# ROUNDING OUT THE ROUNDUP LITIGATION: EXPRESS PREEMPTION UNDER FIFRA

## INTRODUCTION

Roundup, a consumer herbicide used to kill weeds, has been the subject of extensive product liability litigation. Plaintiffs within these lawsuits allege that glyphosate, Roundup's active ingredient, causes non-Hodgkin Lymphoma, a lymphatic cancer, and that Roundup's manufacturers failed to warn the public about the cancer risks associated with glyphosate.[1] In 1974, the Environmental Protection Agency (EPA) registered glyphosate-based pesticides as approved for sale and distribution in the United States without a cancer warning and has since repeatedly concluded that glyphosate is not likely carcinogenic to humans.[2] Nevertheless, since the International Agency for Research on Cancer's (IARC) 2015 finding that glyphosate is probably carcinogenic,[3] approximately 192,000 lawsuits have been filed against Roundup's manufacturers, Monsanto and Bayer,[4] alleging that Roundup and related pesticides containing glyphosate cause cancer.[5] Of these claims, roughly 131,000 claims "have been resolved or deemed to be ineligible," leaving more than 61,000 claims

1. *In re* Roundup Prods. Liab. Litig., 214 F. Supp. 3d 1346, 1347 (J.P.M.L. 2016).

2. *Glyphosate*, U.S. ENV'T PROT. AGENCY (May 9, 2025), https://perma.cc/J2FR-7HSW; *see also* Schaffner v. Monsanto Corp., 113 F.4th 364, 373 (3d Cir. 2024) (recounting history of EPA glyphosate evaluation); Nat'l Fam. Farm Coal. v. EPA, 966 F.3d 893, 905 (9th Cir. 2020).

3. INT'L AGENCY FOR RSCH. ON CANCER, WORLD HEALTH ORG., Q&A ON GLYPHOSPHATE 1 (Mar. 1, 2016), https://perma.cc/Z85E-6QXU. Expert agencies have conflicting opinions as to whether glyphosate has the potential to cause cancer. Although IARC has concluded that glyphosate is "probably carcinogenic to humans," other "national and international agencies . . . have reported that scientific evidence does not show that glyphosate causes cancer." Hardeman v. Monsanto Co., 997 F.3d 941, 951 (9th Cir. 2021).

4. Hannah Fingerhut & David A. Lieb, *Bayer Backs Broadened Effort to Shield Popular Weedkiller from Claims It Failed to Warn of Cancer*, ASSOCIATED PRESS (Feb. 10, 2025), https://apnews.com/article/bayer-roundup-glyphosate-pesticide-liability-cancer-7d7885e55e228fae8ed8ec7b207a65b8. Bayer acquired Monsanto through merger in 2018 and is a named defendant in the litigation. *Bayer Closes Monsanto Acquisition*, BAYER GLOB. (June 7, 2018), https://perma.cc/P3RT-KN4M. This Comment will collectively refer to both defendants as Monsanto.

5. *Schaffner*, 113 F.4th at 373–74 (citing *In re Roundup Prods. Liab. Litig.*, 214 F. Supp. 3d at 1348–49); *Managing the Roundup™ Litigation: Measures At-a-Glance*, BAYER GLOB. (Aug. 22, 2025), https://perma.cc/3YMA-99CT.

pending with over 4,000 cases consolidated in a federal Multi-District Litigation (MDL).[6]

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is the comprehensive federal statute that regulates pesticide registration and labeling in the United States. It outlines what constitutes label "misbranding" and empowers the EPA to promulgate regulations that enforce FIFRA's parameters.[7] Additionally, FIFRA vests pesticide registration approval authority in the EPA Administrator, stating that a pesticide may only be registered "if the Administrator determines that . . . its labeling . . . compl[ies] with the requirements of [FIFRA]."[8] Since Roundup's 1974 registration, the EPA has consistently registered Roundup without a cancer warning on its label and has never required Monsanto to include such a warning.[9]

The crux of the plaintiffs' failure-to-warn arguments in these cases is that Monsanto knew that glyphosate was potentially carcinogenic to humans and failed to include such a warning on its labeling, despite having the power to amend the label.[10] In countering, Monsanto has argued that it could not add a cancer warning to Roundup's label without EPA approval, and any state law that would require this warning is expressly preempted by FIFRA, as it would be "in addition to or different from" FIFRA's requirements.[11] In ruling on whether FIFRA expressly preempts state warnings claims, federal circuits have reached contradictory conclusions in applying the "parallel requirements" test set forth by the Supreme Court in *Bates v. Dow Agrosciences LLC*.[12] The heart of the circuit schism is whether courts, in evaluating the federal law component of the test, should simply use the general misbranding provision of FIFRA as the federal requirement or whether the more specific Preapproval Regulation in the Code of Federal Regulations should be incorporated into such requirement.

This Comment explores the present state of the federal appellate courts' interpretations of express federal preemption under FIFRA, illustrating the implications of a future Supreme Court decision

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6. *Managing the Roundup™ Litigation: Measures At-a-Glance*, *supra* note 5; *see also* Ronald V. Miller, Jr., *Monsanto Roundup Lawsuit Update,* LAWSUIT INFO. CTR. (Sept. 27, 2025), https://perma.cc/7FU7-BR3A.

7. *Schaffner*, 113 F.4th at 372. *See generally* 7 U.S.C. §§ 136–136y.

8. 7 U.S.C. § 136a(c)(5)(B).

9. *See* Hardeman v. Monsanto Co., 997 F.3d 941, 956 (9th Cir. 2021). Indeed, in a 2019 response to California law categorizing glyphosate as carcinogenic pursuant to Proposition 65, the EPA issued a letter challenging California's glyphosate classification and instructing "registrants to remove [Proposition 65] warning statements from labels of glyphosate-based pesticides." *Id.* at 951–52 (quoting Letter from Michael L. Goodis, EPA, Office of Pesticide Programs (Aug. 7, 2019)).

10. *See Hardeman*, 997 F.3d at 958; *Schaffner*, 113 F.4th at 382–83.

11. *See Hardeman*, 997 F.3d at 956; *Schaffner*, 113 F.4th at 380–81.

12. 544 U.S. 431, 447 (2005).

conclusively deciding the circuit split. Part I provides background concerning FIFRA's enactment, its misbranding and uniformity provisions, and the pesticide registration process. Part II delves into the express preemption landscape post-*Bates* that guided the opinions written by the Third, Ninth, and Eleventh Circuits, and juxtaposes their analyses. Part III analyzes the arguments posed by the conflicting circuit decisions, considering the countervailing policy concerns implicated by express preemption of state failure-to-warn claims and arguing why the Third Circuit correctly concluded that express preemption is proper. Finally, this Comment notes the consequences of a presumably forthcoming Supreme Court decision and concludes that express preemption is proper because the EPA's Preapproval Regulation establishes a requirement for preemption purposes.

## I. FIFRA'S STATUTORY AND REGULATORY FRAMEWORK

### *A. FIFRA's Mandate for Pesticide Registration*

Originally passed in 1947 as a labeling law and transformed by the 1972 enactment of the Federal Environmental Pesticide Control Act, FIFRA is a comprehensive regulatory statute that governs "the use, as well as the sale and labeling, of pesticides; regulate[s] pesticides produced and sold in both intrastate and interstate commerce; provide[s] for review, cancellation, and suspension of registration; and [gives the] EPA . . . enforcement authority."[13] Thus, FIFRA's current construction directly regulates pesticides[14] and authorizes the EPA to both supervise the pesticide industry and "prescribe regulations to carry out" its provisions.[15]

To sell and distribute pesticides in the United States, a manufacturer must first register the pesticide with the EPA by filing "a complete copy of the [pesticide's] labeling[,] . . . a statement of all claims to be made for it, any directions for its use[,] the complete formula of the pesticide[,] . . . [and] if requested . . . a full description of the tests made and the results thereof upon which the claims are based . . . ."[16] The EPA shall register a pesticide upon concluding that the application satisfies several conditions, including that "its labeling . . . compl[ies] with the requirements of [FIFRA]."[17]

### *B. FIFRA's Prohibition Against Misbranding of a Pesticide*

As one example of FIFRA's control over the pesticide industry, the Act's misbranding provision prohibits distributing or selling "any

13. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 991–92 (1984).
14. 7 U.S.C. § 136a(a).
15. *Id.* § 136a(a); 7 U.S.C. § 136w(a)(1).
16. 7 U.S.C. § 136a(a), (c)(1)(C)–(D), (F).
17. *Id.* § 136a(c)(5)(B).

pesticide which is . . . misbranded."[18] A pesticide's label is considered misbranded if it contains a statement that is "false or misleading in any particular" or fails to "contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment."[19] The EPA Administrator is vested with the authority to determine what constitutes misbranding and may deny registration or labeling amendments to a prior registration if the Administrator finds that the label is misbranded.[20] Furthermore, unless certain exceptions apply,[21] a pesticide's label cannot be modified and the pesticide cannot be distributed or sold with revised labeling without first obtaining EPA approval.[22] To do so without EPA approval would, in and of itself, constitute "misbranding."[23] Finally, pesticide manufacturers have a continuing obligation to report adverse environmental effects to the Agency, and, with certain exceptions, a manufacturer must submit information regarding incidents affecting humans.[24]

