[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.

ROSENBAUM, Circuit Judge:

State tort litigation plays an important role in protecting consumers from dangerous products. But the federal government, through legislation and regulation, exercises its own authority over those products. And when the two conflict, federal law is supreme. This case requires us to decide whether the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") preempts a state failure-to-warn tort claim.

Plaintiff-Appellant John D. Carson, Sr., used the popular weedkiller Roundup for decades before he developed cancer. Carson alleges that Roundup caused his cancer and sued Monsanto (Roundup's manufacturer) for failure to warn of the product's cancerous effects, among other claims. Monsanto moved for judgment on the pleadings based on FIFRA's preemption provision, 7 U.S.C. § 136v(b). Specifically, Monsanto argued that FIFRA preempted Carson's state-law claims because the Environmental Protection Agency ("Agency") approved Roundup's label without a cancer warning and classified Roundup's main ingredient as "not likely to be carcinogenic."

The district court agreed and found that FIFRA preempted Carson's claims regarding Roundup's packaging or labeling. We

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* The Honorable James S. Moody Jr., U.S. District Judge for the Middle District of Florida, sitting by designation.

reversed the district court's dismissal of Carson's failure-to-warn claim. But sitting en banc, this Court vacated the opinion and clarified the relevant express-preemption inquiry. Now, on remand, we reconsider whether Carson's failure-to-warn claim is preempted, either expressly or impliedly.

We conclude that FIFRA does not expressly preempt Carson's failure-to-warn claim. FIFRA's preemption provision applies to only those state requirements that are "in addition to or different from" federal requirements. And Georgia common law does not impose duties "in addition to or different from" FIFRA's requirements; rather, Georgia common law is less demanding than the federal requirements.

We also conclude that implied preemption does not bar Carson's failure-to-warn claim. Monsanto has not met its burden to show that, in an action that carried the force of law, the Agency would not have approved the warning label that Carson proposes. So Monsanto has not established that it could not have complied with both state and FIFRA requirements. And as a result, Monsanto has failed to show that FIFRA impliedly preempts Carson's state-law claim.

I. BACKGROUND

A. FIFRA

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") regulates the use, sale, and labeling of pesticides. 7 U.S.C. § 136 *et seq*. FIFRA requires all pesticide manufacturers to

register their pesticides with the Environmental Protection Agency ("Agency") before they can be sold. *See* 7 U.S.C. § 136a(a). A manufacturer seeking to register a pesticide must submit a proposed label, as well as certain supporting data, to the Agency. 7 U.S.C. §§ 136a(c)(1)(C), (F). The Agency will register the pesticide if it determines that the pesticide is efficacious, § 136a(c)(5)(A); that the pesticide will not cause unreasonable adverse effects on humans and the environment, §§ 136a(c)(5)(C), (D); and that the pesticide's label complies with the statute's prohibition on misbranding, § 136a(c)(5)(B).

FIFRA also prohibits pesticide manufacturers from selling a pesticide that is "misbranded." 7 U.S.C. § 136j(a)(1)(E). A pesticide is "misbranded" if its label contains a statement that is "false or misleading in any particular" or omits adequate instructions for use, necessary warnings, or cautionary statements. *Id.* §§ 136(q)(1)(A), (F), (G).

During the registration process, the Agency will consider whether a pesticide's label is misbranded. The Agency's initial review does not absolve the registrant's liability if the pesticide is misbranded. Pesticide manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements and must report any adverse effects of the pesticide to the Agency. *See id.* §§ 136a(f)(1); 136d(a)(2).

Similarly, the registration process does not establish a safe harbor for pesticide manufacturers. FIFRA declares that, "[i]n no event shall registration of an article be construed as a defense for

the commission of any offense under [FIFRA]." *Id.* § 136a(f)(2). Rather, registration serves merely as "prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions." *Id.*

FIFRA also addresses a state's role in pesticide regulation. In this respect, FIFRA provides that "[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." *Id.* § 136v(a). In line with this qualification, a preemption provision immediately follows: states may "not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." *Id.* § 136v(b).

B. Factual Background

Plaintiff-Appellant John D. Carson, Sr., used Roundup on his lawn for over thirty years. But when he was diagnosed with malignant fibrous histiocytoma, a form of cancer, he stopped using the product.

Carson filed suit against Monsanto, Roundup's manufacturer, alleging that Roundup contained a dangerous carcinogen, glyphosate, and that Monsanto was aware of Roundup's harmful effects but failed to warn customers of the dangers. In his complaint, Carson alleged four causes of action under Georgia law: strict liability for a design defect (Count I); strict liability for failure to warn (Count II); negligence (Count III); and breach of implied warranties (Count IV).

C. Procedural History

Monsanto moved for judgment on the pleadings on the ground that FIFRA's preemption provision, 7 U.S.C. § 136v(b), expressly preempted Carson's suit. In the alternative, Monsanto claimed that the Agency's previous approval of Roundup's labeling and continued adherence to the reasoning for that decision impliedly preempted Carson's suit. Monsanto argued that because the Agency declined to require a cancer warning when it registered and continued to approve Roundup for sale, requiring a label with such a warning would be "in addition to or different from" FIFRA's requirements, in violation of 7 U.S.C. § 136v(b).

