No. _____

In the
Supreme Court of the United States

MONSANTO COMPANY,
Petitioner,
v.
JOHN L. DURNELL,
Respondent.

On Petition for Writ of Certiorari to the Missouri Court of Appeals

PETITION FOR WRIT OF CERTIORARI

DAVID M. ZIONTS
MICHAEL X. IMBROSCIO
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 2001
(202) 662-6000

K. LEE MARSHALL
BRYAN CAVE LEIGHTON PAISNER
Three Embarcadero Center
San Francisco, CA 94111

PAUL D. CLEMENT
Counsel of Record
MATTHEW D. ROWEN
JAMES Y. XI
NICCOLO A. BELTRAMO*
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-8900
paul.clement@clementmurphy.com

*Supervised by principals of the firm who are members of the Virginia bar

Counsel for Petitioner

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QUESTION PRESENTED

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") creates a comprehensive regulatory scheme governing the use, sale, and labeling of pesticides. The Act preempts any state "requirement[] for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. §136v(b). For decades, EPA has exercised its authority under FIFRA to find that Monsanto's Roundup product line and its active ingredient, glyphosate, do not cause cancer in humans. Consistent with that understanding, EPA has repeatedly approved Roundup's label without a cancer warning. FIFRA prohibits Monsanto from making any substantive change to an EPA-approved label unless it first obtains EPA's permission.

Respondent is one of more than 100,000 plaintiffs across the country that nonetheless seek to hold Monsanto liable for not warning users that glyphosate, the active ingredient in Roundup, causes cancer. The federal courts of appeals and state appellate courts are divided over whether FIFRA preempts such claims. The Third Circuit has held that it does. In the decision below, the Missouri Court of Appeals joined the Ninth and Eleventh Circuits and state appellate courts in California and Oregon in holding that it does not.

The question presented is:

Whether FIFRA preempts a state-law failure-to-warn claim where EPA has repeatedly concluded that the warning is not required and the warning cannot be added to a product without EPA approval.

PARTIES TO THE PROCEEDING

Petitioner Monsanto Company was the appellant in the Missouri Court of Appeals. Respondent John L. Durnell was the appellee.

CORPORATE DISCLOSURE STATEMENT

Petitioner Monsanto Company is an indirect, wholly owned subsidiary of Bayer AG, a publicly held corporation. No other publicly held corporation owns 10% or more of Monsanto's stock.

STATEMENT OF RELATED PROCEEDINGS

Durnell v. Monsanto Co., No. SC100975 (Mo.) (application for transfer denied Apr. 1, 2025).

Durnell v. Monsanto Co., No. ED 112410 (Mo. Ct. App.) (opinion and judgment issued Feb. 11, 2025).

Durnell v. Monsanto Co., No. 1922-CC00221 (Mo. Cir. Ct. of the City of St. Louis) (judgment entered Jun. 24, 2024).

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PETITION FOR WRIT OF CERTIORARI

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") includes a "[u]niformity" provision that expressly preempts all state "requirements for labeling or packaging" that are "in addition to or different from those required under" FIFRA. 7 U.S.C. §136v(b). There is a square and acknowledged circuit split over the scope of that provision as applied to the particular product at issue here. Specifically, in evaluating suits against Petitioner for its Roundup product (of which there are many), the circuits have split over "whether, once the Environmental Protection Agency ('EPA') registers and approves a pesticide label that omits a particular health warning, a state-law duty to include that warning is preempted." *Schaffner v. Monsanto Corp.*, 113 F.4th 364, 370-71 (3d Cir. 2024).

The Third Circuit says yes. In a thorough, 65-page opinion, a unanimous panel of that court held that FIFRA preempted a state-law failure-to-warn claim that sought to hold Monsanto liable for failing to warn users of the alleged carcinogenic effects of glyphosate, the active ingredient in Monsanto's Roundup product. The Third Circuit explained that EPA "regulations promulgated to implement FIFRA require the health warnings on a pesticide's label to conform to the proposed label approved by the EPA during the registration process." *Id.* at 371. Thus, when EPA has conducted "extensive review of [the] scientific evidence" of a potential health issue (as it had with glyphosate) and "approved proposed labels omitting a [health] warning" on that issue, FIFRA

preempts a "state-law duty to include" that same warning. *Id*

As the Third Circuit recognized, however, its "analysis differs from" that of its "colleagues in other courts." *Id.* at 399. Like the Missouri Court of Appeals here, the Ninth and Eleventh Circuits (as well as intermediate appellate courts in California and Oregon) have held that FIFRA does not preempt state-law failure-to-warn claims that seek to hold Monsanto liable for not warning users of the alleged carcinogenic effects of glyphosate. According to those courts, FIFRA does not preempt state-law claims so long as the elements of the claim can be said to "parallel" FIFRA's general misbranding prohibition. *See Carson v. Monsanto Co.*, 92 F.4th 980 (11th Cir. 2024); *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021); *Johnson v. Monsanto Co.*, 554 P.3d 290 (Or. App. 2024), *appeal denied*, 562 P.3d 237 (Or. 2024); *Pilliod v. Monsanto Co.*, 282 Cal.Rptr.3d 679 (Ct. App. 2021), *appeal denied*, No. S270957 (Cal. Nov. 17, 2021). It is immaterial in those courts that EPA has repeatedly "approv[ed] … individual pesticide registrations and corresponding labels" without the relevant warning, or that "manufacturers cannot change the label's contents without the Agency's prior approval." *Carson*, 92 F.4th at 990, 992.

The Court should resolve this split now. The legal issues have been exhaustively ventilated and explored from every angle in lengthy opinions from multiple federal and state appellate courts. There is no material chance the split will resolve itself, as the Third and Eleventh Circuits have each denied en banc review. And as this case exemplifies, the

consequences are enormous. More than 100,000 cases have been filed seeking to hold Monsanto liable based on a supposed link to cancer that the EPA has exhaustively studied and rejected as unfounded. The litigation has already forced Monsanto to remove glyphosate from its consumer version of Roundup, but the continuing overhang of these lawsuits threatens Monsanto's ability to continue to supply glyphosate to farmers who need it to remain world leaders in food production. More broadly, without this Court's intervention, the circuit conflict will engender confusion in litigation over any pesticide whose safety EPA has reviewed and whose label it has approved. And it will breed uncertainty in the interpretation of myriad other similarly worded preemption provisions.

This Court previously recognized the importance of the question presented when it called for the views of the Solicitor General in *Hardeman*, No. 21-241. In response, the United States recommended that this Court not "grant review unless and until a conflict in authority emerges." U.S. Br.19, *Monsanto Co. v. Hardeman*, No. 21-241 (U.S. filed May 10, 2022). That conflict has now emerged. There is no reason for further delay. The Court should grant this petition and resolve that conflict.

OPINIONS BELOW

The opinion of the Missouri Court of Appeals is reported at 2025 WL 451540 and reproduced at App.2-12. The Missouri Supreme Court's order denying Petitioner's application for transfer is unreported but reproduced at App.1. The opinion of the Missouri trial court denying Monsanto's motion for summary judgment is unreported but reproduced at App.13-16.

JURISDICTION

The Missouri Court of Appeals issued its opinion on February 11, 2025. The Missouri Supreme Court denied Petitioner's application for transfer on April 1, 2025. This Court has jurisdiction under 28 U.S.C. §1257(a).

STATUTORY PROVISIONS INVOLVED

The full text of 7 U.S.C. §136v(a)-(b) is reproduced at App.44.

STATEMENT OF THE CASE

A. Legal Background

Congress created FIFRA through a series of enactments to regulate the use, sale, and labeling of pesticides. *See Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). As originally enacted in 1947, *see* Pub. L. No. 80-104, 61 Stat. 163, FIFRA "was primarily a licensing and labeling statute." *Mortier*, 501 U.S. at 601 (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984)). In 1972, Congress "significantly strengthened FIFRA's registration and labeling standards" in response to "environmental and safety concerns." *Id.*; *see also* Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973. The 1972 amendments effectively "transformed FIFRA from a labeling law into a comprehensive regulatory statute." *Mortier*, 501 U.S. at 601 (quoting *Ruckelshaus*, 467 U.S. at 991).

Under FIFRA, no pesticide may be sold or distributed domestically without EPA registration. 7 U.S.C. §136a(a). To register a pesticide, EPA must determine (among other things) that the pesticide poses no unreasonable risk of adverse effects on

human health and the environment, *see* 7 U.S.C. §§136a(c)(5)(C), 136(bb); 40 C.F.R. §152.112(e), and that its labeling complies with FIFRA's requirements, including its misbranding prohibition, *see* 7 U.S.C. §136a(c)(5)(B). "A pesticide is 'misbranded' if its label contains a statement that is 'false or misleading in any particular,'" *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 438 (2005), or "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).

EPA has published regulations that govern the registration process. *See* 40 C.F.R. pt. 152. Under those regulations, manufacturers must submit voluminous scientific and safety data (including carcinogenicity studies), as well as proposed labeling that includes any precautionary statements regarding potential effects on human health. *E.g.*, 7 U.S.C. §136a(c); 40 C.F.R. §§156.10(a)(1)(vii), 156.60, 158.500. EPA reviews the scientific studies and safety data to ensure that the pesticide does not impose any unreasonable risk of adverse effects on human health, including cancer. And it reviews and approves the proposed label to ensure that it complies with FIFRA's requirements. *See* 40 C.F.R. §§152.40-55. If EPA has reason to believe a pesticide violates FIFRA's provisions, EPA may issue "stop sale, use, or removal" orders, 7 U.S.C. §136k(a), seize and condemn the offending products, *id*. §136k(b), and seek civil and criminal penalties from the manufacturer, *id*. §136l. EPA must review a pesticide's registration every 15 years. *Id*. §136a(g)(1)(A)(iii)(II). This process requires EPA to consider whether any "labeling changes" are necessary given new information and whether the

product still meets FIFRA's requirements, including its misbranding prohibition. 40 C.F.R. §155.58(b)(4).

Pesticide registrants have a continuing obligation to comply with FIFRA's labeling requirements. Once EPA approves a label, the "label is the law." EPA, Pesticide Registration Manual 3 (last updated April 2017), https://perma.cc/3GTB-3892. It is illegal to distribute a pesticide with labeling substantially different from the EPA-approved label. 7 U.S.C. §136j(a)(1)(B). And the manufacturer must seek approval for virtually any substantive change to that label. 40 C.F.R. §§152.44, 152.46; 7 U.S.C. §136a(c)(9)(C). While the manufacturer may make some "minor modifications" through a streamlined "notification" process, it may not change any "precautionary statements" via that notification process. *See* EPA, Office of Pesticide Programs, *Pesticide Registration Notice 2000-5* (May 10, 2000), https://perma.cc/ANB4-UGG9; EPA, Office of Pesticide Programs, *Pesticide Registration Notice 98-10* (Oct. 22, 1998), https://perma.cc/EZ7M-62MY; 40 C.F.R. §156.70(c). Instead, for such changes, it may proceed only by formal amendment.

FIFRA establishes a program for federal-state cooperation in regulating pesticides. *See Mortier*, 501 U.S. at 601-02. Section 136v, titled "Authority of States," sets forth key principles of that relationship. *See* 7 U.S.C. §136v. Section 136v(a) recognizes that, as a general matter, states retain their historic authority to regulate pesticide sale or use, provided that a state does not permit a sale or use that FIFRA, or EPA's implementing regulations, prohibit:

> (a) In general
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

Id. §136v(a).

But when it came to labeling, FIFRA sought to ensure that manufacturers would not have to comply with "50 different labeling regimes." *Bates*, 544 U.S. at 452. FIFRA thus forbids a state from imposing any additional or different requirements on pesticide labeling or packaging than those imposed under FIFRA:

> (b) Uniformity
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. §136v(b).

B. Factual Background

Monsanto produces Roundup, "a weed-killer that employs glyphosate as its active ingredient." *Schaffner*, 113 F.4th at 373.[1] EPA has registered pesticides containing glyphosate since 1974. *See* EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 12 (Dec. 12, 2017),

[1] While courts have generally referred to a single Roundup product, in reality, Monsanto has produced dozens of Roundup-branded products over the decades, each of which has been approved by EPA for marketing without a cancer warning.

https://perma.cc/UWM2-6BHB. EPA has repeatedly evaluated whether glyphosate is carcinogenic. *Id.* In 1986, for example, EPA found that the evidence did not support a conclusion that glyphosate causes cancer, and EPA prescribed "Required Labeling" with no cancer warning. *Id.*; *see also* EPA, Office of Pesticides and Toxic Substances, *Guidance for the Reregistration of Pesticide Products Containing Glyphosate as the Active Ingredient* 6-8, 20-34 (June 1986), https://perma.cc/DTH7-FR4V. In 1991, EPA's Carcinogenicity Peer Review Committee classified glyphosate "as a Group E chemical: 'Evidence of Non-Carcinogenicity for Humans.'" *Revised Glyphosate Issue Paper* 13. In 1993, EPA completed its statutory re-registration of glyphosate, concluding that "glyphosate products, labeled and used as specified [by EPA], will not pose unreasonable risks or adverse effects to humans." EPA, *Reregistration Eligibility Decision (RED) Glyphosate* 57 (Sept. 1993), https://perma.cc/528H-F4FN. And in subsequent years, EPA has reiterated its conclusion that glyphosate is not carcinogenic. *Revised Glyphosate Issue Paper* 12-13. In 2008, for instance, EPA determined that glyphosate is "not a carcinogen" based on its review of an "extensive database" of research. Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008). Public health regulators worldwide have similarly found that glyphosate does not cause cancer in humans. *See Hardeman*, 997 F.3d at 951.

