No. 22-3075

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

DAVID SCHAFFNER, JR. and THERESA SUE SCHAFFNER,
Plaintiffs-Appellees,

v.

MONSANTO COMPANY,
Defendant-Appellant.

Appeal from the U.S. District Court for the
Western District of Pennsylvania
No. 2:19-cv-1270-CRE
Honorable Cynthia R. Eddy

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1 & 29(a)(4)(A), amicus curiae Public Citizen, Inc. states that it is a nonprofit, non-stock corporation. It has no parent corporation, and no publicly held corporation has an ownership interest in it.

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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) (concerning implied preemption under the Food, Drug, and Cosmetic Act); *Carson v. Monsanto Co.*, No. 21-10994 (11th Cir. pending) (concerning preemption under the Federal Insecticide, Fungicide, and

[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.

Rodenticide Act); *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021) (same); *Bedoya v. Am. Eagle Express Inc.*, 914 F.3d 812 (3d Cir. 2019) (concerning preemption under the Federal Aviation Administration Authorization Act). Public Citizen submits this amicus curiae brief because defendant-appellant 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 that lack adequate warnings.

BACKGROUND AND SUMMARY OF ARGUMENT

Plaintiff-Appellee David Schaffner, Jr. developed non-Hodgkins lymphoma after years of heavy exposure as a landscape worker to Monsanto's product Roundup. In this case, Mr. Schaffner and his wife, Theresa Sue Schaffner, allege that Monsanto failed to provide adequate warnings of the dangerous risks associated with exposure to Roundup. Monsanto contends that the Schaffners' failure-to-warn claim is preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, the federal law that regulates pesticides.

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 it leaves room for state-law claims such as the Schaffners' failure-to-warn claim.

I. The Schaffners' 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 the Schaffners' failure-to-warn claim is based on state law that is equivalent to FIFRA's requirements, it is not preempted.

EPA's registration of Roundup without a cancer warning, and the determinations it made in the registration process, do not cause the state law underlying the Schaffners' claim to diverge from FIFRA's requirements. Contrary to Monsanto's insistence that EPA establishes what is required under FIFRA, FIFRA makes clear that EPA's registration process is not determinative of whether a pesticide and its labeling comply with FIFRA's requirements. *See* 7 U.S.C. § 136a(f)(2).

Thus, as the United States has explained, EPA's approval of labeling that does not warn about particular risks does not preempt a state-law requirement to provide such warnings. *See* Br. for U.S. as Amicus Curiae at 6, *Monsanto Co. v. Hardeman*, No. 21-241 (U.S., filed May 10, 2022) (hereafter, U.S. Br., *Hardeman*) (Appx. 1071). Because the registration process is not determinative of what is required by FIFRA, a state-law claim alleging that the label of a registered pesticide 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 the Schaffners' claim. FIFRA's regulatory scheme does not provide a basis for implied preemption of state labeling requirements. Moreover, Monsanto has not

demonstrated that it could not have complied with both federal and state requirements. Although Monsanto argues that EPA would have rejected its request to add a warning to Roundup's label had it sought to do so, Monsanto never sought to add such a warning, and 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 the Schaffners' Failure-to-Warn Claim.

A. The state law underlying the Schaffners' claim parallels 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 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 Pennsylvania law underlying the Schaffners' claim is 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, Pennsylvania law allows a plaintiff to recover if a manufacturer failed to provide "sufficient warnings to notify the ultimate user of the dangers inherent in the product." *Davis v. Berwind Corp.*, 690 A.2d 186, 190 (Pa. 1997). Because the state law "does not impose a duty inconsistent with or in addition to the duty imposed" by FIFRA's misbranding provisions, it is not preempted. *Indian Brand*

Farms, Inc. v. Novartis Crop Prot. Inc., 617 F.3d 207, 222, 225 (3d Cir. 2010) (holding that a state law imposing liability on a manufacturer where "the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it ... failed to contain adequate warnings or instructions" did not impose a duty to warn "different than or in addition to" FIFRA's requirements).