The district court granted Monsanto's motion in part. Specifically, the court ruled that FIFRA expressly preempted Carson's failure-to-warn and breach-of-implied-warranty claims. *Carson v. Monsanto Co.*, 508 F. Supp. 3d 1369, 1376–77 (S.D. Ga. 2020) ("*Carson I*"). So the district court dismissed Counts II and IV of Carson's complaint. *Id.* at 1377–78. The court also dismissed Counts I (design defect) and III (negligence) as preempted to the extent that those claims related to Roundup's labeling or packaging. *Id.* at 1378.

Because it ruled on express-preemption grounds, the district court did not address Monsanto's alternative claim that Counts II and IV were impliedly preempted. *See id.* But it did address and reject implied preemption with respect to Counts I and III. *Id.* at 1378–79. The court reasoned that, because FIFRA gives states the authority to regulate pesticides, it would not be impossible for

Monsanto to comply with both state-law and FIFRA requirements for manufacturing and design. *See id.* at 1379.

The parties subsequently settled. In accordance with that "high-low" settlement agreement, Carson moved to amend his complaint to dismiss Counts I and III but preserved his right to appeal Count II, the failure-to-warn claim. The district court granted that motion, eliminating Counts I and III from Carson's complaint. Carson timely appealed the district court's grant of judgment on the pleadings as to Count II.

On appeal, this panel determined that FIFRA did not preempt Carson's failure-to-warn claim. *Carson v. Monsanto Co.*, 51 F.4th 1358, 1363 (11th Cir. 2022), *reh'g en banc granted, opinion vacated,* No. 21-10994, 2022 WL 17813843 (11th Cir. Dec. 19, 2022) ("*Carson II*"). We concluded that Georgia's common-law standard for product-safety warnings "imposes less of a duty" than FIFRA's prohibition against marketing "misbranded" pesticides. *Id.* And we held that the Agency's approval of Roundup's labels without a cancer warning did not preempt the Georgia cause of action because "only federal action with the force of law has the capacity to preempt state law." *Id.* at 1362–65. We analyzed whether the Agency's registration process carried the force of law allowing it to preempt Carson's state-law claim and determined that it did not. *Id.* at 1364.

Before the mandate issued, though, the en banc Court vacated the opinion and granted rehearing on the role of a "force-of-law" analysis in the context of express preemption. *Carson v.*

Monsanto Co., No. 21-10994, 2022 WL 17813843 (11th Cir. Dec. 19, 2022). Sitting en banc, the Court held that a "force-of-law" inquiry is "usually irrelevant where Congress has enacted an express preemption provision." *Carson v. Monsanto Co.*, 72 F.4th 1261, 1267 (11th Cir. 2023) (en banc) ("*Carson III*"). Rather, an express-preemption analysis applies the text of the preemption provision in line with "ordinary principles of statutory interpretation." *Id.*

The en banc Court remanded to this panel to address whether Carson's failure-to-warn claim was preempted, whether expressly or impliedly. *Id.* at 1268. The Court also left for our consideration "Carson's argument that section 136v(b)'s reference to 'requirements' compels a force-of-law inquiry as a matter of statutory interpretation." *Id.* We now address those issues.

II. STANDARD OF REVIEW

We review de novo a district court's order granting judgment on the pleadings, treating the facts alleged in the complaint as true and viewing the record in the light most favorable to the nonmovant. *Horsley v. Feldt*, 304 F.3d 1125, 1131 (11th Cir. 2002). We review de novo the affirmative defense of preemption. *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 767 (11th Cir. 1998). Judgment on the pleadings is proper when no issues of material fact exist and the moving party is entitled to judgment as a matter of law. *Ortega v. Christian*, 85 F.3d 1521, 1524 (11th Cir. 1996) (citing Fed. R. Civ. P. 12(c)).

III. DISCUSSION

Our analysis proceeds in two parts. In Part A, we consider Monsanto's express-preemption defense and conclude that FIFRA does not expressly preempt Carson's failure-to-warn claim. Then, in Part B, we address Monsanto's implied-preemption defense and conclude that Monsanto has not met its burden to show impossibility preemption.

A. FIFRA does not expressly preempt Carson's failure-to-warn claim.

The Supremacy Clause of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. Consistent with that command, the Supreme Court has long recognized that state laws that conflict with federal law are "without effect." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). Express preemption occurs when, explicitly in statutory text, Congress manifests its intent to preempt state law. *See Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485–86 (1996). To be sure, "we have long presumed that Congress does not cavalierly preempt state-law causes of action." *Id.* at 485. But when a statute's terms clearly reflect Congress's intent to preempt, that statute bars any state-law claims that fall within its purview.

Indeed, sitting en banc, we have clarified that "[e]xpress preemption turns primarily on 'the language of the preemption statute and the statutory framework surrounding it.'" *Carson III*, 72 F.4th at 1267 (quoting *Lohr*, 518 U.S. at 486). So when we

consider "an express-preemption provision, we identify the state law that it preempts according to ordinary principles of statutory interpretation, and no presumption against preemption applies." *Id.* That is our starting point here.

