21-10994

United States Court of Appeals

for the

Eleventh Circuit

JOHN D. CARSON,

Plaintiff/Appellant,

– v. –

MONSANTO COMPANY,

Defendant/Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF GEORGIA
CASE NO: 4:17-cv-00237-RSB-CLR
(Hon. R. Stan Baker)

EN BANC BRIEF OF ATLANTIC LEGAL FOUNDATION AND WASHINGTON LEGAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF APPELLEE AND AFFIRMANCE

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1. In accordance with 11th Cir. R. 26.1-1 and 28-1(b), *amici curiae* Atlantic Legal Foundation and Washington Legal Foundation hereby adopt the Certificate of Interested Persons submitted by Defendant-Appellee Monsanto Company.

2. In accordance with Fed. R. App. P. 26.1 and 11th Cir. R. 28-1(b), *amici curiae* Atlantic Legal Foundation and Washington Legal Foundation state that they are nonprofit, public interest law firms. Since neither organization issues stock, no publicly traded company owns 10% or more of either organization's stock.

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INTEREST OF THE *AMICI CURIAE* [1]

Established in 1977, the **Atlantic Legal Foundation** (ALF) is a national, nonprofit, public interest law firm whose 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.

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[1] No counsel for a party authored this brief in whole or part, and no party, party's counsel, or other person—other than *amici curiae*, their supporters, and their counsel—contributed money that was intended to fund preparing or submitting the brief.

rule of law. It often appears as an *amicus curiae* in important federal preemption cases, urging courts to ensure that federal law operates efficiently and uniformly—as Congress intended. *See* wlf.org.

* * *

Both ALF and WLF long have advocated for judicial enforcement of express preemption provisions—including § 24(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136v(b)—intended to achieve and maintain nationally uniform, federally regulated labeling for products that are potentially hazardous if misused. Section 136v(b), titled "Uniformity," states as follows:

> [A] State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

A State should not be permitted, either by statutory or regulatory enactments, or through tort law, to flout the clear language of § 136v(b), and thereby undermine congressionally mandated, science-based regulation of pesticide product labeling, such as the Roundup herbicide labeling at issue here.

Equally important, this appeal implicates the vital role played by expert federal regulatory agencies—here, the United States

Environmental Protection Agency (EPA)—which Congress entrusted with the responsibility for regulating, based on extensive review of reliable scientific data, nationally uniform, product-specific, health and safety-related label warnings.

Section 136v(b) broadly prohibits a State from imposing labeling requirements that are "in addition to or different from" federal labeling requirements for a particular pesticide. The record establishes that EPA has rejected as scientifically unwarranted, and as false and misleading, the same cancer-related label warning upon which Plaintiff-Appellant Carson's failure-to-warn claim is predicated. *See* Renewed Pet. for Reh'g En Banc at 5-7 (file-stamp pp. 17-19).

Imposing state tort liability for failing to provide a pesticide label warning that EPA has determined is false and misleading, and thus should not be provided, would place manufacturers such as Monsanto into an impossible quandary: They either are held liable under state law for complying with federal law, or they are subjected to federal civil and/or criminal liability for knowingly violating federal law to comply with state law. By expressly prohibiting a State from regulating the content of pesticide labeling, § 136v(b) not only enables pesticide

manufacturers to avoid this dilemma, but also promotes national labeling uniformity. *See Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 452 (2005) (§ 136v(b) "pre-empts competing state labeling standards—imagine 50 different labeling regimes prescribing the color, font size, and wording of warnings").

ALF and WLF submit this brief not only to urge the Court to affirm the district court's holding that § 136v(b) expressly preempts Carson's Roundup-related failure-to-warn claim, but also, in so doing, to narrowly construe "the 'parallel requirements' reading of §136v(b)" that the Supreme Court adopted in *Bates*, 544 U.S. at 447. Plaintiffs in myriad failure-to-warn suits involving Roundup or other pesticides—including Carson here—have unjustifiably and improperly seized upon the *Bates*' parallel requirements exception as a virtually automatic way to circumvent, and indeed negate, § 136v(b). This case affords the Court an excellent opportunity to enforce the broad preemption of pesticide failure-to-warn claims that the Supreme Court in *Bates* held is encompassed by 136v(b), and to ensure that the narrow "parallel requirements" exception does not swallow the rule.

