In the

Supreme Court of the United States

MONSANTO COMPANY,

Petitioner,

v.

JOHN L. DURNELL,

Respondent.

On Petition for Writ of Certiorari to the Missouri Court of Appeals

BRIEF OF ATLANTIC LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

Lawrence S. Ebner
Counsel of Record
Atlantic Legal Foundation
1701 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 729-6337
lawrence.ebner@atlanticlegal.org

120404



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INTEREST OF THE AMICUS CURIAE 1

Established in 1977, the Atlantic Legal Foundation (ALF) is a national, nonprofit, nonpartisan, public interest law firm. ALF's mission is to advance the rule of law and civil justice by advocating for individual liberty, free enterprise, property rights, limited and responsible government, sound science in judicial and regulatory proceedings, and effective education, including parental rights and school choice. With the benefit of guidance from the distinguished legal scholars, corporate legal officers, private practitioners, business executives, and prominent scientists who serve on its Board of Directors and Advisory Council, ALF pursues its mission by participating as *amicus curiae* in carefully selected appeals before the Supreme Court, federal courts of appeals, and state supreme courts. *See* atlanticlegal.org.

* * *

ALF long has advocated for strict enforcement of express preemption provisions that are intended to achieve and maintain national uniformity of regulation, especially in connection with the warnings provided on federally regulated product labeling. States should not be permitted either through tort law or state enactments

¹ Petitioner's and Respondent's counsel were provided timely notice of this brief in accordance with Supreme Court Rule 37.2. No counsel for a party authored this brief in whole or part, and no party or counsel other than the *amicus curiae* and its counsel made a monetary contribution intended to fund preparation or submission of this brief.

to flout the congressional intent embodied in federal regulatory statutes' express preemption provisions.

The preemption provision at issue here, section 24(b) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b), is titled "Uniformity." It expressly prohibits a State from imposing pesticide labeling requirements that are "in addition to or different from" those imposed under the Act by the U.S. Environmental Protection Agency (EPA). The Court held in Bates v. Dow AgroSciences LLC, 544 U.S. 431, 446 (2005), that § 136v(b) encompasses state-law, pesticiderelated, failure-to-warn claims because they "premised on common-law rules that qualify 'requirements for labeling'... they set a standard for a product's labeling that the . . . label is alleged to have violated by containing . . . inadequate warnings." Despite the expansive language of § 136v(b)'s explicit prohibition against imposition of state labeling requirements that are "in addition to or different from" EPA's, *Bates* carved out an exception for a "state-law labeling requirement if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id.* at 447.

From the day *Bates* was decided two decades ago, the personal injury bar has relentlessly exploited the Court's "parallel requirements' reading of § 136v(b)," *id.*, in an effort to render the preemption provision almost meaningless. The heavily promoted, multitudinous, Roundup litigation is an ongoing egregious example of the plaintiff bar's voracious appetite for a product liability bonanza based on a misreading of this Court's precedents. Indeed, *Bates* "concept of equivalence," *id.* at

454, has engendered a sharp, irreconcilable, inter-circuit split of authority on whether § 136v(b) preempts the tens of thousands of Roundup-related failure to warn suits pending in federal and state courts throughout the United States. See Pet. for Writ of Cert. at 2, 22. This case is a perfect vehicle to resolve the conflict because the premise of the Roundup litigation—that Roundup's labeling failed to provide a human cancer warning—squarely conflicts with EPA's repeated, science-based determination that the product's active ingredient, glyphosate, does not cause cancer in humans, and that a cancer warning on Roundup labeling would be false and misleading and a violation of FIFRA's prohibition against distributing misbranded pesticides. See id. at 8-12, 24.

The Court should grant certiorari to restore the force and effect of the § 136v(b) uniformity/preemption provision.

