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.

On Appeal from the United States District Court for the
Western District of Pennsylvania,
No. 2:19-cv-1270-CRE (Eddy)

BRIEF FOR AMICI CURIAE PUBLIC JUSTICE AND THE AMERICAN ASSOCIATION FOR JUSTICE IN SUPPORT OF PLAINTIFFS-APPELLEES

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DISCLOSURE STATEMENT

In accordance with Rule 26.1(a) of the Federal Rules of Appellate Procedure and Third Circuit Rule 26.1, the undersigned certifies that there is no publicly traded company or corporation with an interest in the outcome of this case that has not already been disclosed to this Court.

April 18, 2023 *s/ Leah M. Nicholls*
Leah M. Nicholls

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INTEREST OF AMICI CURIAE[1]

Public Justice is a national public interest advocacy organization that specializes in precedent-setting and socially-significant civil litigation and is dedicated to preserving access to the civil justice system. Public Justice has a long history of fighting federal preemption in cases involving dangerous products. As part of that work, Public Justice was co-lead appellate counsel in *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022), which affirmed a $25 million judgment in favor of a man who contracted non-Hodgkin's lymphoma from Roundup.

The American Association for Justice (AAJ) is a national, voluntary bar association established in 1946 to strengthen the civil justice system, preserve the right to trial by jury, and protect access to the courts for those who have been wrongfully injured. With members in the United States, Canada, and abroad, AAJ is the world's largest plaintiff trial bar. AAJ's members primarily represent plaintiffs in personal injury actions, employment rights cases, consumer cases, and other civil actions, including product liability claims for injuries caused by herbicides such as Roundup. Throughout its 75-year history, AAJ has served as a leading advocate for the right of all Americans to seek legal recourse for wrongful conduct.

[1] All parties have consented to the filing of this brief. Neither party's counsel authored this brief in whole or in part and no party contributed money intended to fund preparing or submitting this brief.

Public Justice and AAJ have a strong, shared interest in preserving the rights of all persons who have been injured by Roundup—and other dangerous products—to obtain justice via the tort system.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case presents the same issue the Ninth Circuit addressed in *Hardeman v. Monsanto Co.*: whether failure-to-warn claims involving Roundup are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 *et seq.* (FIFRA). As the Ninth Circuit held, the answer to that question is "no": Such claims are neither expressly nor impliedly preempted by federal law. *Hardeman v. Monsanto Co.*, 997 F.3d 941, 954 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022).

Under *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), there is no express preemption of plaintiff's failure-to-warn claims because such claims are substantively equivalent to FIFRA's misbranding requirements, which provide that a duly-registered pesticide can be found misbranded if its label omits necessary warnings. Roundup's label did just that. FIFRA's scheme is different than that of other labeling statutes, rendering Monsanto's contrary arguments pointing to those statutes meaningless.

Monsanto also cannot rely on the Environmental Protection Agency's (EPA's) position on glyphosate as a basis for preemption. The Schaffners' claims here are premised on the carcinogenic nature of Roundup, not glyphosate alone. Roundup is an effective weed killer because it combines glyphosate with surfactants—a combination that is particularly dangerous for humans. At any rate,

EPA's regulatory conclusion, which underpins much of Monsanto's preemption argument, that glyphosate is "not likely" to cause cancer in humans has since been vacated by the Ninth Circuit as arbitrary and capricious. *See NRDC v. U.S. EPA*, 38 F.4th 34, 45-52 (9th Cir. 2022).

Nor is there any basis for finding implied preemption under FIFRA. Under *Bates*, implied preemption is inapplicable under FIFRA because it is foreclosed by the statute itself. But even if implied preemption *were* applicable, it is not available here because there is no conflict between the Schaffners' claims and any EPA decision regarding Roundup. EPA has not taken any of the actions mandated by Congress for declaring a pesticide misbranded. *See Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 36-37 (D.D.C. 2011).

Nor is there any basis for finding implied preemption based on the mere fact that EPA has pre-approval authority over changes to pesticide labels. But if there were any doubt, it would be dispelled by the fact that FIFRA itself expressly states that EPA's approval of a pesticide label is merely *prima facie* evidence that a pesticide is not misbranded, *see* 7 U.S.C. § 136(a)(f)(2)—evidence that can be overcome in a federal misbranding trial (and in a state court lawsuit). Moreover, unlike any other federal statute involving an agency-approved product (such as, for example, prescription drugs), FIFRA allows states to *ban* pesticides that have been approved by EPA. *See id.* § 136v(a). These unique features of FIFRA make it

impossible to conclude that there is any conflict between this lawsuit and FIFRA—let alone "clear evidence" of the type of "irreconcilabl[e] conflict[t]" that can give rise to a finding of impossibility preemption. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019).

