No. 21-10994-E

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

JOHN D. CARSON, SR.,
Plaintiff-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellee.

Appeal from the U.S. District Court for the
Southern District of Georgia
No. 4:17-cv-00237-RSB-CLR

BRIEF FOR AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF PLAINTIFF-APPELLANT

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May 12, 2021

No. 21-10994-E, *Carson v. Monsanto Co.*

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Local Rule 26.1-2, the following parties, not identified in the earlier-filed briefs, have an interest in the outcome of this appeal:

- Public Citizen, Inc. – Amicus Curiae
- Public Citizen Litigation Group – law firm for Public Citizen, Inc.
- Adina H. Rosenbaum – counsel for Public Citizen, Inc.
- Allison M. Zieve – counsel for Public Citizen, Inc.

Pursuant to Federal Rule of Appellate Procedure 26.1, the undersigned counsel certifies that amicus curiae Public Citizen, Inc. is a nonprofit, non-stock corporation. It has no parent corporation, and no publicly-held corporation has an ownership interest in it.

/s/ Adina H. Rosenbaum
Adina H. Rosenbaum
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INTEREST OF AMICUS CURIAE[1]

Public Citizen is a non-profit consumer-advocacy organization. Appearing on behalf of its nationwide membership before Congress, administrative agencies, and courts, Public Citizen works for the enactment and enforcement of laws protecting consumers, workers, and the general public. Public Citizen often represents consumer interests in litigation, including as amicus curiae in cases in the United States Supreme Court and the federal appellate courts.

Public Citizen has a longstanding interest in fighting broad claims that federal regulation preempts state laws that protect consumers, and it has appeared as amicus curiae in many cases raising preemption issues. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019); *Hardeman v. Monsanto Co.*, Nos. 19-16636, 19-16708 (9th Cir. Pending); *Bedoya v. Am. Eagle Express Inc.*, 914 F.3d 812 (3d Cir. 2019); *Jones v. Medtronic, Inc.*, 745 F. App'x 714 (9th Cir. 2018). Public Citizen

[1] All parties have consented to the filing of this brief. No party's counsel authored this brief in whole or in part, and no party or party's counsel made a monetary contribution to fund the preparation or submission of this brief. No person or entity other than Public Citizen made a monetary contribution to the preparation or submission of this brief.

submits this amicus curiae brief because defendant-appellee Monsanto's overly broad reading of the preemptive scope of the Federal Insecticide, Fungicide, and Rodenticide Act, if adopted by this Court, would decrease pesticide manufacturers' incentive to disclose safety risks and deprive consumers of redress for injuries they suffer due to exposure to pesticides with inadequate warnings.

STATEMENT OF THE ISSUE

Whether the Federal Insecticide, Fungicide, and Rodenticide Act preempts plaintiff-appellant's failure-to-warn claim.

BACKGROUND AND SUMMARY OF ARGUMENT

Plaintiff-appellant John Carson, Sr., filed this case asserting several claims arising from his exposure to defendant-appellee Monsanto's product Roundup. The district court granted Monsanto's motion for judgment on the pleadings as to some of those claims, holding, as relevant here, that Mr. Carson's failure-to-warn claim was expressly preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq*. FIFRA, however, "authorizes a relatively decentralized scheme that preserves a broad role for state regulation,"

Bates v. Dow Agrosciences LLC, 544 U.S. 431, 450 (2005), and leaves room for state-law claims such as that brought by Mr. Carson.

I. Mr. Carson's claim is not expressly preempted by FIFRA's preemption provision, which preempts state "requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b). As the Supreme Court has explained, this provision does not preempt state laws that are "equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Bates*, 544 U.S. at 447. Because Mr. Carson's failure-to-warn claim is based on state-law requirements that parallel FIFRA's requirements, it is not preempted.

The Environmental Protection Agency's (EPA) approval of Roundup's label in the course of registering the pesticide does not alter the express preemption analysis. FIFRA makes clear that EPA's registration of a pesticide is not determinative of whether the pesticide and its label comply with FIFRA's requirements. *See* 7 U.SC. § 136a(f)(2). Accordingly, a state-law claim that an EPA-approved label is inadequate does not necessarily rely on requirements that are "in addition to or different from" FIFRA's requirements.