### *C. EPA Regulations Governing Amendments to a Preapproved Label*

Authorized by FIFRA, the EPA promulgated the Preapproval Regulation, governing the amendment of a pesticide's label after its original registration.[25] There are three manners in which a pesticide's label can be amended, depending on the substantive nature of the amendment: one requiring the manufacturer to submit an application for amended registration and seek EPA approval before modifying the label;[26] one requiring notification of minor modifications to the labeling not requiring EPA approval before use;[27] and one allowing label changes without notification to the EPA.[28]

Under § 152.44, "[e]xcept as provided by § 152.46, any modification in the . . . labeling . . . of a registered product must be submitted with an application for amended registration . . . [and] the application must be approved by the Agency before the product, as modified" can be distributed or sold.[29] Amendments allowed under § 152.46 by notification or without notification relate to "certain minor modifications . . . having no potential to cause unreasonable

18. *Id.* § 136j(a)(1)(E).
19. *Id.* § 136(q)(1)(A), (G).
20. *See id.* § 136a(c)(6).
21. *See infra* Section I.C.
22. 40 C.F.R. § 152.44(a) (2024).
23. *See* 7 U.S.C. § 136a(c)(5)(B), (7)(A).
24. *See id.* § 136d(a)(2); 40 C.F.R. § 159.184 (2024).
25. *See* 40 C.F.R. §§ 159.40, .44–.55 (2024).
26. *See id.* § 152.44.
27. *See id.* § 152.46(a).
28. *See id.* § 152.46(b).
29. 40 C.F.R. § 152.44(a) (2024).

adverse effects."[30] In 1998, through the public comment procedure,[31] the EPA issued Pesticide Registration Notice 98-10 (PRN 98-10), enumerating a list of modifications that may be made by notification and without EPA approval prior to the distribution of the product.[32] After listing several modifications that may be made by notification alone, PRN 98-10 contains a final catch-all provision that notification by a manufacturer under § 152.46 is sufficient if the modification "involve[s] no change in . . . precautionary statements."[33] "[P]recautionary statements provide the pesticide user with information regarding the toxicity, irritation, and dermal sensitization hazards associated with the use of the pesticide,"[34] and precautionary statements "pertaining to the hazards of the product and its uses must be approved by the Agency."[35]

Thus, by the plain wording of EPA-promulgated regulations, modifying a pesticide's label with respect to risks of "human hazard" constitutes a precautionary statement. Amendment of precautionary statements requires EPA approval under § 152.44 prior to label modification.[36] Absent EPA approval, a revised label would be considered non-compliant with 7 U.S.C. § 136a and constitute "misbranding."[37]

### *D. FIFRA's Preemptive "Uniformity" Requirement*

In 7 U.S.C. § 136v, titled "Authority of the States," FIFRA sets forth two limitations on the states' ability to regulate pesticides. The first limitation provides, "[a] [s]tate may regulate the sale or use of any federally registered pesticide or device in the [s]tate, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter."[38] More importantly, under the heading "Uniformity," the second limitation provides that a "[s]tate shall not impose or continue in effect any requirements for labeling . . . *in addition to or different from* those required under this subchapter."[39] This latter limitation, § 136v(b), constitutes an express preemption provision, the parameters of which are the subject of the circuit split discussed in this Comment.

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30. *Id.* § 152.46(a)(1), (b).

31. *See id.* § 152.46(a)(1).

32. *See* OFF. OF PREVENTION, PESTICIDES, & TOXIC SUBSTANCES, ENV'T PROT. AGENCY, PESTICIDE REGISTRATION NOTICE (PR) 98-10: NOTIFICATIONS, NON-NOTIFICATIONS AND MINOR FORMULATION AMENDMENTS (1998) [hereinafter PRN 98-10], https://perma.cc/2GES-X3ED.

33. *Id.* at 8.

34. OFF. OF PESTICIDE PROGRAMS, ENV'T PROT. AGENCY, LABEL REVIEW MANUAL ch. 7, at 2 (2018) [hereinafter PESTICIDE LABEL REVIEW MANUAL ch. 7].

35. 40 C.F.R. § 156.70(c) (2024).

36. *Id.*

37. 7 U.S.C. § 136j(a)(1)(E).

38. *Id.* § 136v(a).

39. *Id.* § 136v(b) (emphasis added).

## II. DIVERGING CIRCUIT APPROACHES TO FIFRA'S PREEMPTIVE EFFECT

### *A. The* Bates *"Parallel Requirements" Test*

In *Bates v. Dow Agrosciences LLC*, the Supreme Court held that FIFRA's § 136v(b) "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations."[40] In so holding, the Supreme Court established the two-pronged "parallel requirements" test to determine whether a state law requirement regarding pesticide labeling was preempted by § 136v(b).[41] First, the state requirement must be "for labeling or packaging," and second, "it must impose a labeling or packaging requirement that is 'in addition to or different from those required under this subchapter.'"[42]

Therefore, "to apply the parallel requirements test, a court must identify the labeling requirements imposed under state law and under FIFRA," compare each rule, and "determine whether a pesticide label that violates the state requirement would also violate" FIFRA and its implementing regulations.[43] FIFRA's "Uniformity" clause, § 136v(b), does not preempt state laws "that are fully consistent with federal requirements,"[44] and the state law requirement "need not be phrased in the identical language" as FIFRA's provisions.[45] For example, state laws awarding remedies against manufacturers who breach a FIFRA-imposed requirement are not preempted by § 136v(b), even if FIFRA itself does not provide such remedies.[46]

However, the Supreme Court held that "[s]tate-law requirements must also be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards."[47] For example, state law would be expressly preempted if a law required the word "CAUTION" on a label when 40 C.F.R. § 156.64 instead required the word "DANGER" to be used.[48] Thus, the *Bates* Court specifically dictated that EPA regulations could satisfy the federal law component under the parallel requirements test and that "a manufacturer should not be held liable under a state labeling requirement . . . unless the manufacturer is also liable for misbranding as defined by FIFRA."[49]

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40. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 452 (2005).
41. *Id.* at 444.
42. *Id.* (emphasis omitted) (quoting 7 U.S.C. § 136v(b)).
43. Schaffner v. Monsanto Corp., 113 F.4th 364, 380 (3d Cir. 2024).
44. *Bates*, 544 U.S. at 452.
45. *Id.* at 454.
46. *Id.* at 448.
47. *Id.* at 453.
48. *Id.*
49. *Id.* at 454 (further pointing out that a jury should be instructed on relevant FIFRA standards "as well as any regulations that add content to those standards").

In other words, when a pesticide label violates both state and federal requirements, there is no preemption; however, when a label only violates the state law, there is federal preemption.[50]

### *B. The Parties' Arguments on Applying the* Bates *Test*

Plaintiffs have asked courts applying the parallel requirements test to compare state failure-to-warn claims with FIFRA's general misbranding provision codified at 7 U.S.C. § 136j(a)(1)(E).[51] These plaintiffs argued that the EPA's Preapproval Regulation is not a preemptive federal requirement because it simply establishes a rebuttable presumption that a pesticide's label is not misbranded.[52] Furthermore, plaintiffs asserted that the Preapproval Regulation does not conclusively establish whether a pesticide is misbranded because manufacturers may amend their labels without EPA approval through notification, and manufacturers have the continuing obligation to inform the EPA of adverse effects discovered post-registration.[53] By this reasoning, plaintiffs contended that the Preapproval Regulation fails to establish a federal requirement due to the registration process's inconclusive and revocable nature.[54] Therefore, plaintiffs proposed that FIFRA's general misbranding provision in 7 U.S.C. § 136j(a)(1)(E) is the relevant federal comparison to state laws and that preemption is improper because state failure-to-warn claims are narrower and consistent with this provision.[55]

In its defense, Monsanto has asserted that the state law failure-to-warn claims are preempted by FIFRA because the EPA approved Roundup's label in its original registration, the EPA has repeatedly classified glyphosate as non-carcinogenic since 1974, and that any changes to the label that plaintiffs argue should have been made regarding the alleged carcinogenicity of glyphosate would constitute a "precautionary statement" pursuant to PRN 98-10 and, therefore, require EPA approval.[56] Monsanto contends that the EPA's Preapproval Regulation must necessarily be read in conjunction with the general misbranding provision because the Preapproval

50. Schaffner v. Monsanto Corp., 113 F.4th 364, 380 (3d Cir. 2024).

51. Hardeman v. Monsanto Co., 997 F.3d 941, 955 (9th Cir. 2021); Carson v. Monsanto Co., 92 F.4th 980, 991–92 (11th Cir. 2024); *Schaffner*, 113 F.4th at 381.

