No. 24-1097

IN THE
Supreme Court of the United States

MONSANTO COMPANY,

Petitioner,

v.

NANCY C. SALAS,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF IN OPPOSITION FOR RESPONDENT

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QUESTIONS PRESENTED

In *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), this Court held that the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") preempts only state-law labeling requirements that are broader than the statute's "misbranding" standard.

State-law claims that target product labeling are preempted only if they impose "requirements that are '*in addition to or different from*' the labeling and packaging requirements under FIFRA." *Id.* at 447 (quoting 7 U.S.C. § 136v(b)) (emphasis in *Bates*).

Respondent Nancy Salas sued Monsanto in 2021 after developing non-Hodgkin lymphoma; she had used Roundup for years to kill weeds at her Florida home. Monsanto strategically settled all but one of Salas' claims in an effort to convert her case into a vehicle for quick review in this Court.

The questions presented are:

1. Whether Article III adversity is destroyed when an appellant seeks summary rejection of its own appeal rather than relief which would redress the harm it suffered from the adverse judgment it appealed.

2. If this Court has jurisdiction, whether petitioner failed to preserve the new theory it asserts here after neglecting to raise it below and depriving the Court of Appeals of an opportunity to address it.

3. Assuming both hurdles are overcome, whether the Eleventh Circuit correctly applied *Bates* in holding Salas's Florida failure-to-warn claims were not preempted because they are narrower than FIFRA's misbranding standard.

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INTRODUCTION

Monsanto has known for decades that its product, the popular weedkiller Roundup, that was sold at hardware stores across the country, can cause cancer through repeated exposure. Yet the company deliberately refused to alert consumers to the documented health risks that this common household product potentially posed to unsuspecting users.

Nancy Salas sprayed Roundup for years in her yard to control weeds, unaware that scientists both within Monsanto and at an international body had informed Monsanto about the cancer-causing risks of the active ingredient glyphosate. She was diagnosed with non-Hodgkin lymphoma in 2020. Monsanto litigated her case, asserting common-law claims under Florida law, for three years until, after notching its first victory on federal preemption in a different venue, the Third Circuit, quickly pivoted to enticing Salas to settle her claims on terms structured to posture the stipulated judgment as conflicting with the Third Circuit ruling, in order to present the appearance of conflict among federal circuits to this Court.

In Monsanto's haste to bring this case before this Court, the company created several collateral issues that the Court would have to confront before reaching the merits of the FIFRA-preemption question Monsanto wants the Court to answer, despite the existence of clear guidance from *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). Monsanto did not preserve the express-preemption theory it urges upon the Court, and to consider it in this case would merely reward cunning. More fundamentally, the company created an Article III defect at the Court of Appeals by

seeking summary affirmance of the judgment against it.

Looking past those collateral snags, the Court should decline to grant Monsanto's petition for the same reasons it should deny the petition in *Monsanto Co. v. Durnell*, No. 24-1068. Monsanto's petition in this case adopts lock-stock-and-barrel the company's arguments in its petition in *Durnell*. Pet. i, 16. Salas therefore adopts the applicable responses from Respondent Durnell's brief in opposition, adding points germane to her case and expanding on the explanation of why Monsanto's new express-preemption theory, based on *Schaffner v. Monsanto Corp.*, 113 F.4th 364 (3d Cir. 2024), is deeply flawed. This Court should reject the company's gambit to use this case as a vehicle for review.

STATEMENT

A. Statutory And Regulatory Background

1. FIFRA regulates the sale, distribution, and use of pesticides, including, as relevant here, the labeling on pesticide products.

FIFRA requires pesticide manufacturers to register their products with the Environmental Protection Agency before they may sell and distribute their product domestically. § 136a(a).[1] The agency will register a pesticide if it determines—based on data the pesticide manufacturer submits in support of its registration application, §136a(c)(2)—that the product will not cause unreasonable harm to humans and the environment, and that its labeling complies with FIFRA's requirements. § 136a(c)(5)(B)-(D). That reg-

[1] Unless noted, U.S. Code citations are to Title 7.

istration functions as a license establishing the conditions under which the pesticide may be sold and used, including labeling requirements. §136a(c); 40 C.F.R. §156.10(a) (discussing, among other things, the "[c]ontents of the label," its "[p]rominence and legibility," the "[l]anguage to be used," the "[p]lacement of the label," and "[f]alse or misleading statements"). EPA reviews a pesticide's registration, including its effects on human health, at least every 15 years. § 136a(g)(1)(A).

2. FIFRA prohibits the sale or distribution of "any pesticide which is . . . misbranded." § 136j(a)(1)(E). A pesticide is "misbranded" if, among other things, its label contains a statement that is "false or misleading," § 136(q)(1)(A), or omits adequate instructions for use, necessary warnings, or cautionary statements to protect health and the environment, § 136(q)(1)(F), (G). *See* 40 C.F.R. §156.10(a)(5).

If EPA determines a pesticide is misbranded, it can cancel the pesticide's registration, § 136d(b)(1); issue "stop sale, use, or removal" orders, § 136k(a); and seize for confiscation misbranded products, § 136k(b). Manufacturers that sell misbranded products face civil and criminal penalties. § 136*l*.

Obtaining initial registration does not relieve the registrant of liability if the pesticide is misbranded. § 136a(f)(2) ("In no event shall registration of an article be construed as a defense for the commission of any offense under [FIFRA]."). Instead, registration merely provides "prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions." *Id.* Because it remains unlawful to sell a registered pesticide that is misbranded, manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements and, if

necessary, to update their labels. *Bates*, 544 U.S. at 438 (citing §136j(a)(1)(E); §136a(f)(1)-(2); 40 C.F.R. §159.184(a), (b) (requiring manufacturers to report incidents involving a pesticide's toxic effects that may not be adequately reflected in warning labels)); §136d(a)(2) (duty to submit information regarding adverse effects); 40 C.F.R. §159.158(a) (same).

Monsanto has never sought permission from EPA to warn of Roundup's cancer risks.

3. FIFRA leaves ample room for State regulation of a pesticide within States' respective borders. States may, for example, ban a federally registered pesticide, even if EPA has not determined that it is misbranded. *See* §136v(a). Section 136v(a) defines the wide contours of the States' authority to regulate pesticides:

> **(a) In general**
>
> 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 [FIFRA].

§ 136v(a).

The correspondingly narrow, express preemption provision provides:

> **(b) Uniformity**
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under [FIFRA].

§ 136v(b).

The words "labeling," central to the scope of the preemption provision, as well as "label," are defined terms:

> **(1) Label**
>
> 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.
>
> **(2) Labeling**
>
> The term "labeling" means all labels and all other written, printed, or graphic matter--
>
> **(A)** accompanying the pesticide or device at any time; or
>
> **(B)** to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

§136(p)(1)-(2).

4. Monsanto now contends that 40 C.F.R. §152.44(a) affects the express-preemption analysis as a "requirement for labeling" under §136v(b). That regulation, entitled "[a]pplication for amended registration," states:

> Except as provided by §152.46, any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration. The applicant must submit the information required by § 152.50, as applicable to the change requested. If an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold.

40 C.F.R. §152.44(a).

B. Factual Background

Monsanto's statement of the case is a verbatim repetition of its *Durnell* petition (into page 13). Salas's counter-statement of the facts parallels and incorporates Respondent Durnell's but cites to the record in this case.

1. Monsanto developed Roundup and introduced it on the market as a weedkiller in the 1970s. *E.g.*, *In re: Roundup Prods. Liab. Litig.*, No. 3:16-md-02741-VC (N.D. Cal.), MDL Dkt. 15886-4, 2.