ISSUES PRESENTED

This amicus brief focuses on the following issue: Whether Plaintiff-Appellant Carson's state-law failure-to-warn claim is expressly preempted because it is "in addition to or different from" requirements under FIFRA, where EPA has repeatedly determined that the warning he seeks is not required under FIFRA.

More specifically, this brief addresses the first part of the second issue that the Court has identified for en banc review: "How should a reviewing court identify the federal 'requirements . . . under this subchapter' to which § 136v(b) refers"?

SUMMARY OF ARGUMENT

To identify the federal requirements under FIFRA to which § 136v(b) refers, a reviewing court (i) first should identify EPA's actual, congressionally mandated, case-by-case determinations relating to what warnings, precautionary statements, or other information should—and should not— be included on a specific pesticide product's labeling, and (ii) then view such carefully considered, product-specific, EPA regulatory determinations as imposing federal "requirements for labeling" for purposes of express preemption under § 136v(b). Where, as here, a state-

law tort claim is premised on a manufacturer's "failure" to include a warning on a particular pesticide product's label that EPA has repeatedly and unequivocally determined neither is required nor should be included (such as a cancer warning on Roundup's label), § 136v(b) expressly preempts the claim. Because such a claim necessarily imposes a labeling requirement for that product "in addition to or different from" the labeling requirements that EPA establishes under FIFRA for the product, the claim falls squarely within § 136v(b)'s preemptive sweep.

The Supreme Court held in *Bates* that pesticide-related failure-to-warn claims "are premised on common-law rules that qualify as 'requirements for labeling'" under § 136v(b) because "[t]hese rules set a standard for a product's labeling that the . . . label is alleged to have violated by containing . . . inadequate warnings." 544 U.S. at 446. Again quoting the preemption provision's text, the Court further explained that "§ 136v(b) prohibits state-law labeling requirements that are '*in addition to or different from*' the labeling and packaging requirements under FIFRA." *Id.* at 447. Despite this broad preemptive language, the Court cautioned 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." *Id.* at 448. The Court remanded *Bates* to the lower courts for such an "equivalency" determination, emphasizing that "[s]tate-law requirements must . . . be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." *Id.* at 453.[2]

Contrary to Carson's assertion, *see* En Banc Br. for Plaintiff-Appellant at 31-33 (file-stamp pp. 50-52), the so-called "parallel requirements" or "equivalency" exception to § 136v(b) does not apply here. Personal injury claims premised on a supposed state-tort duty to provide the same product-specific label warning that EPA repeatedly has determined neither is required nor should be provided, and indeed would be false and misleading and a violation of FIFRA, cannot possibly be "equivalent to, and fully consistent with" EPA's requirements for labeling of the product.

[2] *Bates* is an agricultural crop damage case that involved a pesticide manufacturer's alleged failure to provide a type of product-specific, efficacy-related, label warning, which (unlike health and safety warnings) EPA does not regulate. *See* 544 U.S. at 440. The *Bates* litigation ultimately was settled prior to final resolution of the preemption issue.

FIFRA's multipart definition of "misbranded" addresses the subject of pesticide label warnings only in very general terms. *See* 7 U.S.C. § 136(q)(1)(G) (A pesticide is "misbranded" if, *inter alia*, its label "does not contain a warning or caution statement . . . adequate to protect health . . . ."). FIFRA includes this vague definition primarily for enforcement purposes. *See id.* § 136j(a)(1)(E) (making it unlawful to distribute or sell a pesticide "which is adulterated or misbranded").

It simply is wrong to view the FIFRA misbranding provision's "broad general mandate" to provide labeling adequate to protect health, 49 Fed. Reg. 37,960, 37,971 (Sept. 26, 1984), as the entirety of FIFRA's "requirements for labeling." Such a short-sighted view does not begin to account for the finely tuned, *product-specific* manner in which EPA actually regulates the warnings and other content of pesticide labeling.

Every State imposes a general tort duty to provide adequate warnings for potentially hazardous products. Neither the Supreme Court nor Congress could have intended the parallel requirements exception to enable a plaintiff to avoid preemption merely by asserting that a general state-law duty to warn and FIFRA's general definition of

misbranded pesticides are parallel or equivalent. Such a gaping loophole would render § 136v(b) a nullity.

ARGUMENT

Appellant Carson Cannot Avoid FIFRA Preemption By Invoking the "Parallel Requirements" Exception To § 136v(b)

In *Bates* the Supreme Court recognized 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. *See* 544 U.S. at 452.

