STATE OF NEBRASKA
Office of the Attorney General
2115 STATE CAPITOL BUILDING
LINCOLN, NE 68509-8920
(402) 471-2682
TDD (402) 471-2682
FAX (402) 471-3297 or (402) 471-4725

MIKE HILGERS
ATTORNEY GENERAL

August 7, 2024

Via Electronic and U.S. Certified Mail

Michael S. Regan, Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington, D.C. 20460
Regan.Michael@epa.gov

Michal Ilana Freedhoff, Assistant Administrator
United States Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
1200 Pennsylvania Avenue, N.W.
Mail Code: 7101M
Washington, D.C. 20460
Freedhoff.Michal@epa.gov

Re: Petition for Rulemaking to Clarify Section 24 of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v

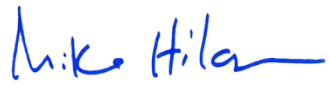
Dear Administrator Regan and Assistant Administrator Freedhoff:

The Attorneys General of the States of Nebraska, Iowa, Alabama, Arkansas, Georgia, Indiana, Louisiana, Montana, North Dakota, South Carolina, and South Dakota submit the enclosed petition to the United States Environmental Protection Agency ("EPA") to start rulemaking proceedings that will end the ongoing confusion as to the application of 7 U.S.C. § 136v with respect to additional labeling or packaging requirements arising under state law for products subject to FIFRA. Petitioners respectfully request EPA to declare that any state labeling requirements inconsistent with EPA's findings and conclusions from its human health risk assessment on human health effects, such as a pesticide's likelihood to cause cancer, birth defects, or reproductive harm, constitute misbranding under FIFRA.

The issue presented by the enclosed Petition for Rulemaking is not new to EPA. The administrative record on this matter is extensive and well developed. Further, adopting the proposed rule would

not require additional technical review or study. The proposed rule merely seeks to clarify ambiguity concerning misbranding under FIFRA. Therefore, Petitioners respectfully request EPA to begin rulemaking within 90 days from the date of submission of this Petition.

Respectfully,



Mike Hilgers
Nebraska Attorney General

Brenna Bird
Iowa Attorney General

Steve Marshall
Alabama Attorney General

Tim Griffin
Arkansas Attorney General

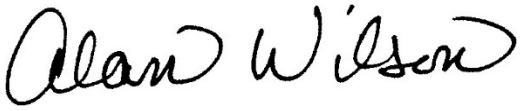
Chris Carr
Georgia Attorney General

Todd Rokita
Indiana Attorney General

Liz Murrill
Louisiana Attorney General

Austin Knudsen
Montana Attorney General

Drew Wrigley
North Dakota Attorney General



Alan Wilson
South Carolina Attorney General

Marty Jackley
South Dakota Attorney General

cc: Jeffrey Prieto, General Counsel
U.S. Environmental Protection Agency
Office of General Counsel
1200 Pennsylvania Avenue, N.W.
Mail Code: 2310A
Washington, DC 20460
Prieto.Jeffrey@epa.gov

Enclosures

BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

IN RE: PETITION FOR RULEMAKING TO CLARIFY SECTION 24 OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT ("FIFRA"), 7 U.S.C. § 136v	))))))))	Submitted August 7, 2024

INTRODUCTION

The United States Environmental Protection Agency ("EPA") has primary responsibility for implementing and enforcing the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136 to 136y. FIFRA generally requires that EPA register pesticides and approve their labels before they may be distributed, sold, or used in any State. 7 U.S.C. § 136a. The label reviewed and approved by EPA is to control. States retain the power to restrict the sale or use of pesticides within their borders but cannot "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required [under FIFRA]." 7 U.S.C. § 136v(b); *see id.* § 136v(a).