The preemption analysis is likewise not altered by the letter that EPA's Office of Pesticide Programs sent to pesticide registrants in August 2019 stating that a California Proposition 65 warning on products containing glyphosate—Roundup's active ingredient—would render those products misbranded. That letter lacks the force of law, and thus does not set forth any "requirements" that can preempt state law under section 136v(b).

II. FIFRA also does not impliedly preempt Mr. Carson's claim. FIFRA contains a provision, 7 U.S.C. § 136v(a), that allows states to regulate or ban EPA-approved pesticides. This provision precludes Monsanto's argument below that it would be impossible for the company to comply with both its federal and state-law duties. And even apart from section 136v(a), Monsanto did not demonstrate that it could not comply with both state and federal law. Although Monsanto argued below that EPA would have rejected its request to add a warning to Roundup's label had it sought to do so, EPA has in the past *approved* applications allowing the addition of a Proposition 65 glyphosate cancer warning to pesticide labels. *See* Doc. 37-3, at 10 (Br. of U.S. as Amicus Curiae in Support of

Monsanto, *Hardeman v. Monsanto Co.*, No. 19-16636 (9th Cir., filed Dec. 20, 2019)).[2]

As the Supreme Court has noted, state-law actions that seek to "enforce federal misbranding requirements," as this case does, "would seem to aid, rather than hinder, the functioning of FIFRA." *Bates*, 544 U.S. at 451. FIFRA neither expressly nor impliedly preempts Mr. Carson's claim, and the district court judgment dismissing this claim should be reversed.

ARGUMENT

I. FIFRA Does Not Expressly Preempt Mr. Carson's Claim.

A. The state-law requirements at issue parallel FIFRA's requirements.

FIFRA's express preemption provision provides that states may not impose or continue in effect "any requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b). In *Bates*, the Supreme Court explained that, for a state requirement to be preempted under this provision, "it must satisfy two conditions." 544 U.S. at 444. "First, it must be a requirement '*for labeling*

[2] "Doc." refers to the document number in the district court docket.

or packaging.'" *Id.* Second, "it must impose a labeling or packaging requirement that is '*in addition to or different from* those required under this subchapter.'" *Id.* "The proper inquiry calls for an examination of the elements of the common-law duty at issue." *Id.* at 445.

Elaborating on the meaning of "in addition to or different from," *Bates* explained that a state law is not preempted by FIFRA "if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id.* at 447. To be equivalent, the law "need not explicitly incorporate FIFRA's standards as an element of a cause of action" nor "be phrased in the *identical* language as its corresponding FIFRA requirement." *Id.* at 447, 454.

Here, the Georgia requirements underlying Mr. Carson's claim are equivalent to 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." *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994). Given the elements of the laws at issue, "it's hard to

see how [Mr. Carson's] failure-to-warn claim[] could be construed more broadly than FIFRA." *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1038 (N.D. Cal. 2016) (internal quotation marks and citation omitted) (appeal pending).

Because the state-law duties at issue parallel FIFRA's requirements, plaintiff's claim is not expressly preempted.

B. EPA's approval of a pesticide's label as part of its registration does not preempt claims based on failure to warn.

Monsanto argued below that Mr. Carson's state-law claim is in addition to or different from FIFRA's requirements because "EPA has approved a label for Roundup® with no cancer warning." Doc. 37, at 17. FIFRA makes clear, however, that "the fact that the EPA has approved a pesticide's labeling claims does not necessarily mean that the pesticide complies with all of FIFRA's requirements—particularly the prohibition against misbranding." *Crespo v. S.C. Johnson & Son, Inc.*, 394 F. Supp. 3d 260, 271 (E.D.N.Y. 2019). As the Supreme Court expressly recognized in *Bates*, a pesticide can be "registered but nevertheless misbranded." 544 U.S. at 438. Although registration is prima facie evidence that the pesticide and its labeling comply with FIFRA's registration provisions,

the statute specifies that "in no event shall registration of an article be construed as a defense for the commission of any offense under" FIFRA. 7 U.S.C. § 136a(f)(2). That is, a pesticide's labeling can violate FIFRA even though the product was registered by EPA. Thus, a state-law claim based on the label's inadequacy is not necessarily based on a requirement that is in addition to or different from a requirement imposed by FIFRA.