Prior to marketing and selling the product, Monsanto successfully registered Roundup's active ingredient, glyphosate, with EPA based in part on studies conducted by the Industrial Bio-Test Laboratories, which EPA later learned to be fraudulent. MDL Dkt. 15973-4, 3, 10 (summarizing findings from Food and Drug Administration's audits revealing "serious deficiencies" in the IBT tests). Widespread discrepancies between the studies and the raw data prompted EPA to order affected registrants, like Monsanto, to submit the raw data for the IBT studies underlying the registration, and to order replacement studies in 1983. *See*

MDL Dkt. 15973-4, 10. The 1983 EPA report summarizing the IBT's fraud stated that the IBT case "caused serious concern and uncertainty about the potential hazards of hundreds of pesticides involved, [including glyphosate,] both for the EPA and the public," with some experts advocating "that all 212 pesticides tested in whole or in part by IBT be removed from the market pending retesting." MDL Dkt. 15973-4, 5. That option, however, was deemed unavailable under then-current law. *Id.*

2. Monsanto submitted the first valid study assessing glyphosate's effect on laboratory mice in 1983. MDL Dkt. 15973-5, 2. Based on that study, EPA classified glyphosate as a possible human carcinogen. *Id.* at 3. In response, Monsanto committed to "do[ing] all that is possible in order to have the Agency reverse its decision." MDL Dkt. 15973-7, 3.

Through the IBT scandal, the 1983 mouse study, and the resulting EPA "possible human carcinogen" determination, Monsanto did not inform consumers about the fraud, remove Roundup from the market, or add warnings to its Roundup labels.

3. In the late 1990s, four peer-reviewed studies concluded that Roundup and/or glyphosate was possibly genotoxic. MDL Dkt. 15973-9, 6-9. Genotoxic substances damage genetic information in cells, causing mutations that may lead to cancer. *See Salas v. Monsanto Co.*, No. 1:21-cv-21217-KMW (S.D. Fla.), D.Ct. Dkt. 36, 8 (filed Mar. 30, 2021). Monsanto decided to hire Dr. James Parry, a world-renowned genotoxicity expert, to evaluate the four studies and offer his conclusions about them. *See generally* MDL Dkt. 15973-9, 10. When those conclusions proved inconvenient for Monsanto—with Dr. Parry concluding that glyphosate *could* be genotoxic and suggesting additional studies

would be the best way of clarifying the genotoxicity question (MDL Dkt. 15973-9, 3, 10-11)—Monsanto unceremoniously "drop[ped]" him (MDL Dkt. 15973-10, 2).

After reading one of Dr. Parry's reports, Monsanto's Dr. William Heydens emailed Monsanto colleagues advising that the company "simply [wasn't] going to do the studies [Parry] suggests." MDL Dkt. 15973-11, 2. "[W]hat we are really trying to achieve here," Heydens admitted, is to "find/develop someone who is comfortable with the genotox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genotox issues arise." *Id.* "[Parry] is not currently such a person," he concluded. *Id.* Because Roundup is "currently very vulnerable" on genotoxicity, Heydens wrote, Monsanto "should ***seriously*** start looking for one or more other individuals" who could take the positions Monsanto wanted if Dr. Parry could not "become a strong advocate." *Id.* (emphasis in original).

True to Heydens' email, Monsanto did not conduct all of Dr. Parry's suggested tests. MDL Dkt. 15973-12. The company effectively silenced Dr. Parry from speaking to or sharing his findings with regulators since he was bound by a confidentiality agreement. MDL Dkt. 15973-12, 42. And, although FIFRA requires manufacturers to report "factual information regarding unreasonable adverse effects on the environment of [a] pesticide" to EPA on an ongoing basis, § 136d(a)(2); *see* 40 C.F.R. § 159.158(a), Monsanto did not share Dr. Parry's report or suggestions with EPA. MDL Dkt. 15973-12, 43.

4. Consistent with Monsanto's overall approach with Dr. Parry, it continued to downplay glyphosate's health and safety concerns and those of

formulated glyphosate products like Roundup, including by refusing to conduct testing on formulated Roundup. Roundup contains not only glyphosate, but other ingredients and also a surfactant that that decreases surface tension, enabling the product to penetrate the waxy surface of a leaf—or human skin. This surfactant makes Roundup more genotoxic.

Monsanto understood this: a Monsanto employee wrote in 2015 that he believed that the other ingredients in Roundup "played a role" in the positive tumor results of a tumor-promotion study. D.Ct. Dkt. 36, 10. Additionally, in response to an article quoting studies suggesting Roundup is not safe, Monsanto's Donna Farmer internally acknowledged that the company "cannot say that Roundup does not cause cancer" because they had "not done carcinogenicity studies with 'Roundup.'" MDL Dkt. 15973-13, 2.

Monsanto also flooded scientific literature with ghostwritten articles to bolster the safety profile of glyphosate-based herbicides. For instance, the company retained Dr. Gary Williams, a pathologist, to publish a 2000 article concluding that Roundup does not pose a health risk to humans. Dr. Williams did not write that article; Monsanto's Dr. Heydens ghostwrote it. MDL Dkt. 15973, 9 n.3 (link to Williams article); MDL Dkt. 15973-6, 58-62; *see also* MDL Dkt. 15973-14 (Monsanto manuscript clearance form for another ghostwritten article in 2013 entitled "Review of genotoxicity studies of glyphosate and glyphosate-based formulations"); D.Ct. Dkt. 36-41, 10 (another ghostwritten article stating "glyphosate is not a human health risk"). EPA consistently relies on these ghostwritten articles in assessing the safety of glyphosate-based pesticides.

5. In 2015, a working group at the International Agency for Research on Cancer ("IARC"), concluded that glyphosate is probably carcinogenic to humans.

Despite the lack of testing on glyphosate formulations and the IARC classification, Monsanto rushed to ensure that EPA would not adopt the IARC determination. In 2015, for instance, Monsanto conducted discussions with the then-Deputy Director of the Office of Pesticide Programs Health Effects Division regarding a planned review of glyphosate by the Agency for Toxic Substances and Disease Registry, the agency responsible for assessing chemical toxicity. *See* MDL Dkt. 15973-15. The Deputy Director wanted to establish coordination with the company and stated to Monsanto's agency lead for regulatory affairs, "If I can kill [the glyphosate review] I should get a medal." *Id.* at 3. Monsanto obtained EPA's word that the glyphosate review would be put "on hold," and although Monsanto's chief regulatory toxicologist expressed some lingering concerns with the review, he reflected that "at least [EPA] know they are being watched, and hopefully that keeps them from doing anything too stupid[.]" D.Ct. Dkt. 36-42, 2-3.

Despite Monsanto's efforts, in 2017, California determined glyphosate was a chemical known to the State to cause cancer based on the IARC's determination. *See* California Off. of Env't Health Hazard Assessment, *Initial Statement of Reasons: Glyphosate Proposition 65 Safe Harbors* (Mar. 28, 2017), https://perma.cc/BL9Q-MPAY. California's Proposition 65 requires a warning label on glyphosate products if exposures exceed the safe harbor levels. *See* OEHHA, *Glyphosate*, https://perma.cc/E6VM-MCAF.

6. For its part, EPA has not made formal findings about whether *formulated Roundup* causes cancer. The agency observed that the data linking glyphosate exposure and the risk of non-Hodgkin lymphoma were uncertain, partly because "farmers and other applicators apply formulations, not the active ingredient alone." Off. of Pesticide Programs, EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 137 (Dec. 12, 2017), https://perma.cc/2WJM-MT7R. EPA has acknowledged the need for further research "to determine whether formulation components, such as surfactants, influence the toxicity of glyphosate formulations." *Id.* at 144.