EPA has promulgated regulations to govern the pesticide-registration process. But it has never formally codified the preemptive effect of its scientific findings developed during the registration process as they relate to health warnings mandated by state statute or under common-law failure-to-warn claims. The U.S. Supreme Court and multiple U.S. courts of appeals have called on EPA to promulgate regulations to address the misbranding ambiguity in FIFRA. And the Department of Justice recently highlighted EPA's codification authority to resolve the ambiguity in briefing before the Supreme Court. By enacting the rule requested in this Petition, EPA would clarify the role Congress intended EPA to play in the labeling of FIFRA-regulated products and resolve the uncertainty created by the existing gap in the regulatory framework.

REQUESTED ACTION

Petitioners request that EPA initiate rulemaking to clarify the preemptive effect of registration decisions on state labeling requirements and common-law failure-to-warn claims. Petitioners urge EPA to amend 40 C.F.R. § 156.10 to clarify that statements or conclusions on FIFRA-registered products that are different from EPA's express findings and conclusions made during the product's registration review regarding the product's likelihood to cause cancer, birth defects, or reproductive harm shall be deemed false and misleading and thus preempted. In particular, any statements or representations on a label concerning a product's carcinogenic potential or other public-health risks that are different or not otherwise required by EPA constitute misbranding.

Specifically, Petitioners ask EPA to amend 40 C.F.R. § 156.10 "Labeling requirements" by inserting the following bold and underlined language in subsection (a)(5):

> False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:
>
> (i) A false or misleading statement concerning the composition of the product;
>
> (ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
>
> (iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
>
> (iv) A false or misleading comparison with other pesticides or devices;
>
> (v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;
>
> (vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;
>
> (vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;
>
> (viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;
>
> (ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and
>
> (x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
>
> (A) "Contains all natural ingredients";
>
> (B) "Among the least toxic chemicals known"
>
> (C) "Pollution approved"
>
> **(xi) Statements or conclusions regarding the product's human health effects, including the likelihood of causing cancer, birth defects, or reproductive harm, that are different from EPA's findings and conclusions stated in its human health risk assessment conducted during the registration review of the product's principal active ingredients.**

IDENTITY AND INTEREST OF PETITIONERS

Petitioners are the States of Nebraska, Iowa, Alabama, Arkansas, Georgia, Indiana, Louisiana, Montana, North Dakota, South Carolina, and South Dakota.

Agriculture is vital in Petitioners' States. Last year, Nebraska and Iowa alone were home to 131,200 farms and ranches covering about 70 million acres. In Nebraska, farms and ranches cover 92 percent of the State's total land area. In 2023, Nebraska and Iowa farmers produced more than 4.2 billion bushels of corn and over 839 million bushels of soybeans, adding billions of dollars to the economy.[1] These farmers and the crops they grow help feed a growing population, contribute to rural, state, and national economies, and directly and indirectly employ millions of people. The pesticide products regulated under FIFRA are instrumental to these farmers' successes.

Among the products subject to FIFRA, glyphosate is particularly important for farmers in Petitioners' States. The advantages of glyphosate are well documented. Glyphosate controls 300 different weeds and can be applied directly to crops engineered to be glyphosate resistant. Using glyphosate, farmers can effectively manage weeds using fewer chemicals and other inputs. Better weed management also increases crop yields by allowing the growing crops to reach yield potential. Producing higher yields with fewer inputs benefits farmers in Petitioners' States, related industries, and downstream consumers.

Glyphosate's benefits for the environment are also well documented. Glyphosate, paired with glyphosate-resistant crops, encourages farmers to adopt conservation tillage. Conservation tillage reduces soil erosion and runoff from fields into the surface waters of Petitioners' States. Glyphosate is also less toxic and harmful than many other herbicides.

But Petitioners' interest in seeking uniformity by this rulemaking goes far beyond glyphosate. Glyphosate is merely the regulated pesticide that courts have considered in finding an ambiguity in FIFRA that the plain language of the statute does not support. The court-made gap in FIFRA's regulatory framework affects countless other pesticides and fungicides currently regulated under FIFRA, including some still being developed. The flawed analysis could have downstream effects for other federally regulated labeling requirements, such as poultry products under the Poultry Products Inspection Act and medical devices, food, and other substances subject to oversight by the Federal Drug Administration.