Bates confirms this point. In *Bates*, as here, the label of the pesticide at issue had been approved by EPA in the course of pesticide registration. Nonetheless, the Supreme Court held that the plaintiff's failure-to-warn claims were not necessarily preempted. Instead, the Court remanded for a determination whether the state labeling requirements were equivalent to FIFRA's requirements. *See* 544 U.S. at 453. As the Third Circuit has explained, "the remand established that mere inconsistency between the duty imposed by state law and the content of a manufacturer's labeling approved by the EPA at registration did not necessarily mean that the state law duty was preempted." *Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc.*, 617 F.3d 207, 222 (3d Cir. 2010).

Indeed, rather than holding that FIFRA broadly preempts claims based on the inadequacy of an EPA-approved label, the Supreme Court

recognized that state-law actions based on the failure to include warnings on the label of a registered pesticide could "aid … the functioning of FIFRA." 544 U.S. at 451. "By encouraging plaintiffs to bring suit for injuries not previously recognized as traceable to pesticides," the Court explained, a state failure-to-warn action "may aid in the exposure of new dangers associated with pesticides. Successful actions of this sort may lead manufacturers to petition EPA to allow more detailed labeling of their products; alternatively, EPA itself may decide that revised labels are required in light of the new information that has been brought to its attention through common law suits." *Id.* (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541 (D.C. Cir. 1984)). It is inconceivable that the Supreme Court would have been extolling the ability of failure-to-warn claims to convince manufacturers and EPA to revise a pesticide's labeling if the fact that the warning at issue was not already on the label meant that the failure-to-warn claim was preempted.

Below, Monsanto attempted below to distinguish *Bates*—and to avoid the clear import of the remand in that case—by noting that *Bates* involved a failure to warn related to efficacy, rather than safety, and that EPA had waived conducting a review of the pesticide's efficacy. Doc. 37,

at 19. *Bates* did not indicate, however, that the state-law claims at issue were not preempted because EPA had not conducted an efficacy review. *See Holyfield v. Chevron U.S.A., Inc.*, No. 1:20-CV-00165-JAR, 2021 WL 1380280, at *3 (E.D. Mo. Apr. 12, 2021) ("The Supreme Court did not limit its analysis in *Bates* to claims regarding pesticide efficacy."). In analyzing whether the plaintiffs' claims were preempted, the "Court only mentioned that the EPA waived efficacy review of certain pesticides as additional support [for the point] that it is 'unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability.'" *Bourbia v. S.C. Johnson & Son, Inc.*, 375 F. Supp. 3d 454, 463–64 (S.D.N.Y. 2019) (quoting *Bates*, 544 U.S. at 450). Moreover, the Court quoted *Ferebee* for the proposition that "a state tort action *of the kind under review* may aid in the exposure of new dangers associated with pesticides." *Bates*, 544 U.S. at 451 (quoting *Ferebee*, 736 F.2d at 1541; emphasis added). Notably, *Ferebee* involved a failure to include a warning related to safety, not efficacy. *See* 736 F.2d at 1539.

More fundamentally, whether the failure to warn at issue relates to safety or efficacy does not alter the underlying regulatory scheme,

under which EPA's approval of a label is not dispositive of whether the label complies with all of FIFRA's requirements. The statute provides that "*in no event* shall registration of an article be construed as a defense for the commission of any offense under" FIFRA. 7 U.S.C. § 136a(f)(2) (emphasis added). This provision makes clear that, regardless of the underlying analysis conducted by EPA, EPA's registration, including the approval of the label during registration, does not determine whether that labeling complies fully with FIFRA.