B. Neither EPA's registration of a pesticide nor the determinations that EPA makes in the registration process preempt failure-to-warn claims.

Monsanto contends that any state-law duty it had to warn about Roundup's association with cancer is necessarily "in addition to or different from" FIFRA's requirements because Roundup went through EPA's registration process—which required the agency to determine that the pesticide's labeling complies with FIFRA's requirements, *see* 7 U.S.C. § 136a(c)(5)(B)—and EPA allowed Monsanto to register Roundup without a cancer warning. According to Monsanto, the registration process establishes what FIFRA requires for a pesticide, and any state-law requirement that differs from EPA's determinations during that process is preempted. *See* Monsanto Br. 30. Contrary to Monsanto's argument, however, EPA's registration process does not conclusively establish what

FIFRA requires with respect to labeling. Thus, as the United States explained to the Supreme Court in a brief addressing the petition for a writ of certiorari from the Ninth Circuit's decision in *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022), "EPA's approval of labeling that does not warn about particular chronic risks does not by itself preempt a state-law requirement to provide such warnings." U.S. Br., *Hardeman*, at 6 (Appx. 1071); *see also id.* at 12 (Appx. 1077) (explaining that "EPA's approval of pesticide labeling without a chronic-risk warning is not naturally characterized as a FIFRA 'requirement' that no such warning appear").

1. As the Supreme Court expressly 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). "The Act thus makes clear that a particular pesticide may be found to violate FIFRA's misbranding prohibition even though EPA approved the labeling when registering the pesticide." U.S. Br.,

Hardeman, at 8 (Appx. 1073). That is, EPA's approval of the label in the registration process "is not conclusive of FIFRA compliance." *Hardeman*, 997 F.3d at 956. "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." *Id.*

The Supreme Court's decision in *Bates* confirms that a state-law claim based on the inadequacy of a registered pesticide's labeling is not necessarily based on a requirement that is in addition to or different from a requirement imposed by FIFRA. In *Bates*, as here, EPA had registered the pesticide at issue and approved the labeling in the course of the registration. Nonetheless, the Supreme Court held that the plaintiff's 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. As this Court 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,* 617 F.3d at 222.

2. Monsanto attempts to distinguish *Bates*—and to avoid the clear import of the remand in that case—by noting 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. *See* Monsanto Br. 34. According to Monsanto, it is not "rely[ing] on the bare fact of registration to preempt state law," but on the "regulatory determinations" EPA made in the registration process. *Id*. at 22. The Supreme Court, however, "did not limit its analysis in *Bates* to claims regarding pesticide efficacy." *Holyfield v. Chevron U.S.A., Inc.*, 533 F. Supp. 3d 726, 732 (E.D. Mo. 2021). And the Supreme 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 related to safety, not efficacy. *See* 736 F.2d at 1539.

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 the environment, those 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)—making clear that the assessments EPA makes during the registration process are not dispositive of whether the pesticide's labeling complies with FIFRA's requirements and do not conclusively establish what FIFRA requires. *See Hardeman*, 997 F.3d at 957 n.8 (explaining that a determination that glyphosate is not carcinogenic made as part of an EPA registration decision "is not necessarily at odds with [a] future failure-to-warn claim," because the registration decision "only supports presumptive (not conclusive) compliance with FIFRA"); *Carias v. Monsanto Co.*, No. 15-CV-3677, 2016 WL 6803780, at *7 (E.D.N.Y. Sept. 30, 2016) ("[I]f the EPA's registration decision [under FIFRA] is not preemptive, it follows that the factual findings on which it relied in making that decision also are not preemptive." (citation omitted)).

Moreover, the Ninth Circuit has held that EPA's 2020 determination in its registration review of glyphosate that glyphosate is not likely to be carcinogenic to humans was not supported by substantial evidence. *See Nat. Res. Def. Council v. EPA*, 38 F.4th 34, 51 (9th Cir. 2022). Explaining that the agency's determination was "in tension with parts of the agency's own analysis and with the guidelines it purports to follow," *id.* at 46, the court vacated the human-health portion of the agency's interim registration review decision and remanded to the agency for further proceedings, including "a new public-comment process," *id.* The vacatur of EPA's registration-review determination that glyphosate is not likely to be carcinogenic to humans provides a further reason why that determination does not preempt state law.