As we've mentioned, FIFRA includes an express-preemption provision. That provision provides that a "State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b). We must determine the scope of that provision's state-law displacement.

The Supreme Court has explained that FIFRA is not "a sufficiently comprehensive statute to justify an inference that Congress had occupied the field to the exclusion of the States." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 441–42 (2005) (quoting *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 607 (1991)). "To the contrary, [FIFRA] leaves ample room for States and localities to supplement federal efforts." *Mortier*, 501 U.S. at 613. For instance, "[n]othing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law." *Bates*, 544 U.S. at 442. So at a minimum, state requirements "that merely duplicate" FIFRA's requirements do not violate FIFRA's preemption provision. *See id.*

To determine whether FIFRA preempts state requirements that go beyond "mere[] duplication" of FIFRA's requirements, we turn to *Bates*. There, the Supreme Court clarified the reach of

FIFRA's preemption provision. FIFRA preempts a state requirement if it (1) is a "requirement '*for labeling or packaging*'"; and (2) that requirement "is '*in addition to or different from* those required under'" FIFRA. *Id.* at 444 (quoting 7 U.S.C. § 136v(b)). In other words, FIFRA preempts any state-law labeling or packaging requirement that is not "fully consistent" with FIFRA's requirements. *Id.* at 447. But FIFRA does not preempt state-law requirements that do not relate to labeling or packaging—for example, those that concern only product design or manufacture. *See id.* at 444.

We now apply *Bates*'s two-step framework to Carson's failure-to-warn claim.

1. *FIFRA establishes at least three requirements for labeling.*

We begin by identifying FIFRA's labeling requirements for pesticide manufacturers. A "requirement is a rule of law that must be obeyed; an event . . . that merely motivates an optional decision is not a requirement." *Bates*, 544 U.S. at 445. Starting with the statutory text, FIFRA prescribes at least three relevant requirements.

First, FIFRA prohibits misbranding, including on a pesticide's label. *See* 7 U.S.C. § 136j(a)(1)(E). A pesticide may be misbranded if its label contains a "false or misleading statement," "does not contain adequate directions for use," or "omits necessary warnings or caution statements." *Bates*, 544 U.S. at 438. If the Agency determines that a pesticide is misbranded, it may institute cancellation proceedings, *see* 7 U.S.C. § 136d(b), or impose other civil or criminal penalties, *id.* § 136l.

Second, FIFRA mandates pesticide registration with the Agency. *Id*. § 136a(a). To register, the manufacturer must submit a proposed label to the Agency along with certain supporting data. *Id*. §§ 136a(c)(1)(C), (F). Once the Agency approves a label during the registration process, manufacturers cannot change the label's contents without the Agency's prior approval and a new registration application, except for "minor modifications." 40 C.F.R. §§ 152.44, 152.46. The Agency reviews a pesticide's registration, including its effects on human health, every 15 years. *Id*. § 136a(g)(1)(A). Manufacturers must also re-register certain pesticides after a certain amount of time has passed. *Id*. § 136a-1(a). Re-registration involves five "phases," including data gathering and analysis and the Agency's independent verification of that data's adequacy. *Id*. § 136a-1(b).

Third, FIFRA imposes an ongoing reporting requirement. Under that requirement, manufacturers must report to the Agency (1) "additional factual information regarding unreasonable adverse effects on the environment," 7 U.S.C. § 136d(a)(2), and (2) incidents involving a pesticide's toxic effects on humans that may not be adequately reflected in its label's warnings, *see* 40 C.F.R. § 159.184(a). This reporting alerts the Agency to any developments that may render a previously approved label misbranded.

To sum up, FIFRA's labeling "requirements" that bear on our preemption analysis are its (1) prohibition on misbranding, (2) required registration of pesticides and their labels, and (3) ongoing reporting requirements.

2. Georgia state law does not impose duties in addition to or different from FIFRA's requirements.

Next, we consider the state-law requirements that Carson's failure-to-warn suit, if successful, would impose. Under Georgia law, "the duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product." *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994). That includes the duty to warn of "nonobvious foreseeable dangers from the normal use of its product." *Thornton v. E.I. Du Pont De Nemours & Co., Inc.*, 22 F.3d 284, 289 (11th Cir. 1994). A manufacturer breaches that duty to warn "if it fails to '[(1)] adequately communicate the warning to the ultimate user or (2) fail[s] to provide an adequate warning of the product's potential risks.'" *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1219 (11th Cir. 1999) (quoting *Thornton*, 22 F.3d at 289). At bottom, breach occurs when the warning does not advise "the user of the dangers associated with the use of the product." *Id.*

Carson claims that Monsanto breached its state-law duty to warn. He alleges that Roundup's warning "failed to contain relevant warnings, hazards, and precautions," and instead, Monsanto "disseminated information that was inaccurate, false and misleading and which failed to communicate accurately . . . [the] extent of the risk of injuries with use and/or exposure to Roundup." In Carson's view, Monsanto should have included a warning about glyphosate's potentially carcinogenic effects on its label.

