No. 24-1068

IN THE

Supreme Court of the United States

MONSANTO COMPANY,

Petitioner,

v.

JOHN L. DURNELL,

Respondent.

On Writ of Certiorari to the
Court of Appeals of Missouri, Eastern District

BRIEF OF THE HEARTLAND HEALTH RESEARCH ALLIANCE (HHRA) AS *AMICUS CURIAE* SUPPORTING RESPONDENT

Jesse A. Buss
Counsel of Record
WILLAMETTE LAW GROUP, PC
411 Fifth Street
Oregon City, OR 97045
503-656-4884
jesse@WLGpnw.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Statutes:

Other Authorities:

(continued)

(continued)

INTEREST OF THE *AMICUS CURIAE*[1]

The Heartland Health Research Alliance (HHRA) is a non-profit founded to address public health issues arising at the interface of farming, food safety, and the environment. The Heartland Study (HS) is the organization's major ongoing project; the protocol paper is published.[2] This birth cohort study is focused on the health impacts in the Midwest of prenatal and early-life herbicide exposures. The HS has been funded via grants from philanthropic organizations. Since 2019, over 1,800 pregnant women have been enrolled from Indiana, Iowa, and Wisconsin. Outcomes of concern include preeclampsia—a major global cause of maternal and fetal mortality that causes approximately 75,000 maternal and 500,000 infant deaths annually—and the rapid rise of metabolic syndrome among children, including evidence from a study funded by the National Institutes of Health (NIH) that glyphosate may be associated with the onset of liver disease in children as young as age four.[3]

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that no counsel for any party authored this brief in whole or in part and no entity or person, aside from *amicus curiae*, its members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

[2] Marlaina Freisthler et al., BMC Public Health, *Perinatal health effects of herbicides exposures in the United States: the Heartland Study, a Midwestern birth cohort study* (Nov. 2023), https://perma.cc/P5SR-QC8R.

[3] Brenda Eskenazi et al., Environ Health Perspect., *Association of Lifetime Exposure to Glyphosate and Aminomethylphosphonic Acid (AMPA) with Liver Inflammation*

HHRA is committed to helping the nation achieve the regulatory goals set forth in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq*. Toward that end, recent HS data on herbicides in human urine have been provided to the EPA (the only such data available) for use in tracking changes in exposure levels. Since 2016 state pesticide regulatory authorities have played key roles in addressing risks arising from wider use of volatile herbicides, risks HHRA is tracking and addressing through multiple activities. HHRA is convinced that the role of states in pesticide regulation is growing—and will continue to grow—in step with the rising diversity of ways pesticides are used across the country.

Scientists working with HHRA have been involved in pesticide rulemaking and litigation (including this case in the lower courts), and cases involving the impacts of pesticides on cancer, Parkinson's disease, and childhood neural development. HHRA submitted comments to the EPA in August 2025 addressing agency re-approval of the volatile herbicide dicamba for post-emergence applications on GMO soybeans and cotton.[4] Further,

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and Metabolic Syndrome at Young Adulthood: Findings from the CHAMACOS Study (March 2023), https://pubmed.ncbi.nlm.nih.gov/36856429/.

[4] Heartland Health Research Alliance, EPA Docket EPA-HQ-OPP-2024-0154, *Heartland Health Research Alliance Comments* (Aug. 2025), https://perma.cc/X6X7-9B65.

in March 2025 HHRA submitted comments[5] opposing a preemption-supportive regulatory petition submitted to EPA by 11 Attorneys General. Those comments highlight the ways that preemption[6] would impact the state-federal partnership created by FIFRA. The Attorneys General petition seeks an outcome via regulatory reform comparable to that sought here by Bayer/Monsanto and by the pesticide industry more generally.

In sum, HHRA has a scientific and institutional interest in the interpretation and implementation of FIFRA.

INTRODUCTION AND SUMMARY OF ARGUMENT

The relief sought by Bayer/Monsanto would markedly curtail the role of states in avoiding "unreasonable" adverse human, economic,[7] and environmental effects stemming from pesticide use. In some venues (*e.g.*, state legislatures) proponents of preemption have described its impact as narrow. Not so. The effectiveness of FIFRA rises and falls on the

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[5] Heartland Health Research Alliance, EPA Docket EPA-HQ-OPP-2024-0562, *Comments* (March 2025), https://perma.cc/HBP5-MJRV.

[6] Throughout this brief HHRA generally refers to the petitioner as "Bayer/Monsanto", but uses "Monsanto" when discussing matters that predated Bayer's acquisition of Monsanto in 2018.