OVERVIEW OF RELEVANT FACTS

This appeal involves Roundup, a weedkiller containing the active ingredient glyphosate. Roundup also contains a number of additional ingredients—in particular, surfactants—that make it more carcinogenic than glyphosate alone.

Starting in 2015, thousands of cancer victims sued Monsanto in state and federal courts, alleging that Roundup caused their cancer. Several thousand of these cases—including this one—were consolidated into a multidistrict litigation (MDL) in the Northern District of California. *See Hardeman*, 997 F.3d at 950.

Hardeman was the only bellwether trial in the MDL and is the only federal case yet to be tried regarding Roundup. The plaintiff, Edwin Hardeman, regularly sprayed Roundup for over 25 years on his property, and he was diagnosed with non-Hodgkin's lymphoma (NHL). He sued Monsanto, alleging his cancer was caused by his long-term exposure to Roundup. *Id.* at 952. After a month-long trial, the jury returned a verdict in favor of Hardeman, awarding him roughly $5 million in compensatory damages and $75 million in punitive damages for Monsanto's decades of undermining the science, failing to test its own product, and recklessly

endangering Hardeman. *Id.* at 954. The district court reduced the punitive damages award to $20 million. *Id.*

Monsanto appealed, and the Ninth Circuit affirmed. *Id.* at 950. The Ninth Circuit held that Hardeman's claims are not preempted. Monsanto sought review in the U.S. Supreme Court, which denied certiorari. 142 S. Ct. 2834.

The California Court of Appeal reached the same conclusion as the Ninth Circuit in a similar case, rejecting Monsanto's arguments that the plaintiff's state-law failure-to-warn claims about Roundup are expressly or impliedly preempted by FIFRA. *Pilliod v. Monsanto Co.*, 282 Cal. Rptr. 3d 679, 699-701 (Cal. Ct. App. 2021), *review denied* (Nov. 17, 2021), *cert. denied*, 142 S. Ct. 2870 (2022). Again, Monsanto sought U.S. Supreme Court review and, again, certiorari was denied. *Id.*

To date, there are no appellate decisions, state or federal, that have accepted Monsanto's arguments that failure-to-warn claims about Roundup are preempted.

RELEVANT STATUTORY AND REGULATORY BACKGROUND

A. Statutory Background.

FIFRA requires pesticide manufacturers to register their products with EPA. 7 U.S.C. § 136a(a). FIFRA states, however, that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." *Id.* § 136(a)(f)(2). Rather, registration of a pesticide is merely "prima facie evidence that the pesticide, its labeling and packaging comply with the

registration provisions of the subchapter." *Id.*

EPA can bring various enforcement actions against the manufacturer of a registered pesticide if it determines that the product is "misbranded," including seeking civil and criminal penalties. *Bates*, 544 U.S. at 439 & n.11. A duly-registered pesticide is misbranded if, inter alia, the label "does not contain adequate instructions for use, or if its label omits necessary warnings or cautionary statements." *Id.* at 438.

EPA's decision to register a pesticide does not immunize manufacturers from state regulation. To the contrary, states can regulate (or even ban) a federally-registered pesticide although EPA does not consider it misbranded under FIFRA. *Id.* at 446 (citing 7 U.S.C. § 136v(a)).

FIFRA's only limitation on state authority is set forth in the Act's preemption clause: 7 U.S.C. § 136v(b). As *Bates* explained, this provision is "narrow." 544 U.S. at 452. Although § 136v(b) "reaches beyond positive enactments . . . to embrace common-law duties," *id.* at 443, it "prohibits only state-law labeling and packaging requirements that are '*in addition to or different from*' the labeling and packaging requirements under FIFRA," *id.* at 447 (quoting 7 U.S.C. § 136v(b)). By way of illustration, the Court explained that a tort suit challenging specific labeling language mandated by a duly-promulgated EPA *regulation* would be preempted. *Id.* at 453. But, the Court ruled, a state tort claim that merely challenges an EPA-approved pesticide label based on a substantive tort standard that mirrors FIFRA's

misbranding standard is not preempted by FIFRA. *Id.* at 447.

B. Regulatory Background.

1. EPA Has Made Findings Regarding Glyphosate Only, Not Roundup.

Since 1974, EPA has registered various pesticide formulations containing glyphosate, the active ingredient in Roundup. *See* EPA, Glyphosate: Proposed Interim Registration Review Decision (2019), https://tinyurl.com/y6h2u8w6 (2019 Interim Glyphosate Review). A glyphosate-based formulation (GBF) is a product that contains glyphosate *plus* other ingredients that make the product more effective. *See* EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential 19 (2017), https://tinyurl.com/eparevdglyphosate (2017 Glyphosate Issue Paper).

