No. 24-1068

IN THE

Supreme Court of the United States

MONSANTO COMPANY,
Petitioner,

v.

JOHN L. DURNELL,
Respondent.

On Writ of Certiorari to the
Missouri Court of Appeals

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF RESPONDENT

ADINA H. ROSENBAUM
Counsel of Record
ALLISON M. ZIEVE
SCOTT L. NELSON
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
arosenbaum@citizen.org

Counsel for Amicus Curiae Public Citizen

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Other Authorities

INTEREST OF AMICUS CURIAE[1]

Public Citizen is a nonprofit consumer advocacy organization with members and supporters in every state. Public Citizen advocates before Congress, administrative agencies, and courts on a wide range of issues, including the enactment and enforcement of laws protecting consumers, workers, and the general public.

Public Citizen has a longstanding interest in fighting exaggerated claims that federal law preempts state laws that protect consumers, such as state laws that require manufacturers to provide adequate warnings about the risks of their dangerous products. Such laws help ensure that consumers choose appropriate products and take necessary steps to protect themselves from harm. And state-law claims enforcing such laws help ensure that manufacturers follow the laws and disclose the risks of their products. Public Citizen submits this brief because Petitioner Monsanto Company's overly broad reading of the preemptive scope of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), if adopted by this Court, would decrease pesticide manufacturers' incentive to disclose safety risks and deprive consumers of redress for harm caused by exposure to pesticides that lack adequate warnings.

SUMMARY OF ARGUMENT

FIFRA regulates the sale, use, and labeling of pesticides, with a goal of protecting people and the

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[1] This brief was not written in whole or in part by counsel for a party. No one other than amicus curiae or its counsel made a monetary contribution to the preparation or submission of the brief.

environment from the dangers posed by toxic pesticides. Reflecting this goal, a product is misbranded under FIFRA if, among other things, its "label does not 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).

FIFRA contains a provision expressly preempting state "requirements for labeling or packaging" that are "in addition to or different from those required under" FIFRA. *Id.* § 136v(b). In *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), this Court explained that this provision is "narrow" and does not preempt state requirements that are "equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id.* at 447, 452.

In this case, Respondent John Durnell, who developed cancer after using Monsanto's pesticide Roundup, brought a state-law failure-to-warn claim against Monsanto for failure to provide adequate warnings of the cancer risk posed by Roundup. The Missouri Court of Appeals compared FIFRA's misbranding provisions, which require warnings adequate to protect health and the environment, with the state-law requirement underlying Mr. Durnell's claim, which requires manufacturers to give adequate warnings of their products' dangers, and determined that the state-law requirement is equivalent to FIFRA's misbranding provisions. Pet. App. 6–7. Accordingly, the court held that FIFRA's preemption provision does not preempt Mr. Durnell's claim.

Despite the parallel between the state-law requirement and FIFRA's misbranding provisions, Monsanto contends that FIFRA expressly preempts

Mr. Durnell's claim because the Environmental Protection Agency (EPA) has concluded that glyphosate, Roundup's active ingredient, does not cause cancer and has repeatedly registered Roundup products without requiring a cancer warning. FIFRA makes clear, however, that EPA's registration of a pesticide is not determinative of whether the pesticide and its labeling comply with FIFRA's requirements. *See* 7 U.S.C. § 136a(f)(2). Thus, EPA's registration of a pesticide with a label that does not warn about a particular risk does not establish that FIFRA does not require a warning about that risk and does not preempt a state-law requirement to warn about the risk. Accordingly, in *Bates*, where this Court considered a claim based on a failure to warn where the relevant warning was not included on the label approved by EPA during registration, the Court made clear that such claims are not necessarily preempted. There is no meaningful difference between this case and *Bates*.

Monsanto also contends that FIFRA impliedly preempts Mr. Durnell's claim. FIFRA's regulatory scheme, however, does not provide a basis for implied preemption of state warning requirements. Moreover, Monsanto has not demonstrated that it would have been impossible for it to comply with both federal and state requirements. Pesticide manufacturers draft their products' labeling. And because Monsanto never sought to include a cancer warning on Roundup's label, its argument that EPA would have rejected its request to do so is speculation. Indeed, EPA has in the past *approved* applications allowing the addition of a cancer warning to labels of glyphosate products.