EPA has noted that "[m]any commenters [have] expressed concerns that glyphosate formulations are more toxic than glyphosate alone and [have] questioned the toxicity of inert ingredients[.]" EPA, *Glyphosate: Proposed Interim Registration Review Decision*, No. 0178, at 10 (Apr. 2019), https://perma.cc/P84R-A93H. EPA acknowledged that "few research projects" had tried to compare "technical grade glyphosate" to glyphosate-based formulations like Roundup for purposes of assessing human health risk. *Id.* at 11. EPA stated in 2019 that, if "at any time, information becomes available that indicates adverse human health effects of concern for exposure to glyphosate or its formulations, EPA intends to review it and determine the appropriate regulatory action." *Id*.

In August 2019, the Director of the Registration Division within EPA's Office of Pesticide Programs issued a letter to all glyphosate-based product registrants. Letter from EPA to Glyphosate Registrants

(Aug. 7, 2019), https://perma.cc/6ZL4-JF8P. The letter stated EPA would no longer approve Proposition 65 labeling that warned consumers glyphosate was a chemical known to California to cause cancer, and that manufacturers must remove such a warning. *Id.* This letter did not address whether Roundup or glyphosate formulations cause cancer.

In April 2022, a different, higher-ranking EPA official, the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, wrote that "EPA could approve" California's newly proposed glyphosate-specific cancer warning "if pesticide registrants" like Monsanto "requested it for inclusion on glyphosate product labels." Letter from EPA to Cal. Off. of Envtl. Health Hazard Assessment (Apr. 8, 2022).[2]

7. The Ninth Circuit recently vacated EPA's conclusion that glyphosate is not likely to cause cancer. *NRDC v. EPA*, 38 F.4th 34, 40 (9th Cir. 2022). Earlier, in January 2020, the agency, having completed its re-registration review of glyphosate under FIFRA, "determined that there are no risks to human

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[2] *See* https://www.epa.gov/system/files/documents/2025-05/2022-epa-letter-to-ca-oehha-on-ca-prop-65_0.pdf. EPA has since withdrawn this letter based on *National Association of Wheat Growers v. Bonta*, 85 F.4th 1263, 1266-67, 1283 (9th Cir. 2023), which held that compelling use of California's warning label violated the First Amendment rights of a coalition of agricultural-sector businesses. The Ninth Circuit acknowledged that its previous decision vacating EPA's January 2020 interim decision on glyphosate, *NRDC v. EPA*, 38 F.4th 34 (9th Cir. 2022), "has little bearing on the First Amendment analysis." *Bonta*, 85 F.4th at 1280 n.14. *Bonta* addresses only compelled warning labels and does not speak to, much less prohibit, a situation where a glyphosate registrant like Monsanto voluntarily requests the revised label for inclusion on glyphosate product labels.

health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." *Id.* at 43. The Ninth Circuit, however, vacated EPA's "not likely to be carcinogenic" conclusion, calling EPA's reasoning "the hallmark of arbitrary action." *Id.* at 51. The agency's determination, the Ninth Circuit concluded, was "in tension with parts of the agency's own analysis and with the guidelines it purports to follow," and thus not supported by "substantial evidence." *Id.* at 46, 51. For example, "most studies EPA examined indicated that human exposure to glyphosate is associated with an at least somewhat increased risk of developing [non-Hodgkin lymphoma]." *Id.* at 46.

C. Procedural History

1. This case was filed in Florida state court in 2021, and Monsanto removed it to the United States District Court for the Southern District of Florida. D.Ct. Dkt. 1. Salas alleged that she was diagnosed with non-Hodgkin lymphoma in 2020 after using Roundup products year-round between 2004 through 2014 to control weeds at her Florida residences. D.Ct. Dkt. 1-1, ¶¶134-41. The complaint advanced five claims against Monsanto: strict products liability, negligence, breach of express warranties, fraudulent misrepresentation, and negligent misrepresentation. *Id.* ¶¶142-97.

Shortly after it was filed, the case was tagged and transferred to the multi-district litigation, which had been proceeding before Judge Vince Chhabria in the Northern District of California for over four years. *See In re: Roundup Prods. Liab. Litig.*, 214 F. Supp.3d 1346 (J.P.M.L. 2016); D.Ct. Dkt. 14. In the MDL,

Salas' case became one of the "Wave 5" group of cases. *See* MDL Dkt. 51.

Prior to *Salas*'s inclusion in the MDL, Monsanto had already presented its express-preemption theories to the District Court. In what became the lead case in the MDL, *Hardeman*, Monsanto had filed motions to dismiss and for summary judgment arguing FIFRA preemption. In those proceedings, the company's express-preemption arguments never raised the theory which now occupies a central place in its petition: that 40 C.F.R. §152.44(a) constitutes a requirement for labeling under §136v(b) and *Bates* because it "'specifically identif[ies] the contents required to be included on' Roundup's label," *Durnell* Pet. 20 (quoting *Schaffner*, 113 F.4th at 390); Pet. i, 16 (adopting *Durnell* petition). *See* Mot. to Dismiss 6-8, Dkt. 18, *Hardeman v. Monsanto Co.*, No. 3:16-cv-00525-VC (N.D. Cal.) (filed Mar. 1, 2016); S.J. Mot. 5, MDL Dkt. 2419 (filed Jan. 3, 2019).[3]

The MDL court denied Monsanto's motions to dismiss and for summary judgment on express-preemption grounds—naturally without addressing that unpresented theory. *See Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1038-39 (N.D. Cal. 2016); Order No. 101, 1-2, MDL Dkt. 2937. When Monsanto appealed *Hardeman*, it did not advocate that theory either. The regulation (40 C.F.R. §152.44(a)) thus does not even appear in the Ninth Circuit's decision rejecting Monsanto's express-preemption defense. *See Hardeman v. Monsanto Co.*, 997 F.3d 941, 954-58 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (U.S. 2022).[4]

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[3] Monsanto referenced the regulation only as part of its separate argument on implied preemption. S.J. Mot 7, 9-10.

[4] The question Monsanto presented in its petition for writ of certiorari in *Hardeman* was: "Whether FIFRA preempts a state-

When Salas's case was transferred to the MDL, Monsanto moved for summary judgment on FIFRA-preemption grounds, incorporating by reference its briefing from prior motions against earlier tranches of plaintiffs. S.J. Mot. 2, *In re Roundup Prods. Liab. Litig.*, No. 3:21-cv-06173 (N.D. Cal.), *Salas* MDL Dkt. 38 (filed June 15, 2023). Monsanto therefore did not raise in the District Court the theory that 40 C.F.R. §152.44(a) supplies a labeling-content requirement. That court denied the motion based on "the Ninth Circuit's decision in *Hardeman*." Respondent's Appendix ("R.App.") 5a (citing *Hardeman*, 997 F.3d at 955-56, 970-74); D.Ct. Dkt. 72-3 (same).

2. At the end of 2023, the Judicial Panel on Multidistrict Litigation remanded this case back to the Southern District of Florida. In Monsanto's rendition of the procedural history, only two events merit mention at this point:

> After the case returned to Florida, the Eleventh Circuit issued its decision in *Carson v. Monsanto Co.*, 92 F.4th 980 (11th Cir. 2024). The parties here *then* reached a settlement agreement.