Roundup is such a product: It contains glyphosate, water, and surfactants, which make it a particularly potent weedkiller (and also, as it turns out, a particularly carcinogenic herbicide). Over the past 40 years, EPA has only made findings regarding the carcinogenicity of *glyphosate*, not the formulated product *Roundup*. *Id.* at 137-38, 144-46.

2. EPA's Mixed Conclusions Regarding Glyphosate.

And EPA's conclusions about glyphosate have been decidedly mixed. In 1985, an EPA review of a mouse study found that glyphosate was oncogenic in male mice, causing rare tumors. *See* EPA, Consensus Review of Glyphosate 4 (1985), https://tinyurl.com/tnpxj2ph. EPA classified glyphosate as a possible human

carcinogen. *Id.*

In 1991, EPA changed its designation of glyphosate to non-carcinogenic based in part on new evidence submitted by Monsanto—evidence that turned out to have been falsified, as Hardeman ultimately discovered and proved at trial. *See* Edwin Hardeman's Principal and Response Brief at 26-30, *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2020) (No. 19-16636), 2020 WL 1452847 (describing trial evidence); EPA, Second Peer Review of Glyphosate 1 (1991), https://tinyurl.com/3v8mnp96.

But even at the time, EPA's Scientific Advisory Panel (SAP) was internally divided on whether glyphosate causes cancer. Several voted *not* to reverse the agency's initial designation of glyphosate as a possible human carcinogen. Although the dissenting scientists were overruled, EPA's divided SAP cautioned "that designation of an agent [as non-carcinogenic] is based on the available evidence . . . and *should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances.*" *Id.* (emphasis added).

3. IARC's 2015 Finding that Glyphosate Is Carcinogenic.

Dozens of independent studies emerged in the 1990s showing that glyphosate and Roundup pose a cancer risk to humans.

In 2015, the International Agency for Research on Cancer (IARC), part of the World Health Organization, assembled 17 experts from 11 countries to form a

working group, which thoroughly reviewed data relating to glyphosate and concluded that the chemical is "*probably carcinogenic to humans*."[2] Unlike EPA, which relied heavily on industry-generated studies and data from Monsanto that focused predominantly on glyphosate in isolation, IARC relied mostly on peer-reviewed studies, and focused more on glyphosate formulations, like Roundup.[3]

4. EPA's Registration Review for Glyphosate.

In 2015, the same year IARC found glyphosate a probable human carcinogen, EPA began its reexamination of the carcinogenic potential of glyphosate—a process FIFRA requires every 15 years after a pesticide's registration.

Just as in 1991, the agency's scientists and external advisors disagreed as to the carcinogenicity of glyphosate. In 2017, the agency admitted that EPA's advisors had "conflicting views on how to interpret the overall results for NHL." 2017 Glyphosate Issue Paper 67; *see also id.* at 133.

Part of the difficulty, EPA explained, was that "uncertainties" exist in the data, partly because "farmers and other applicators apply *formulations, not the active ingredient alone*." *Id.* at 137 (emphasis added). The agency acknowledged a need

[2] IARC, *Some Organophosphate Insecticides and Herbicides: Glyphosate*, *in* 112 IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 321, 398 (2017), https://tinyurl.com/vrawvrpt.

[3] Charles Benbrook, *How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides?*, 31 Envtl. Scis. Eur., 2019, at 11, 14, https://tinyurl.com/p9k9mxeh.

for additional research "to determine whether formulation components, such as surfactants, increase the toxicity of glyphosate formulations," but nevertheless proposed a "not likely to be carcinogenic to humans" designation. *Id.* at 144.

In April 2019—shortly after the jury verdict in *Hardeman*—EPA published an interim review of glyphosate. In it, EPA noted that many commenters "expressed concerns that glyphosate formulations are more toxic than glyphosate alone." 2019 Interim Glyphosate Review 10.

EPA again acknowledged that, "there are few research projects that have attempted to directly compare technical grade glyphosate to the formulations under the same experimental design." *Id.* at 11. EPA stated that "[i]f at any time, information becomes available that indicates adverse human health effects of concern for exposure to glyphosate *or its formulations*, the EPA intends to review it and determine the appropriate regulatory action." *Id.* (emphasis added).

On January 22, 2020, EPA issued its Interim Registration Review Decision. Once again, EPA did not exclude the possibility that glyphosate-containing formulations (such as Roundup) can be harmful to humans. Instead, it merely reiterated that, "glyphosate is not likely to be carcinogenic to humans." EPA, Glyphosate Interim Registration Review Decision 10 (2020), https://tinyurl.com/wnklu3d. EPA stated, however, that it "will continue to monitor the open literature for studies that use scientifically sound and

appropriate methodology and relevant routes of exposure that have the potential to impact the risk evaluation of glyphosate." *Id* at 7.