ARGUMENT

I. FIFRA does not expressly preempt state-law claims that a pesticide's label did not adequately warn of a safety risk whenever EPA registered the pesticide without requiring a warning of that risk.

A. FIFRA forbids the sale of pesticides that are not registered with the EPA, and requires pesticide manufacturers, as part of the registration process, to submit a proposed label. *See* 7 U.S.C. § 136a(a), (c)(1)(C). To register the pesticide, the agency must determine, among other things, that the pesticide's labeling complies with FIFRA's requirements. *See id.* § 136a(c)(5)(B). EPA's registration of Roundup without a cancer warning does not establish, however, that a state-law requirement to include such a warning is "in addition to or different from" FIFRA's requirements. *Id.* § 136v(b). As this Court recognized in *Bates*, a pesticide can be "registered but nevertheless misbranded." 544 U.S. at 438. Although registration is generally prima facie evidence that the pesticide and its labeling comply with FIFRA's registration provisions, the statute specifies that "[i]n 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, as relevant here, a pesticide's label may be misbranded under FIFRA, even though the product was registered (and the label found acceptable) by EPA.

Monsanto contends that section 136a(f)(2) prevents registration from being used as a defense *only* to a claim that the pesticide violates the terms of the registration. Monsanto Br. 39. Section 136a(f)(2), however, provides that registration is not a defense to

"any offense" under FIFRA. 7 U.S.C. § 136a(f)(2); *see id.* (providing that in "no event" shall registration be a defense to a FIFRA violation). The broad language of section 136a(f)(2) makes clear that EPA's approval of a label in the registration process does not conclusively establish that the label complies with FIFRA's requirements. "And because EPA's labeling determinations are not dispositive of FIFRA compliance, they similarly are not conclusive as to which common law requirements are 'in addition to or different from' the requirements imposed by FIFRA." *Hardeman v. Monsanto Co.*, 997 F.3d 941, 956 (9th Cir. 2021).

Bates confirms this point. In *Bates*, as here, EPA had registered the pesticide at issue and, in the course of doing so, approved the labeling. Nonetheless, this Court held that the plaintiffs' failure-to-warn claim was 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. That EPA had approved the pesticide without a particular warning, then, did not establish that FIFRA preempted a state-law duty to include such a warning.

Monsanto emphasizes that, after registration, pesticide manufacturers need EPA's permission for most labeling changes. *See, e.g.*, Pet. i. But regardless of whether EPA approval of labeling changes is required, EPA's registration of a pesticide with a particular label cannot "give content to FIFRA's misbranding standards," *Bates*, 544 U.S. at 453, when the statute makes clear that the label can nonetheless violate those standards.

Moreover, Monsanto's argument, if correct, would have applied equally in *Bates*. There, too, the EPA had approved the label of the pesticide at issue in the course of registration. Like Monsanto, the defendant argued that, after registration, a label "may not be changed, except in the most minor and technical ways, without EPA permission." Br. for Respondent, *Bates v. Dow Agrosciences LLC*, No. 03-388, at 7 (U.S. Nov. 24, 2004). And the *Bates* defendant cited the regulation—also invoked by Monsanto here—providing that labeling changes must be approved by the agency before the product can be distributed with amended labeling. *Id*. (citing 40 C.F.R. § 152.44). Nonetheless, the Court did not hold that the plaintiffs' claims were preempted. Instead, it remanded to the court of appeals to consider whether the state-law requirements were equivalent to FIFRA's requirements. The Court's remand would make no sense if Monsanto were correct that EPA registration is dispositive. Moreover, the Court's opinion shows that it found the regulation irrelevant to the preemption issue. *See Bates*, 544 U.S. at 453 n.27 (stating that the defendant had not "identified any EPA regulations that further refine [FIFRA's] general standards in any way that is relevant to petitioners' allegations").