Pet. 13 (emphasis added). This matter-of-fact juxtaposition of events casts the issuance of *Carson*, which

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law failure-to-warn claim where the warning cannot be added to a product without EPA approval and EPA has repeatedly concluded that the warning is not appropriate." Pet. I, *Hardeman*, No. 21-241 (Aug. 16, 2021). This Court requested the views of the Solicitor General. The United States said, "EPA's approval of pesticide labeling … is not naturally characterized as a FIFRA 'requirement' that no such warning appear," since a "'requirement is a rule of law that must be obeyed.'" U.S. Amicus Brief, *Monsanto Co. v. Hardeman*, No. 21-241 (U.S., filed May 10, 2022) ("SG *Hardeman* Br.") 11-12 (quoting *Bates*, 544 U.S. at 445).

rejected Monsanto's FIFRA-preemption defenses, as the impetus for Monsanto's settlement. That suggestion obscures Monsanto's maneuverings that betray its opportunistic strategy to position this case as a vehicle to reach this Court.

Carson was decided in February 2024. By the summer, as the litigation continued in this case, Monsanto contemplated seeking certiorari in *Carson*. It filed an application in this Court for an extension of time for that purpose. *Monsanto Co. v. Carson*, No. 24A-89, 3 (filed July 23, 2024). The Court gave Monsanto until September 5, 2024.

Tellingly, during that interval, mediation was held in this case, on August 7, 2024. *Carson* did not impel settlement, for the mediation ended in impasse. D.Ct. Dkt. 51. One week later, however, the Third Circuit decided *Schaffner*, giving Monsanto its first victory on express-FIFRA preemption of a state-law negligent-failure-to-warn claim.

Monsanto then abandoned its plan to seek a writ of certiorari in *Carson* and, instead, adopted the strategy of using this case to position a federal case before this Court. The day after its deadline to file a petition for a writ of certiorari in *Carson*, and only a month after failing to resolve this case at mediation, the parties in this case announced a settlement. D.Ct. Dkt. 55. "[I]n connection with the parties' settlement," Salas agreed to move to amend her complaint to abandon all of her claims other than the negligent failure-to-warn claim and to "enter into a final and appealable, stipulated judgment on that sole claim." D.Ct. Dkt. 57. Salas received an initial payment from Monsanto, and if Monsanto is unsuccessful in its reversing the entry of judgment on appeal, Salas "will receive

and additional, substantial, monetary payment." *Id.* at 2.

Pursuant to the deal, the parties entered a joint stipulation for entry of judgment through which "Monsanto reserve[d] the right to appeal the Entry of Judgment … based on the portions of the MDL Court's August 21, 2023 order … addressing federal preemption." D.Ct. Dkt. 74. Presented with the parties' settlement, the District Court granted Salas leave to amend her complaint down to a single, narrowed negligent failure-to-warn count under Florida law and entered final judgment "[p]ursuant to the Parties' Joint Stipulation for Entry of Judgment[.]" D.Ct. Dkt. 67, 75.

On appeal to the Eleventh Circuit, facing *Carson* as binding panel precedent on the express-preemption issue, Monsanto chose not to petition that court initially en banc, Fed. R. App. P. 40(g), a procedure that could have allowed it to circumvent *Carson* and, arguably, ventilate before the full Eleventh Circuit the theory that 40 C.F.R. §152.44(a) constitutes a labeling-content requirement. Instead, Monsanto sought a fast track to this Court by falling on its sword, filing a motion for summary affirmance against its own appeal, conceding that "*Carson* controls the outcome[.]" Pet'r CA11 Mot. 8 (capitalization altered). While seeking to "preserve its arguments that Salas's claim is preempted," Monsanto urged the Court of Appeals to follow its law on prior-panel precedent and rule against it. *Id.* at 10, 12-13. Having secured Salas's consent to pretermitting the appeal through a self-defeating motion for summary affirmance, Monsanto's motion was filed as unopposed.

The Eleventh Circuit obliged, giving Monsanto the quick loss it requested in a short, unpublished

opinion which recognized that "*Carson* controls here" under the circuit's prior-panel rule. Pet.App. 1-3.

REASONS FOR DENYING THE PETITION

I. This Case Does Not Present a Clean Vehicle for Review

Monsanto calls this case "a clean vehicle" for review. Pet. 15. That may be the outward appearance Monsanto presents, but a look under the hood reveals a different picture. This case harbors a preservation defect on an essential theory of the express-preemption argument Monsanto seeks to advance. Further, Monsanto's machinations in procuring the settlement in this case betray the kind of "cunning" this Court has hesitated to "reward" by granting review, *United States v. Wells*, 519 U.S. 482, 489 (1997). And in the company's haste to position this case before the Court, by way of the expedient of a motion for summary affirmance against its own position in the Court of Appeals, Monsanto generated an Article III concern. This case does not offer a clean opportunity to address the express-preemption theory Monsanto wants the Cout to adopt, and there is no Circuit conflict over implied-FIFRA preemption.

1. Monsanto predicates the propriety of certiorari on an asserted circuit split over a theory for express preemption adopted in the Third Circuit but which Monsanto never presented for consideration to the courts below. This Court "ordinarily will not decide questions not raised or litigated in the lower courts." *City of Springfield v. Kibbe*, 480 U.S. 257, 259 (1987); *see Rivers v. Guerrero*, 605 U.S. ___, 2025 WL

1657406, *8 (U.S. June 12, 2025); *United States v. Williams*, 504 U.S. 36, 41 (1992).

Specifically, the analytic point of departure between the Third Circuit and other courts involves the too-clever-by-half theory that an EPA procedural regulation which precludes the applicant for a registered pesticide from changing the product's pre-approved labeling without obtaining EPA approval, 40 C.F.R. §152.44(a), constitutes a labeling-*content* requirement under FIFRA's preemption provision, 7 U.S.C. §136v(b). Monsanto's petition invokes the Third Circuit's interpretation of the effect of that regulation (Pet. 2; *Durnell* Pet. 20-21), which that court dubbed the "Preapproval Regulation," *Schaffner*, 113 F.4th at 371. The Preapproval Regulation lies at the core of the Third Circuit's decision and, hence, Monsanto's claim to a circuit split.

The Third Circuit's opinion highlights the narrowness of its point of departure from other courts, though Monsanto's petition suppresses that detail. The petition states: "As the Third Circuit recognized, … its 'analysis differs from' that of its 'colleagues in other courts.'" Pet. 2 (quoting *Schaffner*, 113 F.4th at 399). What the Third Circuit actually said is that its analysis differs "chiefly in how we define the Federal Comparator that must be employed in applying the parallel-requirements test" from *Bates*. *Schaffner*, 113 F.4th at 399. By "Federal Comparator," the Third Circuit means "the federal requirement that must be compared with the [state law requirement]" for purposes of the "parallel-requirements test" for express preemption under FIFRA. *Schaffner*, 113 F.4th at 380. The Third Circuit reasoned that because 40 C.F.R. §152.44(a) prohibits the modification of health

warnings on a pesticide's EPA-approved label, it "constitutes a 'requirement' for the purposes of section 136v(b)." *Id.* at 399.

Despite the truncated nature of Monsanto's petition in this case, there is no question the company intends to make this regulation a central feature of its express-preemption argument before this Court. The petition (at 16) incorporates the arguments from Monsanto's petition in *Durnell*, No. 24-1068, where the company elaborates its theory. *Durnell* Pet.20, 22.