In 2015, against that global consensus, a working group of the International Agency for Research on Cancer ("IARC") classified glyphosate as a "Group 2A" agent—meaning it is, in IARC's view, "probably

carcinogenic to humans" based on "limited" evidence of cancer in humans. IARC, 112 Some Organophosphate Insecticides and Herbicides 398 (2015), https://perma.cc/9TPL-278R. IARC's classification reflected a hazard assessment, meaning a theoretical determination of carcinogenic potential; it did not assess the *actual* risk glyphosate poses under real-world conditions. *Id.* at 10-11; *see also In re Roundup Prods. Liab. Litig.*, 390 F.Supp.3d 1102, 1108, 1113-14 (N.D. Cal. 2018) (noting the "limited" and "abstract" nature of IARC's assessment).

When IARC released its assessment of glyphosate, EPA was already engaged in its statutory registration review. During that review, the agency developed an extensive database on the carcinogenic potential of glyphosate, reviewing 736 studies as part of an open literature review as well as "numerous studies … submitted to the agency" by independent parties. *Revised Glyphosate Issue Paper* 21-22. The agency specifically examined the studies "included in the evaluation by IARC." *Id.* at 23. It further convened a scientific advisory panel to contribute to its analysis. After considering IARC's classification, EPA again determined that "[t]he strongest support" is for classifying glyphosate as "not likely to be carcinogenic to humans." *Id.* at 143. And in 2019, after accounting for public comments, EPA issued a proposed registration review decision in which the agency reiterated both its conclusion that glyphosate is not carcinogenic to humans and its disagreement with IARC—noting that its evaluation was "more robust" and "more transparent" than IARC's and "consistent with" those of "other regulatory authorities and international organizations." EPA,

Glyphosate Proposed Interim Registration Review Decision 7-8 (Apr. 2019), https://perma.cc/8K63-HD36. EPA was hardly the only authority to reject IARC's findings. No shortage of national and international health organizations rejected IARC's position, including the European Union's European Chemicals Agency, its European Food Safety Authority, and the national health authorities of Australia, Canada, Germany, and New Zealand. *See Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1270 (9th Cir. 2023).

In an August 2019 letter rejecting a cancer warning for glyphosate, EPA again reaffirmed its determination that glyphosate is "not likely to be carcinogenic to humans." App.38. The proposed warning, which California law automatically requires because of IARC's classification, would have required manufacturers to add a label stating that glyphosate is "known" to cause cancer. In its letter, EPA explained that it "disagrees with IARC's assessment" and that it had "considered a more extensive dataset than IARC." App.38. "Given EPA's determination," EPA concluded that a warning stating glyphosate causes cancer would render a pesticide "misbranded pursuant to section 2(q)(1)(A) of FIFRA." App.39.[2] That conclusion was consistent with how state environmental protection agencies had addressed

[2] EPA more recently stated that it "could approve" labels noting *both* the IARC classification *and* the contrary findings of EPA and other regulatory authorities. App.41-43. But it simultaneously reiterated its assessment that glyphosate is likely not carcinogenic and its rejection of a warning that glyphosate causes cancer. App.41-42.

glyphosate products for decades. Before California, *none* had attempted to require a cancer warning.

After considering public comments for a second time, EPA in 2020 finalized its interim registration review determination that glyphosate does not cause cancer, and again approved labeling with no cancer warning. Various parties challenged that decision in the Ninth Circuit. In response to those suits and a change in administration, EPA again reviewed its decision in early 2021. The agency reaffirmed the view espoused without interruption over the last six administrations: "[G]lyphosate is not likely to be a human carcinogen and … it does not pose human-health risks of concern." EPA.Br.17, *NRDC v. EPA*, Nos. 20-70787, 20-70801 (9th Cir. May 18, 2021). The Ninth Circuit vacated EPA's 2020 Interim Decision in June 2022 after concluding that the agency failed to offer enough "analysis and explanation." *Nat. Res. Def. Council v. U.S. Env't Prot. Agency*, 38 F.4th 34, 52 (9th Cir. 2022). Consistent with the Ninth Circuit's ruling, EPA announced that it will "revisit and better explain its evaluation of the carcinogenic potential of glyphosate," but that "EPA's underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic to humans," remain the same. Memorandum from Cathryn Britton, Branch Chief, Risk Management and Implementation Branch V, Pesticide Re-evaluation Division, to Glyphosate Registration Review Docket (EPA-HQ-OPP-2009-0361) at 5-6 (Sept. 21, 2022), https://perma.cc/3KDJ-JT2N. Since then, EPA has continued to approve labels of numerous glyphosate-based pesticide products

without cancer warnings. *See* EPA, Chemical Name: Glyphosate, https://perma.cc/7PHA-8UXP.[3]

C. Procedural History

In the wake of the IARC decision, more than 100,000 plaintiffs filed lawsuits in federal and state courts nationwide, alleging that Roundup caused their cancer and that Monsanto is liable for failing to warn them of glyphosate's purportedly carcinogenic properties.[4] In 2016, the Judicial Panel on Multidistrict Litigation centralized cases alleging that Roundup caused plaintiffs' non-Hodgkin's lymphoma in the Northern District of California, where several cases were already pending. *In re Roundup Prods. Liab. Litig.*, 214 F.Supp.3d 1346, 1348 (J.P.M.L. 2016); *see also, e.g., Hardeman v. Monsanto Co.*, No. 3:16-cv-00525 (N.D. Cal. filed Feb. 1, 2016). This tidal wave of litigation forced Monsanto to remove glyphosate from the consumer version of Roundup.

That removal—and the ongoing litigation—has sparked fear among American farmers that Monsanto will be forced to remove glyphosate from the

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[3] EPA has on at least two prior occasions approved labels that included a cancer warning. But EPA has acknowledged that those decisions were the result of an "implementation mistake." U.S. Br. at 17-19 & n.14, *Monsanto Co. v. Hardeman*, No. 19-16636 (9th Cir. filed Dec. 20, 2019).

[4] The massive volume of the litigation stems from two main factors. First, millions of Americans have used Roundup. And second, non-Hodgkin's lymphoma is a common and naturally occurring blood cancer. As of 2022, the plaintiffs' bar had spent an estimated $131 million on more than 625,000 television advertisements for Roundup litigation. *See* T. Joyce, Am. Tort Reform Ass'n, *When Plaintiffs' Attorneys Mislead the Public*, Bloomberg Law (Sept. 28, 2022), https://perma.cc/SV28-9BFW.

agricultural version of Roundup as well. Farmers describe Roundup as "a fabulous tool" and "one of the least harmful chemicals [they] use." P. Cohen, *Roundup Weedkiller Is Blamed for Cancers, but Farmers Say It's Not Going Away*, N.Y. Times (Sept. 20, 2019), https://perma.cc/J2LQ-BEKS. Indeed, farmers "continue to depend on Roundup," especially given global "increases [in] the demand for food." *Id.* And while the glyphosate lawsuits have been "a boon to trial lawyers who have made a career and a fortune" off of them, they risk forcing American farmers to return to the "miserable," "mind-numbing," and "back-breaking labor" that was necessary before Monsanto introduced glyphosate to the agricultural industry in the 1970s. B. Hurst, *Roundup Lawsuits Pose a Threat to My Missouri Farm*, Wall Street Journal (Sept. 13, 2024), https://perma.cc/M24F-TJTB. Moreover, removing glyphosate from shelves would force farmers to turn to other herbicides that are "harsher, more toxic[,] and more likely to drift and cause damage to surrounding vegetation." *Id.*

Since removing glyphosate from its consumer version of Roundup, Monsanto has settled many claims against it. But tens of thousands of claims remain pending in courts across the country. This is one of those cases.

In January 2019, Respondent John Durnell sued Monsanto in Missouri state court, alleging that he had developed non-Hodgkin's lymphoma as a result of exposure to Roundup. App.3. Durnell brought Missouri common-law products-liability tort claims, including strict liability defective design, strict liability failure to warn, and negligence. App.3. Those

claims were tried to a jury in September 2023. App.3. Both at the close of Durnell's case in chief, as well as after the close of all evidence, Monsanto moved for a directed verdict on the ground that FIFRA preempts Durnell's claims. App.3. The court denied both motions. App.3; *see also* App.17-18.

The jury ultimately found Monsanto not liable on all of Durnell's claims except his failure-to-warn claim. App.3. As for the failure-to-warn claim, the jury found Monsanto liable and awarded Durnell $1.25 million in damages. App.3. Monsanto promptly moved for entry of judgment notwithstanding the verdict, again on the ground that FIFRA preempted Durnell's failure-to-warn claim. App.3. The trial court again denied Monsanto's motion and entered final judgment, and Monsanto appealed. App.3; *see also* App.19, 20-21.

On appeal, Monsanto once again argued that FIFRA preempted Missouri's state-law failure-to-warn claims. App.4. The court rejected Monsanto's argument that FIFRA expressly preempts Durnell's failure-to-warn claim. The court recognized that "FIFRA will preempt a state law requirement—including a common-law cause of action—that is not fully consistent with FIFRA's requirements." App.5. Here, that analysis turns on whether the state failure-to-warn claim would require Monsanto to carry a label "in addition to or different from" the one FIFRA required. App.5-6; 7 U.S.C. §136v(b). The court ultimately concluded that an adverse jury verdict would not impose an additional requirement because the "practical effect" of FIFRA's misbranding prohibition and Durnell's failure-to-warn claim "are

the same: both require a pesticide manufacturer to adequately warn users of the potential dangers of using its product." App.7. Durnell's claim therefore did not impose a requirement "in addition to or different from" the requirements of FIFRA. App.7. The court acknowledged that the Third Circuit had come to a different conclusion in *Schaffner*. App.10. But because it did "not find *Schaffner* persuasive," the Court chose instead to follow decisions in the Ninth and Eleventh Circuits rejecting Monsanto's express preemption arguments. App.11 (citing *Hardeman*, 997 F.3d 941 (9th Cir. 2021), and *Carson*, 92 F.4th 980 (11th Cir. 2024)).

The court also rejected Monsanto's implied-preemption argument. The court recognized that state tort claims are preempted if it is "impossible to comply with both federal and state law." App.8. And it acknowledged that EPA had repeatedly concluded that glyphosate does not cause cancer in humans and repeatedly approved Roundup labels that did not include a cancer warning. The court nevertheless held that that was not enough. Because Monsanto had not specifically sought EPA's approval to add a cancer warning, the court could not say with certainty that such a request for approval would be denied. App.9. The mere "possibility of impossibility" was insufficient to preempt Respondent's failure-to-warn claim. App.9. The court appeared to recognize that this Court found impossibility preemption in similar circumstances in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). But the Court declined to rely on that decision because it involved a different statutory scheme. App.11.

REASONS FOR GRANTING THE PETITION

EPA has repeatedly determined that glyphosate, the world's most widely used herbicide, does not cause cancer. EPA has consistently reached that conclusion after studying the extensive body of science on glyphosate for over five decades. Consistent with that determination, EPA has approved hundreds of labels for dozens of Roundup products without requiring a cancer warning. EPA has not only determined that such a warning is unnecessary under FIFRA. It has told registrants that including a glyphosate-causes-cancer warning would render their products affirmatively "misbranded" under the Act. Once EPA approves a label, moreover, FIFRA makes it unlawful for a pesticide manufacturer to add additional warnings without EPA's permission. It is thus no surprise that Monsanto has never tried to unilaterally include a cancer warning on its Roundup products. Not only is such a label against the overwhelming weight of scientific evidence, including it would have exposed Monsanto to civil and criminal penalties under FIFRA.

The premise of this lawsuit, however, and the thousands like it, is that Missouri law requires Monsanto to include the precise warning that EPA rejects. The Third Circuit correctly held that FIFRA squarely preempts such suits. The court below had the benefit of that thorough, 65-page opinion, but deemed the analysis of the Ninth and Eleventh Circuits more persuasive. Splits of authority do not get any clearer than that. The circuits are squarely and irrevocably split not just on the scope of FIFRA preemption in the abstract; they have reached

diametrically opposed conclusions in lawsuits involving the exact same product.