3. In arguing that EPA establishes what is required under FIFRA, Monsanto relies on an example 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."). A state law requiring a pesticide to state DANGER when the signal word for the toxicity level to which it has been assigned is CAUTION would be preempted because the *regulation* requires the pesticide to contain a "signal word, reflecting the highest Toxicity Category … to which the product is assigned." 40 C.F.R. § 156.64. The uncontroversial proposition that FIFRA regulations, as well as the statutory text, can establish requirements under FIFRA, does not suggest that the registration of a pesticide, or assessments made in the registration process, also have preemptive effect. As the United States has explained, EPA can, "through rulemaking or through some other regulatory action carrying the force of law … make a binding determination that the labels of pesticides containing glyphosate should not contain cancer warnings" and such a "determination would preempt any state-law tort claim premised on a manufacturer's failure to provide such warnings." U.S. Br., *Hardeman*,

at 13 (Appx. 1078). "But neither EPA's repeated statements that glyphosate is unlikely to be carcinogenic to humans, nor its approval of pesticide labeling without cancer warnings, imposes any such prohibition." *Id.*

Monsanto analogizes cases concerning FIFRA to *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), in which the Supreme Court 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. *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 agency'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) distinguishes cases concerning FIFRA from *Riegel*. *See Hardeman*, 997 F.3d at 956 n.6; *see also Crespo v. S.C. Johnson & Son,*

Inc., 394 F. Supp. 3d 260, 272 (E.D.N.Y. 2019) (rejecting comparison to federal statutes that lack an analog to section 136a(f)(2)). Section 136a(f)(2) likewise distinguishes FIFRA cases from the cases Monsanto cites concerning the Federal Meat Inspection Act and Poultry Products Inspection Act (PPIA). *Compare Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1288 (9th Cir. 2021) (relying on *Riegel* in holding that PPIA preempts claims based on label reviewed and approved by Food Safety and Inspection Service), *with Hardeman*, 997 F.3d at 956 n.6 (in decision authored by one of the judges who decided *Cohen*, distinguishing *Riegel* on the ground that the MDA lacks a provision like section 136a(f)(2), "which clarifies that the agency's approval of a label is not determinative of compliance with the statute").

In an effort to downplay section 136a(f)(2), Monsanto cites the pre-*Bates* decision in *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994), in which the Fifth Circuit stated that section 136a(f)(2) "has no bearing" on preemption because a common-law claim is "not an offense under FIFRA." Monsanto Br. 43. As this Court has recognized, however, *MacDonald* is inconsistent with the Supreme Court's construction of FIFRA in *Bates*. *See Indian Brand Farms*, 617 F.3d at

221 (explaining that "*Bates* introduced a different analysis of FIFRA preemption," which "compels [the Court] to depart from this pre-*Bates* precedent"). *MacDonald* stated that a state-law claim that manufacturers failed to provide an adequate warning on an approved pesticide "necessarily" sought warnings in addition to or different from those required by FIFRA, and thus that, where a pesticide's labeling has been approved, "it is unnecessary to compare specifically the common law labeling requirements asserted by the [plaintiffs] with FIFRA's labeling requirements." 27 F.3d at 1025 n.4. In contrast, *Bates* held that a state-law claim that a pesticide manufacturer did not place adequate warnings on its registered pesticide does *not* necessarily rest on requirements that are in addition to or different from FIFRA's requirements and, thus, that it *is* necessary to compare specifically the state-law requirements for packaging or labeling with FIFRA's labeling requirements. *See* 544 U.S. at 453–54. Although section 136a(f)(2) might have been irrelevant under *MacDonald*'s incorrect understanding of FIFRA preemption, it *is* relevant to the analysis set forth in *Bates*, demonstrating that the fact that a pesticide has gone through the registration process does not establish that its labeling complies with FIFRA's requirements. *See*

Indian Brand Farms, 617 F.3d at 222 n.13 (noting relevance of section 136a(f)(2)).