SUMMARY OF ARGUMENT

The Court recognized in *Bates* the "important role" that § 136v(b) plays in achieving and maintaining a system of nationally uniform, product-specific pesticide labeling, whose content, including health and safety warnings, is regulated solely by EPA. *Bates*, 544 U.S. at 452 (explaining that § 136v(b) "pre-empts competing state labeling standards . . . prescribing the . . . wording of warnings."). *Bates* holds that state-imposed pesticide labeling requirements "in addition to or different from" EPA's pesticide labeling requirements include those that are imposed through state common-law failure-to-warn

claims. Such claims—like the cancer-related failure-to-warn claims upon which the Roundup litigation is predicated—not only "set a standard for a product's labeling" in contravention to § 136v(b), *id.* at 446, but also undermine EPA's careful, scientifically based determinations concerning what specific warnings are, and are not, warranted on a particular pesticide's labeling. False, misleading, or unnecessary health and safety warnings on a pesticide label are deleterious. They discourage use of highly beneficial products such as Roundup, and detract from warnings and precautionary statements that truly are needed to protect health and the environment.

Bates' exemption from preemption for "parallel" state labeling requirements enables a State to impose a pesticide-specific labeling requirement that is "genuinely equivalent" to, i.e., not in addition to or different from, EPA's labeling requirements for the same pesticide. Bates, 544 U.S. at 454. As Bates makes clear, this narrow exception merely allows a State to provide a remedy if a pesticide manufacturer fails to comply with labeling requirements imposed by EPA for a particular pesticide product or active ingredient. See id. at 447, 448. The parallel requirements exception is *not* a license to impose a state tort duty to provide an additional label warning especially where, as here, EPA has repeatedly rejected as scientifically unwarranted the cancer warning on which virtually all Roundup failure-to-warn claims are predicated. Yet, for two decades the personal injury bar has seized upon the parallel requirements exception as a supposedly simple way to circumvent § 136v(b) and avoid preemption of pesticide failure-to-warn claims. See, e.g., Leslie A. Brueckner, Why Bates Matters: A Response to the Critique of the U.S. Supreme Court's Holding in Bates v. Dow AgroSciences, 20 BNA Toxics Law Rptr. 784 (Aug. 25, 2005) ("[M]ost failure to warn . . . claims will easily pass this test.").

The Court should grant certiorari and hold that § 136v(b) applies—and the "parallel requirements" exception does not—where, as here, EPA has rejected a cancer-related label warning on the ground that it is scientifically unwarranted, and would be false and misleading and in violation of FIFRA's misbranding standards. A state tort duty to provide, for a particular product, a cancer-related label warning that EPA repeatedly has rejected cannot possibly be "parallel" or "genuinely equivalent" to, or "fully consistent with," EPA's labeling requirements. Section 136v(b), therefore, expressly preempts state-law tort claims based on Monsanto's "failure" to provide a cancer warning on Roundup's labeling.

ARGUMENT

The Court Should Grant Certiorari To Clarify the Scope of the "Parallel Requirements" Exception To FIFRA's Express Preemption Provision

- A. Section 136v(b) vests EPA with exclusive authority to regulate the content of pesticide labeling, including warnings
- 1. Section 136v(b)'s express prohibition against state labeling requirements that are "in addition to or different from" those imposed under FIFRA establishes

EPA's exclusive authority to regulate the content of each pesticide product's labeling, including by determining, based on sound science, what health-related warnings should—and should not—be provided to product users.

"[S]purred by growing environmental and safety concerns," Bates, 544 U.S. at 437, Congress, as part of an overhaul of FIFRA extensive in 1972. § 136v(b) to the Act in order "to completely preempt State authority in regard to labeling." H.R. Rep. No. 92-511, at 16 (1971); see Bates, 544 U.S. at 437-40 (discussing FIFRA's legislative history); Ruckelshaus v. Monsanto Co., 467 U.S. 986, 991, 992 (1984) (explaining that the 1972 amendments transformed FIFRA into comprehensive regulatory statute" and "gave EPA greater enforcement authority"). Of particular relevance here, the amendments "significantly strengthened FIFRA's registration and labeling standards." Wisconsin Pub. Intervenor v. Mortier, 501 U.S. 597, 601 (1991).

