "determine[s]" whether a product is "misbranded as that term is defined in FIFRA," including whether it provides all necessary health warnings. 40 C.F.R. §152.112(f).

In *Bates*, the Supreme Court held that state labeling requirements must be "*genuinely* equivalent" to federal ones to escape preemption. 544 U.S. at 454. And it gave a specific example of *genuine* equivalence, explaining that if EPA determined that a pesticide should say "CAUTION," a "failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted." *Id*. at 453. An EPA regulation defines the toxicity levels that correspond to "DANGER" and "CAUTION"—but critically, the regulation does not *assign* toxicity levels or warning language to any particular pesticide. 40 C.F.R. §156.64. EPA makes pesticide-by-pesticide toxicity determinations *through registration*—the statutory process the panel deemed irrelevant. *See*, *e.g.*, Supp.App.80-90 (1993 Reregistration Decision) (glyphosate toxicity determinations). By the panel's logic, a State *could* require a "DANGER" warning when EPA requires a "CAUTION" warning, simply by disagreeing with what EPA determined during registration. In other words, under the panel's upside-down reading of FIFRA, States can do exactly what *Bates* says they cannot.

Riegel v. Medtronic makes the point inescapable. *Riegel* concerned the Medical Device Amendments ("MDA"), which has a "similarly worded pre-emption

provision" to FIFRA. *Bates,* 544 U.S. at 447. And *Riegel* held that when the Food and Drug Administration ("FDA") (which administers the MDA) grants "premarket approval," which is permissible "only after it determines that a device offers a reasonable assurance of safety and effectiveness," it "imposes 'requirements' under the MDA." *Riegel*, 552 U.S. at 322-23; *see Caplinger v. Medtronic, Inc.,* 784 F.3d 1335, 1340 (10th Cir. 2015) (Gorsuch, J.) ("device-specific federal requirements apply" because "once the FDA approves a device's label … the manufacturer usually may not alter the label's warnings without prior agency approval"). *Riegel* did not hunt for "agency action with the force of law," or interrogate the formality of FDA's approval process. Rather, the MDA is what preempts requirements additional to "requirements under the MDA," and FDA follows a congressionally prescribed approval process to give device-specific content to those requirements. The same must be true under FIFRA's materially identical preemption provision: FIFRA is what preempts requirements additional to "requirements under FIFRA," and EPA follows a congressionally prescribed registration process to give pesticide-specific content to those requirements.

Other circuits apply the same approach to similar preemption provisions. *See*, *e.g.*, *Thornton v. Tyson Foods, Inc.*, 28 F.4th 1016, 1024 (10th Cir. 2022); *Webb v. Trader Joe's Co.*, 999 F.3d 1196, 1204 (9th Cir. 2021); *see also Kuenzig v. Hormel Foods Corp.*, 505 F.App'x 937 (11th Cir. 2013). The Federal Meat Inspection Act,

for example, prohibits state requirements "in addition to, or different than, those made under this chapter." 21 U.S.C. §678. Where a federal agency "approved defendants' labels, concluding that they are not deceptive or misleading under the FMIA," state law may not "impose a requirement different from what the [agency] has already approved as consistent with the FMIA." *Thornton*, 28 F.4th at 1024. Nowhere did the Tenth Circuit demand "agency action with the force of law" or formal rulemaking.

Without addressing any of this authority, the panel relied on a misreading of a different FIFRA provision, which provides that the fact of registration is not a "defense for the commission of any offense under this subchapter." 7 U.S.C. §136a(f)(2). In the panel's view, by clarifying the import of registration in enforcement proceedings, Congress somehow "undermined the formality of EPA registration" itself. Op.9. That conclusion sides with the Ninth Circuit, *see Hardeman*, 997 F.3d at 956, against the Fifth, which holds that §136a(f)(2) "has no bearing on" preemption, since "[a] claim grounded in state common law is not an offense under FIFRA." *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994); *see also Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 45 (D.D.C. 2011) ("Section [136a(f)(2)] stands for the unremarkable proposition that a registration is not a defense against an allegation that a product violates the terms of

that registration, just as a valid driver's license is not a defense against a speeding ticket.").