Further, Petitioners have a substantial interest in this rulemaking because state speech mandates, such as the warning label required by the State of California's Office of Environmental Health Hazard Assessment ("OEHHA"), are fundamentally at odds with Petitioners' consumer protection policies. Most States have adopted legal provisions prohibiting businesses from branding their products with false or misleading statements. Yet California is seeking to compel companies to display labels on their products that are inconsistent with, and contrary to, the long-held position of EPA, not to mention a broad list of international organizations and regulatory

[1] The statistics are drawn from the U.S. Department of Agriculture. *See* 2023 State Agriculture Overview: Nebraska, U.S. Dep't of Ag., https://perma.cc/K8U5-2HG8 (May 24, 2024); 2023 State Agriculture Overview: Iowa, U.S. Dep't of Ag., https://perma.cc/A7JS-NQNN (May 24, 2024).

bodies. The Ninth Circuit recently enjoined enforcement of California's labeling requirement as applied to glyphosate on First Amendment grounds. *See Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263 (9th Cir. 2023). But the threat of labeling rules that differ by State, common-law failure-to-warn claims, and future, needless litigation continues.

As the entities charged with implementing and enforcing FIFRA, Petitioners also have an interest in a national, uniform standard for pesticide labeling under FIFRA. Congress was explicit in its intent for EPA's registration decisions to be given primacy over labeling and packaging requirements arising under state law. Moreover, the court-created ambiguity in FIFRA relegates the work of EPA's scientists to an afterthought despite their extensive time and expertise devoted to studying FIFRA-regulated products. If EPA does not act quickly to clarify its primacy over labeling, Petitioners and industry will be left to address state-imposed labeling obligations that differ from EPA's long-held scientific findings in an area of law where Congress intended EPA to have the final word.

LEGAL FRAMEWORK

I. General Statutory and Regulatory Framework

FIFRA was enacted in 1947. *See* Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 80-104, 61 Stat. 163 (1947). Under the original version of FIFRA, all pesticides sold in interstate commerce had to be registered with the Secretary of Agriculture. *Id.* § 6(c). The Secretary would register a pesticide if it complied with FIFRA's labeling standards and was determined to be efficacious and safe. *Id.* In 1970, EPA assumed responsibility for this registration process. Reorganization Plan No. 3 of 1970, § 2(8)(i), 84 Stat. 2086, 2088 (July 9, 1970).

In 1972, Congress adopted extensive amendments to FIFRA, transforming it from a labeling law into a comprehensive regulatory regime. *See* Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973. "As amended, FIFRA regulated the use, as well as the sale and labeling, of pesticides; regulated pesticides produced and sold in both intrastate and interstate commerce; provided for review, cancellation, and suspension of registration; and gave EPA greater enforcement authority." *Ruckelshaus v. Monsanto*, 467 U.S. 986, 991–92 (1984).

Before registering a pesticide for sale in the United States, EPA first "determine[s] that the pesticide will not cause 'unreasonable adverse effects on the environment,"' including potential carcinogenicity. *Id.* (quoting 7 U.S.C. § 136a(c)(5)(C)); *see also* 7 U.S.C. §§ 136(j), 136a(d)(1)(C). EPA analyzes voluminous scientific data before making a registration determination. FIFRA also requires EPA to review a pesticide's registration, including its effect on human health, at least every 15 years. 7 U.S.C. § 136a(c)(1)(F)(ii)(II), (g)(1)(A)(i), (g)(1)(A)(iv).