52. *Hardeman*, 997 F.3d at 957; *Carson*, 92 F.4th at 992; *Schaffner*, 113 F.4th 364 at 380.

53. *Hardeman*, 997 F.3d at 958–60; *Carson*, 92 F.4th at 998–99; *Schaffner*, 113 F.4th 364 at 382–83.

54. *Hardeman*, 997 F.3d at 956; *Carson*, 92 F.4th at 993; *Schaffner*, 113 F.4th 364 at 382.

55. *Hardeman*, 997 F.3d at 958; *Carson*, 92 F.4th at 992; *Schaffner*, 113 F.4th 364 at 380.

56. *Hardeman*, 997 F.3d at 959–60; *Carson*, 92 F.4th 980 at 986; *Schaffner*, 113 F.4th 364 at 370.

Regulation mandates when a label change requires EPA approval.[57] Additionally, Monsanto has relied on the Supreme Court's decision in *Riegel v. Medtronic, Inc.*,[58] where the Court held that the Medical Device Amendments' (MDA) premarket approval scheme for medical devices established a "requirement" for preemption purposes.[59] In turn, Monsanto has claimed that the EPA's approval process mirrors the MDA's premarket approval structure because, under both processes, registrants must submit extensive supporting data in their applications and agency approval drastically limits changes that can be made to the approved label.[60]

### *C. The Ninth and Eleventh Circuits Reject Express Federal Preemption*

The Ninth and Eleventh Circuits were the first federal circuits to review the express preemption issue posed by FIFRA.[61] Both concluded that the EPA's Preapproval Regulation did *not* constitute a federal "requirement" under the *Bates* "parallel requirements" test and that federal law did not expressly preempt the state laws.[62]

Following the Supreme Court's direction in *Bates*, the Ninth and Eleventh Circuits analyzed the parallel requirements test, requiring that California's and Georgia's state laws, respectively, be "equivalent to and fully consistent with FIFRA" in order to survive preemption.[63] The circuits agreed with the plaintiffs' arguments, deciding that the Preapproval Regulation did not establish a federal requirement and that the Supreme Court's *Riegel* decision was not instructive to the FIFRA preemption issue.[64] Thus, both circuits held that FIFRA's general "misbranding" provision, and not the Preapproval Regulation promulgated at 40 C.F.R. pt. 152, was the proper federal law for comparison.[65]

#### 1. *The Preapproval Regulation Was Not the Comparable*

57. *Hardeman*, 997 F.3d 941 at 958; *Carson*, 92 F.4th at 987; *Schaffner*, 113 F.4th 364 at 380.

58. 552 U.S. 312 (2008).

59. *See Hardeman*, 997 F.3d at 956 n.6; *Carson*, 92 F.4th at 993–94; *Schaffner*, 113 F.4th at 387.

60. 7 U.S.C. § 136a(c)(1)(C)–(D), (F); *Carson*, 92 F.4th at 993–94.

61. The Ninth Circuit decision, *Hardeman v. Monsanto Co.*, was decided in 2021, and writs taken by Monsanto were denied by the Supreme Court. Hardeman v. Monsanto Co., 997 F.3d 941 (2021), *cert denied*, 142 S. Ct. 2834 (2022). The Eleventh Circuit decision discussed in this Comment, Carson v. Monsanto Co., 92 F.4th 980 (11th Cir. 2024), was rendered after the original panel decision was vacated on rehearing *en banc*. 51 F.4th 135 (11th Cir. 2022), *vacated en banc*, 72 F.4th 1261 (11th Cir. 2023). Following the Eleventh Circuit decision discussed in this Comment, no writs were taken to the Supreme Court.

62. *See Hardeman*, 997 F.3d at 958; *Carson*, 92 F.4th at 995–96.

63. *Hardeman*, 997 F.3d at 954–58; *Carson*, 92 F.4th at 990–96.

64. *Hardeman*, 997 F.3d at 956 n.6, 957 n.7; *Carson*, 92 F.4th at 992–95.

65. *Hardeman*, 997 F.3d at 955–56; *Carson*, 92 F.4th at 991–92.

*"Federal Requirement"*

Both the Ninth and Eleventh Circuits found that the Preapproval Regulation did not preempt state law claims because it was not a "requirement."[66] Introducing a standard not espoused in *Bates*,[67] the Ninth Circuit stated, "only where there is a relevant EPA action carrying the force of law are state failure-to-warn claims prohibited from imposing requirements inconsistent with that action."[68] In finding that the Preapproval Regulation did not carry the "force of law," the Ninth Circuit relied on the rebuttable presumption in 7 U.S.C. § 136a(f)(2) that "registration of an article [shall not] be construed as a defense for the commission of any offense under [FIFRA]. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with [FIFRA's] registration provisions."[69] The court reasoned that the "EPA's approval of Roundup's label is prima facie evidence of FIFRA compliance,"[70] and that "[i]t would defy logic to say a rebuttable presumption carries the force of law necessary to have preemptive effect, as doing so would deny any ability to rebut the presumption."[71]

Three years later, the Eleventh Circuit echoed the Ninth Circuit's reasoning, stating that EPA approvals are revocable and "provide only 'prima facie evidence,' not conclusive proof, that a pesticide is not misbranded."[72] Because the EPA's approval is "neither conclusive nor irrevocable," the Eleventh Circuit similarly found that Monsanto failed to establish the Preapproval Regulation as the comparable federal requirement.[73]

*2. Distinguishing the Riegel Decision*

Next, the Ninth and Eleventh Circuits refuted Monsanto's argument that the *Riegel* decision is instructive due to the similarity between the MDA and FIFRA.[74] The Ninth Circuit summarily disposed of the argument, noting that, although the preemption clauses are similar, the MDA does not contain a rebuttable presumption provision like 7 U.S.C. § 136a(f)(2), "which clarifies that

66. *Hardeman*, 997 F.3d at 957 & n.7; *Carson*, 92 F.4th at 992–95.

67. Indeed, the *Bates* Court never questioned that an EPA regulation alone could qualify as the federal law in the parallel requirements test, as the Court specifically referred to regulations such as 40 C.F.R. § 156.64 as "giv[ing] content to FIFRA's misbranding standards" and, thus, preemptive under § 136v(b). Bates v. Dow Agrosciences LLC, 544 U.S. 431, 453 (2005).

68. *Hardeman*, 997 F.3d at 957 (emphasis omitted).

69. *Id.* at 956 (emphasis omitted) (quoting 7 U.S.C. § 136a(f)(2)).

70. *Id.* at 956.

71. *Id.* at 957.

72. Carson v. Monsanto Co., 92 F.4th 980, 993 (11th Cir. 2024).

73. *Id.*

74. *See Hardeman*, 997 F.3d at 956 n. 6; *Carson*, 92 F.4th at 994–95.

[EPA] approval of a label is not determinative of compliance with [FIFRA]."[75]

The Eleventh Circuit more thoroughly addressed Monsanto's *Riegel* argument, drawing distinctions between the EPA and the Food and Drug Administration (FDA) processes.[76] The Eleventh Circuit noted that the FDA's premarket approval process is more "rigorous" than the EPA's preapproval system.[77] Additionally, FIFRA and the MDA differ in their statutory structure as FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation,"[78] while the MDA's structure is "decidedly centralized."[79] Furthermore, the Eleventh Circuit stated that the FDA's premarket approval process constituted a "requirement" while the EPA's process did not because, "[o]nce the FDA has approved a device, manufacturers cannot change a device's label . . . without the FDA's permission."[80] The court distinguished the EPA's approval process, because "through its ongoing reporting requirements, 'FIFRA contemplates that pesticide labels will evolve over time . . . .'"[81] Thus, the court surmised that federal preemption would undermine FIFRA's goal of pesticide evolution as "state tort litigation 'may lead manufacturers to petition [the EPA] to allow more detailed labeling of their products,' or the Agency 'itself may decide that revised labels are required in light of' the litigation."[82] Based on these perceived differences between the Acts, the Eleventh Circuit also distinguished *Riegel*.[83]

*3. State Warnings Laws Were Narrower Than FIFRA's Misbranding Provision*

Declining to incorporate the Preapproval Regulation into the federal component of the parallel requirements test, both circuits held that FIFRA's general misbranding provision was the proper federal law to compare to the respective state laws.[84] Each circuit interpreted FIFRA's misbranding provision as a strict liability standard and

75. *Hardeman*, 997 F.3d at 956 n.6.

76. *Carson*, 92 F.4th at 994–95.

77. *Id.* at 994. The court noted that the FDA "spends an average of 1,200 hours reviewing each application," and grants premarket approval only if it finds a "reasonable assurance" of the device's "safety and effectiveness." *Id.* (first quoting Riegel v. Medtronic, Inc., 552 U.S. 312, 318 (2008); then quoting 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.* (citing § 360e(d)(1)(A)).

78. *Id.* at 994 (quoting Bates v. Dow Agrosciences LLC, 544 U.S. 431, 450 (2005)).

79. *Id.*

80. *Id.* at 995 (citing 21 U.S.C. § 360e(d)(5)(A)(i)).