Section 136a(f)(2) meaningfully distinguishes this case from *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008), on which Monsanto relied below, Doc. 37, at 20. *Riegel* held that an express preemption provision in the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act expressly preempts claims challenging the safety and effectiveness of a medical device that received premarket approval from the Food and Drug Administration (FDA). Like FIFRA's preemption provision, the MDA's preemption provision preempts certain state requirements that are different from, or in addition to, certain federal requirements. Importantly, however, the MDA does *not* contain a provision similar to 7 U.S.C. § 136a(f)(2), which makes clear that the

agency's approval of a label does not determine whether the label complies with the statute's requirements. *See Crespo*, 394 F. Supp. 3d at 272 ("[T]o the extent that the defendant relies upon cases involving federal statutes that do not contain a similar warning about the ongoing, post-registration duty to comply with the statutory scheme, these cases are not persuasive to the court.").

Moreover, regardless of the scope of preemption under other statutes, in the context of FIFRA, the Supreme Court has already considered EPA's registration process and concluded that the fact that EPA has approved a pesticide's label does not mean that a claim based on a failure to warn about a risk that was not included in the EPA-approved labeling is based on a requirement that is "in addition to or different from" FIFRA's requirements. *See Bates*, 544 U.S. at 453. That *Bates* involved a claim about efficacy rather than safety does not matter; it is the same registration process. Either the approval of the label conclusively sets forth what is required by FIFRA, such that any claim that the label is inadequate is necessarily based on a requirement that is in addition to or different from FIFRA's requirements, or it does not. *Bates* makes clear that it does not.

Monsanto relied below (Doc. 37, at 19) on a passage in *Bates* in which the Supreme Court explained 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 because it is inconsistent with 40 CFR § 156.64 (2004), which specifically assigns these warnings to particular classes of pesticides based on their toxicity." 544 U.S. at 453. The Supreme Court used the DANGER/CAUTION example, however, as part of its explanation that requirements set out in EPA regulations, as well as requirements set out in the statute, can have preemptive effect. *See id.* ("State-law requirements must also be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards."). Because EPA registration and approval of labeling is not a regulation, the DANGER/CAUTION example does not help Monsanto here. Indeed, the fact that *Bates* specifically noted that a state-law requirement must be measured against both the requirements set forth in FIFRA and those set forth in FIFRA's implementing regulations to determine whether the state-law requirement is equivalent to FIFRA's requirements—but did not suggest that the state-law requirement must be compared to the EPA-approved

label—reinforces that EPA's approval of the label does not have preemptive force.

In sum, EPA's registration of a pesticide without a certain warning on its label does not mean that a state-imposed requirement to include that warning is "in addition to or different from" FIFRA's requirements. "[T]o the extent that defendant is arguing that the EPA's registration of glyphosate and approval of the Roundup label carry any preemptive force, defendant is simply mistaken." *Blitz v. Monsanto Co.*, 317 F. Supp. 3d 1042, 1050 (W.D. Wis. 2018).

C. The August 2019 letter does not establish any requirements and, therefore, cannot preempt state-law claims.

In holding that Mr. Carson's failure-to-warn claim is preempted, the district court relied on an August 2019 letter from the director of EPA's pesticide registration division to certain pesticide registrants, in which the director stated that a California Proposition 65 warning about glyphosate would render a pesticide misbranded. Doc. 49, at 2–3, 8 (discussing Doc. 37-2). The August 2019 letter, however, does not set forth any "requirements" under FIFRA that can preempt state law. 7 U.S.C. § 136v(b).

As the Supreme Court noted in *Bates*, "[a] requirement is a rule of law that must be obeyed." 544 U.S. at 445. Thus, to establish requirements that can preempt state law under section 136v(b), federal action must have the force of law. The August 2019 letter does not. As EPA acknowledged when it sent the letter, it is simply "guidance." EPA, News Release, *EPA Takes Action to Provide Accurate Risk Information to Consumers, Stop False Labeling on Products* (Aug. 8, 2019), https://www.epa.gov/newsreleases/epa-takes-action-provide-accurate-risk-information-consumers-stop-false-labeling. Guidance documents, like other agency "rules" issued without notice-and-comment rulemaking, "do not have the force and effect of law and are not accorded that weight in the adjudicatory process." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 97 (2015) (citation omitted); *see also Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000) (explaining that interpretations contained in opinion letters, policy statements, agency manuals, and enforcement guidelines all lack the force of law).