On their face, Carson's claims concern labeling and packaging. And in *Bates*, the Supreme Court held that a common-law duty constitutes a state-law "requirement" within the scope of FIFRA's preemption provision in section 136v(b). 544 U.S. at 446. Indeed, "[t]he parties agree that Carson's suit relies on a Georgia 'requirement[] for labeling or packaging.'" *Carson III*, 72 F.4th at 1267 (quoting *Bates*, 544 U.S. at 443). So we must determine whether Carson's failure-to-warn claim would impose any duties "in addition to or different from" FIFRA's requirements. *See Bates*, 544 U.S. at 447.

As we've noted, FIFRA does not preempt state-law duties, including common-law claims, that "parallel" or "are fully consistent with" federal requirements. *Bates*, 544 U.S. at 447. So while FIFRA may preempt additional state "requirements," it does not preempt additional state "remedies" for violations of federal law. *Id.*; *cf. Lohr*, 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part). Rather, FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450. As long as Carson's state-law claim "parallel[s]" FIFRA's requirements, section 136v(b) does not expressly preempt that claim. *See id.* at 447.

With that in mind, we revisit FIFRA's "requirements." Under FIFRA, a pesticide is misbranded if, for example, its "label does not 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). FIFRA's prohibition on

misbranding effectively imposes a strict-liability standard, as it contains no element of knowledge or intent. So long as the pesticide's label omits a "necessary" warning "to protect health and the environment," the manufacturer is liable under FIFRA. *See id.*

By comparison, under Georgia common law, a pesticide manufacturer breaches its duty to warn if it "fail[s] to provide an adequate warning of the product's potential risks." *Watkins*, 190 F.3d at 1219 (quoting *Thornton*, 22 F.3d at 289). But this is not a limitless standard—the manufacturer is liable only if it "knows or reasonably should know of the danger arising from the use of its product." *Chrysler Corp.*, 450 S.E.2d at 211. And that duty extends to only "nonobvious foreseeable dangers from the normal use of its products." *CertainTeed Corp. v. Fletcher*, 794 S.E.2d 641, 645 (Ga. 2016) (quoting *Thornton*, 22 F.3d at 289).

True, Georgia common law does not exactly track FIFRA's requirements. But the Supreme Court has explained that "state law need not explicitly incorporate FIFRA's standards as an element of a cause of action in order to survive pre-emption." *Bates*, 544 U.S. at 447. Rather, so long as the state-law duty parallels or is "fully consistent" with FIFRA, FIFRA does not preempt it. *Id.* And here, the practical effect is the same: both FIFRA and Georgia common law require pesticide manufacturers to warn users of potential risks to health and safety.

If anything, Georgia common law about failure-to-warn claims imposes *less* of a duty on pesticide manufacturers than FIFRA. Georgia common law requires manufacturers to warn of

nonobvious and foreseeable dangers of which they know or reasonably should know. *See, e.g.*, *Thornton*, 22 F.3d at 289. By contrast, FIFRA imposes a blanket duty on pesticide manufacturers, regardless of knowledge or foreseeability. Because Carson's state failure-to-warn claim is "fully consistent with" or even narrower than federal requirements, FIFRA does not expressly preempt that claim. *See Bates*, 544 U.S. at 447; *Hardeman v. Monsanto Co.*, 997 F.3d 941, 955 (9th Cir. 2021) ("Because FIFRA's misbranding requirements parallel those of [the state's] common law duty, [the plaintiff's] failure-to-warn claims effectively enforce FIFRA's requirement against misbranding and are thus not expressly preempted."), *cert. denied*, 142 S. Ct. 2834 (2022). After all, as the Supreme Court has reasoned, "[w]hile such a narrower requirement might be 'different from'" FIFRA's requirements "in a literal sense," that would be "a strange reason for finding pre-emption of a state rule insofar as it duplicates" FIFRA. *Bates*, 544 U.S. at 547 (quoting *Lohr*, 518 U.S. at 495). So FIFRA does not expressly preempt "narrower" state requirements.

3. FIFRA's registration process does not preempt Carson's state-law failure-to-warn claim.

Monsanto argues that FIFRA's "requirements" sweep far more broadly—namely, that FIFRA's registration process itself carries preemptive effect. In Monsanto's view, the Agency's approval of individual pesticide registrations and corresponding labels also qualify as "requirements" under FIFRA. In other words, Monsanto contends, because the Agency approved Roundup's registration

and re-registration, all state-law claims related to the registered label are preempted. Carson responds that the Agency's individual approvals are not "requirements" because they do not carry the force of law.

We agree with Carson. As the en banc Court clarified, we do not undertake a force-of-law analysis before interpreting an express-preemption provision. *See Carson III*, 72 F.4th at 1267. As a congressionally enacted statute, FIFRA of course carries the force of law, and its plain text preempts state labeling requirements that are "in addition to or different from" federal requirements. *See* 7 U.S.C. § 136v(b).