81. *Id.* (quoting *Bates*, 544 U.S. at 451).

82. *Id.* (quoting *Bates*, 544 U.S. at 451).

83. *Id.*

84. *See* Hardeman v. Monsanto Co., 997 F.3d 941, 955 (9th Cir. 2021); *Carson*, 92 F.4th at 991–92.

reasoned that state failure-to-warn laws that are narrower than FIFRA's strict liability cannot be "in addition to or different from" FIFRA's misbranding provision and are not expressly preempted.[85] Under this interpretation, failure-to-warn laws that impose negligence standards are "narrower" and therefore not "in addition to or different from" this provision. As such, the circuits concluded that there was no federal preemption because the state laws were narrower than FIFRA's misbranding provision.[86]

### *D. The Third Circuit Holds That FIFRA Expressly Preempts State Warnings Law*

*Schaffner v. Monsanto Corp.*[87] is the first federal appellate decision to conclude that FIFRA expressly preempts certain state tort claims, directly countering the reasoning of the Ninth and Eleventh Circuits.[88] Just as in the sister circuits, the primary dispute in *Schaffner* centered on how the court should identify which federal requirement must be compared to the applicable state failure-to-warn law, Pennsylvania's here, when applying the parallel requirements test.[89] To decide whether the Pennsylvania Duty to Warn was preempted, the Third Circuit similarly applied the parallel requirements test created in *Bates* and methodically analyzed the issue in a three-step approach: (1) determining which EPA regulations give content to FIFRA's misbranding standards, (2) determining whether, under § 136v(b), the preapproval process establishes a "requirement" for preemption purposes, and (3) applying the conclusions of the first two steps to the parallel requirements test.[90]

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85. *Hardeman*, 997 F.3d at 955–56; *Carson*, 92 F.4th at 992.

86. *Hardeman*, 997 F.3d at 955; *Carson*, 92 F.4th at 992. Notably, California's law requires manufacturers to warn of "known or knowable" health risks—a strict liability standard—or to warn of risks "a reasonably prudent manufacturer would have known and warned about"—a negligence standard. *Hardeman*, 997 F.3d at 955 (quoting Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 310 (Cal. Ct. App. 2008)). The Ninth Circuit therefore concluded that California's negligence standard is narrower than FIFRA's misbranding provision and, "at minimum, [FIFRA is] consistent with California's requirement under strict liability." *Id.* In *Carson*, the Eleventh Circuit determined that Georgia's law imposed a negligence standard, requiring proof that the manufacturer "knows or reasonably should know of [a] danger," which the court found "impose[d] less of a duty on pesticide manufacturers than FIFRA." *Carson*, 92 F.4th at 991–92 (emphasis omitted) (quoting Chrysler Corp. v. Batten, 450 S.E.2d 208, 211 (Ga. 1994)).

87. 113 F.4th 364 (3d Cir. 2024).

88. *See id.* at 371.

89. *Id.* at 380.

90. *Id.* at 381.

1. *Regulations That Give Content to FIFRA's Misbranding Standard*

To determine whether the Preapproval Regulation establishes a federal requirement under FIFRA, the Third Circuit first dissected how the Preapproval Regulation gives content to FIFRA's misbranding provision. The court recounted that the EPA is empowered "to prescribe regulations to carry out" its provisions and has done so through regulations governing the registration of pesticide labels.[91] Once a pesticide's label is approved by the EPA, the court noted that the Preapproval Regulation further governs the label's modification, as "any modification in the . . . labeling . . . of a registered product must be submitted with an application for amended registration" except as provided by 40 C.F.R. § 152.46.[92] Moreover, "[i]f an application for amended registration is required," it must "be approved by the Agency before the product, as modified, may legally be distributed."[93] Thus, the circuit concluded that whether Monsanto could add a cancer warning to its label depended on whether cancer warnings require an application for amended registration.[94]

Referring to § 152.46, the court noted that a pesticide may be modified without EPA approval via the notice process when the label change contains "minor modifications to registration" that have "no potential to cause unreasonable adverse effects."[95] The types of modifications sanctioned under § 152.46 are listed in PRN 98-10, which specify the labeling amendments that "may be accomplished by notification."[96]

The Third Circuit concluded that "PRN 98-10 does not allow the [c]ancer [w]arning to be added by notification."[97] PRN 98-10 enumerates a list of modifications that may be made by notification, and the court concluded that the list does not enumerate a category that might allow for the addition of a cancer warning to a pesticide's label via notification.[98] Furthermore, the Third Circuit noted that the final catch-all provision in PRN 98-10 "expressly provides that modification by notification must 'involve no change in . . . precautionary statements.'"[99] Precautionary statements warn pesticide users of "the toxicity . . . [and] hazards associated with the

91. *Id.* at 382 (first citing 7 U.S.C. § 136w(a)(1); and then citing 40 C.F.R. §§ 152.40–.55 (2024)).

92. *Id.* (quoting 40 C.F.R. § 152.44(a) (2024)).

93. *Id.* (quoting 40 C.F.R. § 152.44(a) (2024)).

94. *Id.* at 383–85.

95. *Id.* at 383 (quoting 40 C.F.R. § 152.46(a)(1) (2024)).

96. *Id.* (quoting PRN 98-10, *supra* note 32, at 8). The EPA issued Public Registration Notice 98-10 in 1998 to clarify registration modification through notification. *See supra* Section I.C.

97. Schaffner v. Monsanto Corp., 113 F.4th 364, 383 (3d Cir. 2024).

98. *Id.*

99. *Id.* (quoting PRN 98-10, *supra* note 32, at 8).

use of the pesticide,"[100] and precautionary statements "pertaining to the hazards of the product and its uses must be approved by the Agency."[101] Because a cancer warning would caution that Roundup may cause a deadly disease, the Third Circuit concluded that a cancer warning constituted a "[s]pecific statement pertaining to the hazards of [Roundup] and its uses,"[102] and, therefore, addition of a cancer warning to Roundup's label could not be accomplished under § 152.46 and "must be approved by the Agency."[103]

*2. Whether the Preapproval Regulation Establishes a Federal Requirement*

Finding that the Preapproval Regulation prohibited Monsanto from adding a cancer warning to its label without EPA approval,[104] the Third Circuit held that the regulation established a federal requirement based on two primary lines of reasoning: (1) the Preapproval Regulation met the definition of "requirement" adopted by the Supreme Court in *Bates*, and (2) the Supreme Court's decision in *Riegel* indicated that registration schemes such as the Preapproval Regulation carry preemptive effect.[105]

The Third Circuit found instructive the Supreme Court's holdings in *Bates* that "[a] requirement is a rule of law that must be obeyed"[106] and in *Perez v. Mortgage Bankers Ass'n*[107] "'that [r]ules issued through the notice-and-comment process,' such as section 152.44(a) 'have the force and effect of law.'"[108] The Third Circuit held that the Preapproval Regulation was a requirement because it was promulgated to "revise[] procedures for the registration of pesticide products under section 3 of [FIFRA]."[109] Therefore, the Preapproval Regulation was enacted under the EPA's authority "to prescribe regulations to carry out the provisions of [FIFRA]," establishing a requirement under § 136v(b).[110]

The Third Circuit noted that, in *Bates*, the Supreme Court held that the duty to honor a label's express warranty does not impose a requirement because it fails to compel a manufacturer to say anything in particular in its warranty, but instead simply requires a manufacturer to uphold its "contractual obligation to honor an

100. *Id.* at 384 (quoting PESTICIDE LABEL REVIEW MANUAL ch. 7, supra note 34, at 2).
101. *Id.* at 385 (quoting 40 C.F.R. § 156.70(c) (2024)).
102. *Id.* (quoting 40 C.F.R. § 156.70(c) (2024)).
103. *Id.* (quoting 40 C.F.R. § 156.70(c) (2024)).
104. *Id.* at 385.
105. *Id.* at 386–89.
106. *Id.* (quoting Bates v. Dow Agrosciences LLC, 544 U.S. 431, 445 (2005)).
107. 575 U.S. 92 (2015).
108. *Schaffner*, 113 F.4th at 386 (quoting *Perez*, 575 U.S. at 96).
109. *Id.* (quoting Pesticide Regulation Procedures, 53 Fed. Reg. 15952 (May 4, 1988) (to be codified at 40 C.F.R. pt. 152)).
110. *Id.* (quoting 7 U.S.C. § 136w(a)(1)).

express warranty."[111] Although it can be argued that the Preapproval Regulation similarly fails to require particular language, the Third Circuit believed this argument was unfounded because the EPA will only approve "labels that it deems compliant with federal law."[112] Thus, following *Bates*, the Third Circuit found that "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 content that the EPA deems compliant with federal law."[113]

The Third Circuit bolstered its determination that the Preapproval Regulation establishes a requirement under federal law by comparing FIFRA's regulatory structure to the MDA process discussed in the 2008 Supreme Court's *Riegel* decision.[114] In *Riegel*, the Court held that the MDA premarket approval scheme established a requirement for preemption purposes.[115] The Third Circuit initially drew comparisons between FIFRA's preemption provision—a "[s]tate shall not impose or continue in effect any requirements for labeling . . . in addition to or different from those required" by FIFRA[116]—which "closely echoes" the MDA's preemption provision—a state shall not "impos[e] a requirement for a medical device 'which is different from, or in addition to, any requirement applicable under'" the MDA.[117] Next, the court compared the FDA's premarket approval process with that of the Preapproval Regulation.[118] The circuit focused specifically on the *Riegel* Court's holding that "premarket approval does establish 'requirements' for purposes of the MDA's preemption provision" and that this "holding rested squarely on the two regulatory elements common to both premarket approval under the MDA and pesticide registration under FIFRA—namely, the safety review that regulated products must undergo before they are marketed, and the prohibition in subsequent modifications of such products once they are reviewed and approved."[119] The Third Circuit reasoned that "[i]f the prohibition on modifying medical devices following their approval . . . establishes 'requirements' . . . then FIFRA's regulatory approach, which employs the same two elements,

111. *Id.* at 386–87.