Moreover, the point is not that "registration" preempts, but that Congress directed EPA to make safety and labeling determinations *during* registration. As in *Riegel*, those safety and labeling determinations "impose[] 'requirements' under [FIFRA]," *Riegel*, 552 U.S. at 322, and States may not impose requirements "in addition to" or "different from" those requirements. Congress does not hide elephants in mouseholes, and it did not transform the normal operation of an express preemption provision through an unrelated clause it captioned "Miscellaneous." Pub. L. No. 92-516, §3(f)(2), 86 Stat. 973, 982 (1972).[3]

II. The Panel's Decision that Labeling Determinations Made Through EPA's Formal Registration Process Lack The "Force of Law" Conflicts With Decisions of the Supreme Court and This Court.

If "force of law" is the standard, EPA's formal registration process meets it. The point of this inquiry is that "whatever the means the [agency] uses to exercise its authority, those means must lie within the scope of the authority Congress has lawfully delegated." *Merck*, 139 S.Ct. at 1679. Congress unmistakably delegated

[3] Whatever role §136(a)(f)(2) might play if EPA were to "miss a misbranded label," Op.6, EPA here missed nothing—it focused on the cancer question for decades. That is also unlike the situation in *Bates*. Congress authorized EPA to "stop[] evaluating pesticide efficacy for routine label approvals," so EPA never determined whether omission of crop damage warnings constituted misbranding. *Bates*, 544 U.S. at 440.

authority to EPA to make determinations about pesticide safety and labeling through a comprehensive registration process. *Supra* 4-5. EPA exercised its authority using exactly "the means" Congress prescribed.

The only way to disregard EPA's actions is to disregard statutory text. Where the panel opined that "registration itself does not lead to any formal agency action," Op.13 n.12, the statute defines re-registration to conclude with "regulatory action by the Administrator," 7 U.S.C. §136a-1(b)(5). Where the panel found no EPA actions that "naturally bind Monsanto," Op.13 (quotations omitted), the statute makes it unlawful to make claims that "substantially differ from any claims made for [a pesticide] as a part of the statement required in connection with its registration," *i.e.*, the approved labeling, 7 U.S.C. §136j(a)(1)(B). *See Reckitt Benckiser, Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010) ("FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed"). And nowhere did the panel mention EPA's statutory obligation to "determine" whether the label has necessary health warnings. *Supra* 4.

The panel also declined to discuss the Supreme Court's instructions about what agency action has the "force of law" for implied preemption purposes. In *Merck*, the Court considered preemptive ways FDA could "communicate its disapproval of a warning." 139 S.Ct. at 1679. FDA can "formally reject[] a warning

label" by sending a "complete response letter" to the applicant stating its position on a drug. *Id.* (citing 21 C.F.R. §§314.110, 314.25(b)(6)). That process is not specifically provided for by statute, leaves no trace in the Federal Register, and is not subject to comment. FIFRA's registration process is indisputably more formal than this regulatory process the Supreme Court endorsed, so must be sufficient to support preemption.

Merck also referred to FDA's obligation to determine whether "new information" requires a change to "the labeling of the drug," 21 U.S.C. §355(*o*)(4)(a), referring to this as "other agency action carrying the force of law," 139 S.Ct. at 1679. A three-justice concurrence elaborated that when "FDA declines to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified," which is "highly relevant to the pre-emption analysis." *Id*. at 1684-85 (Alito, J., concurring). If FDA *inaction* even arguably supports preemption, EPA *action* approving a label in the face of a statutory obligation to ensure the adequacy of health warnings must support preemption.

After ignoring *Merck*, the panel misconstrued *Mead*. *Mead* recognized that "a *relatively* formal administrative procedure tending to foster … fairness and deliberation" yields "administrative action with the effect of law." *United States v. Mead Corp.*, 533 U.S. 218, 230-31 (2001) (emphasis added). *Mead*'s flexibility

cannot be reconciled with the panel's rigid insistence on a "rule produced from notice-and-comment rulemaking," such that even something "akin to a notice and comment requirement" is not enough. Op.13 n.12.