Monsanto also suggests that section 136a(f)(2) only prevents registration from being used as a defense to a claim that the pesticide violates the terms of the registration. Such a limitation, however, has no basis in section 136a(f)(2), which provides that registration is not a defense to "any offense" under FIFRA.

Monsanto notes that 136a(f)(2) is not part of FIFRA's preemption provision. Of course, statutory provisions do not need to be part of a preemption provision or otherwise explicitly mention preemption to be relevant to a preemption analysis. Indeed, Monsanto itself relies on provisions besides FIFRA's express preemption provision in its preemption argument. Section 136a(f)(2) is relevant to the analysis required by FIFRA's express preemption provision because it makes clear that EPA's approval of a label is "not dispositive of FIFRA compliance" and thus is "not conclusive as to which common law requirements are 'in addition to or different from' the requirements imposed by FIFRA." *Hardeman*, 997 F.3d at 956. Given that section 136a(f)(2) is specifically about the effects of registration, it is not surprising that it is codified in

section 136a, which addresses "[r]egistration of pesticides." Its location in the statute does not deprive it of force when the effects of registration are relevant to the preemption analysis.

In sum, EPA's registration of a pesticide without a certain warning on its label, and the determinations that it 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" FIFRA's requirements. 7 U.S.C. § 136v(b).

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

Monsanto contends that EPA has determined "that a cancer warning is *prohibited* under FIFRA." Monsanto Br. 38. In support, it relies 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 the association between glyphosate and cancer would render a pesticide misbranded. *See* Appx. 192–93. 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) ("EPA is issuing guidance to registrants of glyphosate.").[2] EPA "did not follow any 'formal administrative procedure' that would give the letter the force of law." *Hardeman*, 997 F.3d at 957 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)); *see also* U.S. Br., *Hardeman*, at 13 (Appx. 1078) (explaining that "[n]o FIFRA provision or EPA regulation authorizes an agency official to impose binding FIFRA 'requirements' on manufacturers through an informal letter").

[2] https://www.epa.gov/newsreleases/epa-takes-action-provide-accurate-risk-information-consumers-stop-false-labeling.

The August 2019 letter is similar to the letter that this Court 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 California Proposition 65 warnings regarding mercury on tuna labels would be misleading and therefore render tuna products sold with such a warning misbranded. This Court 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 "merely expressed an informal policy opinion in a letter," long after Mr. Schaffner was diagnosed with cancer, and the informal views expressed in the letter did not establish requirements under FIFRA.

In any event, in a letter sent from EPA's Assistant Administrator to California regulators in April 2022, EPA stated that it "could approve"

specific glyphosate-warning language proposed by California "if pesticide registrants requested it for inclusion on glyphosate product labels." Appx. 1045–46. That language, the letter stated, "would not be considered false and misleading," and products containing it "would not be considered misbranded." *Id*. at 1046. The April 2022 letter further confirms that the August 2019 letter did not establish that Monsanto could not have placed a cancer warning on Roundup's label without rendering the pesticide misbranded—and that the letter is irrelevant to the preemption analysis.

II. FIFRA Does Not Impliedly Preempt the Schaffners' Failure-to-Warn Claim.

Under *Wyeth v. Levine*, 555 U.S. 555, 571 (2009), and *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1676 (2019), state failure-to-warn claims against name-brand prescription 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. Relying on those cases, Monsanto argues that the Schaffners' failure-to-warn claim is preempted because EPA would have rejected a request to add a cancer warning to Roundup's label. Differences between FIFRA and the regulatory scheme governing prescription drugs, however, render the analysis in *Wyeth* and *Merck* inapplicable here. 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." Br. of U.S. as Amicus Curiae in Support of Monsanto at 10, *Hardeman v. Monsanto Co.*, No. 19-16636 (9th Cir., filed Dec. 20, 2019) (hereafter, U.S. Br., Ninth Cir.) (Appx. 208); *see also* U.S. Br., *Hardeman*, at 4 (Appx. 1069).