The August 2019 letter is similar to a letter that the Third Circuit held had no preemptive effect in *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237 (3d Cir. 2008). There, the FDA Commissioner sent a letter to

the California Attorney General stating that Proposition 65 warnings regarding mercury on tuna labels would be misleading and therefore render tuna products sold with such a warning misbranded. The Third Circuit stated that, if the FDA had "exercised its misbranding authority to establish that a warning … would be false or misleading under federal law," a state failure-to-warn claim "would be preempted." *Id.* at 255. However, the court explained, the FDA had taken "no regulatory action establishing mercury warnings as misbranding under federal law." *Id.* "Instead, the FDA merely expressed an informal policy opinion in a letter, and it did so only after [the plaintiff's] injuries were allegedly suffered." *Id.* Likewise, here, EPA has "merely expressed an informal policy opinion in a letter," and the informal views expressed in the letter do not establish requirements under FIFRA.

Simply put, the August 2019 letter is too informal to authoritatively "give content to FIFRA's misbranding standards." *Bates*, 544 U.S. at 453. The August 2019 letter does not affect the express preemption analysis in this case, and section 136v(b) does not preempt the plaintiff's failure-to-warn claim.

II. FIFRA Does Not Impliedly Preempt Mr. Carson's Claim.

Mr. Carson's failure-to-warn claim likewise is not impliedly preempted. Monsanto argued below (Doc. 37, at 21) that it was impossible for it comply with both federal law and its state-law duty to warn because federal law forbade it from adding a warning to its label without prior EPA approval, and because EPA would have rejected a request to add a warning to Roundup's label. Monsanto's impossibility arguments, however, are foreclosed by FIFRA's distinctive regulatory regime. Moreover, Monsanto has not established that EPA would have rejected a request for it to put a warning on Roundup's label, particularly given that, in the past, EPA approved "applications allowing the addition of a Proposition 65 glyphosate cancer warning to pesticide labels when requested." Doc. 37-3, at 10.

A. Monsanto has not presented clear evidence that EPA would have prohibited it from placing the warning that state law requires on Roundup's label.

Monsanto argued below (Doc. 37, at 21–22) that Mr. Carson's claim was preempted under the reasoning of *Wyeth v. Levine*, 555 U.S. 555, 571 (2009), and *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1676 (2019), which establish that state failure-to-warn claims against

name-brand drug manufacturers are preempted if there is "'clear evidence' that the FDA would not have approved the warning that state law requires," *id.* at 1676. Even assuming that *Wyeth* and *Merck*'s "clear evidence" standard applies to the FIFRA regulatory scheme, Monsanto failed to provide the requisite evidence that EPA would have forbidden it from placing a warning on Roundup's labeling.

Below, Monsanto cited the August 2019 letter, claiming it showed that EPA "would not approve" a warning. Doc. 37, at 22. The relevant question under *Wyeth* and *Merck,* however, is not whether it would be possible for the manufacturer to put a warning on its label *now,* but whether it was possible for the manufacturer to put a warning on its label during the period at issue in the lawsuit. The August 2019 letter does not demonstrate that, had Monsanto requested permission to add a warning to Roundup's label during a time period in which such a warning could have helped Mr. Carson, EPA would have rejected that request. To the contrary, there is reason to think that, if Monsanto had asked, EPA would have allowed it to warn about the risks of glyphosate: In the past, EPA *approved* "applications allowing the addition of a Proposition 65

glyphosate cancer warning to pesticide labels when requested." Doc. 37-3, at 10.

In any event, the letter is too informal to constitute "clear evidence" that EPA would have rejected a warning label. *See Merck*, 139 S. Ct. at 1679 (noting that "[f]ederal law permits the [agency] to communicate its disapproval of a warning by means of notice-and-comment rulemaking setting forth labeling standards, … by formally rejecting a warning label that would have been adequate under state law, … or with other agency action carrying the force of law"). The letter is not a "formal[] reject[ion of] a warning label that would have been adequate under state law," nor does it establish, with "the force of law," what constitutes misbranding under the statute. *Id.* It is guidance expressing an informal opinion on Proposition 65 warnings about glyphosate, stating an intent regarding future requests to place such warnings on labels, and making a request of registrants whose products contain EPA-approved Proposition 65 warnings about glyphosate on their labels.