112. *Id.* at 387.

113. *Id.* (citation omitted) (quoting Bates v. Dow Agrosciences LLC, 544 U.S. 431, 445 (2005)).

114. *Id.* at 387–89.

115. Riegel v. Medtronic, Inc., 552 U.S. 312, 322 (2008).

116. 7 U.S.C. § 136v(b).

117. *Schaffner*, 113 F.4th at 387 (quoting 21 U.S.C. § 360k(a)(1)). Indeed, the Supreme Court in *Bates* observed that the MDA and FIFRA preemption clauses are "similarly worded." *Bates*, 544 U.S. at 447.

118. *Schaffner*, 113 F.4th at 387.

119. *Id.* at 388.

should likewise establish 'requirements' under a similar preemption provision."[120]

The Court in *Riegel* also noted that laws do not establish a preemptive requirement if they fail to require products to "take any particular form for any particular reason."[121] Because, in "approving applications for a new or amended pesticide registration, the EPA substantively restricts what precautionary statements may appear on a pesticide's label," the Third Circuit held that the Preapproval Regulation requires labels to "take a particular form" and therefore constitutes a "requirement" under § 136v(b).[122]

*3. Applying the Parallel Requirements Test*

In applying the parallel requirements test, the Third Circuit held that *Bates* instructs courts to identify the federal component "at the more specific level."[123] The Third Circuit pointed to the Supreme Court's guidance in applying the parallel requirements test through its "illustrations of state failure-to-warn claims that would not be equivalent to the relevant [f]ederal [requirement] and would therefore be preempted."[124] One such illustration indicated that "[a] state-law requirement . . . employ[ing] 'DANGER' on a pesticide label would thus be preempted were it 'inconsistent with 40 CFR § 156.64 (2004), which specifically assigns ["DANGER" and "CAUTION"] to particular classes of pesticides based on their toxicity.'"[125] The Third Circuit aptly noted that the *Bates* Court "did not consider or even mention the statutory definition of misbranding" in this illustration, indicating that state laws should be compared to specific regulations, where applicable, for preemption purposes.[126]

The Third Circuit also concluded that the Preapproval Regulation gives content to FIFRA's misbranding provision similar to the *Bates* Court's instruction that 40 C.F.R. § 156.64 gives content to the same misbranding provision.[127] Just as § 156.64 does not define misbranding but, instead, prohibits labels from lacking "requisite signal words"—CAUTION or DANGER—where applicable,[128] the Preapproval Regulation does not define "misbranded"; it simply states that the EPA will approve a pesticide label only if it "has determined that the product is not misbranded as that term is defined in FIFRA."[129]

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120. *Id.* at 388–89.

121. Riegel v. Medtronic, Inc., 552 U.S. 312, 323 (2008) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 493 (1996)).

122. *Schaffner*, 113 F.4th at 389.

123. *Id.* at 390.

124. *Id.*

125. *Id.* (quoting Bates v. Dow Agrosciences LLC, 544 U.S. 431, 453 (2005)).

126. *Id.* at 391.

127. *Id.*

128. *Id.*

129. *Id.* (quoting 40 C.F.R. § 152.112(f)).

Additionally, the Third Circuit concluded that the Preapproval Regulation's bar on modifying an approved label to include a precautionary statement—such as a cancer warning—renders such an alteration an act of misbranding.[130] Therefore, the Third Circuit concluded that "[e]ach regulation requires pesticide labels to conform to the EPA's opinion as to whether specific labels would constitute misbranding, and thus each 'give[s] content to' the broad requirement that such labels not be misbranded."[131] As a result, the Third Circuit held that the federal requirement imposed by the Preapproval Regulation mandated that Monsanto omit the cancer warning, while the Pennsylvania Duty to Warn mandated the inclusion of the cancer warning.[132] Because the state requirement is "in addition to or different from" the federal requirement, the Third Circuit held that federal preemption was proper.[133]

## III. ANALYSIS

After the newly created circuit split, the Supreme Court is now more likely to grant certiorari on the issue of FIFRA's express preemption clause, a decision that will carry extensive implications for federal preemption law and state tort remedies, undoubtedly strengthening one and weakening the other. The forthcoming analysis addresses the arguments and decisions of each circuit involved in this preemptive battle, first explaining why the Third Circuit correctly held that preemption was proper, and second, analyzing the policy considerations encompassing federal preemption within FIFRA's arena.

### *A. Why the Third Circuit Correctly Favored Federal Preemption*

As evidenced above, the Ninth and Eleventh Circuits differ from the Third Circuit in their legal interpretations in several ways. Although each circuit essentially consulted the same statutory, regulatory, and case law, the Third Circuit managed to arrive at a conclusion opposite its sister circuits. Although alone in its decision, the Third Circuit correctly concluded that federal preemption was proper for three principal reasons.[134] First, the Eleventh Circuit

130. *Id.*

131. *Id.* (quoting Bates v. Dow Agrosciences LLC, 544 U.S. 431, 453 (2005)).

132. *Id.* at 393.

133. *Id.* at 393–94.

134. Since the Third Circuit's decision in *Schaffner*, the Missouri Court of Appeals and the Pennsylvania Superior Court appear to be the only courts to render a decision concerning this nationwide dispute. *See* Durnell v. Monsanto Co., 707 S.W.3d 828, 834 (Mo. Ct. App. 2025); Caranci v. Monsanto Co., 338 A.3d 151, 167–70 (Pa. Super. Ct. May 8, 2025). Regarding Monsanto's argument that FIFRA expressly preempts state failure-to-warn claims, the Missouri Court of Appeals followed the "weight of authority" provided by the Ninth and Eleventh Circuit decisions in holding that FIFRA does not expressly preempt these state laws. *Durnell*, 707 S.W.3d at 834. Nevertheless, the Missouri appellate court did

incorrectly followed an underlying presumption-against-preemption analysis espoused in *Bates* that has since been rejected by the Supreme Court in the context of express preemption.[135] Second, both the Ninth and Eleventh Circuits inaccurately branded the EPA's preapproval of a pesticide label as simply prima facie evidence that lacks the "force of law."[136] In doing so, the two circuits failed to properly incorporate the Preapproval Regulation into the federal requirement, instead identifying FIFRA's general misbranding provision as the federal requirement, which effectively makes all state law requirements "parallel" to the federal requirement and, thus, not preempted.[137] Third, both the Ninth and Eleventh Circuits erroneously distinguished the Supreme Court's ruling in *Riegel* regarding the MDA from FIFRA's very similarly structured regulatory process, improperly preserving the circuits' desire to uphold state law tort remedies in the face of express federal preemption.[138]

*1. The Misplaced Presumption Against Preemption*

In *Bates*, the Supreme Court stated that "[t]he long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly."[139] However, more recently, in 2016, the Supreme Court stated that when a statute "'contains an express pre-emption clause,' [the Court] do[es] not invoke any presumption against pre-emption but instead 'focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress's pre-emptive intent.'"[140] This view was also set forth in Justice Thomas's concurrence in *Bates*, where he noted that the majority's presumption requiring an interpretation of § 136v(b) "that disfavors pre-

not address Monsanto's argument that the Preapproval Regulation is the proper federal requirement to be compared to state requirements, and the Missouri court failed to consider the impact of the Supreme Court's *Riegel* decision with respect to the preemptive effect of federal agency registration processes. Similarly, the Pennsylvania court held that federal preemption was improper, primarily following the Ninth and Eleventh Circuits' rebuttable presumption reasoning. *Caranci*, 338 A.3d at 168–69. However, the superior court rejected *Schaffner*'s reasoning without properly understanding or discussing how the inability to amend precautionary statements absent additional EPA approval creates a federal requirement for Monsanto. *Id.* at 169–70. As in Missouri, the superior court did not discuss the effect of *Riegel*.

135. *See infra* Section III.A.1.

136. *See infra* Section III.A.2.

137. *See infra* Sections III.A.1–2.