Under FIFRA, a manufacturer seeking to register a pesticide must also submit a proposed label to EPA and certain supporting data. *See id.* § 136a(c)(1)(C), (F). EPA will register the pesticide if it determines that the pesticide is efficacious, will not cause unreasonable adverse effects on humans and the environment, and its label complies with the statute's prohibition on misbranding. *See id.* § 136a(c). A pesticide is "misbranded" if its label contains a statement that is "false or misleading in any particular," including a false or misleading statement related to the

pesticide's efficacy. 7 U.S.C. § 136(q)(1)(A); 40 C.F.R. § 156.10(a)(5)(ii). A pesticide is also misbranded if its label does not contain adequate instructions for use or omits necessary warnings or cautionary statements. 7 U.S.C. § 136(q)(1)(F), (G).

It is unlawful under FIFRA to sell a pesticide that is registered but misbranded. *See* 7 U.S.C. § 136j(a)(1)(E). Selling a misbranded product subjects a registrant to civil and criminal liability. *Id.* § 136*l*. Additionally, manufacturers must report incidents involving a pesticide's toxic effects that may not be adequately reflected in its label's warnings. 40 C.F.R. § 159.184(a), (b). EPA may institute cancellation proceedings and take other enforcement action if it determines that a registered pesticide is misbranded. *See* 7 U.S.C. § 136d(b).

FIFRA also contemplates the States playing a role in pesticide regulation. *See* 7 U.S.C. § 136v. In the case of most environmental programs, Congress typically delegates power to an agency, such as the EPA, to develop and implement the program through regulation. EPA may then delegate implementation to individual States. Once delegated, a State becomes the primary entity for implementing and enforcing the program. FIFRA fits this typical pattern. It authorizes a State to regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent that the regulation does not permit any sale or use prohibited by FIFRA. *Id.* § 136v(a).

Unlike other environmental programs, however, FIFRA prohibits States from enacting more stringent or even different labeling requirements than those imposed by EPA. Section 136v(b), titled "Uniformity," provides that States "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." *Id.* § 136v(b). Thus, a State may not impose different, additional, or more stringent labeling requirements than those imposed by federal law. The Supreme Court has held that the term "requirements" in § 136v(b) reaches beyond statutes and regulations to embrace common-law duties if those duties require manufacturers to label or package their products in a particular way. *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 443–44 (2005).

II. Evolution of Misbranding under FIFRA

Numerous cases have looked at FIFRA preemption of state law liability claims. Those cases generally focus on whether the state claims are based on allegedly inadequate labeling rather than alleged violations of state sale or use requirements of pesticides. Before *Bates*, the federal courts in the First, Fourth, Fifth, Seventh, Eighth, Ninth, Tenth, and Eleventh Circuits concluded that § 136v(b) preempted state common-law failure-to-warn or inadequate labeling claims.[2]

In 2005, the Supreme Court found that failure-to-warn claims arising under state tort law constitute "requirements for labeling or packaging," thus implicating FIFRA's preemption provision. *Bates*, 544 U.S. at 446. But FIFRA preempts state tort law only if state law requires

[2] *See e.g. Taylor AG Indus. V. Pure-Gro*, 54 F.3d 555, 560 (9th Cir. 1995); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887, 888 (8th Cir. 1994); *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1024–25 (5th Cir. 1994); *Worm v. Am. Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir. 1993); *King v. E.I. Dupont De Nemours & Co.*, 996 F.2d 1346, 1349 (1st Cir. 1993); *Shaw v. Dow Brands Inc.*, 994 F.2d 364, 371 (7th Cir. 1993); *Ark.-Platte & Gulf P'ship v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1179 (10th Cir. 1993).

labeling "in addition to or different from" the labeling and packaging requirements of FIFRA. *Id.* at 447. The Supreme Court adopted a "parallel requirements" reading of § 136v(b), holding that a state-law labeling requirement is *not* preempted by § 136v(b) if it is equivalent to and consistent with FIFRA's misbranding provisions. *Id.*

Under *Bates*'s "equivalency" test, a state-law labeling requirement must equal FIFRA's labeling requirement and "must also be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." 544 U.S. at 453. As the Court observed, "[a]t present, there appear to be relatively few regulations that refine or elaborate upon FIFRA's broadly phrased misbranding standards. To the extent that EPA promulgates such regulations in the future, they will necessarily affect the scope of preemption under § 136v(b)." *Id.* at 453 n.28.