"a establish coordinated Federal-State administrative system" for the regulation of pesticides, H.R. Rep. No. 92-511, at 1, Congress allowed the States to retain a "supplementary role." *Bates*, 544 U.S. at 442; see 7 U.S.C. § 136v(a) ("A State may regulate the sale or use of any federally registered pesticide "); see also Mortier, 501 U.S. at 614 (discussing 7 U.S.C. § 136v(a)). For example, States have "primary enforcement authority for pesticide use violations." 7 U.S.C. § 136w-1(a); see id. § 136j(a)(2)(G) (making it unlawful "for any person . . . to use any registered pesticide in a manner inconsistent with its labeling"). Congress, however, vested EPA alone with authority to regulate the *content* of pesticide labeling, including health and safety warnings. *See Mortier*, 501 U.S. at 615 (regulation of pesticide labeling "fall[s] within an area that FIFRA's 'program' pre-empts.").

2. Although *only* EPA has authority to regulate the content of pesticide labeling, the Court noted in *Bates* that "[n]othing in the text of FIFRA would prevent a State from making the violation of a *federal* labeling . . . requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate *federal* law." *Bates*, 544 U.S. at 442 (emphasis added). For example, if a pesticide manufacturer failed to comply with an EPA requirement that a particular pesticide product's label include the signal word "CAUTION," a State could impose sanctions on the manufacturer (e.g., fines; cancellation of the product's state registration) for violating that federal labeling requirement.

Section 136v(b), however, expressly preempts a State from imposing its own additional or different requirements for the warnings on a particular pesticide's labeling. Preempted state requirements for labeling not only include those imposed by state statutes and regulations, but also through state-law failure-to-warn claims. See Bates, 544 U.S. at 453 ("[T]he term 'requirements' in § 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties.") Therefore, § 136v(b) "preempts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." *Id.* at 453.

For example, as the Court explained in *Bates*, "a failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted" if EPA required CAUTION rather than DANGER on the product's label. Id. Any such state-law failure-to-warn claim would "set a standard for a product's labeling," id. at 446, that is "in addition to or different from" the specific labeling requirements imposed by EPA for that product. "While States are free to impose liability predicated on a violation of the federal standards set forth in FIFRA and in any accompanying regulations promulgated by the Environmental Protection Agency, they may not impose liability for labeling requirements predicated on distinct state standards of care." Id. at 454 (Thomas, J., concurring) (emphasis added).

B. The "parallel requirements" exception does not enable a State to add warnings to a pesticide's labeling

1. Although the Court held in *Bates* that "a state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions," 544 U.S. at 447, it is implausible that Congress intended this implied exception virtually to nullify the broad, express preemption provision to which it is appended.

Instead, the Court's "parallel requirements' reading of § 136v(b)" merely enables States to provide a remedy (in the absence of a federal remedy) to pesticide users "who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements." Id. at 447, 448 (emphasis added); cf. Medtronic, Inc. v. Lohr, 518 U.S. 470, 513 (1996) (O'Connor, J., concurring in part and dissenting in part) ("Section 360k [of the FDCA Medical Device Amendments] does not preclude States from imposing different or additional remedies, but only different or additional requirements."); Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (Section "360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements" (emphasis added)).

For example, if an agricultural worker is injured because a pesticide's manufacturer distributes the product with labeling that fails to include an EPArequired statement mandating use of a particular type of respirator, § 136v(b) would not preempt a state-law liability suit based on the manufacturer's noncompliance with that EPA-imposed labeling requirement. See Bates. 544 U.S. at 451 ("Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA."). But § 136v(b) would preempt a liability suit based on labeling that does not specify use of that type of respirator if EPA did not impose such a specific labeling requirement for the product at issue. Any such suit would impose a state-law requirement for labeling that is in addition to or different from—not parallel or equivalent to, consistent with—FIFRA's labeling requirements

implemented by EPA for that product, and therefore, would fall within §136v(b)'s express preemptive scope.

Bates repeatedly explains that the "concept of equivalence" under § 136v(b) is narrow. Id. at 454. For example, the Court "emphasize[d] that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive preemption." Id. at 453 (emphasis added). "[N]ominally equivalent [state-law] labeling requirements" are not enough; they must be "genuinely equivalent" to avoid preemption. Id. at 454.