However, in this case, Monsanto has never before raised the theory that this regulation gives rise to express preemption, except insofar as it slipped a veiled reference to it into its unilateral, unopposed presentation to an Eleventh Circuit panel bound to affirm based on prior circuit precedent. In the district court, Monsanto argued express preemption but did not raise the theory that 40 C.F.R. § 152.44(a) imposed a labeling-content requirement. *See* Pet'r Mot. 3-6, MDL Dkt. 2419. The MDL court's disposition of that motion for summary judgment, not surprisingly, did not consider that issue. R.App. 5a.

Nor was the new theory that 40 C.F.R. §152.44(a) imposes a labeling-content requirement supporting express preemption fairly raised or passed upon by the Court of Appeals. Given that Monsanto's appeal of the express-preemption ruling bound up in the stipulated judgment would be foreclosed by *Carson*, Monsanto had three options: (1) fully ventilate its arguments, including its new theory, before a panel of the Eleventh Circuit, await the obligatory affirmance, and then seek rehearing en banc to ask the full Court of Appeals to revisit *Carson*; (2) try to accomplish the same thing through a petition for initial hearing en

banc; or (3) minimize the chance of any consideration of the new theory at the Eleventh Circuit by filing a motion for summary affirmance against its own appeal, based on *Carson*. Monsanto chose the last course. Prior to filing a motion for summary affirmance its counsel contacted Salas' counsel to secure Salas's non-opposition. *See* Pet'r CA11 Mot. 1. Monsanto then filed, unopposed, a motion to reject its own appeal. *Id*.

Taking advantage of the lack of opposition and the Eleventh Circuit panel's lack of power to consider the Third Circuit's reasoning, Monsanto obliquely sought to inject, for the very first time, the seeds of the new express-preemption theory it advocates here. Under the guise of "*preserv[ing]* its arguments that Salas's claim is preempted," Monsanto instead slipped into its (supposed) "summar[y]" of arguments it had made in the district court the brand-new theory it now advocates, by means of this vague reference:

> Once EPA preapproved Roundup's label, regulations prohibited Monsanto from deviating from the approved label. *See* 40 C.F.R. §152.44(a).
>
> The Third Circuit has explained in detail why, *under these circumstances*, a claim such as Salas's is preempted. *Schaffner*, 113 F.4th at 379-393.

Pet'r CA11 Mot. 10-11 (footnote omitted; emphasis added). The panel, bound by *Carson*, predictably gave Monsanto the quick adverse ruling it wanted, by summary disposition. Pet.App. 1-3.

Monsanto's stealth approach to bringing its new theory of express preemption before this Court through this case should founder because it was not

preserved and lacks the benefit of scrutiny by the Court of Appeals. *Rivers*, 2025 WL 1657406, at *8; *Kibbe*, 480 U.S. at 259. Monsanto did not raise the theory that 40 C.F.R. §152.44(a) constitutes a labeling-content requirement in the District Court. Nor did it do so in the Court of Appeals, where the oblique reference in an unopposed motion for summary affirmance predictably went unaddressed. Where a petitioner failed to direct lower courts to "the source of authority upon which [it] relies" for its "new theory" in this Court, the issue has not been properly presented. *Rivers*, 2025 WL 1657406, at *8. To be sure, the courts below passed on the broader issue of express preemption under FIFRA. And the Court of course has discretion to overlook Monsanto's failure to have litigated this theory and thereby engaged opposing counsel and the courts in subjecting it to scrutiny.

2. But the Court should not exercise that discretion here. Doing so would merely "reward cunning." *Wells*, 519 U.S. at 489. The present posture of this case, as well as the asserted conflict Monsanto asks the Court to resolve, is purely a construct of the company's strategic behavior. Monsanto was unwilling to settle this case in early August 2024, on its own terms, through mediation. D.Ct. Dkt. 51. But when Monsanto learned, a week later, that another one of its engineered settlements to narrow issues for appeal had paid off in *Schaffner*, 113 F.4th at 375, the company abruptly changed gears. It abandoned its opportunity to seek certiorari in *Carson* and pivoted to striking a strategic deal to settle this case to present a different vehicle for review to this Court. D.Ct. Dkt. 55. Upon that prefab foundation in the District Court, Monsanto sought a "fast pass to the Supreme Court,"

by way of securing an unopposed "summary affirmance against [it]s own interest" in the Eleventh Circuit. *United States v. Aguilar-Torres*, 116 F.4th 341, 342 & n.1 (5th Cir. 2024), *vacated and reh'g en banc granted*, 130 F.4th 450 (5th Cir. 2024).

3. In its rush to this Court, Monsanto may have planted this case in jurisdictional quicksand, creating an Article III issue the Court must consider before it could reach the merits. By employing the expedient of seeking an adverse judgment against itself below, rather than fully ventilating its arguments and using the procedures available in the Court of Appeals to vindicate its position, *see* Fed. R. App. P. 40(g), Monsanto created an Article III standing problem.

This Court "has a special obligation to 'satisfy itself not only of its own jurisdiction, but also that of the lower courts in a case under review.'" *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 95 (1998) (citation omitted). Standing must "'persist throughout all stages of litigation.'" *W. Virginia v. Env't Prot. Agency*, 597 U.S. 697, 718 (2022) (citation omitted). While Monsanto's injury (the obligation to pay money) was no doubt fairly traceable to the stipulated judgment, for the company to maintain a "cognizable Article III stake" in the appeal, it was also necessary that "a 'favorable ruling' from the appellate court 'would redress [that] injury.'" *Id.* (quoting *Food Marketing Inst. v. Argus Leader Media*, 588 U.S. 427, 433 (2019)). "'Redressability requires that the court be able to afford relief *through the exercise of its power*[.]'" *Haaland v. Brackeen*, 599 U.S. 255, 294 (2023) (quoting *Franklin v. Massachusetts*, 505 U.S. 788, 825 (1992) (Scalia, J., concurring in part and concurring in the judgment; emphasis in original)). But Monsanto elected to request relief from the Eleventh Circuit that

would *not* redress its injury. The exercise of judicial power it requested was to "summarily *affirm* the judgment of the district court." Pet'r CA11 Mot. 14 (emphasis added). By asking the Eleventh Circuit *not* to redress its injury, but instead to prolong it in the hopes the company can get before this Court, Monsanto took a "shortcut" that at least one court has flagged as an Article III defect. *Aguilar-Torres*, 116 F.4th at 342 & n.1.

Neither of the cases Monsanto cites grappled with this particular "jurisdictional obstacle," Pet. 15. The settlement agreement in *Havens Realty Corporation v. Coleman* merely liquidated potential damages. 455 U.S. 363, 371 (1982). The parties reached that deal in the shadow of a petition for writ of certiorari, apparently after both the district court and court of appeals had ruled. *Id.* at 370-71. The defendant-petitioner in *Havens* did not do what Monsanto did here: seek relief against its own interests in the Court of Appeals. (Nor did it orchestrate a settlement to try to tailor the substantive contours of the remaining claim for purposes of presentation of a conflict to this Court.) The other case Monsanto cites, *Linde v. Arab Bank, PLC*, 882 F.3d 314, 324 (2d Cir. 2018), is distinguishable on the same basis.

For all of the above reasons, this case does not present the "clean vehicle" Monsanto contends.

II. Nor Does This Case Implicate Any Circuit Conflict

The decision below does not conflict with the Third Circuit because it falls within the circumstances that court expressly declined to address. As Respondent Durnell points out, *Schaffner* involved a "unique quirk": "[t]he plaintiff there had not argued that

'FIFRA required Monsanto' to seek 'EPA approval for a modified Roundup label that included' a cancer warning." *Durnell* BIO 21 (quoting *Schaffner*, 113 F.4th at 386 n.13). But Salas *did* assert such a claim. So the aspect of the Third Circuit's analytic path that diverged from that of the Eleventh Circuit (in *Carson* at least) does not traverse this case.