[7] Economic losses, for example, like reduced crop yields (*Bates*), income and health-care expenses (this case), harm to companion animals, and damage to bee hives.

fluidity and coherence of state *plus* federal contributions to labeling.

Petitioner claims EPA controls all aspects of labeling. This is also not true. FIFRA provides states multiple mechanisms to alter existing label provisions, to add new ones via supplemental labeling, and to approve Section 18 "Emergency Exemption" and Section 24 "Special Local Need" labels.

Yes, EPA must approve almost all state-specific labeling that flows from a state regulator to EPA and then onto federal labels. This happens routinely thousands of times every year. But that does not make EPA the "author" of such pesticide labeling, ***nor does it mean that EPA has rendered judgment on the need for or adequacy of such label changes***. EPA cannot render such judgments since it does not have the data, nor time, to assess the impacts of the vast majority of state-driven label changes. The only ones that trigger EPA science reviews are those expected to increase risks above those allowed under current labels.

Pesticide registrants write labels and decide what is needed on them to avoid misbranding and to prevent "unreasonable" adverse effects. Petitioner's and the government's briefs argue that label provisions approved at the federal level should be regarded as fully meeting the requirements of FIFRA *because EPA approved them*. They take this argument a big step further in asserting that the content of EPA-approved labels, *including what is missing in them*, preempts the obligation of registrants to mitigate high-risk exposures and issue warnings of possible harm. FIFRA does no such thing and HHRA urges the

Court to put this industry fantasy to rest once and for all.

For food-use pesticides, the EPA's decision to approve a label is based on general population exposures and risk from residues of the pesticide's active ingredient(s) in food, drinking water, and beverages. The case under review is not about Mr. Durnell's dietary exposure to glyphosate. It is about his long-term, dermal exposures to formulated Roundup.

Petitioner Bayer/Monsanto asks the Court to uncritically accept that the EPA's judgment that ***glyphosate*** is unlikely to pose elevated cancer risk from residues in the diet is equally applicable to Durnell's dermal exposures to ***formulated Roundup***. Such exposures and risks are not equivalent, as the jury came to understand during trial.

On any given spray day, Mr. Durnell was exposed to glyphosate at much higher levels when formulated Roundup spray landed on his skin, compared to the much smaller amount of glyphosate he was exposed to via his diet (if any). Plus, formulated Roundup contains both glyphosate and polyethoxylated tallow amine (POEA) surfactants that markedly alter the toxicity and risks from exposures to formulated Roundup, compared to exposures from pure glyphosate residues in food.

To avoid misbranding, labels must alert people handling and spraying pesticides to possible high-exposure and high-risk application scenarios. Labels should require or suggest practical steps users can take to keep their exposures below the threshold between "acceptable" and "unreasonable" health

risks.[8] The EPA's analysis of glyphosate toxicology and dietary risks led to the agency's "not likely" to pose cancer risk finding for the general population. Petitioner asks this Court to assume that the same finding—and same sort of label provisions—are equally satisfactory when applied to the lawn and garden uses of the Roundup products purchased by Durnell. They are not, as became clear to the jury.

Since *Bates v. Dow Agrosciences*, 544 U.S. 431 (2005), the demands on state regulators have expanded steadily. Emerging and new state responsibilities include dealing with the health risks and economic damage when volatile herbicides like dicamba move in the air—sometimes for miles—as well as the proliferation of new pesticide uses that sometimes lead to high-risk exposure patterns.[9]

Preemption would also undermine state courts' role in hearing and deciding tort cases based on the actual evidence. When problems emerge with pesticide efficacy or human injury, courts are called upon to sort out who is liable and what constitutes fair compensation. If preemption applies, then a registrant could simply claim that "we did what EPA required us to do," and effectively exclude any evidence of actual knowledge of potential harm that falls outside the scope of the label. That artifice—and incursion into state evidence and tort law—would not

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[8] An "acceptable" risk level is one "supported" by the data submitted to EPA. The term "support" means that the data available to EPA does not point to exposures above EPA's "acceptable" risk threshold.

[9] *E.g.*, certain uses inside homes, schools, or in state-of-the-art greenhouses, and pesticides marketed to kill fleas and ticks that can spread disease among livestock and companion animals.

pass the laugh test. Preemption should not shield pesticide registrants from liability when they write and retain labels that fail to avoid unreasonable adverse effects, *e.g.,* non-Hodgkin's lymphoma.

The Court should not solve Bayer/Monsanto's near-term, litigation-driven fiscal crisis via expanding the scope of preemption. Doing so would create problems that would plague U.S. farmers and pest managers, the general public, and regulatory officials for decades.