Several groups filed petitions for review of the 2020 Interim Decision under the Administrative Procedures Act challenging, among other things, EPA's analysis of and conclusions as to glyphosate's impact on human health. *NRDC*, 38 F.4th at 44. In June 2022, the Ninth Circuit held that EPA's conclusion that glyphosate was "not likely" to be carcinogenic in humans was arbitrary and capricious because EPA's decision was "not supported by substantial evidence" and because EPA failed to follow its own guidelines in assessing cancer risk. *Id.* at 51. The court vacated the 2020 Interim Decision and remanded to the agency for further analysis and explanation. *Id.* at 52.

In September 2022, EPA withdrew the remaining portions of the 2020 Interim Review because the agency would be unable to comply with the Ninth Circuit's deadlines for revisions.[4] EPA noted that its prior findings that glyphosate is unlikely to be carcinogenic to humans may be used as support for future agency determinations.

[4] Memorandum from Cathryn Britton, Branch Chief, EPA Pesticide Re-evaluation Div., to Glyphosate Registration Review Docket (Sept. 21, 2022), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-14447 (2022 Memorandum).

5. The Office of Pesticide Program's Letters to California.

In August 2019—five months after the jury verdict in *Hardeman*—EPA announced that it had sent a two-page letter to "Registrants" of glyphosate-containing products.[5] The 2019 Letter, which was not the product of any formal proceedings, was not published in the Federal Register, cites no new scientific findings, and takes no position on whether Roundup causes cancer.

Instead, it challenges California's inclusion of glyphosate on Proposition 65 as contrary to the "EPA's determination that glyphosate is 'not likely to be carcinogenic.'" 2019 Letter 1. Given this determination, EPA "considers the Proposition 65 warning language based on the chemical glyphosate to constitute a false and misleading statement" under FIFRA. *Id.* The 2019 Letter also makes clear that, prior to its issuance, EPA *had* been approving Proposition 65 warnings for glyphosate products. *Id.* at 2 (stating that EPA "will no longer approve" such warnings and ordering registrants to submit "amended labeling that removes such language"); *see also* Brief for the United States as Amicus Curiae ("U.S. Brief Opposing Certiorari") at 4, *Monsanto Co. v. Hardeman*, 142 S. Ct. 2834 (2022) (No. 21-241) (admitting EPA had approved Proposition 65 warnings on

[5] Letter from Michael L. Goodis, Registration Div. Dir., EPA Office of Chem. Safety and Pollution Prevention, to Registrants of Products that Contain Glyphosate (Aug. 7, 2019), https://www.epa.gov/sites/default/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf (2019 Letter).

glyphosate products).

In April 2022, two months before the Ninth Circuit vacated EPA's determination that glyphosate was not likely to cause cancer, EPA issued a second letter walking back its position as to whether a Proposition 65 warning would be misbranded under federal law.[6] EPA stated that a Proposition 65 warning that included EPA's position that glyphosate is not likely to cause cancer in humans—as opposed to the generic Proposition 65 warning at issue in 2019—could be approved by EPA and would not be considered misbranded. *Id.*

ARGUMENT

I. Plaintiff's Claims Are Not Expressly Preempted.

A. Plaintiff's Claims Are Not Expressly Preempted Because They Are Equivalent to Federal Misbranding Standards.

State-law requirements are not preempted if they are "equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Bates*, 544 U.S. at 447. The Schaffners' failure-to-warn claims readily pass this test.

The analysis under *Bates* is straightforward: State law and FIFRA are "equivalent" when a violation of state law would violate FIFRA's misbranding

[6] Letter from Michael Freedhoff, Assistant Admin., EPA Office of Chem. Safety and Pollution Prevention, to Dr. Lauren Zeise, Office of Envtl. Health Hazard Assessment Dir., Cal. EPA (Apr. 8, 2022) (2022 Letter), https://oehha.ca.gov/media/downloads/crnr/usepaaafreedhofftooehhadirzeiseglyphosate40822.pdf.

provisions. *Id.* FIFRA, in turn, provides that even a duly-registered pesticide can be found misbranded if its label "does not contain adequate instructions for use, or if its label omits necessary warnings or cautionary statements." *Id*. at 438 (citing 7 U.S.C. §§136(q)(1)(F), (G)). Thus, importantly—and unlike in some of the statutory schemes cited by Monsanto—under FIFRA, a product may be misbranded *even if* it was duly registered with the agency prior to sale. *Id.* (explaining "it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded).[7]

Pennsylvania law, under which the Schaffners bring their claims, requires products to have "adequate warnings or instructions required for a product's safe use." *Walton v. Avco Corp.*, 610 A.2d 454, 458 (Pa. 1992). Thus, a manufacturer's duty under Pennsylvania law is substantially the same as its duty under FIFRA. FIFRA "require[s] a warning that is 'necessary' and 'adequate' to protect human health." *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1038 (N.D. Cal. 2016); *see* 7 U.S.C. §§ 136(q)(1)(F), (G). Both Pennsylvania law and FIFRA require warnings that are adequate and necessary to avoid injury to humans. Given that the