Since *Bates*, two courts of appeals have considered whether FIFRA's labeling requirement preempts other state common-law claims. The Ninth Circuit applied the preemption framework established in *Bates* to a failure-to-warn claim under California common law brought against a pesticide manufacturer for a product containing glyphosate. *See Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021). It decided that the failure-to-warn claim constituted a "requirement for labeling or packaging" under § 136v(b), thus satisfying the first prong of the preemption analysis. *Id.* at 955. But the court held that California's duty to warn and FIFRA's misbranding provision were equivalent and consistent with one another, such that state law did not impose a requirement "in addition to or different from" FIFRA's labeling requirements. *Id.* at 955–56. The court stated that "only where there is a relevant EPA action *carrying the force of law* are state failure-to-warn claims prohibited from imposing requirements inconsistent with that action." *Id.* at 957. According to the Ninth Circuit, EPA's registration of a product raises only a "rebuttable presumption" that the pesticide and its label comply with FIFRA but does not itself carry the force of law and does not preempt state law. *Id.*

Similarly, the Eleventh Circuit recently considered whether a plaintiff's failure-to-warn claim against a pesticide manufacturer for a product containing glyphosate was preempted by FIFRA. *Carson v. Monsanto Co.*, 92 F.4th 980 (2024). The court held that FIFRA did not preempt the claim because Georgia's common law and FIFRA's labeling requirements are consistent, even if not identical. *Id.* at 992–93. The Eleventh Circuit concluded that EPA's registration of a pesticide was not an agency action that counted as a "requirement" under FIFRA because the FIFRA registration process lacked the formality of notice-and-comment rulemaking or formal adjudication. *Id.* at 993. The court, however, did not foreclose the possibility that formal EPA action—like the rulemaking requested here—would receive preemptive effect. *See id.* The deadline to file a petition for certiorari has not yet expired in that case.

Neither the Ninth Circuit nor the Eleventh Circuit gave weight to EPA's own conclusion that state labeling requirements constitute misbranding. On August 7, 2019, EPA issued a letter to manufacturers expressly disagreeing with the International Agency for Research on Cancer's ("IARC") classification of glyphosate as "probably carcinogenic to humans." The 2019 letter was prompted by California's efforts to require that a Proposition 65 warning label be placed on glyphosate products. The 2019 letter notes that, based on EPA scientists' independent evaluation of available data since the IARC classification, EPA had concluded that glyphosate is "not likely to be carcinogenic to humans." Letter from Michael L. Goodis, Director of EPA's Registration

Division (Aug. 7, 2019), https://perma.cc/W42T-GW7N. Given this independent determination and its consistency with several other international expert panels and regulatory authorities, EPA concluded state labeling laws requiring a statement that glyphosate may cause cancer is false and misleading and thus violates FIFRA's misbranding provision.

The Ninth Circuit dismissed EPA's position, concluding that the 2019 letter was not subject to formal administrative rulemaking procedures and therefore lacked the force of law to preempt the California failure-to-warn claim. *Hardeman*, 997 F.3d at 957–58; *see also Carson*, 92 F.4th at 998 (reading letter narrowly). The pesticide manufacturer in *Hardeman* petitioned the U.S. Supreme Court for a writ of certiorari. Petition for Writ of Certiorari, *Monsanto Co. v. Hardeman*, 142. S. Ct. 2834 (No. 21-241) (mem.). The United States filed an amicus brief opposing certiorari. The United States admitted that its position was a complete reversal from the position it took in its Ninth Circuit amicus brief because of a "change in Administration." Brief for the United States as Amicus Curiae Opposing Certiorari at 6, *Hardeman*, 142. S. Ct. 2834 (No. 21-241).