138. *See infra* Section III.A.3.

139. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005).

140. Puerto Rico v. Franklin Cal. Tax-Free Tr., 579 U.S. 115, 125 (2016) (quoting Chamber of Comm. v. Whiting, 563 U.S. 582, 594 (2011)).

emption . . . . does not apply . . . when Congress has included within a statute an express pre-emption provision."[141] Justice Thomas stated that the Court's task is not to resolve whether Congress silently intended to preserve state tort claims but to "determine which state-law claims § 136v(b) pre-empts, without slanting the inquiry in favor of either the Federal Government or the States."[142]

In *Carson v. Monsanto Co.*,[143] the Eleventh Circuit "gave lip service to the abolition of the presumption against preemption"[144] when recognizing the Eleventh Circuit en banc panel's clarification that "[e]xpress preemption turns primarily on 'the language of the preemption statute and the statutory framework surrounding it.'"[145] Nevertheless, the Eleventh Circuit continued to follow an underlying presumption-against-preemption analysis when stating that "FIFRA is not 'a sufficiently comprehensive statute to justify an inference that Congress had occupied the field to the exclusion of the States.'"[146] Furthermore, at the end of its analysis, the Eleventh Circuit denoted "the long history of tort litigation" as evidence of the unlikelihood "that Congress considered a relatively obscure provision like [section] 136v(b) to give pesticide manufacturers virtual immunity from . . . tort liability."[147]

First, the obscurity of a federal statute's express preemption provision is questionable, and second, the goal of an express preemption provision is to provide uniform standards, whether or not the uniformity disadvantages states.[148] As the Supreme Court said, removal of "'judicial recourse' [such as state tort remedies] . . . . is exactly what a pre-emption clause . . . does by its terms."[149] Although not entirely central to the Eleventh Circuit's reasoning, the circuit's underlying presumption against preemption and desire to preserve state tort remedies seemed to conflict with its duty to determine whether express preemption was proper here.

### *2. The Preapproval Regulation Establishes a Requirement*

According to the Supreme Court, "[a] requirement is a rule of law that must be obeyed."[150] The Ninth and Eleventh Circuits found that whether an EPA action establishes a requirement under FIFRA is

141. *Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part).

142. *Id.*

143. 92 F.4th 980 (11th Cir. 2024).

144. James M. Beck, *Rounding Up the Eleventh Circuit Zombie*, DRUG & DEVICE L. (Mar. 11, 2024), https://perma.cc/7HJM-GTVG.

145. *Carson*, 92 F.4th at 989 (quoting Carson v. Monsanto Co., 72 F.4th 1261, 1267 (11th Cir. 2023) (en banc)).

146. *Id.* at 989 (quoting *Bates*, 544 U.S. at 441–42).

147. *Id.* at 995 (quoting *Bates*, 544 U.S. at 449–50).

148. *See generally* Gibbons v. Ogden, 22 U.S. 1 (1824).

149. Riegel v. Medtronic, Inc., 552 U.S. 312, 326 (2008).

150. *Bates*, 544 U.S. at 445.

based upon whether the "Agency action carries the force of law."[151] Both circuits concluded that EPA registration lacks the force of law because it only creates a rebuttable presumption as to whether a pesticide label is misbranded.[152] Allowing a rebuttable presumption to carry the force of law, in the Ninth Circuit's words, "would defy logic . . . [and] deny any ability to rebut the presumption."[153] However, the Supreme Court has concluded that regulatory "'[r]ules issued through the notice-and-comment process,' such as § 152.44(a), 'have the force and effect of law.'"[154] Thus, the Preapproval Regulation carries the force of law, and the true question is whether the EPA's registration and amendment process must be obeyed by manufacturers.[155]

Considering the rebuttable presumption language in § 136a(f)(2) and FIFRA's ongoing reporting requirements,[156] the Eleventh Circuit stated that the inconclusive and revocable nature of an approved label undermined the proposition that registration under the Preapproval Regulation established a requirement for purposes of preemption.[157] True, "[i]f the EPA automatically approved any proposed pesticide label without reviewing its contents in whole or in part," then EPA registration would not pose a requirement.[158] Instead, the EPA only approves "labels that it deems compliant with federal law."[159]

The Third Circuit itself addressed the rebuttable presumption argument and agreed that EPA approval is not necessarily

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151. *Carson*, 92 F.4th at 993; *accord* Hardeman v. Monsanto Co., 997 F.3d 941, 957 (9th Cir. 2021).

152. *See supra* Section II.B.

153. *Hardeman*, 997 F.3d at 957.

154. Schaffner v. Monsanto Corp., 113 F.4th 364, 386 (3d Cir. 2024) (quoting Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 96 (2015)).

155. Notably, the Supreme Court's recent overruling of the *Chevron* doctrine does not change the present analysis. Although the Court held that courts, and not agencies, are the arbiters of interpreting statutory text, such as the proper interpretation of "misbranding," the Court maintained that a "statute's meaning may well be that the agency is authorized to exercise a degree of discretion" by "empower[ing] an agency to prescribe rules to 'fill up the details' of a statutory scheme." Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2263 (2024) (quoting Wayman v. Southard, 23 U.S. (10 Wheat.) 1, 43 (1825)). FIFRA expressly authorized the EPA "to prescribe regulations to carry out [FIFRA's] provisions," which led the Third Circuit to properly conclude that FIFRA is one such statute that *Loper Bright* recognized as allowing agency discretion. *Schaffner*, 113 F.4th at 381 n.9 (quoting 7 U.S.C. § 136w(a)(1)). Bolstering the Third Circuit's reasoning is FIFRA's provision codified at 7 U.S.C. § 136a(c)(6), which gives the EPA Administrator authority to deny registration if a pesticide is mislabeled. Thus, the Court's decision in *Loper Bright* does not discount the EPA's authority to define what constitutes "misbranding" under FIFRA during the EPA's registration process.

156. *See generally* 40 C.F.R. §§ 159.152–.155 (2024).

157. Carson v. Monsanto Co., 92 F.4th 980, 993 (11th Cir. 2024).

158. *Schaffner*, 113 F.4th at 387.

159. *Id.*

"dispositive of FIFRA compliance."[160] Therefore, the Third Circuit stated, regulations promulgated under FIFRA cannot be interpreted "to implement a rule under which the mere fact of registration would entail, dispositively, that a pesticide was not misbranded."[161] The court, correctly, did not adopt such an interpretation.[162] Instead, the circuit concluded that the Preapproval Regulation gives content to FIFRA's misbranding provision similar to the regulations *Bates* cited in its illustrations of the proper way to analyze parallel requirements issues.[163] The Preapproval Regulation does not present dispositive evidence that a label is not misbranded. The regulation, instead, "affects the content of the requirements imposed under FIFRA, as registration determines what label the pesticide must bear (at least in certain respects),"[164] and, in specific instances, the regulation prohibits alteration of a registered label without further EPA approval.[165]

Because the Preapproval Regulation gives content to FIFRA's misbranding provision by substantively restricting the contents of pesticide labels, the Third Circuit properly incorporated the Preapproval Regulation into the federal requirement. The Supreme Court in *Bates* indicated that state requirements should be compared to specific regulatory requirements, where applicable, for preemption purposes.[166] Thus, in accordance with FIFRA's express preemption provision § 136v(b), when a state requirement is determined to be "in addition to or different from" a properly implemented regulatory requirement, the federal regulatory requirement preempts the state requirement.

In failing to incorporate the Preapproval Regulation into the federal requirement, the Ninth and Eleventh Circuits compared state requirements to FIFRA's misbranding provision, which prohibits distributing or selling "any pesticide which is . . . misbranded,"[167] a standard the courts described as "effectively . . . strict-liability."[168] In *Carson* and *Hardeman v. Monsanto Co.*,[169] the state law requirements established negligence standards that the circuit courts correctly concluded were "narrower" than FIFRA's strict liability standard.[170] The courts' use of the general misbranding provision as the federal

160. *Id.* at 396.
161. *Id.* at 397.
162. *See id.*
163. *Id.*
164. *Id.*
165. *See supra* Section I.C.
166. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 447 (2005); *see supra* Section II.A.
167. 7 U.S.C. § 136j(a)(1)(E).
168. Carson v. Monsanto Co., 92 F.4th 980, 991 (11th Cir. 2024); *see* Hardeman v. Monsanto Co., 997 F.3d 941, 955 (9th Cir. 2021).
169. 997 F.3d 941 (9th Cir. 2021).
170. *See supra* note 86 and accompanying text.

requirement would almost always result in concluding that federal preemption is improper when the state requirement is narrower than the misbranding provision. Since a law can hardly be drafted more broadly than FIFRA's "strict liability," it seems that, when following these circuits' logic, most state failure-to-warn claims would be narrower or, at minimum, not "in addition to" FIFRA's misbranding provision and, therefore, not preempted.