Salas's complaint alleged that both FIFRA and Florida law imposed a duty upon Monsanto to register Roundup and furnish EPA with information concerning its toxicity to humans. D.Ct. Dkt. 1-1, ¶¶35-37, 39, 154-155, 156(k). Her complaint was patterned after that of the lead plaintiff in the MDL, which likewise asserted a state-law failure-to-warn claim "base[d] … on Monsanto's alleged violation of FIFRA." *Hardeman*, 216 F. Supp. 3d at 1038. When Monsanto sought summary judgment on FIFRA-preemption grounds against Salas's claims, the MDL Court denied the motion based "the Ninth Circuit's decision in *Hardeman*." R.App. 5a. The Ninth Circuit viewed the claim as asserting "a state cause of action that seeks to enforce a federal requirement" under FIFRA. *Hardeman*, 997 F.3d at 955 (quotation omitted).

To be sure, Monsanto purchased an amendment to Salas's complaint as part of its settlement. But the resulting pleading did not cleanly excise Salas's reliance on FIFRA as a parallel source of duty for Monsanto to present EPA with updated data. *See* D.Ct. Dkt. 73, ¶¶ 18-20, 22, 118-119, 120(c). Even if it did, Monsanto represented to the District Court in the stipulation for entry of judgment that its appeal would be "based on the portions of the MDL Court's August 21, 2023 order" rejecting its preemption defense.

D.Ct. Dkt. 74 1.[5] That order from the MDL court (R.App. 5a) addressed the earlier version of Salas's complaint, before it was sanitized to Monsanto's liking. *See* D.Ct. Dkt. 57. If Monsanto were to quibble that the operative complaint is the only relevant pleading, and that the Court should ignore the history of the case, that contention would only underscore the wholly contrived nature of the asserted Circuit split Monsanto seeks to leverage here.

Further, there is no Circuit split on the issue of impossibility preemption. The Third Circuit did not reach that issue. *Schaffner*, 113 F.4th at 379 n.8.

III. The Decision Below Is Correct

A. Salas's Failure-to-Warn Claim Is Not Expressly Preempted

The Eleventh Circuit correctly held that Salas's failure-to-warn claim was not expressly preempted, based upon *Carson*, because Florida's common law on negligent failure to warn "parallels FIFRA." Pet.App.-2. Since "*Carson*'s analysis govern[ed]" in *Salas*, *id.*, the Eleventh Circuit did not have to elaborate to grant Monsanto's motion for summary affirmance. So that court's reasoning resides almost exclusively in *Carson*.

The *Carson* court properly applied the *Bates* "two-step framework" to a state-law failure-to-warn claim concerning Roundup. *Carson*, 92 F.4th at 990. The plaintiff in *Carson* asserted a failure-to-warn claim under Georgia common law, *id.* at 991, whereas Salas's is a Florida law failure-to-warn claim. *See*

[5] Monsanto claims it "expressly retained the right to appeal the judgment on FIFRA preemption grounds" (Pet. 14), but its reservation of rights in the filed stipulation was narrower.

D.Ct. Dkt. 73. "Florida law, like Georgia law, 'require[s] pesticide manufacturers to warn users of potential risks to health and safety[.]'" Pet.App.-2 (quoting *Carson*, 92 F.4th at 992). As Monsanto told the Eleventh Circuit, "Florida law, like Georgia law, requires manufacturers who know or reasonably should know 'of the potential danger in the use of the product' to warn users when it is foreseeable that those users may sustain 'damage or injury.'" Pet'r CA11 Mot. 9 (quoting *Advance Chem. Co. v. Harter*, 478 So. 2d 444, 447 (Fla. Dist. Ct. App. 1985)); *see High v. Westinghouse Elec. Corp.*, 610 So. 2d 1259, 1262 n.4 (Fla. 1992) (citing *Advance Chem.* and *Tampa Drug Co. v. Wait*, 103 So. 2d 603, 607-08 (Fla. 1958)).

"If anything, [Florida] common law about failure-to-warn claims imposes *less* of a duty on pesticide manufacturers than FIFRA." *Carson*, 92 F.4th at 992. Florida common law requires manufacturers to warn of "foresee[able]" "potential danger in the use of the product" that they "knew, or by the exercise of reasonable care, should have known, of." *Advance Chem.*, 478 So. 2d at 447. "By contrast, FIFRA imposes a blanket duty on pesticide manufacturers, regardless of knowledge or foreseeability." *Carson*, 92 F.4th at 992. "FIFRA's prohibition on misbranding effectively imposes a strict-liability standard, as it contains no element of knowledge or intent." *Id.* at 991. "So long as the pesticide's label omits a 'necessary' warning 'to protect health and the environment,' the manufacturer is liable under FIFRA." *Id.* at 991-92 (quoting §136(q)(1)(G)). Therefore, Salas's Florida common law, failure-to-warn claim is "'fully consistent with' or even narrower than federal requirements," such that FIFRA does not expressly preempt it. *Id.* (quoting *Bates*, 544 U.S. at 447).

B. Monsanto's Express Preemption Arguments Lack Merit

Because Monsanto's petition simply adopts its merits arguments from its petition in *Durnell*, this brief will not compound the Court's labor with a point-by-point response and, instead, adopts Respondent Durnell's persuasive rejoinder. *See Durnell* BIO 21-30. Durnell's arguments apply with equal force in this case because the Missouri Court of Appeals relied on the Eleventh Circuit's decision in *Carson*. *See Durnell v. Monsanto Co.*, 707 S.W.3d 828, 832-33 (Mo. Ct. App. 2025).

One of Durnell's points, regarding 40 C.F.R. §152.44, warrants elaboration given the starring role that regulation plays in Third Circuit's analysis and, hence, Monsanto's position now. That regulation "does not forbid [Monsanto] from warning of Roundup's cancer risks" but "just establishes *procedures* for manufacturers to update their labels." *Durnell* BIO 22 (emphasis added). The distinction between substance and procedure is material to FIFRA's preemption regime.

1. The distinction originates in the key text of the preemption provision, "requirements for labeling." §136v(b).[6] That phrase concerns mandatory *content* on labels, not procedures which affect them. Both "labeling" and "label" are defined terms in the statute, and both concern informational substance. A "label"

[6] The phrase "requirements for labeling" is the referent of the pronoun "those" in "in addition to or different from those required under this subchapter." §136v(b).

is "the written, printed, or graphic matter on, or attached to, the pesticide … or any of its containers or wrappers." §136(p)(1). "Labeling," in turn, is a noun that encompasses broader territory: the label, plus "other written, printed, or graphic matter" "accompanying the pesticide" or "reference[d] … on the label or in literature accompanying the pesticide[.]" §136(p)(2). The preposition "for" in this context is "used as a function word to indicate purpose." *For*, Webster's Seventh New Collegiate Dictionary (7th ed. 1972). A "requirement" is "a rule of law that must be obeyed." *Bates*, 544 U.S. at 445. So, "requirements for labeling" are most naturally read as mandatory rules for the *informational content* that must go on or with the pesticide.