The panel also disregarded this Circuit's recognition that under *Mead*, the question is not whether the agency engaged in rulemaking, but whether it acted pursuant to a "delegation of authority." *Heimmermann v. First Union Mortg. Corp.*, 305 F.3d 1257, 1262 (11th Cir. 2002). Thus, a "statement of policy," issued without notice-and-comment, had the force of law because "the power to issue interpretations is expressly delegated." *Id*. at 1261-62. Labeling determinations made in the registration process similarly have the force of law not just because that process is so formal, but because Congress delegated to EPA the authority to make those determinations in that process.

"The EPA approved label is a very formal affair." Supp.App.39 (*Hardeman* U.S. CA9 Br.).[4] Through formal, notice-and-comment registration procedures, EPA did exactly as Congress directed: determined that glyphosate labeling, without a cancer warning, complies with requirements under FIFRA. Unless nothing short of rulemaking will do—a position the Supreme Court consistently rejects—it is hard to imagine what could more clearly have the force of law.

[4] The Government changed its interpretation of FIFRA's preemption clause, but not of the formality of label approvals. *See* U.S. Br., *Monsanto Co. v. Hardeman*, No. 21-241 (U.S. May 10, 2022) ("SG Brief").

III. The Panel's Effective Nullification of FIFRA Preemption Will Have Harmful Consequences for Pesticides, Medicines, and More.

Under the panel's opinion, a provision enacted to secure labeling "Uniformity," 7 U.S.C. §136v(b), instead permits "50 different labeling regimes," *Bates*, 544 U.S. at 452. So long as States parrot FIFRA's standards at a high level of abstraction, they can *apply* those standards differently, mandating warnings that EPA determines are unnecessary or even prohibited.

The panel renders irrelevant EPA's views on what safety warnings are required for any pesticide. Understandably, EPA long ago rejected making such labeling "determin[ations] on a case-by-case basis" because "it is impossible to prescribe … exact statements for all combinations of ingredients, formulation types, and uses" by rule. Labeling Requirements for Pesticides and Devices, 49 Fed. Reg. 37960, 37965 (Sep. 26, 1984). Since EPA does not make pesticide-specific labeling decisions by rulemaking, the panel treats FIFRA's preemption clause as a virtual nullity.

Under this chaotic regime, even if EPA follows statutory procedures to determine what safety warnings are and are not required under FIFRA, Georgia could disagree with EPA, Florida could disagree with Georgia, and California can set its own standards, so long as all purport to require "necessary" health warnings. "Manufacturers might have to print 50 different labels, driving consumers who buy [pesticide] products in more than one state crazy." *Turek v. Gen. Mills, Inc.*, 662

F.3d 423, 426 (7th Cir. 2011); *cf. Moss v. Parks Corp.*, 985 F.2d 736, 739 (4th Cir. 1993) (Congress provided for preemption under "a similar federal statute" to FIFRA to alleviate "the impracticality of having the states [require] potentially fifty different labels").

In the context of Roundup® alone, the consequences are far-reaching. More than 100,000 cases have been filed. Tens of thousands remain pending. In what remains of this year, 11 are scheduled for trial, with 90 to follow next year. At the same time, opportunities for federal appellate review in this litigation are quite limited, with the multi-district litigation operating as "an antipercolation device." Coenen & Davis, *Percolation's Value*, 73 Stan. L. Rev. 363, 386 (2021). The Solicitor General recently told the Supreme Court that the outcome of *this specific appeal*, if it results in a disagreement with the Ninth Circuit, may determine whether there is a "sound reason for the [Supreme] Court to grant review" on this issue. SG Br. 19.

Further, numerous preemption provisions incorporate similar "in addition to or different from" language. Courts regularly borrow FIFRA case law to interpret those statutes. *See, e.g.*, *Thornton*, 28 F.4th at 1026 (FMIA) (citing *Bates*); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) (MDA) (same). Now, a plaintiff who disagrees with USDA food labeling decisions would be stymied in the Tenth Circuit, *supra* 10-11, but can demand a different label here.