*3.* Riegel*'s Reasoning Applies with Equal Force*

Arguably, the most important distinction between the three circuits' interpretations is their differing approaches to the Supreme Court's *Riegel* decision and its comparison to preemption under FIFRA. The *Riegel* Court held that the FDA's premarket approval scheme created by the MDA establishes a preemptive requirement when a state law for a medical device "is different from, or in addition to, any requirement applicable" under the MDA.[171] This language directly mirrors FIFRA's preemption provision, § 136v(b), which provides that state requirements that are "in addition to or different from" FIFRA are preempted.[172]

The *Schaffner* court observed that the Supreme Court's reasoning in *Riegel* rested on features it viewed as common to both the MDA's premarket approval process and FIFRA's preapproval process: "namely, the safety review that regulated products must undergo before they are marketed, and the prohibition on subsequent modifications of such products once they are reviewed and approved."[173] Because the premarket approval process "substantively restricts" a medical device's form before market entry, the Supreme Court reasoned that the MDA established a requirement that must be obeyed.[174] Similarly, the Preapproval Regulation in conjunction with FIFRA mandates that pesticide labels take a particular form to "adequate[ly] protect health and the environment."[175]

Nevertheless, the Ninth Circuit and the Eleventh Circuit distinguished *Riegel*. They argued that the two statutory schemes were distinct because the MDA contained no provision that made FDA premarket approval inconclusive of statutory compliance—similar to FIFRA's rebuttable presumption provision in § 136a(f)(2).[176] Thus, the circuits claimed that EPA approval fails to

171. Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (quoting 21 U.S.C. § 360k(a)(1)).

172. Indeed, the Supreme Court in *Bates* turned to the "similarly worded preemption provision" in the MDA when determining whether damages remedies imposed by state laws were parallel to FIFRA under § 136v(b). *Bates*, 544 U.S. at 447–48.

173. Schaffner v. Monsanto Corp., 113 F.4th 364, 388 (3d Cir. 2024).

174. *Id.* (citing *Riegel*, 552 U.S. at 323).

175. *Id.* (quoting 7 U.S.C. § 136(q)(1)(G)).

176. Carson v. Monsanto Co., 92 F.4th 980, 993 (11th Cir. 2024); Hardeman v. Monsanto Co., 997 F.3d 941, 957 (9th Cir. 2021).

carry the same force of law intrinsic to FDA approval.[177] Yet, the circuits cannot ignore that the Preapproval Regulation carries the force of law because "[r]ules issued through the notice-and-comment process . . . have the force and effect of law."[178] Furthermore, the Preapproval Regulation creates a requirement for preemption because it gives content to FIFRA's misbranding provision and substantively restricts a registrant's ability to add material, particularly precautionary statements, to its pesticide label.

The Eleventh Circuit further distinguished *Riegel* by arguing that the FDA's premarket approval process is quite different from the EPA's preapproval process. First, the circuit noted that the FDA's premarket approval process is "rigorous," implying that the EPA's registration process is not.[179] Second, the Eleventh Circuit concluded that a premarket approved medical device practically cannot be amended without FDA authorization, while an approved pesticide label is expected to change over time considering FIFRA's "ongoing reporting requirements" and that EPA-approved labels can be altered without EPA authorization through the notification process.[180] Although the MDA and FIFRA have differences, the Eleventh Circuit gave improper weight to these disparities.

But each of these arguments fails. First, one registration process being more "rigorous" than another does not determine that the latter registration process fails to establish a requirement. The FDA's and EPA's registration processes establish virtually equal requirements on their registrants, specifically regarding the EPA's labeling requirements for precautionary statements.[181] Although the MDA's premarket approval process may be considered more "rigorous" than the EPA's preapproval process because the FDA's premarket procedure may delegate more time to reviewing each application,[182] the varying level of scrutiny does not change whether each agency's process imposes a requirement upon its registrants. In other words, the scrutiny at which an application is reviewed does not change the fact that approval of the application depends on whether the registrant satisfies the requirements imposed by the reviewer.

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177. *Carson*, 92 F.4th at 993; *Hardeman*, 997 F.3d at 957.

178. *Schaffner*, 113 F.4th at 386 (quoting Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 96 (2015)).

179. *Carson*, 92 F.4th at 995.

180. *Id.* The Eleventh Circuit also found that FIFRA's statutory scheme leaves open room for state regulation while the MDA centralizes regulation at the federal level. *Id.* at 994. However, this reasoning favors an argument that FIFRA's statutory structure does not impliedly preempt state laws, and it holds little weight in deciding whether § 136v(b) expressly preempts state laws that conflict with the registration process implemented by FIFRA and EPA regulations.

181. *See* 40 C.F.R. § 156.70(c) (2025); 21 U.S.C. § 360e(c)(1).

182. *Carson*, 92 F.4th at 994 (noting that the FDA averages 1,200 hours reviewing each application).

Second, the Eleventh Circuit's distinction between the conclusive nature of FDA premarket approval versus the "inconclusive" nature of EPA approval disregards two key facts: similar to FIFRA, the MDA establishes reporting requirements that empower the FDA to withdraw premarket approval based on new data,[183] and amendments of precautionary statements on preapproved pesticide labels face similar restrictions to amendments made to medical device registration.[184] In *Riegel*, the Supreme Court noted that approved medical device manufacturers are "obligat[ed] to inform the FDA of new . . . scientific studies . . . and to report incidents in which the device may have caused . . . death or serious injury."[185] Similar to the EPA's ability to withdraw pesticide registration approval, "[t]he FDA has the power to withdraw premarket approval based on newly reported data or existing information."[186] Thus, the "ongoing reporting requirements" and the revocability of approval under FIFRA are not distinguishable from the MDA's requirements.

Furthermore, although "minor modifications . . . having no potential to cause unreasonable adverse effects" can be made to a pesticide's label without EPA approval,[187] the modification at issue in this case is not minor. In fact, addition of a cancer warning to Monsanto's label constitutes an addition of a precautionary statement because a cancer warning would alert consumers that they risk getting a deadly disease from the product.[188] Addition of such a precautionary statement requires EPA approval and the submission of "such data as would be required to obtain [original] registration" of the pesticide.[189] Thus, circumstantially, the Preapproval Regulation establishes a similarly unalterable requirement for labeling amendments as does the MDA for medical devices.

Therefore, the common characteristics between the statutory and regulatory schemes under the MDA and FIFRA certainly outweigh the differences when considering the facts of this case. Because the addition of a cancer warning would almost surely require further EPA approval, the Preapproval Regulation, in this case, establishes as much of a requirement as the MDA established in *Riegel*, and *Riegel* is therefore instructive.

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183. *See* 7 U.S.C. § 136d(b); *cf.* 21 U.S.C. § 360e(e)(1)(B).

184. *See* 7 U.S.C. § 136a(c)(9)(A)–(C); *cf.* 21 U.S.C. § 360e(d)(6)(A)(i).

185. Riegel v. Medtronic, Inc., 552 U.S. 312, 319 (2008) (citation omitted) (citing 21 C.F.R. § 814.84(b)(2)).

186. *Id.*

187. 40 C.F.R. § 152.46 (1996).

188. *See supra* Sections I.C, II.D.1.

189. 7 U.S.C. § 136a(c)(7)(A).

### *B. The Policy Implications of Federal Preemption Under FIFRA*

#### *1. Uniform Pesticide Regulation: The Good and the Bad*

There are primarily two policies at arms in FIFRA's preemption arena: uniformity in pesticide regulation versus the preservation of state tort remedies. Preserving one comes at the cost of destroying the other. The consequences of uniformity are wide-ranging. Regarding positive effects, maintaining a uniform body of law governing pesticide warning labels would simplify compliance for pesticide manufacturers, decrease litigation expenses, and serve as an economic boon to the pesticide industry.[190] National uniformity simplifies compliance by avoiding patchwork regulations at the state level that submit companies to varying state regulations requiring pesticide labels to meet different warning criteria. This patchwork is not only costly but also inefficient, diverting companies' resources from agroscientific advancements to tedious compliance issues.[191] An efficient and uniform federal regulatory approach improves interstate commerce.[192] Uniformity, therefore, increases market size, lowers prices for farmers and consumers,[193] and allows farmers and other consumers to purchase products subject to a nationwide federal safety standard. Conversely, restrictions in access to pesticide products have negative impacts such as lower production yields for farmers,[194] a concerning proposition for a country with a population of roughly 340 million.[195]

The downsides of national uniformity are primarily rooted in the federal government's encroachment on state sovereignty and the dissipation of remedial damages for injured plaintiffs. The EPA's job

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190. *See* Brief of the Chamber of Commerce of the United States of America et al. as Amici Curiae Supporting Petitioner at 18, Monsanto Co. v. Durnell, 707 S.W.3d 828 (Mo. Ct. App. 2025), *petition for cert. filed*., 2025 WL 1414057 (U.S. May 9, 2025) (No. 24-1068).

191. DANIEL R. PEREZ & ZHOUDAN XIE, GEORGE WASHINGTON UNIV. REGUL. STUD. CTR. & U.S. DEP'T OF AGRIC., THE RELATIONSHIP BETWEEN FORM & PRODUCTIVITY: AN EMPIRICAL APPLICATION TO AGRICULTURE 5 (2018), https://perma.cc/MYU7-LPEC.