But the en banc Court left for us to consider whether "section 136v(b)'s reference to 'requirements' compels a force-of-law inquiry as a matter of statutory interpretation." *Carson III*, 72 F.4th at 1268. To establish whether a particular Agency action amounts to a "requirement" under FIFRA, we must determine whether that Agency action carries the force of law. If it is not "a rule of law that must be obeyed," then as the Supreme Court has directed, it is not a "requirement." *Bates*, 544 U.S. at 445. So though we need not perform a threshold force-of-law analysis before defining the scope of FIFRA's preemption, we must do that analysis to determine whether an Agency action qualifies as a "requirement."

We "assume . . . that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure[.]" *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001). That category includes "notice-and-comment

rulemaking or formal adjudication," *id.*, but may extend to other processes, like cancellation proceedings, as well. Our analysis, then, turns on whether the FIFRA registration process is "relatively formal," *id.*, and creates "a rule of law that must be obeyed," *Bates*, 544 U.S. at 445. If it is not, it does not carry the force of law and cannot preempt state-law duties.

On the record before us, we have little trouble concluding that the Agency's individual approvals are not "requirements" under FIFRA. FIFRA sets forth "broadly phrased misbranding standards." *Bates*, 544 U.S. at 453 n.28. Agency regulations, promulgated after notice and comment, "give content to" those standards. *Id.* at 453. And Congress has given the Agency the authority to determine whether a particular pesticide's label complies with those broad standards. But we cannot conflate FIFRA's broad prohibition on misbranding—indisputably a "requirement"—or even generally applicable agency regulations, with an individualized finding that a particular pesticide is not misbranded.

This is especially true because Agency approvals provide only "prima facie evidence," not conclusive proof, that a pesticide is not misbranded. *See* 7 U.S.C. § 136a(f)(2); *Hardeman*, 997 F.3d at 956. Indeed, FIFRA specifies that "[i]n no event shall registration . . . be construed as a defense for the commission of any offense under" its provisions. 7 U.S.C. § 136a(f)(2). By approving a pesticide's registration, the Agency signals that the pesticide "compl[ies] with" FIFRA's "requirements," 7 U.S.C. § 136a(c)(5)(B), but it does not impose any new requirements beyond FIFRA's. And significantly, the

Agency can later retract its approval. Since the Agency's determination is neither conclusive nor irrevocable, it would make little sense to deem it a "requirement" on equal footing with FIFRA's prohibition on misbranding. *See Hardeman*, 997 F.3d at 956 ("[B]ecause 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.").

Still, though, Monsanto argues that registration under FIFRA preempts state-law claims. For support, Monsanto relies on *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

Riegel concerned the "rigorous" pre-market approval process for medical devices under the Medical Device Amendments ("Amendments") to the Federal Food, Drug, and Cosmetic Act—a statute that the Federal Food and Drug Administration ("FDA") administers. *Id.* at 317. To initiate the pre-market approval process under the Amendments, a medical-device "manufacturer must submit what is typically a multivolume application," including "full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant." *Id.* at 318 (citing 21 U.S.C. § 360e(c)(1)). The FDA "spends an average of 1,200 hours reviewing each application," *id.*, and grants premarket approval only if it finds a "reasonable assurance" of the device's "safety and effectiveness," 21 U.S.C. § 360e(d). As part of that process, the FDA must determine that the device's proposed label is not false or misleading. *Id.*

§ 360e(d)(1)(A). Once a device has received premarket approval, the manufacturer cannot change its label (or anything else that would affect the device's safety or effectiveness) without the FDA's permission. *Id*. § 360e(d)(5)(A)(i).

In *Riegel*, the plaintiffs brought common-law strict-liability, breach-of-implied-warranty, and negligence claims against a catheter manufacturer, including over the device's labeling. 552 U.S. at 320. The Supreme Court concluded that the Amendments expressly preempted those state-law claims. Like FIFRA, the Amendments to the Federal Food, Drug, and Cosmetic Act contain an express-preemption clause: no State "may establish or continue in effect with respect to a device . . . any requirement—(1) which is different from, or in addition to, any requirement applicable under [the Amendments] to the device, and (2) which relates to the safety or effectiveness of the device . . . ." 21 U.S.C. § 360k(a).

As we do here, the Supreme Court interpreted the term "requirement" within the Amendments' preemption provision. The Court concluded that the premarket approval process imposed "requirement[s] relating to safety [and] effectiveness" because, after the FDA grants premarket approval, the manufacturer can make "almost no deviations" (including labeling) from its application. *Riegel*, 552 U.S. at 323, 328. And, the Court reasoned, because the plaintiffs' tort claims concerned the device's "safety and effectiveness," they fell within the scope of the Amendments' preemption provision. *Id*. at 327–29. But because the plaintiffs had not fully briefed it, the Court declined to address whether the plaintiffs'

state-law claims imposed "parallel" requirements to those of the Amendments. *Id*. at 330.

We think the differences between *Riegel* and the circumstances here show why the Agency's individualized determinations about a particular pesticide do not qualify as "requirement[s]." First, the *Riegel* Court expressly declined to consider whether state tort law imposed parallel requirements to the Amendments' federal requirements. *Id*. Here, that question is before us, and, as we've explained, Georgia common law parallels FIFRA's labeling requirements.