The panel's cramped view of what agency action has the "force of law" will also reverberate to medicines. The stakes for striking the right implied preemption balance for life-saving medicines could not be higher. *See Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1102 (10th Cir. 2017) ("overwarnings" can "discourage use of beneficial medications"). The Supreme Court recognizes various ways FDA can communicate its disapproval of a warning with preemptive effect—with *less* formality than EPA's process. *Supra* 13-14. But in this Circuit, absent "a rule produced from notice-and-comment rulemaking," Op.13 n.12, FDA's normal ways of making warning decisions will be deemed not to have the force of law, and discarded from "any preemption analysis," Op.7.

CONCLUSION

Rehearing *en banc* should be granted.

Respectfully submitted,

Dated: August 2, 2022

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CERTIFICATE OF COMPLIANCE

1. This Petition complies with the type-volume limitation of 11th Circuit Rule 35-1 because it contains 3897 words, excluding the parts of the Petition exempted by 11th Circuit Rule 35-1.

2. This Petition 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*

CERTIFICATE OF SERVICE

I hereby certify that on August 2, 2022, I caused the foregoing document to be electronically filed with the United States Court of Appeals for the Eleventh using the appellate CM/ECF System for filing and transmittal of a Notice of Electronic Filing to counsel of record.

/s/ *David M. Zionts*

[PUBLISH]

In the United States Court of Appeals

For the Eleventh Circuit

No. 21-10994

JOHN D. CARSON,

Plaintiff-Appellant,

versus

MONSANTO COMPANY,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Georgia
D.C. Docket No. 4:17-cv-00237-RSB-CLR

Before ROSENBAUM, TJOFLAT, Circuit Judges, and MOODY, District Judge.

TJOFLAT, Circuit Judge:

Federal preemption is a bitter pill. We should administer it carefully. And, applying such care to the present case, we hold that John Carson's Georgia failure to warn claim is not preempted by the federal requirements under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") or the Environmental Protection Agency's ("EPA") actions pursuant to it.

I.

John Carson regularly used Roundup® on his lawn for about 30 years until 2016. Around 2016, Carson was diagnosed with malignant fibrous histiocytoma, which he believes was linked to the compound glyphosate, the main chemical ingredient in Roundup®.

Carson filed suit against Monsanto, the manufacturer of Roundup®, on December 5, 2017. In his four-count complaint, Carson alleged strict liability for a design defect under Georgia law (Count I); strict liability for failure to warn under Georgia law

(Count II); negligence under Georgia law (Count III); and breach of implied warranties under Georgia law (Count IV).[1]

Monsanto filed an answer to the Complaint and subsequently moved for judgment on the pleadings.[2] The District Court partially granted the motion. The District Court ruled that Carson's Count II failure to warn claim was preempted under FIFRA because the EPA had classified glyphosate as not likely to be carcinogenic to humans and ruled that Carson's Count IV breach of implied warranties claim under Georgia law was preempted for the same reason. The District Court also dismissed Counts I and III for the strict liability design defect and negligence to the extent that those claims related to how Roundup® was labeled or packaged. Carson moved to amend his complaint to dismiss Counts I and III of the complaint pursuant to a settlement agreement with Monsanto but preserved his right to appeal Count II, the failure to warn claim. The District Court granted that motion, thereby eliminating Counts I and III from the Complaint. Carson timely appealed the District Court's judgment on the pleadings as to Count II.

On appeal, we are essentially tasked with deciding whether the District Court erred in concluding that Carson's failure to warn

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[1] Carson did not specify that his cause of action was under Georgia law in his Complaint, but the District Court determined that his common law claims fell under Georgia law, and Carson does not challenge that determination.

[2] The judgment on the pleadings challenged the legal sufficiency of the Complaint based on federal preemption grounds.

claim was preempted under FIFRA because the EPA had classified glyphosate as not likely to be carcinogenic to humans and approved the Roundup® label. We conclude it did, reverse the District Court's ruling, and remand for further proceedings.

II.