The other evidence on which Monsanto relied below likewise does not demonstrate that it was impossible for Monsanto to comply with both its federal and state-law duties. In particular, Monsanto pointed to EPA's

findings that glyphosate is not carcinogenic. Doc. 37, at 22. That EPA did not itself believe a warning was necessary does not demonstrate, however, that it would have affirmatively prohibited Monsanto from adding a warning had Monsanto asked to do so. And when other manufacturers *did* request to be allowed to add Proposition 65 glyphosate cancer warnings to their pesticide labels, EPA approved those requests. Doc. 37-3, at 10.

Because Monsanto has not proffered the requisite clear evidence that EPA would not have approved a change to Roundup's label, Monsanto's impossibility arguments based on *Wyeth* and *Merck* fail.

B. EPA's label-amendment process did not make it impossible for Monsanto to comply with state law.

Relying primarily on *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), which concerned preemption under the federal regulatory scheme governing generic drugs, Monsanto also argued below (Doc. 37, at 23) that it would have been impossible for it to comply with its state-law duty to warn because it could not add a warning to its label without prior EPA approval. As the Supreme Court noted in *PLIVA*, however, "different federal statutes and regulations may … lead to different pre-emption

results." *PLIVA*, 564 U.S. at 626. Here, Monsanto's arguments fail in light of FIFRA's distinctive regulatory regime.

1. To begin with, Monsanto's impossibility preemption argument is foreclosed by 7 U.S.C. § 136v(a), which provides that a "State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter." Under this provision, "a state agency may ban the sale of a pesticide if it finds, for instance, that one of the pesticide's label-approved uses is unsafe." *Bates*, 544 U.S. at 446; *see also id.* at 450 ("States may ban or restrict the uses of pesticides that EPA has approved[.]"). "This provision strongly suggests that a state has the authority to impose obligations upon pesticide manufacturers that would, in practice, require them to obtain EPA approval for labeling changes before their products can be sold in the state." *Crespo*, 394 F. Supp. 3d at 274. "[I]f [the state] can stop Monsanto from selling Roundup entirely, surely it can impose state-law duties that might require Monsanto to seek EPA approval before selling an altered version of Roundup in [the state]." *In re Roundup Prod. Liab. Litig.*, 364 F. Supp. 3d 1085, 1088 (N.D. Cal. 2019) (appeal pending).

Section 136v(b) buttresses the conclusion that Mr. Carson's state-law claim is not impliedly preempted. Although an express preemption provision does not "bar the ordinary working of conflict pre-emption principles," *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) (citation omitted), it "supports a reasonable inference … that Congress did not intend to pre-empt other matters," *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001) (citation omitted); *see Lawson-Ross v. Great Lakes Higher Educ. Corp.*, 955 F.3d 908, 920 (11th Cir. 2020). In section 136v(b), Congress specified exactly which types of labeling claims it meant to exclude from section 136v(a)'s general provision of permission for states to regulate pesticides. *See Bates*, 544 U.S. at 449 (noting that Congress "inten[ded] to draw a distinction between state labeling requirements that are pre-empted and those that are not"). Holding that labeling requirements that are *not* "in addition to or different from" those required under FIFRA were preempted would eradicate Congress's careful delineation of which labeling claims it sought to preempt and which it sought to preserve, and would render section 136v(b) superfluous.