The brief opposing certiorari acknowledged that "EPA has long concluded that glyphosate is not likely to be carcinogenic to humans and has repeatedly articulated that view in registration decisions spanning decades." *Id.* at 12. According to the United States, mere inconsistency between state and federal risk assessments alone does not preempt enforcement of state tort law:

> EPA could—either through rulemaking or through some other regulatory action carrying the force of law—make a binding determination that the labels of pesticides containing glyphosate should not contain cancer warnings. Such a determination would preempt any state law tort claim premised on a manufacturer's failure to provide such warnings. But neither EPA's repeated statements that glyphosate is unlikely to be carcinogenic to humans, nor its approval of pesticide labeling without cancer warnings, imposes any such prohibition.

Id. at 13. Petitioners ask that EPA do just that—give its scientific findings and conclusions preemptive effect.

GROUNDS FOR REQUESTED RULEMAKING

Courts and States should not be allowed to undermine EPA's risk assessments under FIFRA. With its knowledge and expertise on FIFRA-regulated products, EPA should stand with its scientists and use its rulemaking authority to formally codify the preemptive effect of its risk assessment findings about FIFRA labeling. EPA's regulations that implement FIFRA already require that a label include EPA's toxicity findings and EPA's required "signal" word for toxicity categories. The same should hold true for EPA's other health-related findings.

The confusion over glyphosate is an excellent example of the problems that may arise if EPA does not engage in rulemaking to clarify the preemptive nature of its scientific findings and conclusions. In its amicus brief to the Ninth Circuit in *Hardeman*, filed December 20, 2019, the United States explains:

> The potential that glyphosate is carcinogenic to humans is not something that EPA has ignored. EPA has studied and expressly addressed the carcinogenic potential of glyphosate a number of times over the past three decades. And EPA continues to assess it. Through FIFRA, Congress determined that EPA should make these scientific judgments for the nation as a whole. States may, of course, restrict or prohibit the sale or use of pesticides in the State if they disagree with EPA's assessment. But States are prohibited from second-guessing EPA's determination of what risks should be reflected on pesticide labeling.

Brief for the United States as Amicus Curiae Supporting Monsanto Co. at 20, *Hardeman*, 997 F.3d 941 (No. 19-16636) (citations omitted).

Since 2009, EPA has been reviewing its registration of glyphosate under FIFRA. *See* EPA-HQ-OPP-2009-0361. In May 2019, EPA published its interim registration review decision for glyphosate in the Federal Register, which summarized EPA's proposed conclusions weighing the costs and benefits of glyphosate and setting forth specific proposed label requirements. *See* Glyphosate Proposed Interim Registration Review Decision; Notice, 84 Fed. Reg. 19,782 (May 6, 2019). On January 22, 2020, the Interim Decision was signed by EPA. *See* EPA, Glyphosate: Interim Registration Review Decision, Case No. 0178 (Jan. 22, 2020). As to human health, EPA "thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." *Id.* at 10.

The Rural Coalition and the Natural Resources Defense Council filed petitions for review in the Ninth Circuit challenging the findings of EPA's Interim Decision on glyphosate registration. *See Nat. Res. Def. Council v. EPA (NRDC)*, 38 F.4th 34 (9th Cir. 2022). The petitioners there, like California with its Proposition 65 efforts, held up the findings of the IARC and asserted that IARC's carcinogenicity findings should be given credence.