The Court should affirm the judgment of the Missouri Court of Appeals.

ARGUMENT

I. The pesticide industry's 2026 quest for preemption

Bates v. Dow Agrosciences LLC offers guidance regarding preemption. In *Bates* Texas peanut farmers had suffered economic losses from lawful applications of Strongarm (diclosulam), a then-new Dow herbicide.

The original Dow-written and EPA-approved Strongarm label did not warn peanut farmers that the product could damage plants growing in high-pH soils. The case revolved around whether EPA approval of the Strongarm label, ***excluding such a warning***, relieved Dow of its obligation under FIFRA to add use directions and/or warnings sufficient to avoid "unreasonable" damage to peanut crops grown in high

pH soils.[10] In *Bates*, evidence established that Dow was aware that elevated soil pH extended the persistence of Strongarm, and hence posed heightened risk of crop damage. So, in reference to the Strongarm label, the jury in *Bates* concluded that there was a failure to warn peanut farmers with high pH soils, and that Dow knew or should have known that such a warning was needed to avoid economic losses for farmers.

The Bayer/Monsanto argument advanced in support of preemption rests upon the dubious assumption that the EPA-approved label on the lawn and garden Roundup products purchased by Durnell contained all use directions, requirements, and warnings needed to avoid "unreasonable adverse effects" under all lawful application scenarios. On page four of its amicus brief, the government states that FIFRA "vests EPA with responsibility to determine," what constitutes an effective warning, but fails to acknowledge that registrants are obligated to craft and include such warnings on their labels, and EPA rarely assesses the adequacy of efficacy-related warnings, or the lack thereof.

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[10] The *Bates* opinion discusses in some detail the impacts of the 1978 amendments to FIFRA that relieved EPA of the obligation to assess pesticide efficacy, a task that was particularly onerous for EPA in the area of weed management and herbicide labeling. The *Bates* opinion points out that: "This general waiver was in place at the time of Strongarm's registration; thus, the EPA ***never passed on the accuracy of the statement*** in Strongarm's original label recommending the product's use 'in all areas where peanuts are grown.'" 544 U.S. at 440 (emphasis added)

The EPA never has and never will possess all the knowledge and scientific insight required to fully anticipate and mitigate all unreasonable adverse effects stemming from lawful pesticide use. FIFRA implicitly, and in practice, recognizes that fact. As this Court noted in *Bates*, EPA's ability and authority to address all local and regional risk scenarios under FIFRA is limited:

> "Although the [local aerial spray] ordinance [in *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991)] imposed restrictions not required by FIFRA or any EPA regulation, we unanimously rejected the pre-emption claim. In our opinion, we noted that FIFRA was not a 'a sufficiently comprehensive statute to justify an inference that Congress had occupied the field to the exclusion of the States. To the contrary, the statute leaves ample room for States and localities to supplement federal efforts even absent the express regulatory authorization of [FIFRA]."[11]

544 U.S. at 441-42. If the Court embraces Bayer/ Monsanto's argument here, it would "... give pesticide manufacturers virtual immunity from certain forms of tort liability." *Id.* at 450. And it is ironic that many farmers and most farm organizations are among the most ardent proponents of preemption since it would

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[11] Because of rapid advances in pesticide risk-assessment science, the FIFRA statute is markedly ***more insufficient*** in 2026 than it was in 1991 when the *Wisconsin Public Intervenor* case was argued.

shift the burden of preventing herbicide crop damage from registrants to them. When damage occurs, preemption would largely eliminate the only viable path to compensation opened up by the Texas peanut farmers in *Bates*.

A. Distinctions between glyphosate and formulated roundup

In considering whether Monsanto had a duty to warn about *Roundup* causing a heightened risk of cancer, it is vital to acknowledge the distinctions between the oncogenicity of pure, technical glyphosate and the oncogenicity of the formulated lawn and garden "Roundup" products that Durnell bought and applied. Durnell handled and sprayed formulated Roundup that contained glyphosate, plus polyethoxylated tallowamine (POEA) surfactants, plus other so-called inert ingredients ("inert" in terms of contributing to weed control), as well as certain toxic contaminants not present in pure glyphosate.

The differences between the toxicity and oncogenic potential of pure glyphosate versus formulated Roundup are significant. The presence of surfactants, along with certain toxic contaminants, increased the toxicity of the Roundup applied by Durnell compared to pure glyphosate in two primary ways: the innate toxicity of the additional ingredients, and second, the increase in the rate at which the glyphosate in Roundup spray solution moves through human skin and cell walls, due to the presence of POEA surfactants.