2. Monsanto's argument is also "difficult—if not impossible—to square with *Bates*." *In re Roundup Prod. Liab. Litig.*, 364 F. Supp. 3d at 1088. In *Bates*, the pesticide manufacturer argued that FIFRA both expressly and impliedly preempted the plaintiff's state-law claims. *See, e.g.*, Br. for Respondent, *Bates v. Dow Agrosciences LLC*, No. 03-388, at i (U.S. Nov. 24, 2004) (stating that the question presented by the case was whether "petitioners' claims for crop damages … are expressly or impliedly preempted" by FIFRA). The Court held that FIFRA does not expressly preempt state-law duties that parallel FIFRA's misbranding requirements and remanded to the court of appeals to determine whether the state-law duties at issue were equivalent to FIFRA's requirements. "[I]t is logical to conclude that the *Bates* Court first considered all 'arguments that, if successful, would have affirmed the lower court decision finding preemption,' before it held that the plaintiff's claims in that case were not necessarily preempted." *Crespo*, 394 F. Supp. 3d at 273 n.6 (quoting *Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270, 1281 (D. Haw. 2015)). Indeed, Justice Thomas described the Court's opinion as "comport[ing] with th[e] Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied

pre-emption." *Bates*, 544 U.S. at 459 (Thomas, J., concurring in the judgment in part and dissenting in part).

Moreover, the Supreme Court noted in *Bates* that "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA," *id.* at 451, including by "'lead[ing] manufacturers to petition EPA to allow more detailed labeling of their products,'" *id.* (quoting *Ferebee*, 736 F.2d at 1541). It is thus clear that the Supreme Court was aware that manufacturers might have to petition EPA if they wanted to alter their labeling and that it assumed that suits based on inadequate labeling could not only co-exist with that requirement, but would benefit FIFRA's functioning.

3. Even apart from section 136v and *Bates*, the regulatory scheme for pesticides meaningfully differs from the regulatory scheme for generic drugs at issue in *PLIVA*. Generic drug manufacturers neither draft their products' initial labeling nor have the power to revise labeling. Instead, they are required to use the same labeling as the corresponding name-brand drug. Because of this duty of "sameness," 564 U.S. at 613 (citation omitted), the Supreme Court held in *PLIVA* that it was impossible for generic drug manufacturers to comply with both federal labeling

requirements and state common-law duties to provide adequate warnings, where those duties required warnings different from the FDA-required labeling, *id.* at 618. And although generic-drug manufacturers could ask the FDA for assistance in convincing the name-brand manufacturer to change its labeling, the Court found the "conjecture[]" that "had the Manufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label" too speculative to overcome the preemption defense. *Id.* at 621; *see id.* at 619 (in describing the chain of events that might lead to an amended label, stating that, "[i]f [the Manufacturers] had [asked the FDA for help], and if the FDA decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the Manufacturers would have started a Mouse Trap game that eventually led to a better label"). The Court concluded:

> [W]hether a private party can act sufficiently independently under federal law to do what state law requires may sometimes be difficult to determine. But this is not such a case. Before the Manufacturers could satisfy state law, the FDA—a federal agency—had to undertake special effort permitting them to do so. To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and

> assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.

Id. at 623–24.

Pesticide manufacturers exercise significantly more control over their products' labeling than do generic drug manufacturers. Unlike generic drug manufacturers, pesticide manufacturers are responsible for drafting their products labels, *see* 7 U.S.C. § 136a(c)(1)(C), and they are not required to maintain the same labeling as another manufacturer. Once the pesticide is registered, the manufacturer has "a continuing obligation to adhere to FIFRA's labeling requirements," *Bates*, 544 U.S. at 438, including ensuring that the product is not misbranded through failure to include necessary warning or caution statements, 7 U.S.C § 136(q)(1). If the label must be changed, the responsibility is on the manufacturer to change the label, under regulations governing the process. *See* 40 C.F.R. § 152.50(e). And although the manufacturer generally must submit that label to EPA for approval, EPA "shall" approve the label if it determines the change will not violate FIFRA. 7 U.S.C. § 136a(f)(1).

Thus, unlike the generic-drug manufacturers in *PLIVA*, Monsanto drafted Roundup's initial labeling, and it was responsible for drafting and submitting label revisions. And unlike the generic-drug manufacturers in *PLIVA*, Monsanto would not have required "special permission and assistance" from EPA to put a warning on its label. *PLIVA*, 564 U.S. at 623–24. The usual way in which pesticide labels get changed is through revisions that manufacturers initiate by drafting them and submitting them to EPA for review. Under these circumstances, the manufacturer can act "sufficiently independently" under federal law that federal law poses no hurdle to a state-law duty to provide adequate warnings. *Id.* at 623.