On May 18, 2021, EPA submitted its brief on appeal, providing a detailed description of the Agency's historical study of glyphosate. Brief for EPA, *NRDC*, 38 F.4th 34 (9th Cir. 2022) (Nos. 20-70787, 20-70801). EPA vigorously defended its own scientists' conclusions that glyphosate did not pose any risks of concern. *Id.* at 30–39. EPA expressly noted that, although the IARC characterized glyphosate as "probably carcinogenic to humans" in 2015, every other agency and organization that has recently conducted a scientific review of glyphosate has concluded that glyphosate does not pose a likely risk of cancer in humans. *Id.* at 32. Finally, EPA expressly addressed IARC's findings and explained why EPA's conclusion was both more robust and transparent than IARC's analysis. *Id.* at 33–39.[3]

Congress intended EPA to be the preeminent authority on the health effects of products registered under FIFRA. Petitioners respectfully request that EPA start rulemaking to prevent

[3] The Ninth Circuit ultimately vacated EPA's interim decision to register glyphosate. 38 F.4th at 40. EPA subsequently withdrew its interim decision stated that it anticipates issuing a final registration review for glyphosate in 2026. Memorandum from Cathryn Britton, Branch Chief of Risk Management and Implementation Branch in the Pesticide Re-evaluation Division of EPA 1, 6 (Sept. 21, 2022).

courts and regulatory agencies from engaging in backdoor challenges to EPA's conclusions and creating a patchwork of labeling requirements across the country.

Though the Ninth Circuit incorrectly held in *Hardeman* that FIFRA does not preempt California's Proposition 65, the Ninth Circuit recently found that Proposition 65 runs into a separate legal barrier: the First Amendment. The court concluded that California's requirement that glyphosate contain a warning that it is known to cause cancer constituted compelled commercial speech on a contested and controversial matter that does not survive intermediate scrutiny. *Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1266–67 (9th Cir. 2023). The Ninth Circuit thus permanently enjoined California from enforcing Proposition 65 as applied to glyphosate labeling. *Id.* at 1283. But the opinion leaves the door open for California to try again, if it can muster a label requirement that is "purely factual." *See id.* at 1276–80. And the opinion says nothing about the status of state law failure-to-warn claims, which do not compel commercial speech.

EPA can avoid the onslaught of litigation and continual review of state labeling requirements if it proceeds with Petitioners' requested rulemaking. EPA has authority and needs to adopt a rule clarifying that any statements on a product's carcinogenic potential or other public-health risks not otherwise required by EPA labeling under FIFRA constitute misbranding. The Supreme Court raised the ambiguity as to the preemptive nature of EPA's labeling requirements in *Bates*: "At present, there appear to be relatively few regulations that refine or elaborate upon FIFRA's broadly phrased misbranding standards. To the extent EPA promulgates such regulations in the future, they will necessarily affect the scope of preemption under § 136v(b)." *Bates*, 544 U.S. at 453 n.28. The lack of clarity was also acknowledged by the Third Circuit in *Indian Brand Farms, Inc. v. Novartis Crop Protection, Inc.*, 617 F.3d 207, 222 (3rd Cir. 2010) (citing *Bates*, 544 U.S. at 453, n.28). The Ninth Circuit's decision in *Hardeman* raises the concern as well. *See* 997 F.3d at 958 ("because EPA's actions—such as registering Roundup, approving Roundup's label, and issuing the 2019 letter—do not have the force of law" there is no preemption of state-law claims for failure to warn).

Since 2005, courts have signaled to EPA the need to engage in rulemaking on this issue. Nearly 20 years later, the problem has not been addressed. Petitioners respectfully request that action be taken now.

CONCLUSION

For these reasons, Petitioners request that EPA initial rulemaking to codify the preemptive effects of its scientific findings developed during the registration process as they relate to health warnings mandated by state law or under common law failure-to-warn claims. The courts and the Department of Justice have consistently observed the authority of EPA to do so. The basis and support for the requested rulemaking is already well developed and does not require EPA to engage in additional technical review or study. Petitioners therefore request that EPA issue the proposed rule for public comment within 90 days of submission of this Petition.