Second, and more importantly, FIFRA's statutory scheme differs from the Amendments'. Again, FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450. By contrast, the Amendments' scheme is decidedly centralized: the Federal Food, Drug, and Cosmetics Act Amendments "swept back . . . state obligations and imposed a regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. So while the preemption provisions are similar, we must read them in context.

The statutes' distinct approval processes confirm this significant difference. Premarket approval under the Amendments represents a "rigorous" conclusion that a device is safe and effective. *See id*. at 317–18. Once the FDA has approved a device, manufacturers cannot change a device's label (or design, etc.) without the FDA's permission. *See* 21 U.S.C. § 360e(d)(5)(A)(i). By contrast, the Agency's approval of a pesticide's registration serves as only "prima

facie evidence" that the pesticide complies with FIFRA's requirements. 7 U.S.C. § 136a(f)(2). And through its ongoing reporting requirements, "FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings." *Bates*, 544 U.S. at 451. As the Supreme Court has reasoned, state tort litigation "may lead manufacturers to petition [the] [Agency] to allow more detailed labelling of their products," or the Agency "itself may decide that revised labels are required in light of" the litigation. *Id.* at 451 (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541 (D.C. Cir. 1984)).

What's more, the Amendments' preemption provision expressly contemplates device-specific application, as it preempts requirements "with respect to a device." 21 U.S.C. § 360k(a). FIFRA, on the other hand, contains no such limitation—it imposes only "general standards." *Bates*, 544 U.S. at 453 n.27. And "different federal statutes and regulations may . . . lead to different preemption results." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 626 (2011).

Given the differences between FIFRA and the Amendments' statutory schemes, *Riegel* does not control here. And we conclude that neither FIFRA's labeling requirements nor the Agency's registration process preempts Carson's state-law failure-to-warn claim. After all, given "the long history of tort litigation," it "seems unlikely that Congress considered a relatively obscure provision like [section] 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability." *Bates*, 544 U.S. at 449–50.

Rather, FIFRA expressly contemplates a role for states in pesticide regulation, and that role includes common-law claims that parallel FIFRA's requirements. *See id.* at 447.

At bottom, we conclude that FIFRA does not expressly preempt Carson's state-law failure-to-warn claim, so Monsanto was not entitled to judgment on the pleadings on this ground.

4. *No other Agency action preempts Carson's failure-to-warn claim.*

Monsanto also points to other Agency actions that it claims have preemptive effect. We are not convinced.

For instance, Monsanto cites the Agency's interim registration reviews and re-registration eligibility decision for glyphosate-containing pesticides ("Agency's 2020 Interim Decision"), as well as accompanying comments. *See, e.g.*, EPA, Reregistration Eligibility Decision (RED) – Glyphosate (Sept. 1993); EPA, Glyphosate: Interim Registration Review Decision Case No. 0178 (Jan. 2020); EPA, Response from the Pesticide Re-evaluation Division (PRD) to Comments on the Glyphosate Proposed Interim Decision (Jan. 16, 2020).

But the Ninth Circuit vacated the human-health portion of the Agency's 2020 Interim Decision as arbitrary and "not supported by substantial evidence." *Nat. Res. Def. Council v. U.S. Env't Prot. Agency*, 38 F.4th 34, 51–52 (9th Cir. 2022). And the Agency withdrew "all remaining portions of the interim registration review decision for glyphosate" in 2022. EPA, EPA Withdraws Glyphosate

Interim Decision (Sept. 23, 2022).[1] So, that 2020 determination cannot carry the force of law or any preemptive effect. *See, e.g.*, *Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 50 (D.D.C. 2020) (Jackson, J.) ("In essence, a vacatur order takes the unlawful agency action off the books[.]" (citation and internal quotation marks omitted)).

Monsanto also relies on a 2019 Agency letter concluding that glyphosate is "not likely to be carcinogenic to humans" and that California's warning of glyphosate's potential carcinogenic effects was "false or misleading." EPA, Letter to Glyphosate Registrants Regarding Labeling Requirements (Aug. 7, 2019). We note that the Agency issued the 2019 letter after Carson was diagnosed with cancer and filed this lawsuit. And while the letter rejected California's specific Proposition 65 warning, it did not foreclose any and all warnings related to glyphosate's potentially harmful effects.

In any event, the 2019 letter did not carry the force of law because it neither reflected sufficient formality, *Mead*, 533 U.S. at 230, nor created "a rule of law that must be obeyed." *Bates*, 544 U.S. at 445. Rather, the Agency issued the letter "without any written notice, gave no hearing or opportunity to respond, and lacked any sort of dispute-resolution process." *Hardeman*, 997 F.3d at 957; *cf. Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 255 (3d Cir. 2008) (finding, in the implied-preemption context, no preemptive effect

[1] In its announcement of the withdrawal, the EPA nonetheless reiterated "its finding that glyphosate is not likely to be carcinogenic to humans" but noted that it "intends to revisit and better explain its evaluation of the carcinogenic potential of glyphosate." *Id.*

where the agency "merely expressed an informal policy opinion in a letter, and it did so only after [the plaintiff's] injuries were allegedly suffered"). So the 2019 letter does not expressly preempt Carson's state-law failure-to-warn claims.