A. FIFRA's regulatory scheme does not provide a basis for implied preemption of state labeling requirements. To begin with, unlike the drug provisions of the Food, Drug, and Cosmetic Act, FIFRA contains an express preemption provision that specifies exactly which state laws Congress intended to preempt. 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). In section 136v(b), Congress "dr[ew] a distinction between state labeling requirements that are pre-

empted and those that are not." *Bates*, 544 U.S. at 449. 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.

Moreover, apart from its express preemption provision, FIFRA "preserves a broad role for state regulation," *id.* 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."). The preemption of state labeling requirements that fall outside the scope of FIFRA's express preemption provision would run counter to this "concurrent authority" by the states to regulate and ban pesticides. *Id.* at 451; *see Pilliod v.*

Monsanto Co., 282 Cal. Rptr. 3d 679, 701 (Cal. Ct. App. 2021) (stating that the court was "not persuaded that the doctrine [of impossibility preemption] can be reconciled with FIFRA, which confirms that states are authorized to regulate the sale and use of pesticides and authorizes states to ban the sale of a pesticide that it finds unsafe"), *cert. denied*, 142 S. Ct. 2870 (2022).

Monsanto's implied preemption argument is also "difficult—if not impossible—to square with *Bates*." *In re Roundup Prods. Liab. Litig.*, 364 F. Supp. 3d 1085, 1088 (N.D. Cal. 2019) (Appx. 22). 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 question presented was whether petitioners' claims were "expressly or impliedly preempted" by FIFRA). The Supreme 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*, 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).

B. Monsanto's argument would fail even under *Wyeth* and *Merck*'s "clear evidence" standard, because Monsanto failed to provide clear evidence that EPA would not have approved a warning on Roundup's labeling. "'[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." *Merck*, 139 S. Ct. at 1672. Monsanto's argument fails both parts of this test.

First, Monsanto has not shown that it fully informed EPA of the justifications for including a cancer warning on Roundup. Indeed, as explained in the Schaffners' brief (at 8–9), Monsanto did not provide the report of its genotoxicity expert to EPA or conduct the studies that that expert recommended. *See*, *e.g.*, Appx. 512, 536; *see also Chapman v. Monsanto Co.*, No. CV H-22-738, 2022 WL 3971287, at *8–*10 (S.D. Tex. Aug. 31, 2022). And Monsanto has not conducted studies about the cancer risk of Roundup as formulated, including its surfactants. *See* Schaffners' Br. at 10–11.

Moreover, Monsanto has not demonstrated that EPA informed it that EPA would not approve adding a warning to Roundup's label. Monsanto cites the August 2019 letter in support of its argument. 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 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. Schaffner, 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." U.S. Br., Ninth Cir., at 10 (Appx. 208). And the April 2022 letter likewise shows that, even after the August 2019 letter, it is possible to craft glyphosate cancer warnings that EPA will approve. *See* Appx. 1045–46.

In any event, the August 2019 letter was 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.*; *see Hardeman*, 997 F.3d at 958 (stating that the letter lacks the force of law); U.S Br., *Hardeman*, at 15 (Appx. 180) (explaining that the letter "expressed the

[Director of the Registration Division's] view about the application of FIFRA's misbranding prohibition, but did not impose an independent legal barrier to inclusion of a cancer warning" on Roundup's label). 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 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 classification of glyphosate as non-carcinogenic and its conclusion that registered glyphosate products were eligible for reregistration. EPA's determination that a warning was 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

Proposition 65 glyphosate cancer warnings to the products' labels, EPA approved those requests.

As the Supreme 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, and the Schaffners' failure-to-warn claim is not impliedly preempted.

CONCLUSION

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

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Respectfully submitted,

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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 April 18, 2023.

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