[7] In permitting state-law claims challenging a product with a registered or preapproved label as misbranded, FIFRA is different from other statutory schemes to which Monsanto urges this Court to look. *See* Appellant's Br. 31-33. For example, with regard to the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), it is generally understood that *any* state-law claim challenging an agency-approved label is preempted. *See, e.g.*, *Thornton v. Tyson Foods, Inc.*, 28 F.4th 1016, 1024 (10th Cir. 2022) (FMIA); *Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1288 (9th Cir. 2021) (PPIA). As *Bates* makes explicit, that is not true with regard to FIFRA.

Schaffners seek to enforce a duty under Pennsylvania law that is equivalent to FIFRA's misbranding standard, FIFRA's express preemption clause is facially inapplicable. *See Bates*, 544 U.S. at 447 n.23.

B. EPA Decisions Regarding Glyphosate Alone Cannot Be the Basis for Preempting Claims Regarding Roundup.

Nevertheless, Monsanto urges this Court to look to EPA's conclusion that glyphosate is unlikely to be carcinogenic in humans. But the Schaffners are not suing about *glyphosate*. They are bringing claims about the dangers of *Roundup*, which contains surfactants that, when used in combination with glyphosate, create an elevated cancer risk.

EPA itself has stated expressly that it has not studied the question whether Roundup and similarly formulated products are carcinogenic, and it has taken no position on that issue. In 2017, EPA stated that more study was needed to determine whether glyphosate combined with surfactants increases toxicity. *See, supra*, at 10-11. And in 2019, it acknowledged receiving information indicating that glyphosate formulations are more dangerous than glyphosate alone and again noted that there was a dearth of data on that question. *See, supra*, at 11.[8]

To put it bluntly, there cannot be preemption of state-law claims for cancer warnings when EPA has never studied whether the product in question causes

[8] The dearth of data is likely because Monsanto admits that *it* has never studied whether Roundup (as opposed to glyphosate) is carcinogenic. *See infra*, at 25.

cancer.

But even if EPA's decisions regarding cancer risk posed by glyphosate were relevant, EPA's recent determinations about glyphosate (and its view on the preemptive effect of its determinations) are invalid or informal and cannot be the basis for preemption. For starters, EPA's final determination that glyphosate is unlikely to be carcinogenic in humans, made through notice and comment rulemaking and finalized in 2020 after being proposed in 2017, has been vacated as arbitrary and capricious. *See NRDC*, 38 F.4th at 52.

The informal letters issued in 2019 and 2022, on which Monsanto relies for the agency's position, face even more problems. Monsanto relies heavily on the 2019 Letter stating that glyphosate products with California Proposition 65 cancer warnings would now be deemed misbranded in light of the federal agency's position on glyphosate—a pivot following years of EPA registering glyphosate products with Prop 65 warning labels. But the 2022 Letter clarified that its earlier letter did not mean that *all* cancer warnings would necessarily render the product misbranded, a clarification fatal to Monsanto's view that the 2019 Letter means the cancer warning the Schaffners argue Pennsylvania law requires is prohibited by EPA's position. 2022 Letter; U.S. Brief Opposing Certiorari 13.

Regardless, the 2019 Letter was premised on EPA's 2017 proposed determination that glyphosate is "not likely" to cause cancer. *See* 2019 Letter 1.

Because EPA determined that glyphosate is unlikely to cause cancer, the letter reasons, warnings stating glyphosate causes cancer would be false and misleading. *Id.* But that determination has since been vacated.

Further, the letter, issued by a lone, subordinate EPA official, quite obviously lacks force of law. *See Hardeman*, 997 F.3d at 956-57. Agency actions only have preemptive effect if they "carry the force of law under [*United States v. Mead Corp.*, 533 U.S. 218 (2001)] and its progeny." *Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015); *see also Merck*, 139 S. Ct. at 1679 ("[T]he only agency actions that can determine the answer to the pre-emption question, of course, are agency actions taken pursuant to the [agency]'s congressionally delegated authority.").[9]

Under *Mead*, an agency action has force of law when it results from "a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force"—typically, notice-and-comment rulemaking or formal adjudication. 533 U.S. at 230.

The 2019 Letter is a paradigmatic example of action lacking force of law under *Mead*. The opinion in the Letter—that "pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are

[9] The 2022 Memorandum—which reiterates EPA's position that glyphosate is not carcinogenic, despite the vacatur of its final rule, and states it may use its findings about glyphosate to support agency action in the future—suffers from many of the same deficiencies as the 2019 Letter.

misbranded"—was not the result of any formal or even quasi-formal agency procedure. It was simply published on EPA's website as an attachment to a press release. *See* Press Release, EPA, EPA Takes Action to Provide Accurate Risk Information to Consumers, Stop False Labeling on Products (Aug. 8, 2019), https://tinyurl.com/u656c3x.