The decision below is wrong. It avoided finding preemption by distorting FIFRA's text and misreading this Court's decisions. And the stakes are high. There are tens of thousands of Roundup suits in the Missouri court system and thousands more in state and federal courts throughout the country. Those suits have already forced Monsanto to remove glyphosate from the consumer version of Roundup, and they threaten Monsanto's ability to continue to supply glyphosate to farmers who need it to stay competitive. Moreover, while there is a Roundup-specific circuit split, the division and confusion extend to all other pesticides subject to FIFRA and EPA jurisdiction. There is no reason to allow this confusion to linger and every reason for this Court to grant review.

I. The Decision Below Deepens A Square And Acknowledged Circuit Split.

As the decision below recognized, and multiple courts have acknowledged, the courts of appeals are divided over whether FIFRA preempts state failure-to-warn claims that require pesticide manufacturers to include a warning on glyphosate products. Like the Missouri Court of Appeals, the Ninth and Eleventh Circuits have held that FIFRA does not preempt state failure-to-warn claims that would require Monsanto to warn consumers that glyphosate causes cancer. The Third Circuit, by contrast, has squarely held that it does.

1. Like the Missouri Court of Appeals, the Ninth Circuit has held that FIFRA does not preempt state failure-to-warn claims that would require pesticide

manufacturers to warn consumers that glyphosate causes cancer. In *Hardeman*, the plaintiff alleged that Monsanto's failure to warn him of the purportedly carcinogenic effects of Roundup caused him to develop non-Hodgkin's lymphoma. 997 F.3d at 952. Monsanto argued that FIFRA preempted the plaintiff's failure-to-warn claim, but the Ninth Circuit disagreed. According to the Ninth Circuit, a jury verdict requiring Monsanto to add a cancer warning to Roundup's label would not impose a requirement "in addition to or different from" what FIFRA already requires because, at a general level, "FIFRA's requirement that a pesticide not be misbranded is consistent with, if not broader than, California's common law duty to warn." *Id.* at 954. The Ninth Circuit acknowledged that EPA, applying FIFRA, has repeatedly concluded that Monsanto was not required to include a cancer warning for glyphosate, including by "repeatedly register[ing] Roundup for sale without a cancer warning on the label" and by notifying manufacturers in 2019 that EPA would consider any glyphosate product including a cancer warning to be misbranded. *Id.* at 956. But the court deemed those facts insufficient for express preemption, reasoning that, because registration is not "a defense for the commission of any offense under this subchapter," EPA's approval of a label "is not conclusive of FIFRA compliance." *Id.* (quoting 7 U.S.C. §136a(f)(2)). The court discounted EPA's approval of Roundup and its 2019 letter because neither "carr[ied] the force of law." *Id*.

The Eleventh Circuit took the same approach as the Ninth. In *Carson*, the Eleventh Circuit held that FIFRA did not preempt the plaintiff's failure-to-warn

claim because, at a general level, "both FIFRA and Georgia common law require pesticide manufacturers to warn users of potential risks to health and safety." 92 F.4th at 992. The Eleventh Circuit recognized that, by registering a pesticide without a cancer warning, EPA necessarily makes "an individualized finding that a particular pesticide is not misbranded." *Id.* at 993. But, like the Ninth Circuit, the Eleventh Circuit nevertheless deemed EPA's registration of Roundup irrelevant to the preemption question because EPA's "approvals provide only 'prima facie evidence,' not conclusive proof, that a pesticide is not misbranded." *Id.* (citing 7 U.S.C. §136a(f)(2) and *Hardeman*, 997 F.3d at 956). And while the court acknowledged EPA's 2019 determination that including a cancer warning on glyphosate products would be affirmatively "false or misleading," the court discounted that conclusion because it "did not foreclose any and all warnings related to glyphosate's potentially harmful effects" and "did not carry the force of law." *Id.* at 996.[5]

2. The Third Circuit, by contrast, has squarely held that FIFRA preempts state-law failure-to-warn claims that would require Monsanto to warn purchasers about glyphosate's supposedly carcinogenic effects. The plaintiff in *Schaffner* alleged that he developed non-Hodgkin's lymphoma because Monsanto failed to warn him of the purportedly

[5] The California Court of Appeal and the Oregon Court of Appeals have likewise rejected Monsanto's argument that FIFRA preempts state failure-to-warn claims that would require Monsanto to warn consumers that glyphosate causes cancer. *See Pilliod*, 282 Cal.Rptr.3d 679, *appeal denied*, No. S270957 (Cal. Nov. 17, 2021); *Johnson*, 554 P.3d 290, *appeal denied*, 562 P.3d 237 (Or. 2024).

carcinogenic effects of glyphosate. The Third Circuit held that FIFRA expressly preempted the plaintiff's claim because a jury verdict in his favor would impose labeling requirements that are "in addition to or different from" what EPA required in administering FIFRA. 113 F.4th at 395-96, 399. The Third Circuit acknowledged that the Ninth and Eleventh Circuits had gone the other way on the theory that FIFRA's misbranding prohibition is, at a high "level[] of generality," equivalent to the common law duty to warn. *Id.* at 389 (citing *Carson*, 92 F.4th at 991-92, and *Hardeman*, 997 F.3d at 955-56). But the Third Circuit expressly rejected the notion that a "state-law duty can[] survive preemption simply because its standard of liability is equivalent to the broad statutory definition of misbranding." *Id.* at 390. The court explained that under §136v(b), "federal requirements must be articulated at [a] more specific level." *Id.* So, if "EPA regulations specifically identify the contents required to be included on a pesticide label, a state-law requirement is preempted unless it is equivalent to that specific regulatory requirement." *Id.*

Applying those principles, the Third Circuit concluded that "EPA regulations specifically identify the contents required to be included on" Roundup's label. *Id.* Consistent with its longstanding view that glyphosate does not cause cancer, EPA repeatedly registered Roundup for use and approved its label without a cancer warning. *Id.* at 373-75. And because EPA approved Roundup's label, EPA's regulations prohibited Monsanto from modifying the label to include a cancer warning without EPA's permission. *Id.* at 382-85 (citing 40 C.F.R. §152.44(a)). While EPA

regulations permit some minor modifications to a pre-approved label, they do not permit changes to "precautionary statements," which a cancer warning unquestionably is. *Id.* at 383-84. Because the plaintiff's state-law failure-to-warn claim would require Monsanto to include a cancer warning that EPA's regulations did not require—and in fact affirmatively forbade it from adding without EPA's permission—FIFRA preempted the plaintiff's claim. *Id.* at 393.

In so holding, the Third Circuit squarely rejected the Ninth and Eleventh Circuits' reliance on §136a(f)(2), which specifies that registration is merely "prima facie evidence" (rather than conclusive proof) that the pesticide is not "misbranded." *Id.* at 396 (citing *Carson*, 92 F.4th at 993, and *Hardeman*, 997 F.3d at 956). The Third Circuit explained that while registration alone is not "dispositive" as to whether a pesticide is "misbranded," EPA's treatment of Roundup disposes of the preemption question. After all, once EPA approved Roundup's label, EPA's regulations prohibited Monsanto from adding new "precautionary statements" to the label—including the cancer warning requested by the plaintiff in that case. *Id.* at 396-97.

The Third Circuit likewise rejected the Ninth and Eleventh Circuits' "force of law" analysis. *Id.* at 398 & n.20. As the Third Circuit explained, force of law analysis generally has no place when interpreting an express preemption provision. *Id.* at 398. Because "Congress has decreed in the text of [FIFRA] that federal 'requirements' have preemptive force, no further analysis is necessary" once a FIFRA

"requirement" is identified. *Id.* at 398 (citation omitted). And FIFRA's restriction on changing a pre-approved label was just that. Schaffner sought rehearing en banc, noting that the Third Circuit had "split[] expressly from the Ninth and Eleventh Circuits," En Banc Pet. at 3-4, *Schaffner v. Monsanto Corp.*, No. 22-3075 (3d Cir. filed Sept. 12, 2024), but the court denied the petition without any judge calling for a response, let alone recording a dissent.[6]

In short, the circuits are squarely divided over "whether, once the [EPA] registers and approves a pesticide label that omits a particular health warning, a state-law duty to include that warning is preempted." *Schaffner*, 113 F.4th at 370-71. More specifically, the circuits are divided over whether FIFRA preempts state-law failure-to-warn claims that seek to impose liability on pesticide manufacturers for failing to warn consumers that glyphosate causes cancer. Like the Missouri Court of Appeals, the Ninth and Eleventh Circuits and the California and Oregon appellate courts have held that FIFRA does not preempt such claims. On the other side of the split, the Third Circuit has held that it does. There is no realistic chance that the split will resolve itself given

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[6] Massachusetts and Hawaii courts have likewise held that FIFRA preempts state-law claims that seek to hold Monsanto liable for failing to include a cancer warning on its Roundup products. *See* Mem. of Decision and Order on Defs.' Mot. for Summ. J., Dkt. 40, *Cardillo v. Monsanto Co.*, No. 2177CV00462 (Mass. Super. Ct. filed Oct. 21, 2024), *appeal granted*, No. 2024-P-1382 (Mass. filed Feb. 24, 2025); Order Granting Def.'s Mot. for Partial Summ. J., Dkt. 1058, *Peters v. Monsanto Co.*, No. 1CCV-20-0001630 (Haw. Cir. Ct. filed Oct. 25, 2023), *appeal granted*, *id.*, Dkt. 1166 (filed Mar. 13, 2024).

the Third Circuit's denial of en banc review. Only this Court can resolve the conflict on this important issue of law.

II. The Decision Below Is Wrong.

The decision below not only deepens an acknowledged circuit split, it distorts the text of FIFRA and this Court's precedents. When a state tort claim requires a pesticide manufacturer to add a warning that EPA has repeatedly concluded is not only unnecessary, but also "false and misleading," FIFRA preempts that claim. *See* App.39. Any other rule would undermine the nationwide "[u]niformity" in pesticide labeling that Congress set out to achieve.

1. FIFRA expressly preempts state laws that impose "any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. §136v(b). Respondent claims that Monsanto violated a state-law duty to warn consumers that glyphosate causes cancer. Because the term "requirements" in §136v(b) includes "common-law duties" that "set a standard for a product's labeling," *Bates*, 544 U.S. at 443, 446, Respondent's claim unquestionably seeks to impose a "requirement[] for labeling or packaging." 7 U.S.C. §136v(b). The only question is whether it imposes a requirement that is "in addition to or different from" what EPA requires in administering FIFRA. Text, precedent, and common sense confirm that it does.

A state labeling requirement is "in addition to or different from those required under" FIFRA if it "diverges from those set out in FIFRA and its implementing regulations." *Bates*, 544 U.S. at 442-43, 452. As this Court made clear in *Bates*, it is not

enough for a state requirement to be "nominally equivalent[]" to what FIFRA demands. *Id.* at 454. The "state-law labeling requirement must *in fact* be equivalent to a requirement under FIFRA in order to survive pre-emption." *Id.* at 453 (emphasis added). The quintessential example of such a "parallel requirement" under *Bates* is a state tort claim that simply provides a damages remedy for a violation of the existing federal labeling standards. *Id.* at 448. A "manufacturer should not be held liable under a state labeling requirement subject to §136v(b) unless the manufacturer is also liable" for misbranding under FIFRA. *Id.* at 454.

Respondent's failure-to-warn claim plainly imposes a labeling requirement that is "in addition to or different from" what EPA requires in administering FIFRA. After all, this is not a case in which the plaintiff is seeking to impose a state-law labeling requirement on which EPA has "never passed," such as the pesticide's efficacy. *See id.* at 440. Since Monsanto introduced Roundup in 1974, "EPA has repeatedly evaluated the health risks posed by glyphosate," *Schaffner*, 113 F.4th at 373, and it has "repeatedly … conclud[ed] that it is not likely to be carcinogenic to humans," *Hardeman*, 997 F.3d at 951. Consistent with that conclusion, EPA has repeatedly approved labels for Roundup that do not include a cancer warning.

Those approvals trigger preemption. As the Third Circuit explained, EPA's approvals necessarily "identify the contents required to be included on a pesticide label," *Schaffner*, 113 F.4th at 390, because EPA's approval locks a manufacturer's label in place.

EPA regulations forbid manufacturers from adding new "precautionary statements" without prior EPA approval. A jury verdict requiring Monsanto to add a new cancer warning to Roundup's label is irreconcilable with that regime. It necessarily requires a jury to determine that there was some warning that the manufacturer could have included on the label but failed to. But under EPA's rules, there is no additional warning the manufacturer can add on its own—and certainly not a statement that EPA has determined would render the product misbranded. *See* App.39. State law effectively tells the manufacturer "add this warning," while federal law tells it "do not." Because the jury verdict in this case requires Monsanto to include a cancer warning that EPA's regulations did not require—and in fact affirmatively forbade it from adding—FIFRA preempts Respondent's claim.

This Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), confirms that conclusion. *Riegel* addressed the scope of preemption under the Medical Device Amendments of 1976 ("MDA"), Pub. L. No. 94-295, 90 Stat. 539, a statute with a similarly worded preemption provision. *See* 21 U.S.C. §360k(a)(1) (prohibiting states from imposing a requirement for a medical device "which is different from, or in addition to, any requirement applicable under this chapter to the device"); *see also Bates*, 544 U.S. at 447 (noting that FIFRA and MDA express preemption provisions are "similarly worded"). "[T]he MDA's system of premarket approval" also "operates very similarly to pesticide registration under FIFRA." *Schaffner*, 113 F.4th at 387. In particular, like pesticides under FIFRA, "medical devices must be reviewed and

approved before being marketed, and once approved they cannot be modified unless the proposed modification is itself reviewed and approved." *Id.* at 387-88.

Riegel held that FDA's "premarket approval" of a device "imposes 'requirements'" for purposes of the MDA's preemption provision. 552 U.S. at 322-23. The Court reasoned that "a device that has received premarket approval" must "be made with almost no deviations from the specifications in its approval application," since "the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323. And as the Third Circuit recognized, that analysis "carries over to FIFRA." *Schaffner*, 113 F.4th at 388. "If the prohibition on modifying medical devices following their approval for safety establishes 'requirements' for medical devices, then FIFRA's regulatory approach, which employs the same two elements, should likewise establish 'requirements' under [FIFRA's] similar preemption provision[.]" *Id.* at 388-89.

The Missouri Court of Appeals concluded otherwise by assessing FIFRA's requirements at too high a level of generality. According to the court, Missouri common law "is fully consistent with" FIFRA's misbranding provision because "both require a pesticide manufacturer to adequately warn users of the potential dangers of using its product." App.6-7. That reasoning cannot be squared with this Court's decision in *Bates*. As the Court explained in that case, the question is not whether state and federal law have "nominally equivalent" labeling standards. *Bates*, 544 U.S. at 454. The question is whether the state imposes

a labeling requirement for a particular pesticide that is *in fact* different from what EPA requires for that pesticide. *Id.* at 453. That is why *Bates* explained that FIFRA preempts a state law that requires a label for a particular pesticide to say "DANGER" when EPA has determined that it should say "CAUTION" instead. *Id.* But under the decision below, the state-law requirement to use "DANGER" on a pesticide label "would not be preempted so long as the label satisfies the statutory definition of misbranding." *Schaffner*, 113 F.4th at 390-91.

Assessing FIFRA's requirements at such a high level of generality would render FIFRA's "Uniformity" provision largely meaningless. Under that approach, virtually all failure-to-warn claims are "consistent" with FIFRA's misbranding provision, because virtually all failure-to-warn claims require (as FIFRA's misbranding provision does) the manufacturer to "adequately warn users of the potential dangers of using its product." App.7. Under the decision below, a jury would be free to impose liability on pesticide manufacturers for failing to include all manner of warnings, no matter how different they are from what EPA requires. Worse still, different juries in different states could impose countless different requirements, directly impeding the uniformity Congress sought to achieve through §136v(b). As the Third Circuit recognized, "[s]tate-law duties framed in these vague and broad terms would produce considerable heterogeneity, not uniformity, in the labels that pesticides are required to bear, for different factfinders deciding different individual cases might reasonably disagree about whether a

particular warning was necessary to protect health." *Schaffner*, 113 F.4th at 393.

Nor does §136a(f)(2) support the decision below. That provision, located elsewhere in the statute and grouped with other provisions in a subsection labeled "Miscellaneous," simply says that "registration" of a pesticide under FIFRA is not "a defense for the commission of any offense under this subchapter" but is "prima facie evidence" that a pesticide's labeling "compl[ies] with the registration provisions of the subchapter." 7 U.S.C. §136a(f)(2). That provision has "no bearing on" preemption. *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994); *Schaffner*, 114 F.3d at 396-97. It simply "stands for the unremarkable proposition that a registration is not a defense against an allegation that a product violates the terms of that registration." *Reckitt Benckiser, Inc. v. Jackson*, 762 F.Supp.2d 34, 45 (D.D.C. 2011). If it were otherwise, then EPA's determination that a warning label is unnecessary (or, as here, false and misleading) would never be preemptive. The result would be the very proliferation of divergent state and federal labeling requirements Congress sought to end.

2. Respondent's failure-to-warn claim is doubly preempted because it is "impossible" for Monsanto "to comply with both state and federal requirements." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013). In the context of labeling requirements, impossibility arises where the warning could not have been added without prior federal approval, *see PLIVA*, 564 U.S. at 617-19.

Here, Monsanto could not have added the label required by the jury verdict in this case without prior

federal approval. In *PLIVA,* this Court held that a state-law failure-to-warn claim is preempted where federal law bars a manufacturer from adopting, without prior federal approval, a labeling change that state law requires. *Id.* at 617-18. It is irrelevant, *PLIVA* held, whether the manufacturer might have persuaded the relevant agency to approve that change. *Id.* at 619. Because "[t]he question for 'impossibility' [preemption] is whether the private party could *independently* do … what state law requires," state law is preempted wherever the manufacturer's ability to comply with state law depends upon prior agency approval. *Id.* at 620 (emphasis added).

That is the case here. Selling a pesticide with labeling that makes "any claims" "substantially differ[ent]" from the EPA-approved labeling is unlawful. 7 U.S.C. §136j(a)(1)(B), (2)(G); *see also id.* §136a(a). And pesticide manufacturers may not change substantive aspects of their products' labeling without EPA's prior approval. *See* 40 C.F.R. §§152.44, 156.70(c); *Pesticide Registration Notice 2000-5.* To change labeling, a manufacturer must submit an amended registration application that includes all data relevant to the change. *See id.* §§152.44(a), 152.50. "[T]he application must be approved by [EPA] before the product, as modified, may legally be distributed or sold." *Id.* §152.44(a). Like the manufacturer in *PLIVA*, therefore, Monsanto could not have "independently do[ne] … what state law require[d]." *PLIVA*, 564 U.S. at 620. Nor could Monsanto have added a cancer warning to Roundup's label via EPA's "notification" procedure, as changes to precautionary statements may not be made without

prior agency approval. *See Pesticide Registration Notice 2000-5*; *Pesticide Registration Notice 98-10*.

Even if FIFRA did not expressly bar Monsanto from adding a cancer warning on its own, EPA would unquestionably reject any attempt to add a cancer warning to Roundup. For decades, EPA has assessed the carcinogenic potential of glyphosate and consistently approved both glyphosate and Roundup's labeling *without* a cancer warning. *See supra* at 7-8. Even after the IARC working group's "hazard identification," EPA—following a "systematic review," including of all studies IARC considered—confirmed the conclusion it has reached for years: Glyphosate is "not likely to be carcinogenic to humans." *Supra* at 8-10. EPA eliminated any remaining doubt in 2019 when it informed all glyphosate registrants that, "[g]iven EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,'" EPA considers any warning that glyphosate *is* carcinogenic "to constitute a false and misleading statement" that violates FIFRA's prohibition against "misbranded" substances. App.39.[7]

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[7] While EPA's 2022 letter suggested that EPA might approve a warning that advised consumers both of California's determination that Roundup poses cancer risks and of EPA's disagreement with that determination, Respondent did not ask for this type of warning at trial. Moreover, Respondent's exposure to glyphosate ceased in 2012—five years before California categorized glyphosate as carcinogenic and three years before the IARC report that triggered that categorization. Monsanto thus could not have known to propose the kind of warning the 2022 letter suggests. That letter, moreover, reaffirms EPA's 2019 conclusion that a warning stating that

The Missouri Court of Appeals rejected all that on the ground that none of EPA's actions carried "the force of law." App.9-10. But EPA's actions approving Roundup's labeling without a cancer warning are comparable to the agency actions the Court identified as sufficient to "answer … the pre-emption question" in *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 315 (2019). This Court explained in *Merck* that "agency actions taken pursuant to the [agency's] congressionally delegated authority" can establish that the agency would not have taken a particular action for conflict-preemption purposes. *Id.* The Court listed three ways FDA is authorized to "communicate its disapproval of a warning" and thus "answer … the pre-emption question": (1) "notice-and-comment rulemaking setting forth labeling standards," (2) "formally rejecting a warning label that would have been adequate under state law," and (3) "other agency action carrying the force of law." *Id.* at 315-16.[8]

EPA has taken analogous actions in approving Roundup's labeling. First, in conducting its statutorily required re-registration in 1993, EPA engaged in formal statutory procedures, *see* 7 U.S.C. §136a-1, and went through the notice-and-comment

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glyphosate is known to cause cancer *would* be misbranded, which is the kind of warning Respondent sought.

[8] As an example of the kind of action satisfying the final category, the Court pointed to a provision requiring the FDA to notify the manufacturer if it "becomes aware of new information … that [it] determines should be included in the labeling of [a] drug," 21 U.S.C. §355(o)(4)(A). *Merck*, 587 U.S. at 316.

process before reaffirming its conclusion that "glyphosate products, labeled and used as specified [by EPA], will not pose unreasonable risks or adverse effects to humans." EPA, *Reregistration Eligibility Decision (RED) Glyphosate* 57 (Sept. 1993). Second, EPA has notified glyphosate registrants in a letter that it would not approve glyphosate labeling containing a warning that glyphosate causes cancer. App.38-40. And EPA has declined to require a cancer warning through its registration review process or its approval of individual labels—a process that (like the FDA notification requirement discussed in *Merck*) requires EPA to propose "labeling changes" when necessary, 40 C.F.R. §155.58(b)(4), and requires EPA to determine that the label contains all necessary health warnings.

III. The Question Presented Is Important, And This Case Is An Ideal Vehicle To Resolve It.

1. The question presented is critically important, and the stakes are high. The decision below is just one of tens of thousands of pending tort suits in Monsanto's home state of Missouri. And the litigation is hardly limited to Missouri, as thousands more suits remain pending in state and federal courts across the nation. Simply litigating those suits is financially draining, and losing them in jurisdictions that have erroneously rejected a preemption defense is more costly still. Not only can manufacturers find themselves on the hook for significant sums in compensatory damages stemming from the plaintiffs' injuries, but in many states, they may also be liable for punitive damages too. *See, e.g.*, *Home Ins. Co. v. Am. Home Prods. Corp.*, 550 N.E.2d 930, 935 (N.Y.

1990); *Fischer v. Johns-Manville Corp.*, 512 A.2d 466, 480 (N.J. 1986). Those jury verdicts can be exorbitant. *See, e.g.*, D. Cameron & P. Thomas, *Bayer Told to Pay $1.56 Billion After Losing Roundup Case*, Wall Street Journal (Nov. 18, 2023), https://perma.cc/MZP4-HANE; H. Smolak, *Bayer Shares Fall After Jury Orders $2.25 Billion in Damages in Roundup Case*, Wall Street Journal (Jan. 29, 2024), https://perma.cc/7ZMD-75JH. The cost of managing this veritable flood of litigation has already forced Monsanto to remove glyphosate from the consumer version of Roundup. It threatens Monsanto's ability to supply the product to farmers who depend on it for their livelihoods. And it undermines the United States' position as a world leader in agriculture. *See supra* at 12-13. The stakes for glyphosate alone are therefore enormous.

But as unusual as it is to have a clear circuit split involving a single product line, the consequences of the question presented are hardly limited to glyphosate and Monsanto and other manufacturers of pesticides that include glyphosate. Instead, the divide among the circuits extends to any pesticide that has been studied by EPA and deemed safe for use with an EPA-approved label. More broadly, the decision below and the Ninth and Eleventh Circuit decisions it follows threaten to undermine Congress's statutory goal of ensuring uniformity in pesticide labeling laws, thus restoring the pre-1972 status quo Congress sought to replace. Congress enacted the "[u]niformity" provision specifically to address the chaos and confusion in the pesticide industry engendered by the dozens of disparate state pesticide-labeling regimes. *Bates*, 544 U.S. at 452 n.26. The "crazy-quilt" of "conflicting state

labeling regulations" produced "significant inefficiencies for manufacturers," which could not simultaneously comply with the rules established in each of the nation's many jurisdictions. *Id*. at 448, 452, 453 n.26. Congress sought to impose a uniform regime of pesticide labeling by preempting state efforts to impose labeling requirements that are in addition to or different from what FIFRA requires. 7 U.S.C. §136v(b).