Bates holds that state labeling requirements that are "in addition to or different from" EPA's pesticide labeling requirements include those imposed through common-law failure-to-warn claims. *See id.* at 446. Such claims—like the cancer-related failure-to-warn claim at issue here and in thousands of other Roundup suits—not only are "premised on common-law rules [that] set a standard for a product's labeling" in contravention to § 136v(b), *id.*, but also undermine EPA's scientifically based determinations as to what specific warnings are, and are not, warranted on a particular product's labeling.

Unwarranted health and safety warnings on pesticide labeling 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. *See generally* 49 Fed. Reg. at 37,971 (expressing EPA's concern that providing too many precautionary statements on a pesticide's labeling "result[s] in labeling of greater length, detail, and complexity than is desirable from a user point of view"). By vesting EPA with exclusive authority to regulate the content of pesticide labeling, § 136v(b) prevents a State from imposing labeling requirements that would result in such over-warning.

A. The parallel requirements exception is narrow

1. "[S]purred by growing environmental and safety concerns," *Bates*, 544 U.S. at 437, Congress, as part of an extensive overhaul of FIFRA in 1972, added § 136v(b) ("Uniformity") "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 "a comprehensive regulatory statute" and "gave EPA greater enforcement authority"). As

reflected in FIFRA's text, including in § 136v(b), the 1972 amendments "significantly strengthened FIFRA's registration and labeling standards." *Wisconsin Pub. Intervenor v. Mortier,* 501 U.S. 597, 601 (1991).

To establish "a 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 . . . .") (emphasis added); *see also Mortier*, 501 U.S. at 614 (discussing § 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"). But to prevent "50 different labeling regimes," Congress, through § 136v(b), vested EPA with sole and exclusive authority to regulate the *content* of pesticide labeling. *Bates*, 544 U.S. at 452; *see also 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." 544 U.S. at 442 (emphasis added). States can enforce their own statutes and regulations requiring pesticide manufacturers to comply with *federal* labeling requirements. *See id.* ("The imposition of state sanctions for violating state rules that *merely duplicate federal requirements* is equally consistent with the text of § 136v.") (emphasis added). For example, if a pesticide manufacturer fails 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), or even tort liability, for violating such a product-specific, federal labeling requirement.

Section 136v(b), however, expressly preempts a State from imposing its own additional or different (i.e., divergent) requirements for the *content* of a pesticide's labeling. Preempted state requirements for labeling not only include those imposed by state statutes and regulations,

but also through state common-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."); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) (adhering to the view "that a provision pre-empting state 'requirements' pre-empted common-law duties"). Therefore, § 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." *Bates*, 544 U.S. at 452.

Bates explains, for example, that "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.* Such a 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 EPA has imposed 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); *see also Riegel*, 522 U.S. at 330 (interpreting the Food, Drug, and Cosmetic Act's similarly worded Medical Device Amendments (MDA) express preemption provision) ("State requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. . . . Thus [the MDA preemption provision] 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).

3. 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 pesticide labeling, including determining what health-related warnings should—and should not—be provided. Although *Bates* held 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," *id.* at 447, it is implausible that Congress

intended this implied exception to abrogate § 136v(b) itself. 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; *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 Medical Device Amendments] does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.").

For example, if an agricultural worker is injured because a pesticide's manufacturer distributes a product with a label that fails to comply with an EPA requirement to include directions mandating use of certain personal protective equipment, § 136v(b) would not preempt a state-law liability suit based on that violation. *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 premised on failure to distribute a product with a label mandating use of personal protective equipment that EPA did not require for use of the product. Such a suit would impose

a state-law requirement for labeling that is in addition to or different from—*not* equivalent or parallel to, or consistent with—FIFRA's labeling requirements as implemented by EPA for that product, and thus would be preempted by §136v(b).

Further, *Bates* repeatedly qualifies the Supreme Court's "concept of equivalence." 544 U.S. at 454. Although it "need not be phrased in the *identical* language as its corresponding FIFRA requirement," *id.*, the Court "emphasize[d] that a state-law labeling requirement must *in fact* be equivalent to a requirement under FIFRA in order to survive pre-emption." *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. Even more important, "[s]tate-law requirements must also be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." *Id.* at 453. Such a comparison "will necessarily affect the scope of pre-emption under § 136v(b)." *Id.* at 453 n.28; *see also id.* at 454 (Breyer, J., concurring).