- C. A state tort duty to provide a cancer label warning that EPA has rejected as scientifically unwarranted, and as false and misleading, is expressly preempted by § 136v(b)
- 1. The Missouri Court of Appeals' superficial and erroneous "parallel requirements" analysis follows the same abbreviated and misdirected path as the Ninth Circuit in *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021), and the Eleventh Circuit in *Carson v. Monsanto Co.*, 92 F.4th 980 (11th Cir. 2024). *See Hardeman*, 997 F.3d at 955 ("[I]f a violation of California's duty to warn would also be a violation of FIFRA's misbranding provision, then they impose parallel requirements fully consistent with each other."); *Carson*, 92 F.4th at 992 ("[T]he practical effect is the same: both FIFRA and Georgia common law require pesticide manufacturers to warn users of potential risks to health and safety.").

Similarly, according to the Missouri Court of Appeals,

labeling FIFRA's requirements 7 U.S.C. section 136(q)(1)(G) . . . contain a prohibition on misbranding. . . . This "prohibition on misbranding effectively imposes a strict-liability standard," holding a manufacturer liable for omitting a warning regardless of knowledge or intent... . . Missouri's strict liability cause of action is fully consistent with federal requirements under section 136(q)(1)(G) of FIFRA.... The "practical effect" of both FIFRA's prohibition on misbranding under section 136(q)(1)(G) and a strict liability failure to warn claim in Missouri are the same: both require a pesticide manufacturer to adequately warn users of the potential dangers of using its product, regardless of the manufacturer's knowledge or intent. . . . Based on the foregoing, a strict liability failure to warn claim in Missouri does not impose a requirement "in addition to or different from" the requirements of FIFRA.

App-6–App-7 (quoting *Carson*, 92 F.4th at 991-92).

The foregoing parallel-requirements "analyses" are at the 30,000 foot-level. They rely entirely on a comparison between a general state-law duty to warn and "FIFRA's broadly phrased misbranding standards." *Bates*, 544 U.S. at 453 n.28; *see* 7 U.S.C. § 136(q) (general, multi-part definition of misbranding under

FIFRA); id. § 136(q)(1)(G) (a pesticide is misbranded if "the label does not contain a warning . . . adequate to protect health"). And equally important, they are oblivious to this Court's admonitions in Bates that the equivalency of "[s]tate-law requirements also must be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards," and that such a comparison "will necessarily affect the scope of pre-emption under § 136v(b)." Id. at 453 & 453 n.28; see also id. at 454 (Breyer, J., concurring) ("writ[ing] separately to stress the practical importance" of measuring state requirements against EPA regulations that "give content" to FIFRA's misbranding standards).

When considering EPA regulations that give content to FIFRA's misbranding standards, it is essential to understand that there are many thousands of different FIFRA-registered pesticide products. Individual products differ as to active ingredients, ingredients, concentration, and type of formulation (e.g., As a result, although EPA has liquid; powder) promulgated baseline regulations for pesticide labeling. see 40 C.F.R. Part 156, they are only where EPA's regulation of pesticide labeling begins. In reality, EPA regulates pesticide labeling on a granular level—on a active ingredient-by-active product-by-product (or ingredient) basis that takes extensive pesticide-specific toxicology and other types of EPA-required scientific studies into account. See EPA Office of Pesticide Programs Label Review Manual (reflecting the productspecific manner in which EPA actually regulates the content of each registered pesticide's labeling).²

Monsanto's petition for writ of certiorari summarizes the extensive manner in which EPA has evaluated the glyphosate active ingredient in Roundup and repeatedly concluded that a cancer warning on Roundup labeling would be scientifically unwarranted and should not be provided. See Pet. at 8-12, 24. EPA even took the unusual step of issuing a "Dear Registrant" letter informing glyphosate registrants that it would not approve labels of glyphosate-based products that include a cancer warning, and that such a label warning (such as the cancer warning required by California's Proposition 65 right-to-know law) would be false and misleading, and thus would render the product misbranded in violation of FIFRA. See Pet. at 10; App-38-App-39; see also App-41 (EPA follow-up letter stating that "[t]he Agency continues to stand behind its robust scientific evaluation of the carcinogenic potential of glyphosate. . . . EPA's conclusion remains consistent with many international expert panels and regulatory authorities.").