192. *Coalition Letter Supporting Upcoming Refiling of the Agricultural Labeling Uniformity Act*, NAT'L ASS'N OF STATE DEP'TS OF AGRIC. (May 29, 2025), https://perma.cc/6VJJ-FTKG.

193. COMPETITIVE ENTER. INST., MODERNIZING THE EPA: A BLUEPRINT FOR CONGRESS 163 (Daren Bakst et al. eds., 2025) (stating that "stringent regulations on chemicals or pesticides increase the cost of food production, driving up prices for consumers"); David Zilberman et al., *The Economics of Pesticide Use and Regulation*, 253 SCIENCE 518, 518 (1991) (noting that, "[w]ithout substitutes, pesticide bans result in reduced production levels and higher prices, a substantial loss of discretionary income to consumers, and a redistribution of income among agricultural producers").

194. Zilberman, *supra* note 193, at 518.

195. *Census Bureau Projects U.S. and World Populations on New Year's Day*, U.S. CENSUS BUREAU (Dec. 30, 2024), https://perma.cc/6477-SBER.

is to set regulatory standards to protect the health and safety of both Americans and the environment. However, this authority was traditionally understood to fall within the states' police powers.[196] States have been allowed to have higher standards than those imposed by a federal agency requirement in the past, without the state requirement being deemed a burden on interstate commerce.[197] Thus, the efficiency benefits of national uniformity likely come at the cost of the public's safety, at least through a given state's eyes.

Likewise, under FIFRA's current structure, pesticidal harm to the public currently has no remedy when federal law preempts state failure-to-warn laws.[198] Therefore, the more salient pitfall to national uniformity through federal preemption is the loss of any remedial pathway for plaintiffs injured by pesticides such as Roundup. The clear benefit to preserving state failure-to-warn laws is to hold pesticide companies accountable for injuries caused by unreasonably dangerous products. The new circuit split creates a crossroad where these public policies intersect with preemption law. One thing is clear: these policies will undoubtedly govern the impending Supreme Court or congressional decision regarding preemption under FIFRA.

*2. Where Policy Intersects with Preemption*

Whether a court prioritizes the policy of uniformity or the preservation of state tort law dictates their interpretations of FIFRA preemption, as exemplified by the circuit split. The policy of uniform interpretations of federal law is deeply rooted in federal preemption law. In the context of FIFRA, uniformity emanates from the statute's preemption provision, § 136v(b), titled "Uniformity."[199] Statutory section headings "'supply cues' as to what Congress intended,"[200] and "[e]xpress preemption turns primarily on 'the language of the pre-emption statute and the statutory framework surrounding it.'"[201] Here, the argument follows that Congress intended that pesticide labeling laws remain nationally uniform.[202] Nevertheless, the more vague a statute, the less uniform its application will be across the nation.[203]

196. Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11, 25 (1905).

197. *See, e.g.*, Maine v. Taylor, 477 U.S. 131, 138 (1986).

198. Isabella Eakins, *The Roundup Debate: Why the Supreme Court Should Rule That FIFRA Does Not Preempt Failure to Warn Claims and Recommendations for the EPA*, 12 LSU J. ENERGY L. & RES. 295, 307 (2024).

199. 7 U.S.C. § 136v(b).

200. Merit Mgmt. Grp., LP v. FTI Consulting, Inc., 138 S.Ct. 883, 893 (2018) (quoting Yates v. United States, 574 U.S. 528, 540 (2015)).

201. Carson v. Monsanto Co., 72 F.4th 1261, 1267 (11th Cir. 2023) (en banc) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 486 (1996)).

202. Schaffner v. Monsanto Corp., 113 F.4th 364, 392 (3d Cir. 2024) (quoting Schoenhofer v. McClaskey, 861 F.3d 1170, 1174 (10th Cir. 2017)).

203. *Id.*

Using FIFRA's general misbranding provision as the federal component in the parallel requirements test leads to less national uniformity. Practically all state failure-to-warn laws will circumvent preemption under the *Hardeman*/*Carson* rationale as they are narrower, and, therefore, not "in addition to" the misbranding provision.[204] Thus, using FIFRA's misbranding provision as the relevant federal requirement would expose pesticide manufacturers to a wide variety of state laws instead of a uniform application of federal law promulgated by the EPA. After all, "if the parallel-requirements test were applied to preempt any state-law duty that is not equivalent to EPA regulations requiring pesticide labels to bear certain specific contents, then state-law duties to warn would likely be considerably more uniform."[205] Therefore, the uniformity policy points towards using the EPA Preapproval Regulation as the federal requirement leading to federal preemption.

On the other hand, the policy to preserve state tort law remedies points toward using FIFRA's misbranding provision as the federal requirement because this interpretation leads to few if any situations where state duties to warn are preempted, allowing state citizens to sue pesticide manufacturers for state remedies. As stated in *Bates*, "[i]f Congress had intended to deprive injured parties of a long available form of compensation" through state tort litigation, "it surely would have expressed that intent more clearly."[206] Although the Supreme Court's statement holds weight in an argument that FIFRA does not impliedly preempt state tort laws, the policy does not affect FIFRA's ability to expressly preempt state laws that are inconsistent with the Preapproval Regulation, as explained above.

Nevertheless, the policy still stands. If the Supreme Court adopts the Third Circuit's reasoning that the EPA registration mirrors the FDA registration in *Riegel*, and therefore has preemptive effect, then the availability of state law tort remedies for damages caused by EPA-approved pesticides would undoubtedly diminish. Though appropriate interpretation of current law suggests that federal preemption is proper, the implications are likely detrimental to the American public when EPA-approved products remain unreasonably dangerous to human or environmental health. Because the job of the Judiciary is to interpret law and not create new pesticide law, the onus is on Congress and the EPA to develop procedures that improve EPA screening for hazardous substances and either preserve state tort remedies or create federal avenues for remedial damages caused by pesticides. Although this Comment does not venture to judge the quality of EPA procedures in determining safety and effectiveness of

204. Eakins, *supra* note 198, at 314.
205. *Schaffner*, 113 F.4th at 393.
206. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005).

pesticides as other papers have,[207] it does recognize and support remedying the negative consequences of federal preemption under FIFRA.[208]

## CONCLUSION

The Third Circuit's interpretation of FIFRA's express preemption clause stands most faithful to Supreme Court precedent, recognizing the Preapproval Regulation's force of law and the registration process's substantive restriction on pesticide labels. Grounded in the Supreme Court's emphasis on interpreting statutory text and framework, the Third Circuit appropriately concluded that the Preapproval Regulation is a preemptive federal requirement. In contrast, the Ninth and Eleventh Circuits' underlying presumption-against-preemption led the circuits to improperly use FIFRA's general misbranding provision as the federal requirement. This misstep dilutes FIFRA's preemptive scope, leading to nationwide inconsistency in its application. A Supreme Court decision affirming the Third Circuit's approach would clarify FIFRA's scope but diminish consumers' access to remedies for injurious pesticides. Ultimately, it is the province of Congress to address the resulting remedial gaps. And so, the Roundup Litigation pushes forward, all the while waiting for one of these branches of government to speak.

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207. For thorough discussion regarding this issue, see Eakins, *supra* note 198; Theodore Motz, *Federal Insecticide, Fungicide, and Rodenticide Act Preemption of State Failure-to-Warn Laws*, 34 COLO. ENV'T. L.J. 69 (2023).

208. Two opposing legislative bills have been proposed in Congress. H.R. 4754, 119th Cong. (2025); S. 2324, 119th Cong. (2025). The FY 2026 Interior and Environmental Appropriations Bill contains a section which prohibits the EPA from using funding from any act to alter or update pesticide carcinogenicity classifications. H.R. 4754, § 453. This prohibition stifles advancement in pesticide engineering and pesticide regulation at the cost of public health and environmental protection. *Id.* This act would make federal preemption under FIFRA even more conclusive as courts that disagree with using the Preapproval Regulation as the federal requirement in the parallel requirements test will instead use Section 453 as the federal requirement, barring failure-to-warn claims. Although this Comment argues that federal preemption is already proper under current law, I believe this proposed bill is detrimental to public health and the public's faith in our government and justice system. On the other hand, New Jersey Senator Corey Booker recently proposed an amendment to FIFRA to create a private right of action against pesticide manufacturers for injurious pesticides. S. 2324, § 34. The bill specifically states that "[n]othing in this section shall preempt any State law claim." *Id.* This bill would make it even more difficult and costly for manufacturers to comply with both federal and various state requirements because the risk of litigation would dramatically increase for companies when a federal private right of action exists that does not preempt state claims. The balance between these two bills is the creation of a federal private right of action that *does* preempt state laws. Such a law would provide the necessary remedial pathway for harmed plaintiffs, while reducing compliance costs for companies, allowing them to spend fewer resources on compliance and more resources on creating safe and effective products.

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