4. *Bates* points to FIFRA's prohibition against distribution or sale of "misbranded" pesticides merely as the *general* federal standard for

pesticide labeling. *See id.* at 447. The labeling requirements imposed under FIFRA are not limited to "FIFRA's broadly phrased misbranding standards." *Id.* at 453. FIFRA's labeling requirements also include EPA's baseline pesticide labeling regulations, *see* 40 C.F.R. Part 156, and the Agency's implementing, scientifically based, product-specific labeling determinations, such as its determination that a cancer warning on Roundup labeling is scientifically unwarranted.

It is important to understand that there are thousands of FIFRA-registered pesticide products containing hundreds of different active ingredients. Individual products, even for the same use, vary as to active ingredients (e.g., the glyphosate active ingredient in Roundup products), inert ingredients, concentrations, and types of formulation.

EPA's Part 156 pesticide labeling regulations are merely the starting point for EPA's regulation of pesticide labeling, including health and safety warnings. In reality, EPA regulates pesticide labeling on a product-by-product (or active ingredient-by-active ingredient) basis that takes into account extensive toxicology and other types of EPA-required scientific studies. EPA's extensive Label Review Manual, which "compiles existing interpretations of statutory and regulatory provisions

and reiterates existing Agency policies" for pesticide labeling, reflects the product-specific manner in which EPA's Office of Pesticide Programs regulates the content of pesticide labeling. EPA, Label Review Manual,[3]

B. The parallel requirements exception does not apply to Carson's failure-to-warn claim

Carson's state-law failure-to-warn claim "most definitely" imposes "a requirement for labeling." Dist. Ct. Order (Dec. 21, 2020) at 7 (A. 95) (citing *Bates*, 544 U.S. at 446). Further, "a warning on Roundup® that glyphosate causes cancer would be in direct conflict with the EPA's approved label because . . . the EPA considers glyphosate products with cancer warnings to be misbranded." *Id.* at 7-8 (A. 95-96). Carson's failure-to-warn claim, therefore "is preempted by FIFRA" because it "would require the imposition of a duty upon Monsanto that is different—and in direct conflict—with the requirements set up under the FIFRA statutory scheme." *Id.* at 8 (A. 96).

Indeed, it is difficult to imagine a more clear-cut case for FIFRA preemption of state-law failure-to-warn claims than Roundup. As Monsanto's rehearing petition explains, EPA not only has exhaustively

[3] https://www.epa.gov/pesticide-registration/label-review-manual (last visited March 5, 2023).

reviewed scientific studies on glyphosate and concluded that it does not cause cancer in humans, but also has squarely and repeatedly rejected adding a cancer warning to Roundup's labeling. EPA even notified Monsanto and other glyphosate registrants that such a warning would be false and misleading and in violation of FIFRA's prohibition against distribution of misbranded products. *See* Renewed Pet. for Reh'g En Banc at 5-7 (file-stamp pp. 17-19); Supp. App. 11-12.

According to Carson, his "failure-to-warn claim parallels FIFRA's misbranding provisions so it is not preempted." En Banc Br. for Plaintiff-Appellant at 31 (file-stamp p. 50). He asserts that § 136v(b) does not apply because "Georgia law imposes the same or narrower requirements as FIFRA's misbranding provisions." *Id.* This facile misinterpretation of *Bates* completely ignores the product-specific manner in which EPA implements FIFRA's requirements for a pesticide product's labeling. Contrary to Carson's argument, § 136v(b) applies—and the "parallel requirements" exception does not—where, as here, EPA not only has determined that a particular label warning is neither scientifically unwarranted nor required by FIFRA, but also has explicitly prohibited the warning as false and misleading and a violation of FIFRA. A state-

law requirement for inclusion of a cancer warning on a federally regulated pesticide product's label cannot be parallel or equivalent to, or in any way consistent with, an EPA requirement *prohibiting* such a warning on that product's label.