"Judgment on the pleadings is proper when no issues of material fact exist, and the movant is entitled to judgment as a matter of law." *Ortega v. Christian*, 85 F.3d 1521, 1524 (11th Cir. 1996). We review de novo a district court's order granting a judgment on the pleadings, treating the facts alleged in the complaint as true, viewing the record in the light most favorable to the nonmovant, and evaluating any affirmative defenses raised by the moving party (including preemption).[3] *Horsley v. Feldt*, 304 F.3d 1125, 1131 (11th Cir. 2002); *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 767 (11th Cir. 1998).

III.

Starting at the beginning of the EPA's work in a pesticide case like this one, FIFRA requires all pesticide manufacturers to go through a registration process with the EPA before selling a

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[3] In this case, any evidence submitted by Monsanto to support its defense of federal preemption turns out not to be probative because the EPA has not acted with the force of law such as to meet the threshold inquiry for federal preemption, as discussed *infra* Part IV.

particular pesticide. *See* 7 U.S.C. § 136a; 40 C.F.R. § 155.58. As part of that process, the manufacturer submits a proposed label and relevant data for registration to the EPA. 7 U.S.C. §§ 136a(c)(1)(C), (F). In turn, the EPA reviews the efficacy of the pesticide, the adverse health consequences or environmental effects of the pesticide, and the labels on the pesticide for compliance with FIFRA's labeling requirements. *Id.* § 136a(c)(5).

FIFRA prohibits pesticide manufacturers from selling a pesticide that is "misbranded." *Id.* § 136j(a)(1)(E). Misbranding could mean that a pesticide label contains information that is "false or misleading in any particular."[4] *Id.* § 136(q)(1)(A). A pesticide can also be misbranded if the label does not "contain directions for use" or "a warning or caution statement" that is "adequate to protect health and the environment." *Id.* § 136(q)(1)(F), (G).

So, the EPA checks for these possible misbranding violations on labels when completing the registration process for pesticide manufacturers. *Id.* § 136a(c)(5)(B). But, even with EPA oversight at the initial registration process,[5] pesticide manufacturers have a perpetual duty to adhere to FIFRA's labeling requirements and to

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[4] "The term 'label' means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." 7 U.S.C. § 136(p)(1).

[5] The EPA must reconsider a pesticide's registration every fifteen years. 7 U.S.C. § 136a(g)(1)(A)(iv).

report any new adverse effects to the EPA. *Id.* § 136j(a)(1)(E); § 136a(f)(1); § 136d(a)(2); 40 C.F.R. § 159.184. And, sometimes, the EPA might just miss a misbranded label in the registration process. FIFRA accounts for that possibility by explaining that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." 7 U.S.C. § 136a(f)(2). In other words, a pesticide manufacturer can't point to EPA registration as a defense to a misbranding violation under FIFRA.

In sum, we have two things going on here: 1) we have the EPA's registration process for pesticide manufacturers seeking to market their pesticides; and 2) we have FIFRA's statutory labeling requirements and consequences for failing to properly label. These two components underlie the preemption analysis.

IV.

Sometimes, FIFRA or the EPA's actions pursuant to FIFRA may preempt state law. But only federal action with the force of law has the capacity to preempt state law.[6] *See Wyeth v. Levine*,

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[6] Congress created wide latitude for state regulation in the context of FIFRA. *See* 7 U.S.C. § 136v(a) ("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 this subchapter."); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 446, 125 S. Ct. 1788, 1799 (2005) ("Under § 136v(a), a state agency may ban the sale of a pesticide if it finds, for instance, that one of the pesticide's label-approved uses is unsafe.

555 U.S. 555, 576, 580, 129 S. Ct. 1187, 1200 (2009). So, any preemption analysis in the FIFRA context first requires us to do a *Mead* analysis.[7] *United States v. Mead Corp.*, 533 U.S. 218, 230–31, 121 S. Ct. 2164, 2172–73 (2001). If, and only if, the EPA has acted with the force of law, may we move on to a preemption analysis.

In the universe where there is either an applicable FIFRA statute or the EPA has acted with the force of law, we turn to FIFRA's uniformity statute, which says that no state shall "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b). So, a state rule, including a common-law cause of action like Georgia's failure-to-warn claim, is preempted by FIFRA if two conditions are met: 1) the state requirement must be "for labeling or packaging" under the language of the statute; and

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This ban might well induce the manufacturer to change its label to warn against this questioned use.").