The statutory context supports this understanding. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996) (looking to the "statutory framework surrounding" the preemption provision to assess its scope) (quotation marks omitted). A chief purpose of the statute is to ensure true and reliable labeling on pesticides. *See Bates*, 544 U.S. at 451. The statutory enforcement scheme therefore presumes the existence of established informational labeling content. EPA may seize pesticides whose "labeling fails to bear the information required by [FIFRA]." §136k(b)(1)(C). The prohibition on misbranding includes not "prominently plac[ing]" "any word, statement, or other information required by or under the authority of [FIFRA] to appear on the label or labeling." §136(q)(1)(E). EPA therefore promulgated "requirements" for the "[c]ontents of the label," whereby "[e]very pesticide product shall bear a label containing the information specified by [FIFRA] and the regulations in this part." 40 C.F.R. §156.10(a)(1). That regulation alone details

pages of requirements governing information that must appear on pesticide labels, their language, format, and appearance.

In view of this content-based understanding of the meaning of "requirements for labeling," a statutory provision or regulation directly mandating labeling content carries preemptive force, whereas one merely governing procedures that may indirectly affect labeling content does not. As the Court has recognized, FIFRA's misbranding standards contain broadly framed substantive requirements for labeling: "that a pesticide label not contain 'false or misleading' statements, § 136(q)(1)(A), or inadequate instructions or warnings, §§ 136(q)(1)(F), (G)." *Bates*, 544 U.S. at 447. *See also* § 136(q)(2)(D) (requiring labels on highly toxic pesticides to bear "the skull and crossbones" and "the word 'poison' prominently in red on a background of distinctly contrasting color"). In addition, some "EPA regulations … give content to FIFRA's misbranding standards." *Bates*, 544 U.S. at 453 (citing 40 C.F.R. §156.64, which requires "each pesticide product to bear on the front panel a signal word," such as "DANGER" depending on its toxicity category). *See*, *e.g.*, *id.* §156.10(a)(1) (specifying the information which every pesticide shall bear); *id.* §156.66(a) (requiring the child hazard warning, "Keep Out of Reach of Children"); *id.* §156.69 (requiring a first aid statement). As evidenced by the Court's references in *Bates* to the statutory misbranding standards and a regulation prescribing the content of a warning, it is clear that the Court understood "requirements for labeling" to mean laws and regulations prescribing labeling *content*, including "the color, font size, and wording of warnings." 544 U.S. at 452.

2. The Third Circuit acknowledged that *Bates* interpreted "requirements for labeling" in this substantive fashion. *Schaffner*, 113 F.4th at 386 ("In *Bates*, the Court's analysis suggested that a 'requirement' under section 136v(b) must substantively restrict the content of pesticide labels."). Nevertheless, even though the Third Circuit recognized that 40 C.F.R. §152.44(a) "itself does not *directly* identify any particular label contents as permitted, prohibited, or required"—giving rise to the concern that it "fails to substantively restrict the content of pesticide labels," 113 F.4th at 386 (emphasis added)—the court still concluded that it qualifies as a "requirement for labeling." It held that 40 C.F.R. §152.44(a) "requires pesticide labels to conform to the EPA's opinion as to whether specific labels would constitute misbranding," 113 F.4th at 391, so that the regulation "specifically require[s] a pesticide's label to bear the particular precautionary statements on its Preapproved Label," *id*. at 393. *See id.* at 387 ("[B]ecause the EPA will approve only labels that it deems compliant with federal law, the prohibition on modifying a pesticide's Preapproved Label does 'require the manufacturer … to say [some]thing in particular' on the pesticide label—namely, to include only the content that the EPA deems compliant with federal law.") (quoting *Bates*, 544 U.S. at 445).

3. If that analysis seems to have strayed from the textual meaning of "requirements for labeling" in §136v(b), that's because it does. *Schaffner* equates a regulation governing the process for changing a label, but which does not itself mandate any informational content, with one that actually prescribes labeling content. 113 F.4th at 397 (maintaining that "the registration process" "play[s] a[] role in determining the

content" of a labeling requirement). That loose approach expands the scope of FIFRA's preemption provision from substantive requirements that "directly identify any particular label contents," *id.* at 386, to procedural requirements that only do so *indirectly*, if at all. The tight syntax of §136v(b) does not lend itself naturally to such an expansive reading. Nothing in the unmodified adjectival phrase "for labeling"—meaning, most concisely, for the purpose of information on a label—denotes content deriving incidentally from a chain of non-substantive requirements that do not even themselves supply that information. *Cf. United States v. Munoz-Flores*, 495 U.S. 385, 397 (1990) (construing phrase "Bills for raising Revenue" in the Origination Clause of the Constitution as excluding bills "'for other purposes which may *incidentally* create revenue'") (quoting *Twin City Bank v. Nebeker*, 167 U.S. 196, 202 (1897)) (emphasis added).

The Third Circuit's broadening of the scope of the preemption provision to give preemptive force to labeling text imposed solely as a result of EPA preapproval and not mandated by any content requirement in FIFRA (e.g., the absence of a cancer warning on Roundup's label) also elevates the force of EPA preapproval in a manner inconsistent with EPA practice and the statute. EPA does not typically use the registration process to impose "chronic-risk warnings on a pesticide's labeling"; it "primarily seeks to control such risks through use limitations or … cancellation proceedings." SG *Hardeman* Br. 11. It is by "promulgat[ing] … regulations" "that refine or elaborate upon FIFRA's broadly phrased misbranding standards" that EPA can "affect the scope of pre-emption under § 136v(b)." *Bates*, 544 U.S. at 453 n.28. Further, FIFRA

precludes treating EPA approval of a label as a substantive requirement of the misbranding standards. "Agency approvals provide only 'prima facie evidence,' not conclusive proof, that a pesticide is not misbranded." *Carson*, 92 F.4th at 993 (quoting §136a(f)(2)); *Hardeman*, 997 F.3d at 956 (same). "In no event shall registration … be construed as a defense for the commission of any offense" under FIFRA. § 136a(f)(2). The Third Circuit acknowledged that registration is not "dispositive[]" of non-misbranding, *Schaffner*, 13 F.4th at 397, but failed to appreciate how reliant its view is on an implausible and attenuated connection to the text of §136v(b).

It makes sense for Congress to have sought uniformity with respect to the informational labeling content specifically prescribed by federal law for pesticides. Hence this Court's point about "50 different labeling regimes prescribing the color, font size, and wording of warnings." *Bates*, 544 U.S. at 452; *id.* at n.26. But it makes little sense to think Congress would be concerned with states intruding in rogue fashion into the procedures a federal agency uses to regulate those products, such as 40 C.F.R. §152.44(a). For that reason too, it makes little sense to read the federal "requirements for labeling" to include such procedural regulations.

Central to Monsanto and the Third Circuit's analysis is the view that the Court's interpretation of the preemptive scope of the Medical Device Amendments of 1976 ("MDA") in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), is instructive because the MDA's preemption provision is, they say, "so similar" to FIFRA's. *Schaffner*, 113 F.4th at 388; *see Durnell* Pet. 25. But that similarity lies only in both statutes' use of the "different from, or in addition to" formula, not

in their language identifying the scope of the federal comparator that preempts. The MDA uses a modifier with copious scope: "requirement *applicable* under [the MDA] *to* the device, and which relates to [its] safety or effectiveness[.]" 21 U.S.C. § 360k(a) (emphasis added). *See Lohr*, 518 U.S. at 514 (O'Connor, J., concurring in part and dissenting in part) (opining that the Food and Drug Administration's "labeling requirements are certainly *applicable to* the device" at issue) (emphasis added). FIFRA's preemption provision—"requirements for labeling"—is much narrower, using a defined term as its limiter. This textual distinction renders *Riegel* uninstructive as to the scope of the federal comparator.[7]

FIFRA's preemption provision is limited to federal requirements that supply the content for pesticide labels, not requirements governing the procedures or circumstances of when labeling can be changed. Monsanto and the Third Circuit are wrong to treat 40 C.F.R. §152.44 as preemptive of state-law failure-to-warn claims.