If this type of informal agency action could preempt state law, the implications for federalism (not to mention public safety) would be grave indeed. It would mean that state laws could be wiped out at an agency's whim without any concern for, or input from, the public or the states. That would be unacceptable in any realm, but it is especially intolerable in the context of a statute like FIFRA, that was designed to ensure that states have concurrent authority to protect the public from hazardous products. *See Bates*, 544 U.S. at 450-51.

Fortunately, the law is clear that the 2019 Letter does not possess the slightest preemptive effect. *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237 (3d Cir. 2008), makes this strikingly evident. There, the defendant sought preemption based on a letter from FDA to California stating that a Proposition 65 warning on tuna would be misleading. *Id*. at 253. In rejecting that argument, the Court noted that FDA had not exercised any of its many congressionally-authorized methods for enforcing the law's misbranding provisions, but instead "merely expressed an informal policy opinion in a letter, and it did so only after [the plaintiff's] injuries were already

suffered." *Id*. at 255; *see also Wabash Valley Power Ass'n, Inc. v. Rural Electrification Admin*., 903 F.2d 445, 454 (7th Cir. 1990) (holding regulatory letter from agency did not have preemptive effect).

Similarly, here, Congress has provided at least two formal means for EPA to determine that a pesticide is misbranded: misbranding enforcement actions and registration-cancellation procedures. *See Reckitt*, 762 F. Supp. 2d at 36-37.

EPA has done *neither* with respect to glyphosate-based formulations that bear Proposition 65 warnings—warnings, it should be noted, that the United States *admitted* were initially approved by EPA. *See* U.S. Brief Opposing Certiorari 3-4. Rather, EPA merely issued a two-page letter declaring those products "misbranded" under FIFRA. Monsanto is seeking to deploy that thin reed to retroactively preempt all lawsuits against Monsanto.

But as in *Fellner*, EPA cannot eschew the procedures Congress has provided in favor of a cursory letter made accessible to the public through a hyperlink in an online press release. That is true in any case, but especially here, where EPA's statement that Proposition 65 warnings are not permitted on glyphosate-based formulations is a reversal of EPA's decisions approving the addition of such warnings. *See Mead*, 533 U.S. at 228 (inconsistency makes an agency's views less worthy of deference); *Skidmore v. Swift & Co*., 323 U.S. 134, 140 (1944) (same).

Nor does the 2019 Letter provide any reason for distinguishing this case from

Bates. In *Hardeman*, Monsanto argued that *Bates* did not foreclose any finding of express preemption with regard to Roundup because EPA had never rejected the warning at issue in *Bates*, whereas (said Monsanto) the 2019 Letter rejected such a warning for Roundup.

That argument fails for several reasons. First, the argument fails as a matter of fact because, as explained above, the 2022 Letter makes clear that the 2019 Letter did not apply to any possible warning, but rather only the generic Proposition 65 warning at issue. Further, the 2019 Letter merely relates to glyphosate, not Roundup—and EPA has never rejected any cancer warning for Roundup. In that sense, this case is no different than *Bates*.

Second, and equally important, the statutory analysis in *Bates* makes clear that the preemption conclusion here would come out the same way even if EPA *had* rejected a cancer warning on Roundup. In *Bates*, the defendant had argued that the Court's "parallel requirements" reading of § 136v(b) *must* be wrong because it would "establish[ ] a crazy-quilt of anti-misbranding requirements different from the one defined by FIFRA itself and intended by Congress to be interpreted authoritatively by EPA." 544 U.S. at 448 (citations omitted). The Court rejected this argument, stating that "the clear text of § 136v(b) . . . cannot be so easily avoided," particularly given the Court's "duty to accept the reading that disfavors pre-emption." *Id*. at 448-49. In so ruling, *Bates* made clear that even a "crazy-quilt" of

different "anti-misbranding" requirements would not trigger express preemption under FIFRA, so long as the state law underlying a particular plaintiff's warning claim is substantively equivalent to FIFRA's misbranding requirements.

Monsanto counters by pointing to *Bates*'s statement 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 [an EPA regulation], which specifically assigns these warnings to particular classes of pesticides based on their toxicity." *Id.* at 453.