[7] The Supremacy Clause, the source of federal preemption, only applies to agency action that constitutes "federal law." *Marrache v. Bacardi U.S.A., Inc.*, 17 F.4th 1084, 1094 (11th Cir. 2021); *cf. Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) ("In both *Chevron* and preemption contexts, a central inquiry is whether an agency has validly created federal law pursuant to the gap-filling power delegated to it by Congress. In the former situation, we decide whether *Chevron*-level deference is due because Congress intended for the agency's pronouncement to carry the force of law; in the latter, we decide whether state law is preempted because Congress intended for the agency's pronouncement to carry the binding and exclusive force of federal law. Creation of federal law should demand at least the same formality for purposes of preemption as it does for purposes of *Chevron* deference.").

2) the state requirement is "in addition to or different from" requirements derived from FIFRA. *Id.*; *see also Bates*, 544 U.S. at 444, 125 S. Ct. at 1798. Straightforward in recitation. A bit complicated in practice.

Since Carson's failure to warn claim under Georgia law hinges on whether Georgia's cause of action is different from or in addition to the federal law imposed on Monsanto for its marketing of Roundup®, we must first look to the EPA's registration process and then FIFRA's misbranding statutes.

The EPA registered Roundup®, whose main chemical ingredient is glyphosate, for distribution, sale, and manufacture in the United States. Even with that approval, Carson argues that Roundup's® label failed to adequately warn of the harmful nature of glyphosate under Georgia law. So, the question under FIFRA is whether Georgia common law failure to warn would be different from or in addition to any action the EPA has taken that has the force of law. 7 U.S.C. § 136v(b). Connecting the dots, the only way that we could have a preemption problem in the registration process is if the EPA registration process itself carries with it the force of law. Otherwise, the threshold step for preemption—the force of law—is not met, and we can't even continue to the *Bates* analysis for preemption of state law under FIFRA.

The problem for Monsanto is that the EPA's registration process is not sufficiently formal to carry with it the force of law under *Mead*. *See Mead Corp.*, 533 U.S. at 230, 121 S. Ct. at 2172

("It is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force."); *id.* at 234, 121 S. Ct. at 2175 ("[P]olicy statements, agency manuals, and enforcement guidelines" are insufficient to carry the force of law.). Congress itself undermined the formality of EPA registration when it explained that EPA registration served only as prima facie evidence of compliance with the registration requirements of FIFRA.[8] 7 U.S.C. § 136a(f)(2). In short, we can only take EPA registration for what it's worth. And it doesn't amount to a sufficiently formal proceeding to carry the force of law since it at most creates a rebuttable presumption of compliance with FIFRA's registration process and nothing more.[9] *See Hardeman v. Monsanto Co.*, 997 F.3d 941, 956 (9th Cir. 2021) ("So even

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[8] We note that compliance with the registration process does not even serve as evidence of compliance with the labeling provisions of FIFRA. *See* 7 U.S.C. § 136a(f)(2) ("In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter.").

[9] And, even if this were a close case on whether the EPA has acted with the force of law, which it isn't, "[t]he long history of tort litigation against manufacturers of poisonous substances adds force to the [existing] presumption against pre-emption, for Congress surely would have expressed its intention more clearly if it had meant to deprive injured parties of a long available form of compensation." *Bates*, 544 U.S. at 432–33, 125 S. Ct. at 1792.

though EPA approved Roundup's® label, a judge or jury could disagree and find that same label violates FIFRA.").

Next, we turn to the FIFRA labeling provisions, which obviously carry the force of law, to determine whether Georgia's failure to warn claims are different from or in addition to those federal statutes.[10] FIFRA requires that pesticide labels "contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(G). Georgia law subjects a manufacturer to liability for failure to warn when the manufacturer "(a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous." *Greenway*, 294 S.E.2d at 545–46 (quoting Restatement (Second) of Torts § 388). Matching up FIFRA's labeling requirement with the Georgia cause of action for failure to warn, we see that the Georgia law failure to warn claim, if anything, imposes less of a duty on Monsanto than the FIFRA statute does because under Georgia law Monsanto is only required to warn when those who