B. Attempting to distinguish *Bates* and the clear import of the remand in that case, Monsanto notes that *Bates* involved a failure-to-warn claim related to efficacy, rather than safety, and that EPA had waived conducting a review of the pesticide's efficacy. Monsanto Br. 32. "EPA's specific safety determinations that glyphosate does not cause cancer and that a cancer warning is not necessary,"

Monsanto states, "suffice to distinguish the unreviewed efficacy statements in *Bates*." *Id.*

This Court gave no indication in *Bates*, however, that its analysis was restricted to claims concerning pesticide efficacy. Indeed, the Court quoted *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1541 (D.C. Cir. 1984), for the proposition that, rather than hindering the functioning of FIFRA, "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 (emphasis added). Notably, the action under review in *Ferebee* involved a failure-to-warn claim related to safety, not efficacy. *See Ferebee*, 736 F.2d at 1532.

More fundamentally, although EPA registers a pesticide only after determining that its labeling complies with FIFRA and that the product will not have unreasonable adverse effects on people and the environment, those determinations are not "rule[s] of law that must be obeyed." *Bates*, 544 U.S. at 445. Thus, the EPA's determinations do not constitute requirements under FIFRA. Likewise, the determinations do not conclusively establish what *is* required by FIFRA. To the contrary, FIFRA specifies that "*[i]n 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).

Rather than focusing on *Bates*, in which this Court analyzed the statute at issue in this case, Monsanto analogizes this case to *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which involved a different statutory scheme. In *Riegel*, the Court held that a 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 express preemption provision, the MDA's express preemption provision preempts certain state requirements that are different from, or in addition to, certain federal requirements. *See* 21 U.S.C. § 360k(a). The MDA, however, lacks a provision similar to 7 U.S.C. § 136a(f)(2), which makes clear that the EPA's registration of a pesticide does not conclusively determine whether the label complies with the statute's requirements. The absence in the MDA of an equivalent to section 136a(f)(2) makes comparisons between FIFRA cases and *Riegel* inapt.

Monsanto's arguments about the effects of allowing claims like Mr. Durnell's to proceed reprise arguments that this Court rejected in *Bates*. According to Monsanto, ruling against it would "render[] FIFRA's '[u]niformity' provision largely meaningless" and "pave[] the way for massive variation where Congress demanded uniformity." Monsanto Br. 36. As in *Bates*, however, Monsanto "exaggerate[s] the disruptive effects of using common-law suits to enforce the prohibition on misbranding." 544 U.S. at 451. And, as in *Bates*, recognizing that FIFRA's express preemption provision does not preempt state-law claims such as those at issue here preserves a "narrow, but still important, role" for the preemption provision. *Id.* at 452. The provision "pre-empts competing state labeling standards—imagine 50 different labeling regimes prescribing the color, font size, and wording of warnings—that would create significant inefficiencies for manufacturers." *Id.* And

it "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." *Id.* As *Bates* demonstrates, however, the provision does *not* preempt state-law labeling requirements that are equivalent to FIFRA's requirements, regardless of whether EPA registered the pesticide without the relevant warning.

In sum, EPA's registration of a pesticide without a certain warning on its label, and the determinations that EPA makes in that process, do not establish that FIFRA does not require that warning on the pesticide's label. They thus do not establish that a state-law requirement to include that warning falls within the scope of FIFRA's preemption provision, which preempts only state-law requirements "in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b).

II. FIFRA does not impliedly preempt state-law claims that a pesticide's label did not adequately warn of a safety risk when EPA registered the pesticide without requiring a warning of that risk.

Relying primarily on *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), Monsanto argues that complying with its state-law duty to warn was impossible because it could not add a warning to Roundup's label without prior EPA approval. As the Court noted in *PLIVA*, however, "different federal statutes and regulations may … lead to different pre-emption results." *Id.* at 626. Here, Monsanto's implied preemption arguments fail in light of FIFRA's distinctive regulatory regime.

A. FIFRA's express preemption provision renders impossibility preemption irrelevant with respect to state pesticide labeling laws. Implied preemption does not come into play for state laws that fall within the scope of the preemption provision; those state laws are expressly preempted. Thus, the only question is whether FIFRA impliedly preempts state labeling laws that fall *outside* the scope of the express preemption provision. Such state laws, however, are necessarily equivalent to FIFRA's misbranding provisions. *See Bates*, 544 U.S. at 447. That is, a pesticide that violates the state law is also misbranded under FIFRA. *Id.* at 454. And FIFRA makes it illegal to sell misbranded pesticides. 7 U.S.C. § 136j(1)(F). Thus, regardless of the state law, the manufacturer cannot legally sell its pesticide, and there is no conflict between the state and federal requirements.