But the quoted language from *Bates* merely establishes that where a failure-to-warn claim is—to use *Bates*' words—inconsistent with a "relevant EPA *regulations* that gives content to EPA's misbranding standards," the state claim is preempted by FIFRA. *Id.* (emphasis added). That is quite true, but it has nothing to do with this case because the Schaffners' claims are not inconsistent with any EPA misbranding regulations, as *Bates* itself confirms. *See id.* at 453 n.28 (EPA has promulgated "relatively few regulations that refine or elaborate upon FIFRA's broadly phrased misbranding standards"). The 2019 Letter is not a regulation; it is not even a guidance document—it is just a letter from a subdivision of EPA. Nor has EPA taken any of the actions that it *must* take, per Congress's express command, to determine that a pesticide is misbranded: misbranding enforcement actions and registration-cancellation procedures. *See Reckitt*, 762 F. Supp. 2d at 36-37.

At bottom, then, Monsanto is left with the bare assertion that EPA's approval of Roundup's label is itself sufficient to preempt state tort claims. But if the mere approval of a label by EPA had sufficient force of law to trigger express preemption under FIFRA, then the statute would wipe out *all* state-law warning claims involving federally registered products—a result that cannot be reconciled with *Bates*.

II. Plaintiff's Claims Are Not Impliedly Preempted.

A. There Is No Implied Preemption Under FIFRA.

As a threshold matter, any finding of implied preemption is foreclosed by *Bates*, which declined to address impossibility preemption even though that issue was extensively briefed by both parties and their amici. *See* 544 U.S. at 459 (noting that the majority's decision "comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption") (Thomas, J., concurring in judgment in part and dissenting in part); *see also Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270, 1281-82 (D. Haw. 2015) (citing *Bates* briefs and finding that *Bates* necessarily rejected implied preemption). *Bates* "had to consider any arguments that, if successful, would have affirmed the lower court decision finding preemption." *Id.* at 1281. Therefore "[i]t makes no sense" to think that *Bates* did not foreclose implied preemption under FIFRA. *Id.*; *see also Graham v. R.J. Reynolds Tobacco Co.*, 857 F.3d 1169, 1189 (11th Cir. 2017) (en banc) (holding that exclusion of tort claims from express

preemption provision in cigarette labeling law "supports an inference that there is no *implied* preemption of those [claims].").

B. There Is No Basis for Finding "Clear Evidence" Preemption Here.

Even if *Bates* did not foreclose all inquiries into implied preemption, there would be no such preemption here. Monsanto's main implied preemption argument is that failure-to-warn claims involving Roundup are preempted because there is "clear evidence" that EPA would not approve a cancer warning on Roundup. The Ninth Circuit rejected that argument, and this Court should too. *See Hardeman*, 997 F.3d at 958-60.

The burden of proving impossibility preemption under the clear-evidence standard lies with Monsanto—and that burden is a heavy one. The mere "possibility of impossibility [is] not enough." *Merck*, 139 S. Ct. at 1678. Rather, a court must find that the relevant federal and state laws "irreconcilably conflic[t]." *Id.* at 1679 (quoting *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)).

To demonstrate an "irreconcilable conflict," a manufacturer must present "clear evidence" (1) that the manufacturer fully informed the agency of the justifications for the warning that would be required by state law; (2) that the agency, in turn, informed the drug manufacturer that the FDA would not approve the change; and (3) that the agency action at issue "carr[ies] the force of law." *Id.* at 1678-79. None of these factors could be met here.

1. Monsanto Never "Fully Informed" EPA of the Justification for a Cancer Warning on Roundup.

The first clear-evidence factor—that the manufacturer must show it "fully informed" the agency of the justification for a warning—makes little sense in the context of Roundup, because the company has never informed *itself* as to the need for such a warning.

As the district court ruled in *Hardeman* post-trial, "[d]espite years of colorable claims in the scientific community that Roundup causes NHL, Monsanto presented minimal evidence suggesting that it was interested in getting to the bottom of those claims." *In re Roundup Prods. Liab. Litig.*, 385 F. Supp. 3d 1042, 1047 (N.D. Cal. 2019).

The company's internal emails show the same. In 2003, Monsanto spokesperson Donna Farmer stated, "you cannot say that Roundup is not a carcinogen . . . we have not done the necessary testing on the formulation to make that statement." Tr. Ex. 426, *Hardeman v. Monsanto*, No. 3:16-cv-0525-VC (N.D. Cal. 2019), https://tinyurl.com/2xtz3ew9. She repeated that statement in 2009. Tr. Ex. 245, *Hardeman v. Monsanto*, No. 3:16-cv-0525-VC (N.D. Cal. 2019), https://tinyurl.com/42ezuw6e.To this day, Monsanto has *still* never tested whether Roundup causes cancer. How, then, can it claim to have "fully informed" EPA of the need for such a warning? It cannot.

2. EPA Has Never Rejected a Cancer Warning on Roundup.

Nor is there any evidence EPA would reject a cancer warning on Roundup, as *Merck* requires. Monsanto argues that the 2019 and 2022 Letters show that EPA would not approve changing Roundup's labeling to include a cancer warning. But all the Letters show is that EPA—to use the agency's own words—will no longer approve pesticide labels "where the only basis for the warning" is that the product contains glyphosate. 2019 Letter 2. A statement that, of course, has since been clarified by the 2022 Letter.