If EPA had determined otherwise, it would have classified glyphosate as a "restricted use" pesticide and required that EPA-specified warning language be prominently displayed at the top of Roundup products' labels. See 7 U.S.C. § 136a(d)(1)(C) (classification of

² Available at https://www.epa.gov/pesticide-registration/label-review-manual (last updated Dec. 12, 2024).

pesticide for restricted use); 40 C.F.R. § 156.10(j)(2) (labeling requirements for restricted-use pesticides); Label Review Manual at 6-3-6-4 (same).

2. The Third Circuit's discussion and holding in Schaffner v. Monsanto Corp., 113 F.4th 364, 389-93 (3d Cir. 2024), concerning how the Bates "parallel-requirements test" should be applied not only is insightful, but also creates a deep split with Hardeman, Carson, and other Roundup cases, including the Missouri decision below. See Pet. at 17-23. Apparently fearing Supreme Court review of the Third Circuit's preemption analysis, the Schaffner Roundup plaintiffs did not seek Supreme Court review.

The Third Circuit addressed the following question: "When state tort law and a federal statute seem to impose equivalent requirements, but a federal regulation gives different content to that apparently equivalent requirement, should a court articulate the Federal Comparator at the broader statutory level of generality or the more specific regulatory level of generality?" *Schaffner*, 113 F.4th at 390. Answering this question, the court of appeals held that

under both *Bates* and section 136v(b) itself federal requirements must be articulated at the *more specific level* when identifying the Federal Comparator in applying the parallel-requirements test. If EPA regulations specifically identify the contents required to be included on a pesticide label, a state-law requirement is preempted

unless it is equivalent to that specific regulatory requirement. The state-law duty cannot survive preemption simply because its standard of liability is equivalent to the broad statutory definition of misbranding.

Id. at 390 (emphasis added).

Carrying this approach further, the court of appeals what it called EPA's "Preapproval Regulation," 40 C.F.R. § 152.44 (Application for amended registration). See Schaffner, 113 F.4th at 371, 381. The court explained that the Preapproval Regulation prohibits a pesticide registrant such as Monsanto from modifying the health warnings on a pesticide's "Preapproved Label" (i.e., current, EPAapproved label) without EPA's prior approval, and held that "[t]his prohibition imposes a 'requirement' for the purposes of FIFRA's preemption provision." Id. at 371. "Because the Pa. Duty to Warn is not equivalent to that federal regulatory requirement, it is expressly preempted." Id.; see also id. at 393 ("conclud[ing] that the test must be applied by comparing the Pa. Duty to Warn with a Federal Comparator that incorporates the Preapproval Regulation"). Thus, "[w]hile the Cancer Warning was allegedly required by the Pa. Duty to Warn, it was omitted from Roundup's Preapproved Label and could not have been added to the Roundup label without violating the Preapproval Regulation. Accordingly, the Pa. Duty to Warn is not equivalent to the Federal Comparator, and it is thus preempted under section 136v(b)." Id. at 382.

The Third Circuit observed that this "more specific regulatory level of generality" approach to the parallel requirements test promotes the national labeling uniformity that § 136v(b) is intended to achieve. *Id.* at 390.

The parallel-requirements test affects the uniformity state-law of labeling requirements by determining which statelaw duties FIFRA preempts. If state-law duties to warn can survive preemption so long as they are equivalent to the broad statutory definition of misbranding, then FIFRA would not preempt state-law duties to warn that simply require the inclusion of all warnings necessary to protect health But 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 for different factfinders uniform, unlikely to disagree about whether a pesticide label bears the specific contents required by regulation.

Id. at 393. Here, there is no disagreement that Monsanto's Roundup label included all of the information that EPA required, and that EPA rejected the cancer label warning on which Roundup plaintiffs' damages suits are based.

The Court should give force and effect to § 136v(b) by reviewing this case and rejecting any parallel requirements test based on a shallow "parallel requirements" comparison between a general state-law duty to warn and FIFRA's general, non-product-specific, prohibition against misbranded pesticides. Instead, the Court should give controlling weight to EPA's product-specific labeling requirements, including what warnings should be provided, and which should not.

CONCLUSION

The Court should grant the petition for writ of certiorari.

Respectfully submitted,

LAWRENCE S. EBNER

Counsel of Record

ATLANTIC LEGAL FOUNDATION
1701 Pennsylvania Ave., NW
Washington, DC 20006
(202) 729-6337
lawrence.ebner@atlanticlegal.org

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