Yet the toxicology studies Monsanto generated and supplied to EPA to gain Roundup registration approval, and to support the content of Roundup

labels, was based on toxicology data and cancer bioassays conducted with laboratory animals treated with pure glyphosate, and not the formulated Roundup Durnell bought and applied (or ***any*** formulated Roundup). Monsanto has never done a cancer bioassay on Roundup, nor conducted an epidemiology study of its formulation plant workers to assess the association of Roundup and cancer risk.

Petitioner Bayer/Monsanto claims there is "no evidence" that glyphosate increases cancer risk, and notes that the EPA, and other regulators around the world, agree that exposure to glyphosate via residues in food and the diet likely does not pose cancer risk. But as already noted, Mr. Durnell did not allege that his dietary exposures to pure glyphosate contributed to his NHL, but rather his much-higher levels of dermal exposures to formulated lawn and garden Roundup.

From introduction in 1974 through the 1980s, the science supporting this Monsanto and EPA conclusion regarding lack of oncogenic risk from glyphosate residues in food was reasonably strong, although not universally embraced. But since the early 2000s, what was a handful has become a truckload of hundreds of published studies supporting an association between repeated dermal exposures to formulated Roundup and cancer. Here Bayer/Monsanto experts and counsel could not point to a statement by EPA that the agency had analyzed applicator exposure scenarios to formulated Roundup similar to Durnell's and

concluded that such exposures are also "not likely" to pose cancer risk.[12]

In their assessments of glyphosate and cancer risk, both the International Agency for Research on Cancer (IARC) Working Group and the EPA's Office of Research and Development (ORD) placed heavy weight on studies testing the toxicity and metabolism of formulated Roundup and other GBHs in people and human cells. IARC concluded that glyphosate was a "probable" oncogen, and the ORD team felt that classification of glyphosate as a "possible" or "probable" carcinogen was most closely aligned with the data and EPA's cancer risk assessment policies.[13]

B. The illusory distinction in FIFRA between pesticide use and labeling

The government asserts on page seven of its amicus brief that FIFRA draws "a bright line between pesticide use—where States have concurrent authority to regulate—and labeling—where EPA is in charge."

This simplistic dichotomy is divorced from the clear language of FIFRA. The only way states can impact the use of a pesticide product within a state's borders is via label directions that specify what pests

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[12] As acknowledged by EPA, the agency lacks a valid dermal penetration study quantifying how much glyphosate in a formulated Roundup herbicide moves through human skin.

[13] An email exchange about OPP's cancer classification decision among the members of the ORD team was shown to the jury below. It states that the members of the team were split between "possible" and "probable." There was no support for "proven" or "not likely."

can be treated, how a pesticide can be applied and at what rate, in conjunction with what Personal Protective Equipment (PPE), and accompanied by what set of warnings and cautionary statements.

Congress did not vest responsibility in states to regulate pesticide use to avoid "unreasonable" impacts and then take away the tools needed by states to do so via the "uniformity" requirement in FIFRA. 7 U.S.C. § 136v(b). That provision requires uniformity in many "requirements" regarding what labels must cover. It specifies where certain critical information should appear on all labels so that users know where to find important instructions and use directions. Registrants are required to list the percentage concentration of active ingredients in formulated products in the same way and place on labels.

EPA labeling regulations uniformly govern the order in which various information is shared on labels. It controls the selection of signal words, font sizes, how critical information is highlighted. Regulations spell out where various blocks of mostly generic content must appear. But the EPA ***does not specify*** the content of the actual label provisions that registrants craft and advance to the EPA for approval. In the Roundup-NHL litigation, Stephen Wratten, a Monsanto registration specialist, testified that Monsanto wrote about 95% of the content that appears on Roundup labels. He explained that mandatory and/or generic content, (*e.g.*, how to dispose of empty containers) account for the rest of a typical label.

Congress vested responsibility for writing labels on pesticide manufacturers because of the superior knowledge registrants possess about the physical and

chemical properties and toxicity of the formulated pesticide products they sell. At the time EPA evaluates the risks stemming from a new pesticide, or an altered use of a previously approved pesticide, the agency lacks knowledge of many aspects of product toxicity, metabolism, use patterns, exposure pathways, levels of exposure, duration of exposure, and resulting risks. This is especially true of initial EPA approvals of a new product—when there is very little information about the properties of a new pesticide—except inside the company that did the work required to gain EPA approval and bring it to market.