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[7] Such broader language likewise differentiates other statutes Monsanto claims to be similar to FIFRA. *Durnell* Pet. 35. Like the MDA, 49 U.S.C. §30103(b) extends to federal standards "applicable to" motor vehicle performance or equipment. The preemptive scope of 21 U.S.C. §678 extends to federal "requirements … with respect to" slaughterhouse facilities or operations. The same is true for 21 U.S.C. §467e, giving preemptive force to federal requirements "with respect to" poultry facilities and operations.

C. Salas's Failure-To-Warn Claim Is Not Impliedly Preempted

The Eleventh Circuit correctly ruled, based on *Carson*, that Salas's failure-to-warn claims are not barred by impossibility preemption. *See* Pet.App-2 (stating "*Carson* controls here"); *see Carson*, 92 F.4th at 996-99. Monsanto's petition adopts its petition in *Durnell*, where it challenges the rejection of its implied preemption defense. Pet. 16; *Durnell* Pet. 28-32. The Missouri Court of Appeals, like the Eleventh Circuit below, based its implied-preemption ruling on *Carson*. *Durnell*, 707 S.W.3d at 833-35 (repeatedly invoking the analysis in *Carson*). Therefore, Durnell's thorough response to Monsanto covers the same ground Salas would and is adopted by reference. *See Durnell* BIO 30-33.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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June 18, 2025

Appendix

APPENDICES

Appendix A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS
LIABILITY LITIGATION

Case No. 16-md-02741-VC

This document relates to:
Salas v. Monsanto Co.,
Case No. 21-cv-6173-VC
Murdock v. Monsanto Co.,
Case No. 20-cv-1363-VC
Glavanovits v. Monsanto Co.,
Case No. 20-cv-1016-VC
Delorme-Barton v. Monsanto Co.,
Case No. 18-cv-1427-VC

Filed: Aug. 21, 2023

PRETRIAL ORDER NO. 285:
ORDER ON MOTIONS TO EXCLUDE CERTAIN WAVE 5 EXPERTS AND FOR SUMMARY JUDGMENT

Re: Dkt. Nos. 16848, 16849, 16850, 16851, 16852, 16853, 16854, 16856, 16857, 16863, 16868, 16940, 16942, 16944, 16945, 16946, 16947, 16978

The parties have filed evidentiary and summary judgment motions in Wave 5 cases.

1. Monsanto's motions to exclude Drs. Knopf (*Salas*), Schiff (*Murdock* and *Glavanovits*), and Conry (*Delorme-Barton*) are denied for reasons stated in Pretrial Order No. 85. *Accord, e.g.*, Pretrial Order No. 262 (denying motion to exclude Dr. Schiff, noting "[w]hile the experts' opinions may be shaky in some regards, all are admissible, and Monsanto's challenges are best addressed through cross-examination rather than exclusion.").

2. Monsanto's renewed motions to exclude the testimony of Drs. Portier, Ritz, Weisenburger, Jameson and Sawyer are denied, subject to the limitations imposed on these experts in earlier rulings.

3. The plaintiffs' motions to exclude Drs. Smeda (*Salas*), Butts (*Murdock*), and Johnson (*Delorme-Barton*) are denied without prejudice. These witnesses generally are experts in the field of weeds and weeds management. They were not designated to opine on whether Roundup caused the plaintiffs' cancer. *See* Pretrial Order No. 202 at 2. Similarly, Salas's motion to exclude Dr. Schaeffer, an industrial hygienist, is denied without prejudice. *See* Opp. at 1 ("Dr. Schaeffer will not opine on causation in this case….").

4. The plaintiff in *Delorme-Barton* seeks to exclude Dr. Tarone from testifying because he was not disclosed as a retained expert under Rule 26(a)(2). But Dr. Tarone wasn't "retained" by Monsanto for litigation. Dr. Tarone grew critical of IARC's research methodology on his own and published two articles

critiquing Monograph 112 and how IARC supposedly ignored exculpatory data that would have eliminated the basis to conclude glyphosate is a probable human carcinogen. The plaintiff argues that in 2015, Monsanto's attorney contacted Dr. Tarone's employer, the International Epidemiology Institute (IEI), to learn more about IARC's policies and procedures. And for a three-hour meeting with IEI's then-CEO and Dr. Tarone, Monsanto paid $1,500 to IEI. It does not appear that Dr. Tarone received any cut of that payment. Other courts presiding over Roundup cases have recognized that Dr. Tarone is a non-retained expert. *E.g.*, Order at 3, *Alesi v. Monsanto*, Case No. 19SL-CC03617 (Mo. Cir. Ct. Aug. 21, 2022); Order at 34–35, *Cabllero v. Monsanto*, Case No. MSC19-01821 (Cal. Super. Ct. Jan. 24, 2020). The motion is denied.

5. Also in *Delorme-Barton*, the plaintiff moves to exclude the testimony of Dr. Murphy, a hygienist and epidemiologist. The plaintiff mainly seeks to exclude Dr. Murphy from opining that her use of the Dial N' Spray did not produce "driftable droplets" because Dr. Murphy reached that conclusion simply by using a Dial N' Spray outdoors once and eyeballing for any droplets. *Id.* The plaintiff is correct that this method is not very scientific or reliable, so Dr. Murphy is precluded from presenting this observation to the jury.

Nonetheless, Dr. Murphy did do an analysis that assumed the Dial N' Spray hose attachment produced driftable droplets. And even under this assumption in the plaintiff's favor, Dr. Murphy said his opinion remains unchanged—that the plaintiff's exposure to glyphosate was a small fraction of the regulatory limits for exposure set by California and the EPA.

Opp. at 5–6. This analysis may be presented to the jury.

The plaintiff also criticizes Dr. Murphy for using, in part, Google Earth images of the plaintiff's four properties to calculate the square footage that she would have sprayed Roundup. The plaintiff argues that the landscaping on some of the properties might have been different than when she was living at those locations. Perhaps that's true, but whether the landscapes are materially different from when the plaintiff resided there and whether Dr. Murphy underestimated the volume of Roundup used by the plaintiff goes to the weight of his testimony, not its admissibility. The plaintiff may attempt to discredit Dr. Murphy's property footage calculations at trial by explaining, if true, that the landscapes are now different. Relatedly, the plaintiff's assertion that Dr. Murphy is improperly challenging her credibility by providing footage estimates inconsistent with her recollection is unfounded.

Accordingly, the motion is granted in part and denied in part. Dr. Murphy may testify about the matters stated in his report, save for his observation that the Dial N' Spray does not produce driftable droplets.

6. The Court is considering holding a *Daubert* hearing in *Delorme-Barton* for Dr. Tomasetti. The outcome of that hearing could affect the admissibility of the testimony of Drs. Navarro and Slack. The Court will update the parties on its views

regarding these experts around the time of the *Daubert* hearings in the *Engilis* case.

7. In light of the foregoing and the Ninth Circuit's decision in *Hardeman*, Monsanto's motions and renewed motions for summary judgment on causation and non-causation grounds are denied in *Salas*, *Murdock* and *Glavanovits*. *See Hardeman v. Monsanto*, 997 F.3d 941, 955-56 (9th Cir. 2021); *id.* at 970–74. Suggestions of remand will be issued in these cases on or around August 30. The summary judgment motions in *Delorme-Barton* are also denied, and a suggestion of remand will be issued after the *Daubert* motions are resolved.

IT IS SO ORDERED.

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VINCE CHHABRIA
United States District
Judge