Ultimately, the letters are irrelevant; lawsuits like this one are about *Roundup*, not *glyphosate* alone. And EPA has never said that it would reject a warning on Roundup.

3. EPA's Letters Regarding Glyphosate Warnings Lack the Force of Law.

Finally, even if the 2019 and 2022 Letters were relevant here, they lack the requisite force of law to have preemptive effect under *Merck,* for all the reasons explained *supra* at Part I(B). *Merck* squarely held that only actions "carrying the force of law" have the power to preempt. 139 S. Ct. at 1679; *see Hardeman*, 997 F.3d at 958 (rejecting "clear evidence" argument because the 2019 Letter lacks the force of law).

C. EPA's Pre-Approval Authority Over Label Changes Does Not Trigger Impossibility Preemption.

Nor is there any basis for finding any other kind of impossibility preemption in this case. Monsanto argues that because EPA must approve most labeling changes under FIFRA, and approved the label here, impossibility preemption applies. The Ninth Circuit rejected that argument, as should this Court. *See Hardeman*, 997 F.3d at 958-60.

First, that argument is directly contrary to *Bates*. There, Dow could not have changed its label to add the warning advocated by the plaintiffs without prior EPA approval. Despite that, the Court held that tort claims challenging the label's statements regarding the product's efficacy would *not* be preempted so long as they mirror FIFRA's misbranding requirements. *See Bates*, 544 U.S. at 447.

Second, the argument contradicts *Bates*'s "narrow" reading of FIFRA's preemption clause. *Id.* at 452. *Bates* rejected the notion that "Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers *virtual immunity* from certain forms of tort liability." *Id.* at 450 (emphasis added). But that is exactly what Monsanto is seeking here: "virtual immunity" for pesticide manufacturers from *all* state failure-to-warn claims. And *Bates* bars such a result.

Third, Monsanto's argument is contrary to the language of FIFRA's express preemption clause, which "prohibits only state-law labeling and packaging requirements that are '*in addition to or different from*' the labeling and packaging

requirements under FIFRA." *Id.* at 447 (quoting 7 U.S.C. § 136v(b)). This language shows that Congress intended to *preserve* state-law claims that are neither "in addition to [n]or different from" FIFRA's requirements. Holding that EPA's prior-approval authority over changes to pesticide labels impliedly preempts all failure-to-warn claims would render this language superfluous. That cannot be correct. *See Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 166 (2004) (noting that the Court is "loath" to adopt a "reading [that] would render part of the statute entirely superfluous").

Fourth, unlike the federal statutes governing drugs, devices, and meats, FIFRA expressly provides 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. § 136(a)(f)(2). Rather, registration of a pesticide is merely "prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter." *Id.*

This unique provision, which has no counterpart in the other schemes discussed by Monsanto, shows that EPA's approval of a label does not immunize the product from a federal misbranding action. That Congress itself recognized that fact, and wrote it into the statute, should lay to rest any notion that a state-law claim challenging an EPA-approved pesticide label is irreconcilably in conflict with FIFRA.

Fifth, FIFRA permits a state to restrict or completely *ban* pesticide sales and use for any reason—including the state's perception that the label's warning is inadequate or the product is misbranded. *Id.* § 136v(a). As the district court observed in *Hardeman*, "if California 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 California." *In re Roundup Prod. Liab. Litig.*, 364 F. Supp. 3d 1085, 1088 (N.D. Cal. 2019).

Sixth, and finally, finding preemption based on prior-approval flies in the face of FIFRA's goal to protect the public from hazardous pesticides. *See Bates*, 544 U.S. at 437-40. Monsanto is arguing that EPA's prior-approval authority over pesticide labels preempts *all* state-law warning claims, no matter how inadequate the label. If adopted, this would threaten public health because EPA is entirely reliant on pesticide registrants to ensure the adequacy of their own labels. *See Burke v. Dow Chem. Co.*, 797 F. Supp. 1128, 1134 (E.D.N.Y. 1992).

Recognizing this danger, Congress designed FIFRA to "preserve[ ] a broad role for state regulation." *Bates*, 544 U.S. at 450. As *Bates* explained, tort actions like this one help reinforce and support FIFRA's safety goals, both by unearthing the dangers of pesticides that EPA might not know about *and* by creating a financial incentive for pesticide manufacturers to do the right thing. *See id.* at 451.

CONCLUSION

For these reasons, the Court should affirm the judgment below and hold that Plaintiffs' claims are not preempted by federal law.

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Respectfully Submitted,

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COMBINED CERTIFICATIONS

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April 18, 2023

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I certify that the foregoing was served via the Court's electronic case management system upon all counsel of record.

April 18, 2023

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