Decisions like the one below disrupt that design. By allowing state failure-to-warn claims to impose labeling rules in addition to those Congress imposed through FIFRA, such decisions permit precisely what *Bates* feared: "50 different labeling regimes prescribing the … wording of warnings," creating "significant inefficiencies for manufacturers." *Bates*, 544 U.S. at 452. Indeed, this new state of affairs is even worse than the patchwork Congress attempted to eliminate. Before Congress enacted the "[u]niformity" provision, state labeling regulations typically took the form of state statutes. *See, e.g.*, Mont. Rev. Codes Ann. §§27-213 *et seq*. (1971); N.C. Gen. Stat. §§143-434–70 (1971); N.H. Rev. Stat. §§149-D:1-11 (1972). As difficult as it was to comply with multiple statutory labeling requirements, attempting to comply with the requirements reflected in disparate jury verdicts across the country is downright impossible. Those unpredictable and varying requirements create headaches for consumers and manufacturers alike. *Cf. Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011) ("Manufacturers might have to print 50 different labels, driving consumers who buy [pesticides] in more than one state crazy.").

2. Nor are the stakes limited to the FIFRA context. FIFRA's express preemption language appears in a wide range of other statutes, such that any preemption analysis adopted in the FIFRA context will inevitably carry over to those other schemes.

The text that governs the scope of preemption under FIFRA—including its focus on preempting state "requirements" that are "in addition to or different from" those under federal law, 7 U.S.C. §136v(b)—appears in a variety of statutes, including those regulating medical devices, poultry products, meat, and motor vehicles. *See* 21 U.S.C. §360k(a) (MDA) (preempting certain state "requirement[s]" that are "different from, or in addition to, any requirement applicable under" the statute); *id.* §467e (Poultry Products Inspection Act) (preempting certain state "[r]equirements … which are in addition to, or different than those made under" the statute); *id.* §678 (Federal Meat Inspection Act ("FMIA")) (preempting certain state "[r]equirements … which are in addition to, or different than those made under" the statute); *see also* 49 U.S.C. §30103(b) (National Traffic and Motor Vehicle Safety Act) (generally preempting state motor vehicle safety standards not "identical to the standard[s] prescribed under" the statute).

That similarity magnifies the impact of the FIFRA preemption split because courts are "guided by … prior decisions interpreting similar language in other … statutes." *Gomez-Perez v. Potter*, 553 U.S. 474, 479 (2008); *see also Riegel*, 552 U.S. at 324 ("Congress is entitled to know what meaning this Court will assign to terms regularly used in its

enactments."). Indeed, courts routinely look to decisions interpreting similar statutory language when determining the scope of express preemption provisions in particular. *See, e.g.*, *Bates*, 544 U.S. at 447-48 (relying on the interpretation of the MDA's similar preemption provision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)); *Thornton v. Tyson Foods, Inc.*, 28 F.4th 1016, 1026 (10th Cir. 2022) (FMIA) (citing *Bates*); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 488-89 (7th Cir. 2005) (relying on *Bates* in applying the MDA's preemption provision).

All of this means that the conflicting preemption frameworks that the Third, Ninth, and Eleventh Circuits have adopted in the FIFRA context are likely to confuse the preemption analysis that courts employ in those other statutory schemes.

3. This case is an excellent vehicle to resolve the question presented. While Respondent initially brought numerous claims against Monsanto, the jury ruled for him on only a single claim: failure to warn. The upshot is that the sole claim in front of this Court undeniably concerns labeling and packaging, and there are no other state-law claims that might complicate the Court's review. Likewise, the sole issue that Monsanto raised on appeal was the preemption question. And there are no obstacles that would prevent the Court from considering that issue.

Finally, now that a clear circuit split has emerged, there is no reason to delay plenary review. To the contrary, the agricultural community needs clarity about glyphosate's continuing availability and the FIFRA labeling regime more broadly, which governs hundreds of federally regulated registered products.

Moreover, approximately 30 trials are currently scheduled to occur over the course of 2025, and approximately 50 more in 2026. In short, there is no reason for further delay and every reason for this Court to grant review.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for certiorari.

Respectfully submitted,

DAVID M. ZIONTS
MICHAEL X. IMBROSCIO
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 2001
(202) 662-6000

K. LEE MARSHALL
BRYAN CAVE LEIGHTON PAISNER
Three Embarcadero Center
San Francisco, CA 94111

PAUL D. CLEMENT
Counsel of Record
MATTHEW D. ROWEN
JAMES Y. XI
NICCOLO A. BELTRAMO*
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-89000
paul.clement@clementmurphy.com

*Supervised by principals of the firm who are members of the Virginia bar

Counsel for Petitioner

April 4, 2025

APPENDIX

TABLE OF APPENDICES

Appendix A

SUPREME COURT OF MISSOURI

No. SC100975

JOHN L. DURNELL,

Respondent,

v.

MONSANTO COMPANY,

Appellant.

Filed: April 1, 2025

ORDER

Appellant's application for transfer from Missouri Court of Appeals, No. ED112410, is denied.

Appendix B

MISSOURI COURT OF APPEALS
FOR THE EASTERN DISTRICT

No. ED112410

JOHN L. DURNELL,

Respondent,

v.

MONSANTO COMPANY,

Appellant.

Filed: Feb. 11, 2025

OPINION

Monsanto Company ("Monsanto") appeals the judgment entered upon a jury verdict in favor of John L. Durnell ("Plaintiff") on Plaintiff's claim for strict liability failure to warn. The trial court's judgment entered upon the jury's verdict awarded Plaintiff $1.25 million in compensatory damages. We affirm.[1]

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[1] Monsanto filed a motion, which was taken with the case, requesting this Court to take judicial notice of certain materials "which document or relate to key aspects of glyphosate's regulatory history at the federal and state levels." We deny Monsanto's motion taken with the case.

I. BACKGROUND

In January 2019, Plaintiff sued Monsanto alleging his exposure to Monsanto's product Roundup and its ingredient glyphosate caused him to develop non-Hodgkin's lymphoma ("NHL"). Plaintiff's petition alleged claims for strict liability defective design, strict liability failure to warn, and negligence.

The case proceeded to a jury trial beginning in September 2023. At the close of Plaintiff's evidence and again at the close of all the evidence, Monsanto moved for a directed verdict on the grounds that, *inter alia*, Plaintiff's claims were expressly and impliedly preempted by federal law. The trial court denied both motions for directed verdict.

The jury returned a verdict in favor of Plaintiff on his strict liability failure to warn claim, but found in favor of Monsanto on Plaintiff's strict liability defective design and negligence claims. The jury awarded Plaintiff $1.25 million in compensatory damages, and the trial court entered its judgment in accordance with the jury's verdicts. Monsanto subsequently filed a motion for judgment notwithstanding the verdict ("JNOV") and in the alternative a new trial, which again argued, *inter alia*, that federal law both expressly and impliedly preempted Plaintiff's strict liability failure to warn claim. The trial court denied Monsanto's motion. This appeal followed.[2]

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[2] To avoid unnecessary repetition, additional facts relevant to Monsanto's point on appeal will be set forth in Section II.B. of this opinion.

II. DISCUSSION

Monsanto raises a single point on appeal arguing the trial court erred in denying its motion for JNOV because federal law both expressly and impliedly preempted Plaintiff's strict liability failure to warn claim ("failure to warn claim" or "claim").

A. Standard of Review

"Federal preemption is a question of law this Court reviews *de novo*." *Collector of Winchester v. Charter Communications, Inc.*, 660 S.W.3d 405, 416 (Mo. App. E.D. 2022). Similarly, the trial court's ruling challenged by Monsanto on appeal—the denial of a motion for JNOV based on a matter of law—raises a question of law requiring *de novo* review. *See Boggs ex rel. Boggs v. Lay*, 164 S.W.3d 4, 15 (Mo. App. E.D. 2005).

B. Analysis of Monsanto's Sole Point on Appeal

When analyzing federal preemption of a state cause of action, "[i]t is assumed that the historic police powers of the state are not preempted absent 'the clear and manifest purpose of Congress' to do so." *Connelly v. Iolab Corp.*, 927 S.W.2d 848, 851 (Mo. banc 1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). "[T]he purpose of Congress in enacting the federal statute is the ultimate touchstone" in our analysis. *Connelly*, 927 S.W.2d at 851 (citing *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)). Furthermore, preemption of state law by statute may be either express or implied. *Cooperative Home Care, Inc. v. City of St. Louis*, 514 S.W.3d 571, 579 (Mo. banc 2017). In this case, Monsanto argues Plaintiff's failure to warn claim is both expressly and impliedly

preempted by federal law, and we proceed by addressing each type of preemption in turn below.

1. Express Preemption

Express preemption occurs when a federal statute explicitly proscribes a local regulation in a specific area. *Id.*; *Stegall v. Peoples Bank of Cuba*, 270 S.W.3d 500, 503 (Mo. App. S.D. 2008). The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")—the federal statutory scheme which Monsanto argues expressly preempted Plaintiff's failure to warn claim—regulates the use, sale, and labeling of pesticides. *See* 7 U.S.C. section 136 *et seq*.; *Carson v. Monsanto Company*, 92 F.4th 980, 986 (11th Cir. 2024). FIFRA contains an express preemption provision at 7 U.S.C. section 136v(b) ("section 136v(b)") which provides that a "[s]tate shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA. Section 136v(b). In other words, FIFRA will preempt a state law requirement—including a common-law cause of action—that is not fully consistent with FIFRA's requirements. *Id.*; *Carson*, 92 F.4th at 990-91 (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005)). A state law requirement is not fully consistent with FIFRA's requirements when the state law requirement is: (1) for labeling or packaging; and (2) in addition to or different from what FIFRA requires. Section 136v(b); *Carson*, 92 F.4th at 989-91 (citing *Bates*, 544 U.S. at 444, 446-47).

Monsanto does not dispute on appeal that Plaintiff's successful failure to warn claim is a common-law action which effectively imposes a state

law requirement for labeling upon Monsanto.[3] Accordingly, the dispositive question as to express preemption in this case is whether Plaintiff's failure to warn claim imposes a requirement that is "in addition to or different from" FIFRA's labeling requirements. *See id.*

FIFRA's labeling requirements under 7 U.S.C. section 136(q)(1)(G) ("section 136(q)(1)(G)") contain a prohibition on misbranding. *Id.*; *Carson*, 92 F.4th at 991. Section 136(q)(1)(G) provides in relevant part that "[a] pesticide is misbranded if . . . the 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." *Id.* This "prohibition on misbranding effectively imposes a strict-liability standard," holding a manufacturer liable for omitting a warning regardless of knowledge or intent. *Carson*, 92 F.4th at 991-92.

Missouri's strict liability failure to warn cause of action is fully consistent with federal requirements under section 136(q)(1)(G) of FIFRA. *See Carson*, 92 F.4th at 986-87, 991-92 (similarly finding with respect to a failure to warn cause of action under Georgia state law). A claim for strict liability failure to warn under Missouri law requires a plaintiff to prove, *inter alia*, that a defendant "did not give adequate warning of the danger" of a product, and contains no element

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[3] Under the count for strict liability failure to warn, Plaintiff's petition alleges Monsanto's Roundup products are "unreasonably dangerous to consumers . . . because they do not contain adequate warnings or instructions[.]" The count also specifically alleges "Monsanto had a duty to properly . . . label" Roundup products.

requiring proof of the defendant's knowledge or intent. *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. banc 2011); MAI-Civil 25.05 8th ed. (1978 revision).[4] The "practical effect" of both FIFRA's prohibition on misbranding under section 136(q)(1)(G) and a strict liability failure to warn claim in Missouri are the same: both require a pesticide manufacturer to adequately warn users of the potential dangers of using its product, regardless of the manufacturer's knowledge or intent. *See id.*; *Moore*, 332 S.W.3d at 756; MAI-Civil 25.05; *Carson*, 92 F.4th at 992; *see also Bates*, 544 U.S. at 447 ("state law need not explicitly incorporate FIFRA's standards as an element of a cause of action in order to survive pre-emption").

Based on the foregoing, a strict liability failure to warn claim in Missouri does not impose a requirement "in addition to or different from" the requirements of FIFRA. *See Moore*, 332 S.W.3d at 756; MAI-Civil 25.05; sections 136(q)(1)(G) and 136v(b); *Carson*, 92 F.4th at 986-87, 989-92. Accordingly, section 136v(b) of FIFRA does not expressly preempt Plaintiff's strict liability failure to warn claim. *See id.*; *Moore*, 332 S.W.3d at 756; MAI-Civil 25.05; section 136(q)(1)(G); *Carson*, 92 F.4th at 986-87, 989-92 (similarly holding); *Hardeman v. Monsanto Company*, 997 F.3d 941, 954-58 (9th Cir. 2021) (similarly holding).