Furthermore, FIFRA "preserves a broad role for state regulation," *Bates*, 544 U.S. at 450, providing that states "may regulate the sale or use of any federally registered pesticide or device in the State," as long as "the regulation does not permit any sale or use prohibited by" FIFRA, 7 U.S.C. § 136v(a). Under this provision, "States may ban or restrict the uses of pesticides that EPA has approved." *Bates*, 544 U.S. at 450. Thus, for example, a state can ban the sale of a pesticide that lacks warnings of a specific safety risk, regardless of EPA's views of that warning. *See id.* at 446 ("Under § 136v(a), 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.").

Monsanto's implied preemption theory runs counter to this "concurrent authority" by the states to

regulate and ban pesticides. *Id.* at 451. "[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 Prods. Liab. Litig.*, 364 F. Supp. 3d 1085, 1088 (N.D. Cal. 2019).

Bates confirms the absence of implied preemption of state labeling laws under FIFRA. In *Bates*, the pesticide manufacturer argued that FIFRA both expressly and impliedly preempted the plaintiffs' state-law claims. *See, e.g.*, Br. for Respondent, *Bates*, No. 03-388, at i. This 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. 544 U.S. at 453. "[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 v. S.C. Johnson & Son, Inc.*, 394 F. Supp. 3d 260, 273 n.6 (E.D.N.Y. 2019) (internal quotation marks and citation omitted). 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 Court in *Bates* noted 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 Court was aware that manufacturers might have to petition EPA if they wanted to alter their labeling, but concluded that state-law claims based on inadequate labeling not only could co-exist with that requirement, but would benefit FIFRA's functioning.

B. 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 labeling of the corresponding brand-name drug. Because of this duty of "sameness," 564 U.S. at 613 (citation omitted), *PLIVA* held that it would be 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 brand-name 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. 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, however, 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 by ensuring that the product is not misbranded through failure to include necessary warning or caution statements, 7 U.S.C § 136(q)(1)(G). If the manufacturer believes that the labeling must be changed, the manufacturer has a responsibility to do so. And although the manufacturer generally must submit the revised label to EPA for review, EPA "shall" approve the revision unless it determines that the change will 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 revisions. And

unlike the generic drug manufacturers in *PLIVA*, Monsanto would not have required "special permission and assistance" from EPA to add a warning. *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 manufacturers act "sufficiently independently" that federal law poses no hurdle to a state-law duty to provide adequate warnings. *Id.* at 623.

C. Monsanto's *PLIVA*-based argument relies on its contention that it could not alter its labels without prior EPA approval. EPA, however, permits pesticide manufacturers to make minor modifications to their products' labeling without advance 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). During the years in which Mr. Durnell was exposed to Roundup, EPA "repeatedly permitted pesticide manufacturers to use the notification procedure to add notices related to cancer to their products' labels." *Hardeman*, 997 F.3d at 959.[2] Bayer itself used this procedure to add a

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[2] *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), https://www3.epa.gov/pesticides/chem_search/ppls/054705-00006-20170914.pdf; Letter from Kable Bo Davis, Office of Pesticide Programs, EPA, to Laura E. Radevski, Chase Products Co. (June 21, 2017), https://www3.epa.gov/pesticides/chem_search/ppls/000498-00156-20170621.pdf; Letter from Michael Walsh, Office of Pesticide Programs, EPA, to Eric D. Smith, PBI/Gordon Corporation (May 30, 2017), https://www3.epa.gov/pesticides/chem_search/ppls/033955-00394-20170530.pdf; Letter from Michael Walsh, Office of

(footnote continued)

cancer-related notice to a pesticide.[3]