4. Finally, Monsanto's argument below (Doc. 37, at 23) that the label-amendment process made it impossible for it to comply with the state-law duty to warn relied on Monsanto's contention that it could not alter its labels without prior EPA approval. EPA, however, permits pesticide manufacturers to make certain changes to labeling without prior approval. Specifically, EPA allows manufacturers to make various minor modifications to their products' labeling without prior EPA approval by notifying EPA of the change. *See* 40 C.F.R. § 152.46(a); EPA,

Office of Pesticide Programs, *Pesticide Registration Notice 98-10* (Oct. 22, 1998) (PRN 98-10), www.epa.gov/sites/production/files/2014-04/documents/pr98-10.pdf.

Monsanto dismisses this process in a footnote (Doc. 37, at 24 n.9), stating that adding a warning about cancer would not qualify as a minor modification. But EPA has often allowed pesticide manufacturers to use this notification procedure to add Proposition 65 notices to their products' labels, including notices related to cancer. For example, on November 29, 2012, Bayer CropScience submitted a notification to EPA pursuant to PRN 98-10, "notifying the Agency of a minor labeling amendment for LARVIN Technical (EPA Reg. No. 264-343)." Letter from Larry R. Hodges, Registration Manager, Bayer CropScience, to Office of Pesticide Programs, EPA (Nov. 29, 2012), www3.epa.gov/pesticides/chem_search/ppls/000264-00343-20131217.pdf, at 4. Specifically, the letter informed EPA that, "[a]s required by California Proposition 65, the following statement has been added to the label, 'This product contains a chemical known to the state of California to cause cancer.'" *Id.* In response, EPA stated that the "Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds

that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped 'Notification' and will be placed in our records." Letter from Jennifer Gaines, Office of Pesticide Programs, EPA, to Larry Hodges, Bayer CropScience (Dec. 17, 2012), www3.epa.gov/pesticides/chem_search/ppls/000264-00343-20131217.pdf at 2. Numerous other examples illustrate the point.[3] Given that EPA has allowed pesticide companies to place some cancer warnings on their products through its notification process—which does not require prior approval from the agency—Monsanto has not demonstrated that it was impossible for it to place adequate warnings on Roundup's label.

As the Supreme Court has explained, "[i]mpossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 573. Monsanto has failed to

[3] *See, e.g.*, Letter from Kathryn V. Montague, Office of Pesticide Programs, EPA, to Lynne C. Zahigian, Agent for Lawn and Garden Products, Inc. (Sept. 14, 2017), www3.epa.gov/pesticides/chem_search/ppls/054705-00006-20170914.pdf, at 1; Letter from Kable Bo Davis, Office of Pesticide Programs, EPA, to Laura E. Radevski, Chase Products Co. (June 21, 2017), www3.epa.gov/pesticides/chem_search/ppls/000498-00156-20170621.pdf, at 1; Letter from Michael Walsh, Office of Pesticide Programs, EPA, to Eric D. Smith, PBI/Gordon Corporation (May 30, 2017), www3.epa.gov/pesticides/chem_search/ppls/033955-00394-20170530.pdf at 1; Letter from Jennifer Urbanski, Office of Pesticide Programs, EPA, to Veronica Semetis Lawless, Wellmark International (April 21, 2015), www3.epa.gov/pesticides/chem_search/ppls/002724-00702-20150421.pdf, at 1.

satisfy that demanding standard. Because compliance with both federal law and the state-law duty to warn was not impossible, Mr. Carson's failure-to-warn claim is not preempted.

CONCLUSION

For the foregoing reasons, the Court should reverse the judgment below.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief complies with the word limit of Federal Rule of Appellate Procedure 29(a)(5). Excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Eleventh Circuit Rule 32-4, the brief contains 5,741 words, less than half the number of words permitted by the Court for the parties' principal briefs. The brief also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief is composed in a 14-point proportional typeface, Century Schoolbook.

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CERTIFICATE OF SERVICE

I hereby certify that this brief has been served through the Court's ECF system on counsel for all parties required to be served on May 12, 2021.

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