2. Implied Preemption

Although we find Plaintiff's failure to warn claim is not expressly preempted, we must also address Monsanto's argument that implied preemption bars

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[4] All references to MAI-Civil 25.05 are to the 8th ed. (1978 revision).

Plaintiff's claim. *See Mizner v. North River Homes, Inc.*, 913 S.W.2d 23, 25 (Mo. App. E.D. 1995) (implied preemption is still possible where an express preemption provision is present). Monsanto argues on appeal that conflict preemption bars Plaintiff's failure to warn claim because federal law[5] mandates that warnings on pesticide labels be approved by the Environmental Protection Agency ("EPA"), therefore making it impossible for Monsanto to comply with any warning that Plaintiff's claim under Missouri law would require.

Federal law can impliedly preempt state law through conflict preemption when a state law "actually conflict[s] with federal law," which can occur when it is physically impossible to comply with both federal and state law. *State v. Diaz-Rey*, 397 S.W.3d 5, 9 (Mo. App. E.D. 2013) (citing *Arizona v. United States*, 567 U.S. 387, 399 (2012)). The "possibility of impossibility [is] not enough" for the application of conflict preemption. *Carson*, 92 F.4th at 997 (quoting *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 314 (2019)) (bracketed alterations in original). In order for conflict preemption to apply, there must be an irreconcilable conflict between state and federal law. *Carson*, 92 F.4th at 997; *Paul v. Jackson*, 910 S.W.2d 286, 292-93 (Mo. App. W.D. 1995). To show an irreconcilable conflict that would bar Plaintiff's failure to warn claim, Monsanto has the burden of presenting clear evidence that: (1) Monsanto fully informed the EPA of the justifications for the warning that Missouri

[5] Monsanto's implied preemption arguments rely on, *inter alia*, statutory provisions located within both FIFRA and Title 40 of the Code of Federal Regulations.

law would impose; (2) the EPA informed Monsanto that it would not approve changing the label to include the warning; and (3) the EPA undertook its action pursuant to authority that carries the force of law. *See Carson*, 92 F.4th at 997 (citing *Merck*, 587 U.S. at 313-16). The burden on a party attempting to use conflict preemption as a defense is demanding. *Carson*, 92 F.4th at 997 (citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009)).

Monsanto has not met its demanding burden of showing an irreconcilable conflict between state and federal law in this case. *See Carson*, 92 F.4th at 997 (citing *Merck*, 587 U.S. at 313-16 and *Wyeth*, 555 U.S. at 573). The record contains no evidence that Monsanto either informed the EPA of the justifications for a change to its warning label or that the EPA has informed Monsanto it would not approve such a warning, and Monsanto does not specifically make these arguments on appeal. *See Carson*, 92 F.4th at 997 (citing *Merck*, 587 U.S. at 313-16). Instead, Monsanto argues the regulatory history of glyphosate constitutes "clear evidence" the EPA would not approve a cancer warning on Roundup's label. In support of this argument, Monsanto primarily points to the EPA's historical registration and re-registration of Roundup labeling without a cancer warning, along with the EPA's conclusion that glyphosate is "not likely to be carcinogenic to humans." *See* footnote 1 of this opinion.

However, the "possibility of impossibility [is] not enough" for conflict preemption to apply. *Carson*, 92 F.4th at 997 (quoting *Merck*, 587 U.S. at 314) (bracketed alterations in original). The EPA's

historical approval of glyphosate labels without a cancer warning and its past conclusions regarding glyphosate's carcinogenicity do not compel the conclusion that the EPA would inevitably reject a future label with a cancer warning. *See Carson*, 92 F.4th at 997. Said differently, we are not persuaded that the EPA's historical actions regarding glyphosate constitute clear evidence of an irreconcilable conflict between state and federal law, especially in light of Monsanto's demanding burden. *See id*. (citing *Merck*, 587 U.S. at 313-16 and *Wyeth*, 555 U.S. at 573); *see also Hardeman*, 997 F.3d at 958-60 (similarly holding). Accordingly, conflict preemption does not impliedly preempt Plaintiff's failure to warn claim in this case. *See id*.; *Paul*, 910 S.W.2d at 292-93; *see also Diaz-Rey*, 397 S.W.3d at 9 (citing *Arizona*, 567 U.S. at 399).

3. Monsanto's Arguments on Appeal

In its arguments on appeal regarding express preemption, Monsanto primarily relies upon *Schaffner v. Monsanto Corporation*, 113 F.4th 364 (3rd Cir. 2024), where the Third Circuit held that plaintiffs' state law failure to warn claim against Monsanto was expressly preempted by federal law. *See id*. at 370-99. In doing so, Monsanto argues the decisions from two other federal intermediate appellate courts—the Eleventh and Ninth Circuits—and two state appellate courts have "erroneously held" that express preemption did not bar state law failure to warn claims. *See Carson*, 92 F.4th at 986-96; *Hardeman*, 997 F.3d at 950-58; *Johnson v. Monsanto Company*, 554 P.3d 290, 295-98, 303-308 (Or. App. 2024); *Pilliod v. Monsanto Company*, 282 Cal. Rptr. 3d 679, 688-702

(Cal. App. 2021). While the decisions of federal intermediate appellate courts and other state courts do not bind this Court, we do not find *Schaffner* persuasive and choose to follow the weight of the authority in holding that Plaintiff's failure to warn claim is not expressly preempted by federal law. *See Doe v. Roman Catholic Diocese of St. Louis*, 311 S.W.3d 818, 823 (Mo. App. E.D. 2010) (citing, *inter alia*, *State v. Mack*, 66 S.W.3d 706, 710 (Mo. banc 2002)).

Regarding implied preemption, Monsanto asks this Court to follow holdings from three primary cases: *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472 (2013), *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Wyeth*, 555 U.S. 555. However, we find these cases distinguishable because they all involve pharmaceutical products regulated under the Food, Drug, and Cosmetic Act ("FDCA"), and we decline to extend their holdings to pesticide products regulated under FIFRA. *See Bartlett*, 570 U.S. at 476-78; *Mensing*, 564 U.S. at 608-10, 612; *Wyeth*, 555 U.S. at 558-59, 566; *see also Carson*, 92 F.4th at 998 (similarly distinguishing *Mensing*); *Hardeman*, 997 F.3d at 958-59 (discussing at length how "FIFRA's regulatory regime for pesticides differs meaningfully from the [FDCA] regulatory scheme," in relevant part because of the implications surrounding generic and name-brand drug manufacturers under the FDCA which do not exist for pesticide manufacturers governed by FIFRA).

C. Conclusion as to Monsanto's Sole Point on Appeal

Based on the foregoing, Plaintiff's failure to warn claim is not expressly or impliedly preempted by federal law, and the trial court did not err in denying Monsanto's motion for JNOV. Monsanto's sole point on appeal is denied.

III. CONCLUSION

The trial court's judgment entered upon the jury's verdict in favor of Plaintiff is affirmed.

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ROBERT M. CLAYTON III,
Judge

Appendix C

MISSOURI CIRCUIT COURT
TWENTY-SECOND JUDICIAL CIRCUIT

No. 1922-CC00221

JOHN L. DURNELL, et al.,
Plaintiffs,
v.
MONSANTO COMPANY, et al.,
Defendants.

Filed: Sept. 28, 2023

ORDER

The Court has before it Defendant Monsanto Company's (Defendant's) Motion for Summary Judgment. The Court has reviewed the submissions of the parties, the relevant authorities, and the arguments of counsel, and now rules as follows.

Plaintiffs seek recovery for damages as a result of Plaintiff John L. Durnell's development of non-Hodgkin's lymphoma (NHL) allegedly caused by the wrongful conduct of Defendants in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, and/or sale of the product known as Roundup. Plaintiffs claim that Roundup and its active ingredient, glyphosate, are unreasonably dangerous and defective.

Defendant argues that it is entitled to judgment as a matter of law because Plaintiff's claims are expressly and impliedly preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 et seq., and because Plaintiff has not presented admissible expert testimony to prove causation. In addition, Defendant argues that Plaintiff lacks evidence to support his punitive damages claim.

When ruling on a motion for summary judgment, the Court must determine whether the moving party has the "undisputed right to judgment as a matter of law," on the basis of the facts about which there is no genuine dispute. *ITT Commercial Fin. Corp. v. Mid-America Marine Supply Corp.*, 854 S.W.2d 371, 380 (Mo. banc 1993). The party moving for summary judgment bears the burden of establishing a right to judgment as a matter of law. *Id.* at 378. Where the movant is a defending party, the movant may establish a right to judgment by showing facts that negate any one of claimant's elements' facts, that the non-movant after an adequate period of discovery has not been able to produce or will not be able to produce evidence sufficient to allow the trier of fact to find the existence of any one of claimant's elements, or that there is no genuine dispute as to the existence of each of the facts necessary to support the movant's properly pleaded affirmative defense. *Id.*

Once the moving party has met the burden imposed by Rule 74.04(c) by establishing the right to judgment, the non-movant's only recourse is to show by affidavit, depositions, answers to interrogatories, or admissions on file, that one or more of the material

facts shown by movant is in fact genuinely disputed. *ITT*, 854 S.W.2d at 381.

Federal law may preempt state law (1) where Congress defines explicitly the extent to which its enactments preempt state law; (2) in the absence of explicit statutory authority, where the federal law regulates conduct in a field that Congress intended for the federal government to occupy exclusively; and (3) to the extent that state law actually conflicts with federal law. *English v. General Electric*, 496 U.S. 72, 78-79 (1990); *See also Kurns v. R.R. Friction Prods. Corp.*, 565 U.S. 625, 630 (2012), *Wyeth v. Levine*, 555 U.S. 555, 576, 571 (2009).

"Two prerequisites for allowing punitive damages are (1) demonstrating some element of outrageous conduct; and (2) showing the defendant acted with a willful, wanton or malicious culpable mental state." *Poage v. Crane Co.*, 523 S.W.3d 496, 515 (Mo. App. E.D. 2017).

"Whether there is sufficient evidence for an award of aggravating circumstances damages is a question of law." *Clark v. SSM Healthcare St. Louis*, 666 S.W.3d at 221 (citing *Brady v. Curators of Univ. of Missouri*, 213 S.W.3d 101, 109 (Mo. App. E.D. 2006)). "However, '[i]n determining a summary judgment motion, the judge ... is not to decide what the facts are or to make credibility determinations, but simply to determine whether there is a triable issue of fact.'" *Id.*

In this case, there is substantial dispute as to the material facts relied on by Defendant. The Court cannot "weigh conflicting evidence or make credibility determinations" on summary judgment. *Brentwood Glass Co. v. Pal's Glass Serv.*, 499 S.W.3d 296, 300

(Mo. bane 2016). The Court finds that Defendant has not met its burden regarding its preemption arguments given the disputed record and recognizing existing precedent. The Court has denied in whole or in part all of Defendant's motions to exclude Plaintiff's expert testimony. The Court cannot determine from the record before it that Plaintiff has not been able to present admissible expert testimony to prove causation. Finally, it appears from the record that there is a triable issue of fact regarding Plaintiff's punitive damages claims. The Court cannot find that Defendant has met its burden of showing the undisputed right to judgment as a matter of law on the basis of facts about which there is no genuine dispute.

Accordingly, the Court must deny Defendant's motion for summary judgment. This ruling is without prejudice to Defendant to bring the same arguments in a motion for directed verdict at the close of Plaintiff's case.

WHEREFORE, it is Ordered and Decreed that Defendant Monsanto Company's Motion for Summary Judgment is DENIED.

[handwritten: signature]

Timothy Boyer, Judge

Appendix D

MISSOURI CIRCUIT COURT
TWENTY-SECOND JUDICIAL CIRCUIT

No. 1922-CC00221

JOHN L. DURNELL,
Plaintiff,
v.
MONSANTO COMPANY,
Defendant.

Filed: Oct. 17, 2023

ORDER

[handwritten: Comes now the Court, after reviewing the brief and hearing the arguments of counsel, and DENIES Monsanto Company's Motion for Directed Verdict at the Close of Plaintiff's Evidence.

SO ORDERED

Signature]

Appendix E

MISSOURI CIRCUIT COURT
TWENTY-SECOND JUDICIAL CIRCUIT

No. 1922-CC00221

JOHN L. DURNELL,

Plaintiff,

v.

MONSANTO COMPANY,

Defendant.

Filed: Oct. 19, 2023

ORDER

[handwritten: The plaintiffs are not pursuing counts 4, 5, and 6, nor are they pursuing the theory of negligent manufacture.

As to all other counts, Defendant Monsanto Company's Motion for Directed Verdict at the close of all evidence is hereby DENIED.

SO ORDERED

Signature]

Appendix F

MISSOURI CIRCUIT COURT
TWENTY-SECOND JUDICIAL CIRCUIT

No. 1922-CC00221

JOHN L. DURNELL,
Plaintiff,
v.
MONSANTO COMPANY,
Defendant.