D. Relying on *Wyeth v. Levine*, 555 U.S. 555 (2009), and *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019), Monsanto contends that, even if it could have amended its label without EPA approval, it could not have complied with the applicable state-law requirement because EPA would have required Monsanto to rescind a cancer warning for glyphosate. *Wyeth* and *Merck* do not assist Monsanto. Those cases establish that FDA regulation preempts state failure-to-warn claims against brand-name drug manufacturers if there is "'clear evidence' that the FDA would not have approved the warning that state law requires." *Merck*, 587 U.S. at 310. "'[C]lear evidence' is evidence that shows the court that the [pesticide] manufacturer fully informed the [agency] of the justifications for the warning required by state law and that the [agency], in turn, informed the [pesticide] manufacturer that the [agency] would not approve a change to the [pesticide's] label to include that warning." *Id.* at 303. Even assuming this test applies to FIFRA's regulatory scheme, Monsanto fails both parts of it. *See* Pet. App. 9 ("The record contains no evidence that Monsanto either informed the EPA

Pesticide Programs, EPA, to Christopher Zemanek, The Scotts Company LLC (March 1, 2017), https://www3.epa.gov/pesticides/chem_search/ppls/000239-00739-20170301.pdf; Letter from Jennifer Urbanski, Office of Pesticide Programs, EPA, to Veronica Semetis Lawless, Wellmark International (April 21, 2015), https://www3.epa.gov/pesticides/chem_search/ppls/002724-00702-20150421.pdf.

[3] *See* 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.

of the justifications for a change to its warning label or that the EPA has informed Monsanto it would not approve such a warning.").

First, Monsanto has not shown that it fully informed EPA of the justifications for including a cancer warning on Roundup. As Mr. Durnell has explained, for example, evidence introduced in his trial demonstrated that Monsanto did not provide the report of its genotoxicity expert to EPA or conduct the studies that that expert recommended. *See* Resp. Br. in Opp. at 8. And Monsanto did not conduct studies about the cancer risk of Roundup as formulated, including its surfactants. *Id.* at 9; *see also Chapman v. Monsanto Co.*, No. CV H-22-738, 2022 WL 3971287, at *8–*10 (S.D. Tex. Aug. 31, 2022).

Moreover, Monsanto has not demonstrated that EPA informed it that EPA would not approve adding a warning to Roundup's label. Monsanto points to a letter that EPA's Office of Pesticide Programs sent to pesticide registrants in 2019 stating that a California Proposition 65 warning on products containing glyphosate would render those products misbranded. The relevant question under *Wyeth* and *Merck*, however, is not whether Monsanto could have put a warning on its label after 2019, but whether it was possible for it to add a warning during Mr. Durnell's exposure to Roundup, which began in 1996. 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. Durnell, 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: As Monsanto concedes, in the past, EPA "approved two [glyphosate] labels that included a cancer warning." Monsanto Br. 18 n.5.

In any event, the 2019 letter was too informal to constitute "clear evidence" that EPA would have rejected a warning label. *See Merck*, 587 U.S. at 316 (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.*; *see Hardeman*, 997 F.3d at 958 (noting that the letter lacks the force of law).

The other evidence on which Monsanto relies likewise does not demonstrate that it was impossible for Monsanto to comply with both its federal and state-law duties. In particular, Monsanto points to EPA's conclusion that glyphosate is non-carcinogenic and EPA's registration of glyphosate products without cancer warnings. EPA's determination that a warning is not necessary, however, does not demonstrate that EPA would have prohibited Monsanto from adding a warning had Monsanto asked to do so, let alone that it informed Monsanto that it would not approve a warning. And, indeed, when other manufacturers of pesticides containing glyphosate did request to add glyphosate cancer warnings to their products' labels, EPA approved those requests.

As this Court has explained, "[i]mpossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 573. Monsanto has failed to satisfy that demanding standard. Because compliance with both federal law and the state-law duty to warn was not impossible, Mr. Durnell's failure-to-warn claim is not preempted.

CONCLUSION

This Court should affirm the decision of the Missouri Court of Appeals.

Respectfully submitted,

ADINA H. ROSENBAUM
Counsel of Record
ALLISON M. ZIEVE
SCOTT L. NELSON
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
arosenbaum@citizen.org

Counsel for Amicus Curiae
Public Citizen

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