If EPA had determined that glyphosate poses a risk of cancer in humans, it would have classified Roundup as a "restricted-use pesticide" for use only by certified applicators, and required a prominent chronic toxicity warning statement at the top of Roundup's label. *See* 7 U.S.C. § 136a(d)(1)(C)(ii); 40 C.F.R. §§ 152.170(b)(vi) & 156.10(j)(2); EPA, Office of Pesticide Programs, Label Review Manual at 6-3 – 6-4 (Feb. 2021).[4] Because EPA has determined that glyphosate does not cause cancer in humans, it has not classified Roundup as a restricted-use pesticide product. The label warning requirements for restricted-use pesticides do not apply. This further confirms that state-law claims for failure to provide a cancer warning on Roundup's labeling necessarily are "in addition to or different from"—not parallel or equivalent to, or genuinely

[4] https://www.epa.gov/sites/default/files/2021-02/documents/full-lrm_2-22-21.pdf.

consistent with, the federal requirements, as determined by EPA, for Roundup labeling, and thus, are expressly preempted by § 136v(b).

The state-law duty on which Carson's failure-to-warn claim is predicated cannot possibly be "genuinely" or "in fact" equivalent or parallel to, or consistent with, EPA's carefully considered, scientifically based determinations for the content of Roundup labeling. *See Bates*, 544 U.S. at 453-54. This is because "[f]or decades, EPA has followed congressionally prescribed procedures to conclude that glyphosate, the active ingredient in Roundup®, does not cause cancer. It has approved label after label with no cancer warning—necessarily concluding that no such warning is required under FIFRA—and expressly stated that a cancer warning would be false." Renewed Pet. for Reh'g En Banc at 2 (file-stamp p. 14).

As the rehearing petition explains, in 2019 EPA took the extraordinary step of notifying glyphosate registrants "that a cancer warning would 'constitute a false and misleading statement,'" rendering Roundup or other glyphosate pesticides misbranded under FIFRA. *Id.* at 6 (file-stamp p. 18) (quoting 2019 EPA Letter (Supp. App. 11)); *see* 7 U.S.C. 136(q)(1)(A) (defining a pesticide as "misbranded" if, in pertinent

part, "its labeling bears any statement . . . which is false or misleading in any particular"). More specifically, the August 7, 2019 "Dear Registrant" letter signed by the EPA Office of Pesticide Programs' Registration Division Director—which rejected inclusion of a California "Proposition 65" cancer warning statement on glyphosate products' labeling—states:

> Given EPA's determination that glyphosate is "not likely to be carcinogenic in humans," EPA considers the Proposition 65 warning language based on the chemical glyphosate to be *a false and misleading statement*. As such, pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are *misbranded* pursuant to section 2(q)(1)(A) of FIFRA and as such *do not meet the requirements of FIFRA*.

Supp. App. 11 (emphasis added).[5]

As the district court readily found, any state-law labeling requirement that would violate FIFRA's prohibition against distribution of misbranded pesticides, 7 U.S.C. § 136j(a)(1)(E), by requiring inclusion of a false and misleading cancer warning statement on Roundup's

[5] FIFRA prohibits manufacturers from adding or modifying label warnings without EPA's prior approval. *See* 7 U.S.C. § 136j(a)(2)(A) (making it unlawful to "alter . . . in whole or in part, any labeling required under [FIFRA])"; 40 C.F.R. § 152.130(a) (pesticide products may be distributed or sold only with the "labeling currently approved by the Agency"); *id.* § 156.70(c) ("Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency.").

labeling necessarily would be "in addition to or different from" EPA's requirements for Roundup's labeling, and therefore, expressly preempted. Dist. Ct. Order at 8 (A. 96). The rehearing petition explains that EPA has not changed this position. *See* Renewed Pet. for Reh'g En Banc at 6-7 (file-stamp pp. 18-19).

In light of EPA's carefully considered determination prohibiting a Roundup cancer warning as unwarranted and false and misleading, Carson's attempt to equate Georgia's general duty to warn with FIFRA's general misbranding standard cannot transform his failure-to-warn claim into a state-law labeling requirement that is parallel or equivalent to, or genuinely consistent with, EPA's Roundup labeling requirements. Doing so would render § 136v(b) meaningless, thereby destroying the nationwide, product-specific labeling uniformity that Congress sought to achieve through the preemption provision.

C. The Court should clarify the scope of the parallel requirements exception

In view of the sweeping preemptive language that Congress chose for § 136v(b), it would have been forgivable to conclude, as had numerous courts (including the Eleventh Circuit) prior to *Bates*, that FIFRA preempts any state-law claim for failing to provide a pesticide label

warning. *See, e.g.*, *Papas v. Upjohn Co.*, 985 F.2d 516, 518 (11th Cir. 1993); *cf. Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1337 (10th Cir. 2015) (discussing the Medical Device Amendments' analogous express preemption language) ("Given this expansive language one might be forgiven for thinking all private state law tort suits are foreclosed."). Although *Bates* does not hold that *all* failure-to-warn claims against pesticide manufacturers are preempted, the Court emphasized that § 136v(b) "pre-empts *any* statutory or common-law rule that would impose a labeling requirement that diverges from" labeling requirements imposed in accordance with FIFRA. *Bates*, 544 U.S. at 425 (emphasis added).