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[10] We note that the first step of the *Bates* test is met as to the FIFRA statutes. Georgia's common law cause of action for failure to warn is clearly an imposition of a labeling or packaging requirement. *See Greenway v. Peabody Int'l Corp.*, 294 S.E.2d 541, 545–46 (Ga. 1982) (quoting Restatement (Second) of Torts § 388). We need not analyze this step any further.

will be using the product do not realize the dangerous condition of the product. On the other hand, FIFRA imposes a blanket duty, regardless of the knowledge of the consumer, when the warning is necessary to protect health and the environment. In practice, the Georgia failure to warn claim simply enforces the FIFRA cause of action, so it is not expressly preempted. *Bates*, 544 U.S. at 447–48, 125 S. Ct. at 1800.[11]

In its final effort to have Georgia law preempted, Monsanto points to various EPA documents to suggest that the EPA has acted with the force of law, such that Monsanto could not label Roundup® as carcinogenic without consequences from the EPA. In its brief, Monsanto points to the following actions as having the force of law:

- The EPA's Label Registration, and subsequent interim registration reviews and re-registration eligibility decisions of glyphosate pesticides. EPA,

[11] Monsanto also makes a separate argument that Georgia's failure to warn claim is impliedly preempted because Monsanto cannot comply with both state and federal requirements. *See Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 480, 133 S. Ct. 2466, 2473 (2013). Because an implied preemption analysis turns on whether a federal agency has indicated through some action carrying the force of law that it would not accept a label mandated by state law, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678–79 (2019), and we have already determined that the EPA has not acted with the force of law and that FIFRA statutes are consistent with Georgia law, we do not address this argument further.

Reregistration Eligibility Decision (RED) – Glyphosate (Sept. 1993); EPA, Glyphosate: Interim Registration Review Decision Case No. 0178 (Jan. 2020) (1993 reregistration); The EPA's response to comments on the glyphosate proposed interim decision. EPA, Response from the Pesticide Re-evaluation Division (PRD) to Comments on the Glyphosate Proposed Interim Decision (Jan. 2020).

- An EPA Paper written about the EPA Scientific Advisory Panel's independent review of the effects of glyphosate. EPA, Revised Glyphosate Issue Paper (Dec. 12, 2017).

- A letter issued by the EPA in August 2019. EPA, Office of Pesticide Programs, Letter to Glyphosate Registrants Regarding Labeling Requirements (Aug. 7, 2019) ("Letter to Registrants").

- Various papers involving scientific analysis where the EPA concluded that glyphosate does not cause cancer. EPA, Health Effects Division, Second Peer Review of Glyphosate (Oct. 30, 1991); EPA, Report of the Hazard Identification Assessment Review Committee at 6-7 (Apr. 20, 1998), https://tinyurl.com/b95mdvja; Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,935-43 (Sept.

27, 2002); Final Rule: Glyphosate, Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008); EPA, Office of Pesticide Programs, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential at 141 (Sept. 12, 2016), https://tinyurl.com/4d6us439; EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017); EPA, Glyphosate – Proposed Interim Registration Review Decision Case Number 0178 (Apr. 2019).

The problem for Monsanto is again that none of these documents have the indicia of formality to pass the *Mead* standard. Monsanto cannot wave the "formality" wand on EPA actions to accomplish compliance with the *Mead* standard. None of them are the product of "notice-and-comment rulemaking"[12] or "formal adjudication." *Mead*, 533 U.S. at 230. Nor do the EPA letters Monsanto points to "bespeak the legislative type of activity that would naturally bind" Monsanto. *Id.* at 232. So, we find Monsanto's arguments on this front unpersuasive.

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[12] As Monsanto correctly notes, there is something akin to a notice and comment requirement in the registration process. 40 C.F.R. § 155.58. But, because the registration itself does not lead to any formal agency action, like a rule produced from notice-and-comment rulemaking, the fact that the EPA takes comments on its registration decision does not change our analysis.

V.

For the foregoing reasons, we reverse the District Court's ruling on Carson's failure to warn claim and remand for further proceedings.

REVERSED AND REMANDED.