Filed: January 19, 2024

ORDER AND JUDGMENT

Comes now the Court and, after reviewing the evidence presented and arguments of counsel, denies Defendant's Motion for Judgment Notwithstanding the Verdict and in the Alternative for New Trial.

[handwritten: signature]
Timothy Boyer, Judge

Appendix G

MISSOURI CIRCUIT COURT
TWENTY-SECOND JUDICIAL CIRCUIT

No. 1922-CC00221

JOHN L. DURNELL,

Plaintiff,

v.

MONSANTO COMPANY,

Defendant.

Filed: June 24, 2024

JUDGMENT

The cause of Plaintiff John Durnell against Defendant Monsanto Company was tried to a jury from October 3, 2023 through October 20, 2023. The jury returned a verdict as follows:

1. In favor of Defendant Monsanto Company on Plaintiff John Durnell's claim for compensatory damages based on product defect;

2. In favor of Plaintiff John Durnell on Plaintiff's claim for compensatory damages based on product defect–failure to warn;

3. In favor of Defendant Monsanto Company on Plaintiff John Durnell's claim for compensatory damages based on negligence;

4. The jury assessed Plaintiff's compensatory damages at $1,250,000 (one million two hundred fifty thousand dollars);

5. The jury found that Monsanto Company is not liable for punitive damages.

Now therefore, it is ORDERED, ADJUDGED, and DECREED as follows: In accordance with the verdict of the jury set forth above, Plaintiff John Durnell shall have and recover from Defendant Monsanto Company the sum of $1,250,000 (one million two hundred fifty thousand dollars) as and for compensatory damages, together with post judgment interest as provided by law.

Costs assessed against Defendant Monsanto Company.

All matters and things and controversy as between Plaintiff John Durnell and Defendant Monsanto Company having been resolved by the aforementioned jury verdict, pursuant to S.Ct. Rule 74.01(b) of the Missouri Rules of Civil Procedure, this Court finds that this Judgment, and each Part thereof, be, and hereby is, certified as final for purposes of appeal and that there is no just reason for delay.

SO ORDERED:

[handwritten: signature]

Timothy J. Boyer

Circuit Judge

Division 8

Appendix H

United States Environmental Protection Agency Memorandum re: Withdrawal of the *Glyphosate Interim Registration Review Decision* (Sept. 21, 2022)

On June 17, 2022, the United States Court of Appeals for the Ninth Circuit vacated and remanded the human health portion of EPA's interim registration review decision for glyphosate (ID), held that EPA's failure to make an effects determination before issuing the ID violated the Endangered Species Act (ESA), and remanded without vacating the ecological portion of the ID but imposed an October 1, 2022 deadline for EPA to complete the remand. *Natural Resources Defense Council et al. v. EPA*, 38 F.4th 34 (9th Cir. 2022). In light of the court's decision, this memorandum announces EPA's withdrawal of all remaining portions of the glyphosate ID, including the remanded ecological portion.

A copy of the glyphosate ID, now vacated in part and the remainder withdrawn, is posted to the glyphosate registration review public docket (EPA-HQ-OPP-2009-0361) at https://www.regulations.gov.

Background

Issuance of the Glyphosate Interim Registration Review Decision

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide registration continues to satisfy the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for registration, that is, that the pesticide can perform its intended function without

unreasonable adverse effects on human health or the environment. Under FIFRA section 3(g), each pesticide is required to be reviewed every 15 years.

EPA regulations establish procedures for the registration review program required in FIFRA section 3(g). Under 40 C.F.R. § 155.56, EPA may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment, and completing the registration review. Procedures for issuing an interim registration review decision are set forth in § 155.58.

On February 3, 2020, EPA published a notice in the Federal Register (85 Fed. Reg. 5957) announcing the availability of the glyphosate ID. EPA issued the ID pursuant to 40 C.F.R. §§ 155.56 and 155.58, explaining that it was doing so to "(1) move forward with aspects of the registration review case that are complete and (2) implement interim risk mitigation." The ID finalized EPA's draft risk assessments supporting registration review, *Glyphosate Draft Human Health Risk Assessment for Registration Review and Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts*. The ID did not identify any human health risks of concern from exposure to glyphosate but did identify potential ecological risks. It also identified interim risk mitigation measures, in the form of label changes,

including spray drift management language, herbicide resistance management language, a non-target organism advisory, and certain label consistency measures. It concluded that, under FIFRA, the benefits of glyphosate outweigh the potential ecological risks when glyphosate is used in accordance with labels.

The glyphosate ID did not make findings under section 7 of the ESA or under the Endocrine Disruptor Screening Program (EDSP) pursuant to section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), nor did it respond to a 2018 administrative petition submitted by the Environmental Working Group and others (EWG et al.) to reduce the tolerance level for glyphosate residues on oats and require certain label changes based on concerns regarding dietary exposure and carcinogenicity. EPA explained that it would do so before completing registration review for glyphosate, and that the "final registration review decision for glyphosate will be dependent upon the result of the agency's ESA assessment and any needed section 7 consultation with the [U.S. Fish and Wildlife Service and the National Marine Fisheries Service], an EDSP FFDCA section 408(p) determination, and after a resolution of the EWG et al. petition." The glyphosate ID also did not solicit label changes from registrants to implement the interim risk mitigation measures. EPA explained that it would do so once it responded to the EWG et al. petition.

For further background on glyphosate and its registration review history, see the end of this memorandum.

Endangered Species Act Assessment for Glyphosate

ESA section 7(a)(2) requires that federal agencies ensure that the actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of species listed as threatened or endangered under the ESA (listed species) or destroy or adversely modify their designated critical habitat. For pesticides in registration review, EPA's responsibility includes evaluating potential effects to listed species and their designated critical habitat, often through a biological evaluation (BE). If EPA determines that a pesticide's registration "may affect" and is "likely to adversely affect" listed species or designated critical habitat, the Agency initiates formal consultation with the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries Service (NMFS) (together, the Services). The Services prepare their respective biological opinions (BiOps) regarding whether the pesticide's registration is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of designated critical habitats and describing any reasonable and prudent measures or reasonable and prudent alternatives. EPA then uses its authorities under FIFRA to implement, as necessary, any such measures or alternatives described in the BiOps.

On November 25, 2020, EPA released the draft BE for glyphosate for public comment. On November 12, 2021, EPA released the final BE for glyphosate, which found that glyphosate may affect 1,795 listed species and 792 critical habitats and is likely to adversely affect 1,676 of those species and 759 of those habitats. EPA initiated formal consultation with the

Services in November 2021. As noted in the declaration filed in support of EPA's August 1, 2022 petition for panel rehearing of the Ninth Circuit's decision, discussed below, consultation with the Services is ongoing.

For further information on EPA's ESA assessment for glyphosate, see https://www.epa.gov/endangered-species/final-national-level-listed-species-biologicalevaluation-glyphosate.

Challenges to Glyphosate Interim Registration Review Decision

On March 20, 2020, two groups of petitioners filed petitions for review of the glyphosate ID in the Ninth Circuit. *See Natural Resources Defense Council et al. v. EPA*, No. 20-70787 and *Rural Coalition et al. v. EPA*, No. 20-70801. Together these petitions challenged EPA's analysis of the human health and ecological risks and costs of glyphosate, weighing of such risks against the benefits of glyphosate, and the interim risk mitigation measures identified in the ID, and alleged that EPA violated the ESA by issuing the ID before completing consultation with the Services.

While EPA defended its analysis of human health risks and the alleged ESA violation, it moved for partial voluntary remand without vacatur of its analysis of ecological risks and costs, weighing of such risks against benefits, and interim risk mitigation measures. EPA sought remand to:

- Consider how the glyphosate ID may be impacted by the (then) draft BE and whether additional or different risk mitigation measures may be necessary.

- Reconsider its analysis of ecological risks as it relates to in-field effects of glyphosate on monarch butterfly habitat in light of the court decision in *National Family Farm Coalition v. EPA*, 966 F.3d 893 (9th Cir. 2020).
- Consider whether the court decision in *National Family Farm Coalition v. EPA*, 960 F.3d 1120 (9th Cir. 2020) regarding EPA's analysis of spray drift risks and other potential costs of another pesticide (dicamba) affected EPA's analysis of glyphosate.
- Evaluate the glyphosate ID in light of the change in Administration and policy priorities, as reflected in the January 20, 2021 "Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" (86 FR 7037, 1/25/21) and, in particular, consider whether there are other aspects of its analysis of ecological risks and costs related to glyphosate that should be reassessed or for which additional explanation should be provided.
- Consider what risk mitigation measures may be necessary to reduce potential risks following completion of analyses left outstanding in the ID.

The Ninth Circuit heard oral argument on these challenges on January 10, 2022 and issued its decision on June 17, 2022. The court vacated and remanded the human health portion of the glyphosate ID, held that EPA's failure to make an effects determination before issuing the ID violated the ESA, and granted EPA's motion for partial voluntary remand but imposed an

October 1, 2022 deadline for EPA "to issue a new ecological portion." *Natural Resources Defense Council et al. v. EPA*, 38 F.4th 34 (9th Cir. 2022).

On August 1, 2022, EPA filed a petition for panel rehearing that sought relief only from the court's imposition of a deadline to complete remand of the ecological portion of the ID. EPA explained that, while the court did not define what it meant by "issue a new ecological portion," the Agency would not be able to finalize a new ecological portion in a registration review decision for glyphosate by the October 1, 2022 deadline because of the time needed to address the issues for which EPA sought remand and to complete consultation under the ESA. In a declaration filed in support of the petition, EPA set forth its anticipated schedule for completing registration review for glyphosate. EPA also stated that if the court did not lift the deadline, the Agency might exercise its discretion to withdraw the remanded ecological portion of the ID and focus its efforts on the required final registration review decision for glyphosate. A copy of EPA's August 1, 2022 petition for panel rehearing and declaration filed in support of the petition is posted to the glyphosate registration review public docket (EPA-HQ-OPP-2009-0361) at https://www.regulations.gov.

On August 5, 2022, the court denied EPA's petition for panel rehearing without opinion.

Withdrawal

In its June 17, 2022 decision, the Ninth Circuit vacated and remanded the human health portion of the glyphosate ID. EPA is now withdrawing all remaining portions of the ID, including the remanded

ecological portion consisting of the Agency's analysis of the ecological risks and costs of glyphosate, the weighing of such risks against the benefits of glyphosate, and interim risk mitigation measures. Because the ID is an informal adjudication that EPA issued at its discretion, EPA may withdraw all or a portion of it without public comment. Moreover, it would be impracticable for EPA to take public comment here because of the October 1, 2022 deadline imposed by the court to complete remand of the ecological portion of the ID.

EPA has determined that withdrawal is appropriate in light of the Ninth Circuit's June 17, 2022 decision and the particular circumstances of glyphosate's registration review and ESA assessment. Insofar as the court has ordered EPA to finalize a "new ecological portion," doing so through another interim registration review decision or a final registration review decision would involve significant and lengthy steps. As detailed in EPA's August 1, 2022 petition for panel rehearing and declaration filed in support of the petition, the Agency is unable to finalize a new ecological portion in a registration review decision for glyphosate by the court-imposed October 1, 2022 deadline because of the time needed to address the issues for which EPA sought remand and to complete consultation under ESA. Moreover, before issuing such a decision, EPA must first prepare a proposed decision, make it available for a period of public comment of at least 60 days, and consider any comments received. 40 C.F.R. § 155.58. For reference, EPA received approximately 283,300 public comments comprising over 12,000 unique submissions when it published the glyphosate proposed ID in May 2019,

and it then took nine months to finalize and publish the ID in February 2020. EPA cannot complete these processes by the court-imposed October 1, 2022 deadline.

To date, EPA has not solicited label changes from registrants to implement the interim risk mitigation measures identified in the ID. The Agency has not solicited such label changes because EPA's continued work towards completing registration review for glyphosate could affect what risk mitigation measures EPA may determine are necessary, as noted in the declaration filed in support of EPA's August 1, 2022 petition for panel rehearing of the Ninth Circuit's decision. Moreover, the Agency continues to work on a response to the EWG et al. petition, which asks EPA to reduce the tolerance level for glyphosate residues on oats and require certain label changes based on concerns regarding dietary exposure and carcinogenicity. Because of the court's vacatur and remand of the human health portion of the ID, EPA believes it would be appropriate to respond to the EWG et al. petition once it completes its review on remand. To avoid multiple, and potentially conflicting, rounds of label changes, EPA expects to defer solicitation of label changes until it issues a final registration review decision for glyphosate.

For these reasons, EPA believes it is appropriate to withdraw all remaining portions of the glyphosate ID, including the remanded ecological portion, and focus its efforts on completing the required final registration review decision for glyphosate.