For similar reasons, we reject Monsanto's arguments that Agency scientific papers or letters from Agency officials about glyphosate's potentially carcinogenic effects (or lack thereof) carry preemptive effect. *See, e.g.*, EPA, Health Effects Div., Second Peer Review of Glyphosate (Oct. 30, 1991); EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017). In short, we conclude that neither FIFRA nor any other Agency action imposes "requirements" that would preempt Carson's state-law failure-to-warn claim.

B. Carson's failure-to-warn claim is not impliedly preempted.

Though we find no express preemption, our preemption inquiry does not end there. Monsanto contends that Carson's claims are "independently barred by impossibility preemption" because Monsanto "could not have added a cancer warning to the Roundup label over [the] [Agency's] objection." In fact, Monsanto claims, the Agency would not have approved a warning label stating that glyphosate may be carcinogenic to humans, so Monsanto could not comply with both federal directives and Georgia common-law duties.

The district court did not rule on Monsanto's implied-preemption defense to Carson's failure-to-warn claim,[2] as it concluded that Monsanto prevailed on its express-preemption argument. *See Carson I*, 508 F. Supp. 3d at 1377–78. But as we've noted, we reach a different answer on the express-preemption issue. And as it turns out, the parties have briefed the implied-preemption issue before us. Because the resolution of that issue is clear, we decide it. *See LaCroix v. Town of Fort Myers Beach*, 38 F.4th 941, 954 (11th Cir. 2022).

Implied preemption occurs when "it is 'impossible for a private party to comply with both state and federal requirements.'" *Mensing*, 564 U.S. at 618 (quoting *Freightliner Corp. v. Myrick,* 514 U.S. 280, 287 (1995)). The mere "possibility of impossibility [is] not enough." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019) (alteration in original) (quoting *Mensing*, 564 U.S. at 625 n.8). Rather, the state and federal laws must "irreconcilably conflic[t]." *Id*. at 1679 (alteration in original) (citation omitted).

To show an "irreconcilabl[e] conflict" that would bar Carson's failure-to-warn claim, Monsanto must present "clear evidence" that (1) Monsanto "fully informed" the Agency of "the justifications for the warning" that Georgia state law would impose; (2) the Agency "informed [Monsanto] that [it] would not approve

[2] The district court considered only whether impossibility preemption barred Carson's remaining design-defect (Count I) and negligence (Count III) claims. *See Carson I*, 508 F. Supp. 3d at 1378.

changing the . . . label to include that warning"; and (3) the Agency undertook its action "pursuant to . . . congressionally delegated authority" in a way that "carr[ies] the force of law." *Id*. at 1678–79 (citation and internal quotation marks omitted). The Supreme Court has characterized this burden as "demanding." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

As a threshold matter, Carson argues that implied preemption is not an available defense given FIFRA's express-preemption provision. *Cf. Mortier*, 501 U.S. at 613 (1991) (finding that FIFRA does not "otherwise imply pre-emption" beyond section 136v(b)); *Graham v. R.J. Reynolds Tobacco Co.*, 857 F.3d 1169, 1189 (11th Cir. 2017) (reasoning that the fact that "the express-preemption provision" at issue "does not cover the" substance of the plaintiffs' claims "supports an inference that there is no implied preemption of those" claims). But we need not resolve that question, because even if implied preemption is available, Monsanto has not satisfied its burden here.

Monsanto relies on the Agency actions we've already noted—chiefly, the Agency's 1993 determination that glyphosate met FIFRA's requirements for re-registration and its 2019 letter saying that California's cancer warning for glyphosate would be a "false and misleading statement" in violation of FIFRA. These actions don't meet the "demanding" standard for impossibility preemption.

First, the Agency's registration, interim registration review, and re-registration of glyphosate without a cancer warning do not show that a cancer warning would be impossible. Put differently, the Agency's repeated approvals of a label without a cancer warning do not mean the Agency necessarily would have rejected a label with a cancer warning.

Nor does the Agency's concurrent classification of glyphosate as not likely to be carcinogenic to humans alter this conclusion. Based on the record before us, Monsanto did not request—and the Agency did not consider, much less reject—a cancer warning at all. So Monsanto cannot meet its burden to show that the Agency "informed [Monsanto] that [it] would not approve changing the . . . label to include that warning," and impossibility preemption does not apply. *See Merck*, 139 S. Ct. at 1678.

Our conclusion is the same for the Agency's 2019 letter: the Agency action does not meet the "demanding" requirements for impossibility preemption. Of course, the Agency issued the 2019 letter after Carson was diagnosed with cancer and filed this lawsuit, so it does not necessarily reflect the Agency's position during the time Carson used Roundup. But even if it did, the 2019 letter was directed at California's specific Proposition 65 warning and did not conclude that any and all warnings related to glyphosate's potential cancerous effects would render a pesticide "misbranded." That is not enough for impossibility preemption. *See Merck*, 139 S. Ct. at 1678 ("The underlying question for this type of impossibility preemption defense is whether federal law . . . prohibited the [product]

manufacturer from adding any and all warnings to the [product] label that would satisfy state law.").