Nonetheless, despite the Supreme Court's affirmation in *Bates* that FIFRA expressly preempts most pesticide-related failure-to-warn claims, the plaintiffs' bar quickly seized upon its own self-serving misinterpretation of the parallel requirements *exception* as an automatic way to circumvent § 136v(b) and avoid preemption of virtually all 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 Rep. 784

(Aug. 25, 2005) ("[M]ost failure to warn . . . claims will easily pass this test."). The plaintiffs' bar continues to mischaracterize the parallel requirements exception. For example, Public Citizen's en banc amicus brief here asserts that

> the state-law requirements underlying Mr. Carson's claim parallel FIFRA's requirements. FIFRA requires pesticide labels to contain "a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(G). Similarly, Georgia law requires a manufacturer to warn whenever it "knows or reasonably should know of the danger arising from the use of its product." . . . Because the state-law duties at issue parallel FIFRA's requirements, FIFRA does not expressly preempt Mr. Carson's failure-to-warn claim.

En Banc Br. for Amicus Curiae Public Citizen In Support of Plaintiff-Appellant at 22-23 (file-stamp pp. 34-35), *Carson v. Monsanto Co.* (No. 21-10994) (11th Cir. filed Feb. 28, 2023). This superficial comparison ignores the actual, product-specific way that EPA regulates pesticide labeling and imposes requirements for labeling in accordance with FIFRA.

Rather than undertaking the type of meticulous preemption analysis required by *Bates*, *see* 544 U.S. at 453-54, some courts likewise

have misread *Bates* as holding that a cursory comparison of a state-law duty to warn with FIFRA's definition of a misbranded pesticide is all that is needed for a failure-to-warn claim to avoid preemption. *See, e.g.*, *Hardeman v. Monsanto Co.*, 997 F.3d 941, 955 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022) (Roundup personal injury case) ("Because FIFRA's misbranding requirements parallel those of California's common law duty, Hardeman's failure-to-warn claims effectively enforce FIFRA's requirement against misbranding and are thus not expressly preempted."); *see also In re Roundup Prod. Liab. Litig.* (MDL No. 2741), 364 F. Supp. 3d 1085, 1087 (N.D. Cal. 2019) ("FIFRA requires manufacturers to provide a warning that 'may be necessary and if complied with . . . is adequate to protect health.' 7 U.S.C. § 136(q)(1)(G). California law - which asks whether a risk is known or knowable (for strict liability) or reasonably should have been known (for negligence) - is consistent with this requirement.").

The Ninth Circuit's shallow and expansive construction of the parallel requirements exception, and the similar ruling in the Roundup multidistrict litigation, create a gaping loophole that eviscerates

§ 136v(b), and directly conflicts with the product-specific equivalency assessment required by *Bates*, 544 U.S. at 453-54.

In view of such decisions, this Court should not only affirm the district court's express preemption ruling, but also put the parallel requirements exception into its proper place within the FIFRA statutory scheme. This is the express "pre-emption analysis at the pleadings stage of a case" that *Bates* calls upon lower courts to conduct. *Bates*, 544 U.S. at 454. If a manufacturer fails to provide a specific label warning that EPA has required and approved, a state-law damages suit based on that violation of FIFRA would fit within the parallel requirements exception to § 136v(b). But where, as here, a manufacturer omits a label warning that EPA has determined is not only scientifically unwarranted, but also would be false and misleading and a violation of FIFRA, then the parallel requirements exception does not apply to a failure-to-warn claim based on that omission.

CONCLUSION

The Court should affirm the district court's holding that FIFRA preempts Plaintiff-Appellant Carson's failure-to-warn claim.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief contains **5,033** words, excluding those parts exempted by Fed. R. App. P. 32(f).

I certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) as it is written in proportionally-spaced, 14-point Century Schoolbook font using Microsoft Office 365.

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CERTIFICATE OF SERVICE

I certify that on March 10, 2023 I filed the foregoing brief using the Court's CM/ECF System, which effected service on all parties.

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