Although the glyphosate ID is now vacated in part and the remainder withdrawn, that does not

automatically mean that EPA's underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic to humans, are either incorrect or cannot be used as support for a future decision following reconsideration in accordance with the court's decision.

Next Steps

With respect to the vacated human health portion of the ID, in accordance with the Ninth Circuit's June 17, 2022 decision, EPA intends to revisit and better explain its evaluation of the carcinogenic potential of glyphosate and to consider whether to do so for other aspects of its human health analysis. With respect to the withdrawn ecological portion of the ID, EPA intends to address the issues for which it sought remand, including:

- Consider whether additional or different risk mitigation measures may be necessary based on the outcome of ESA consultation for glyphosate.
- Prepare an analysis of in-field effects of glyphosate on monarch butterfly habitat. • Consider whether EPA's analysis of spray drift risks and other potential costs of dicamba are relevant to EPA's analysis of glyphosate's risk from spray drift.
- Consider whether there are other aspects of EPA's analysis of ecological risks and costs related to glyphosate that should be reassessed or for which additional explanation should be provided.

- Consider what risk mitigation measures may be necessary to reduce potential risks following completion of analyses left outstanding in the ID.

EPA also intends to complete ESA consultation with the Services, respond to the EWG et al. petition, and make an FFDCA section 408(p) EDSP determination before issuing a final registration review decision for glyphosate. As noted in the declaration filed in support of EPA's August 1, 2022 petition for panel rehearing of the Ninth Circuit's decision, EPA anticipates issuing a final registration review decision for glyphosate in 2026.

Glyphosate Background and Registration Review History

Glyphosate is a non-selective, systemic herbicide with products registered for use in a wide array of both agricultural and non-agricultural settings. Agricultural uses include stone and pome fruits, citrus fruits, berries, nuts, vegetables, cereal grains, and other field crops. Non-agricultural uses include residential spot treatments, aquatic areas, forests, rights-of-way, recreational turf, ornamentals, non-food tree crops, and Conservation Reserve Program land. Glyphosate products are also registered for use on the glyphosate-resistant crops, including alfalfa, corn, soybean, cotton, canola, and sugar beets.

EPA formally initiated registration review for glyphosate in 2009 with the opening of the registration review docket for the case. The following summary highlights significant milestones that have occurred during the registration review of glyphosate

- July 2009 - The *Glyphosate Preliminary Work Plan (PWP), the Glyphosate Human-Health Assessment Scoping Document in Support of Registration Review, and the Registration Review–Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Glyphosate and Its Salts* were posted to the docket for a 60-day public comment period.
- December 2009 - The Glyphosate Final Work Plan (FWP) was issued. Comments received on the PWP covered the following topics: opposition to the use of glyphosate, the toxicity of glyphosate formulations and inert ingredients, use and usage trends, human health risks, ecological risks, endocrine disruption, and the benefits of glyphosate. The public comments received did not change the schedule, risk assessment needs, or anticipated data requirements in the FWP.
- September 2010 - A Generic Data Call-In (GDCI) for glyphosate was issued for data needed to conduct the registration review risk assessments. All required data were submitted and reviewed. The registration review GDCI for glyphosate is considered satisfied.
- September 2015 - The Agency completed its evaluation of Tier 1 endocrine data submitted under the EDSP and published the Glyphosate: Weight of Evidence Analysis of Potential Interaction with the Estrogen, Androgen, or Thyroid Pathways. EPA found no convincing evidence of potential interaction

with the estrogen, androgen, or thyroid pathways and glyphosate was not recommended for further EDSP testing.

- December 2016 - The agency convened a FIFRA Scientific Advisory Panel meeting to consider and review a set of scientific issues related to the EPA's evaluation of the carcinogenic potential of glyphosate. The meeting agenda, the agency's cancer issue paper, charge questions for the panel, transcript, and final report are available on EPA's website: https://www.epa.gov/sap/meetingmaterials-december-13-16-2016-scientific-advisory-panel. Additional supporting materials and comments received from the public can be found in docket EPAHQ-OPP-2016-0385 at www.regulations.gov.
- December 2017 - The agency published the *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* (dated December 12, 2017), the *Response to the Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) on the Evaluation of the Human Carcinogenic Potential of Glyphosate* (dated December 12, 2017), the *Glyphosate Draft Human Health Risk Assessment for Registration Review* (dated December 12, 2017), and the *Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and its Salts* (dated September 8, 2015) on EPA's website: https://www.epa.gov/

ingredients-used-pesticide-products/draft-human-health-andecological-risk-assessments-glyphosate.

- February 2018 - The agency announced the availability of the human health and ecological risk assessments for a 60-day public comment period. Over 238,000 comments were received during the comment period, most of which came from various mass mail campaigns. Approximately 2,244 unique submissions were received from various stakeholders, including pesticide registrants, industry groups, farmers, grower groups, private citizens, non-governmental organizations, states, and the U.S. Department of Agriculture. The comments did not change the risk assessments or registration review timeline for glyphosate.
- September 2018 - The Environmental Working Group, joined by Ben & Jerry's Homemade, Inc., Happy Family Organics, MegaFood, MOM's Organic Market, National Co+op Grocers, Nature's Path Foods Inc., One Degree Organic Foods USA, Inc., and Stonyfield Farm, Inc. submitted an administrative petition to the Agency. The petition requested that EPA lower the tolerance for residues of glyphosate on oats and require label changes to prohibit the preharvest use of glyphosate on oats. On May 6, 2019, the Agency published a Notice of Filing of the petition in the Federal Register for a 30-day public comment period in docket EPA-HQ-OPP-2019-0066. 103,447 comments were received on the petition, most

of which came from mass mail campaigns and 419 of which represented unique comments. The Agency continues to work on its response to the petition.

- May 2019 - The Agency announced the availability of the *Glyphosate Proposed Interim Registration Review Decision* (PID) for a 60-day public comment period, which was later extended to 120 days. Along with the PID, the following documents were posted to the docket:
    - *Glyphosate: Response to Comments, Usage, and Benefits* (dated April 18, 2018)
    - *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* (dated April 23, 2019)
    - *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate* (dated November 21, 2018)

During the 120-day comment period on the PID, the agency received roughly 283,300 comments. Over 12,000 unique submissions were received from various stakeholders, including glyphosate registrants, grower groups, non-governmental organizations, pesticide industry groups, states, the U.S. Department of Agriculture and members of the general public. Most comments came from mass mailer campaigns, and approximately 120 unique substantive comments were received from various stakeholders. Public comments did not change the Agency's risk conclusions but resulted in changes to the spray drift management labeling and rotational crop instructions.

- February 2020 - The Agency announced the availability of the ID. Along with the ID, the following documents were published in the docket:
    - *Response from the Pesticide Reevaluation Division to Comments on the Glyphosate Proposed Interim Decision* (dated January 16, 2020)
    - *Glyphosate Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment* (dated January 13, 2019)
    - *Glyphosate: Epidemiological Review of Zhang et al. (2019) and Leon et al. (2019) publications for Response to Comments on the Proposed Interim Decision* (dated January 6, 2020)
- November 2020 - The Agency released the draft BE for glyphosate for public comment. Approximately 870 comments that pertained to the draft BE for glyphosate were submitted, including 11 requests for extensions of the public comment period. Additionally, six mass mail campaigns were submitted with approximately 110,000 signatures.
- November 2021 - The Agency released the final BE for glyphosate evaluating potential effects to listed species and critical habitats.

Appendix I

Letter from United States Environmental Protection Agency re: Glyphosate (Aug. 7, 2019)

Dear Registrant,

We are writing to you concerning label and labeling requirements for products that contain glyphosate.

On July 7, 2017, California listed glyphosate as a substance under Proposition 65[1], based on the International Agency for Research on Cancer's (IARC's) classification of the pesticide as "probably carcinogenic to humans." EPA disagrees with IARC's assessment of glyphosate. EPA scientists have performed an independent evaluation of available data since the IARC classification to reexamine the carcinogenic potential of glyphosate and concluded that glyphosate is "not likely to be carcinogenic to humans." EPA considered a more extensive dataset than IARC, including studies submitted to support registration of glyphosate and studies identified by EPA in the open literature as part of a systematic review. For more detailed information on this evaluation, please see the 2017 Revised Glyphosate

[1] California's Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Proposition 65) requires businesses to inform Californians about significant exposures 10 chemicals that, under the terms of Proposition 65, are believed to cause cancer, birth defects or other reproductive harm. *See* California Office of Environmental Health Hazard Assessment, "Proposition 65," at https://oehha.ca.gov/proposition-65.

Issue Paper: Evaluation of Carcinogenic Potential[2]. Further, EPA's cancer classification is consistent with other international expert panels and regulatory authorities, including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan.

On February 26, 2018, the United States District Court for the Eastern District of California issued a preliminary injunction enjoining California from enforcing the state warning requirements involving the pesticide glyphosate's carcinogenicity, in part on the basis that the required warning statement is false or misleading[3].

Given EPA's determination that glyphosate is "not likely to be carcinogenic to humans," EPA considers the Proposition 65 warning language based on the chemical glyphosate to constitute a false and misleading statement. As such, pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded pursuant to section 2(q)(1)(A) of FIFRA and as such do not meet the requirements of FIFRA. In registering pesticides, EPA must determine that the labeling complies with the requirements of FIFRA including that the product

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[2] hnps:www.regulauons.gov/document?D=EPA-HO-OPP-2009--0361-0073

[3] National Association of Wheat Growers, et al. v. Zeise, 309 F.Supp.3d 842 (E.D.Cal.)

not be misbranded. See FIFRA (3)(c)(5)(B). Therefore, EPA will no longer approve labeling that includes the Proposition 65 warning statement for glyphosate-containing products. The warning statement must also be removed from all product labels where the only basis for the warning is glyphosate, and from any materials considered labeling under FIFRA for those products.

For any pesticide product that currently contains Proposition 65 warning language exclusively on the basis that it contains glyphosate, EPA requests the submission of draft amended labeling that removes such language within ninety (90) days of the date of this letter.

Sincerely,

[handwritten: signature]

Michael L. Goodis, P.E.

Director, Registration Division

Office of Pesticide Programs

Appendix J

Letter from United States Environmental Protection Agency to Lauren Zeise, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency (Apr. 8, 2022)

Dear Dr. Zeise:

Thank you for your letter of March 21, 2022, to the U.S. Environmental Protection Agency (EPA) regarding glyphosate and California's Safe Drinking Water and Toxics Enforcement Act of 1986, also known as Proposition 65.

Your letter proposes a revision to previously proposed safe harbor language that businesses could use to satisfy California's notification requirements for certain glyphosate products under Proposition 65. It further requested that EPA provide input on whether the newly proposed language could be approved, if requested by a pesticide registrant, for inclusion on pesticide labels for products containing glyphosate as an active ingredient and sold in California. As explained below, EPA could approve the newly proposed language.

The Agency continues to stand behind its robust scientific evaluation of the carcinogenic potential of glyphosate. Furthermore, EPA's conclusion remains consistent with many international expert panels and regulatory authorities (https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0073).

Nonetheless, EPA recognizes that the revised safe harbor language proposed by the Office of Environmental Health Hazard Assessment (OEHHA)

acknowledges the EPA position: CALIFORNIA PROPOSITION 65 WARNING: Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations. A wide variety of factors affect your potential risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate.

The letter from OEHHA further requests that EPA clarify its position as previously stated in its August 7, 2019, letter to registrants regarding products that contain glyphosate. That 2019 letter focused on the application of the default Proposition 65 safe harbor warning language to products containing glyphosate and advised that EPA would no longer approve glyphosate labeling containing that statement because it was in conflict with the Agency's scientific conclusions regarding glyphosate. The Agency concluded that the standard warning language for products containing glyphosate was false or misleading and therefore, any glyphosate products bearing the statement would be considered misbranded.

While EPA's scientific conclusions regarding the glyphosate cancer classification have not changed since the August 7, 2019, letter to glyphosate registrants, it has determined that the new glyphosate-specific safe harbor language proposed in OEHHA's recent letter is sufficiently clear regarding

EPA's position and thus would not be considered false and misleading. Therefore, this revised language could be approved by EPA if pesticide registrants requested it for inclusion on glyphosate product labels, and the products would not be considered misbranded. As stated in OEHHA's letter, EPA notes that inclusion on the product label is one of several methods that companies can use to satisfy California's notification requirements under Proposition 65.

EPA appreciates the constructive approach that California is pursuing to address this matter and looks forward to further strengthening our relationships with our stakeholders as we forge ahead together in our work. We thank you for taking the time to write on this important matter.

Sincerely,

Michal Freedhoff, Ph.D

Assistant Administrator

Appendix K

RELEVANT STATUTORY PROVISION
7 U.S.C. §136v(a)-(b)

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

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