Monsanto also can't point to caselaw from the Supreme Court or this Court that compels preemption. To be sure, in *Mensing*, the Supreme Court found that impossibility preemption barred the plaintiffs' state-law claims. 564 U.S. at 618. But *Mensing* is materially distinguishable from this case.

In *Mensing*, the prescription-drug manufacturers could not change their labels in the way the plaintiffs sought because the drug was a generic version of a name-brand drug. *See id.* at 612, 618. And under federal law, generic drugs must carry the same labels as their name-brand equivalents, so the generic-brand manufacturers could not unilaterally change their labels if the name-brand label stayed the same. *Id.* at 618; *see also* 21 U.S.C. § 355(j)(4)(G); 21 C.F.R. § 314.150(b)(10). If, in fact, the generic-brand manufacturers "independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id.* As a result, the generic-brand manufacturers in *Mensing* could not comply with both federal and state-common-law requirements. *Id.* This conflict transcended the mere "possibility of impossibility." *See id.* at 625 n.8. And that required the Court to find implied preemption. *Id.* at 618. But here, Roundup's label was not dependent on that of any other pesticide. And Monsanto cannot show that a cancer warning

"would have violated federal law." *See id.* So *Mensing* does not lend any support to Monsanto's claims.[3]

What's more, in 2022, the Agency publicly stated that it "could approve" warning language that "[t]he International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans," and products with that warning "would not be considered misbranded." EPA, Response to California's Office of Environmental Health Hazard Assessment on California's Proposition 65 (Apr. 8, 2022). To be sure, the Agency expressed this position years after Carson filed his lawsuit. But it still undercuts Monsanto's claim of impossibility. If, in the Agency's own words, it "could approve" a warning similar to the one Carson seeks, and products with a warning like that would not be "misbranded" under FIFRA, Monsanto could comply with both state and federal labeling requirements. *See also Hardeman*, 997 F.3d at 959 (noting that the Agency "has repeatedly permitted pesticide manufacturers to use the notification procedure to add notices related to cancer to their products' labels"). And no "irreconcilabl[e] conflict" exists. As a result, FIFRA does not impliedly preempt the warning that Georgia law would require. *See Merck*, 139 S. Ct. at 1679.

Finally, and in any event, as we've explained, none of the Agency's actions on which Monsanto relies carry the force of law.

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[3] We note also that *Mensing* did not involve express preemption, as Congress has "declined to enact [an express-preemption] provision for prescription drugs." *Wyeth*, 555 at 567.

See Mead, 533 U.S. at 230; *Hardeman*, 997 F.3d at 960. So even if the Agency's actions satisfied the first two requirements for impossibility preemption—and as we've explained, they do not—they fail to meet this third requirement. *See Merck*, 139 S. Ct. at 1679. Because Monsanto has not carried its burden of proving impossibility, we conclude that implied preemption does not bar Carson's state-law failure-to-warn claim.

IV. CONCLUSION

For the reasons we've explained, we vacate the district court's conclusion that FIFRA expressly preempts Carson's failure-to-warn claim, hold that neither FIFRA nor any Agency action impliedly preempts Carson's failure-to-warn claim, and remand for further proceedings consistent with this opinion.

VACATED AND REMANDED.

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ELBERT PARR TUTTLE COURT OF APPEALS BUILDING
56 Forsyth Street, N.W.
Atlanta, Georgia 30303

David J. Smith
Clerk of Court

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February 05, 2024

MEMORANDUM TO COUNSEL OR PARTIES

Appeal Number: 21-10994-GG
Case Style: John Carson v. Monsanto Company
District Court Docket No: 4:17-cv-00237-RSB-CLR

Opinion Issued
Enclosed is a copy of the Court's decision issued today in this case. Judgment has been entered today pursuant to FRAP 36. The Court's mandate will issue at a later date pursuant to FRAP 41(b).

Petitions for Rehearing
The time for filing a petition for panel rehearing is governed by 11th Cir. R. 40-3, and the time for filing a petition for rehearing en banc is governed by 11th Cir. R. 35-2. Except as otherwise provided by FRAP 25(a) for inmate filings, a petition for rehearing is timely only if received in the clerk's office within the time specified in the rules. **A petition for rehearing must include a Certificate of Interested Persons and a copy of the opinion sought to be reheard.** See 11th Cir. R. 35-5(k) and 40-1.

Costs
Costs are taxed against Appellee(s) / Respondent(s).

Bill of Costs
If costs are taxed, please use the most recent version of the Bill of Costs form available on the Court's website at www.ca11.uscourts.gov. For more information regarding costs, see FRAP 39 and 11th Cir. R. 39-1.

Attorney's Fees
The time to file and required documentation for an application for attorney's fees and any objection to the application are governed by 11th Cir. R. 39-2 and 39-3.

Appointed Counsel
Counsel appointed under the Criminal Justice Act (CJA) must submit a voucher claiming compensation via the eVoucher system no later than 45 days after issuance of the mandate or the filing of a petition for writ of certiorari. Please contact the CJA Team at (404) 335-6167 or

cja_evoucher@ca11.uscourts.gov for questions regarding CJA vouchers or the eVoucher system.

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OPIN-1 Ntc of Issuance of Opinion