As a result, the EPA cannot be expected to proactively direct registrants to add all necessary instructions for use, requirements for PPE, warnings and cautionary statements, etc. In many cases EPA simply does not have that information. And it is ***the registrant's*** job and responsibility to provide that information under FIFRA.

C. Pesticide manufacturers decide what to place on labels

The fundamental question before this Court is whether an EPA risk-assessment decision specific to one route of exposure (dietary) to a pure pesticide active ingredient (glyphosate) absolves a pesticide registrant (Bayer/Monsanto) from the duty to offer use directions and warnings needed to reduce much higher risks via a different route of exposure (dermal) to a different chemical (formulated Roundup). As explained below, it does not.

A pesticide product is mislabeled if it does not prevent "unreasonable adverse effects on man or the

environment." Pesticide registrants are responsible for content in the labels they submit to EPA for approval. FIFRA also makes clear that EPA approval of a registrant-written label cannot be cited as evidence that the label adheres to all FIFRA requirements. It is up to pesticide registrants to determine whether cautionary statements or warnings are needed to alert users to high-risk scenarios. Some hesitate to do so, fearful that warnings might cut into sales and profits.

Historically, EPA has very rarely objected when a pesticide registrant has included a cautionary statement or warning in proposed labeling, including state-proposed Section 18 and 24 labels.

D. Bayer/Monsanto's claim of "no evidence" of cancer risk is wrong

Three causes of action are cited in most cases brought in the Roundup-NHL litigation: failure to warn, design defect,[14] and negligence. This Court is now asked to determine whether FIFRA preempts the failure to warn cause of action because Monsanto chose not to include a cancer warning, and EPA did not require Monsanto to include one on the labels of the Roundup products bought and applied by Durnell.

At trial, Bayer/Monsanto claimed that it had no reason or scientific basis to include a cancer warning on its Roundup-brand herbicides, and that hundreds of (mostly Monsanto-funded) studies consistently confirmed Roundup posed no cancer risk. However, as

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[14] In the case of formulated, end-use pesticide products, the "design" of the product includes its labeling.

the trial proceeded, jurors learned of hundreds of studies, including several conducted or commissioned by Monsanto, that did identify or support the ability of Roundup to damage DNA and/or increase the risk of cancer.

In addition, juries learned of substantial epidemiological data pointing to an association between users of Roundup and cancer, and in particular NHL. Such data were from studies comparing health outcomes among individuals handling and applying Roundup, or other GBHs, in contrast to those not using a GBH.

Jurors heard evidence showing that non-agricultural users of Roundup like Mr. Durnell typically experienced much higher rates of exposure per area treated or pounds of glyphosate applied, compared to typical agricultural applicators. This is because farmers and commercial applicators typically spray Roundup when sitting inside a steel-glass cab with an air filtration system. Plus, such applicators are able to apply much more glyphosate in a day with far less dermal exposure compared to a person using a handheld sprayer who walks through and around the area where he or she had just applied the product.

The jury also heard extensive testimony, and viewed multiple documents from Monsanto, describing Monsanto's efforts to refute, obscure, or otherwise undermine dozens of published, peer-reviewed studies reporting a possible linkage between Roundup and cancer. Such evidence described instances in which Monsanto did not disclose information to EPA, or obscured the results of some of

its own studies that reinforced an association between Roundup and cancer.[15]

II. States' roles in pesticide regulation and the mitigation of risks

States play key roles in helping registrants and the EPA recognize where and how people are sometimes exposed to dangerous levels of pesticides. As this Court pointed out in the *Bates* decision:

> "Nothing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law. The imposition of state sanctions for violating state rules that merely duplicate federal requirements is equally consistent with the text of [FIFRA]."

544 U.S. at 442.

Congress authorized states to propose and gain EPA approval of supplemental labels.[16] According to EPA, "Compliance with both the product label and

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[15] *E.g.,* three reports on glyphosate genotoxicity by Dr. James Parry, a consultant hired by Monsanto to help the company interpret recently published genotoxicity papers (discussed in more detail later in this brief).

[16] According to EPA, "Supplemental labeling includes labels that contain newly approved uses, use directions, or other instructions that have been added since the last accepted master label." For details see https://www.epa.gov/pesticide-labels/label-review-training-module-1-label-basics-page-20.

supplemental labeling is required to safely and effectively use the product."[17] Such labeling can apply to an existing EPA-approved use, or lead to a new use being added under a Section 18 "Emergency Exemption" label or a Section 24 "Special Local Need" (SLN) label. Many such labels also include additional cautionary statements and warnings.

In discussing SLN labels, EPA explains that states have authority to issue such labels, and that they are effective immediately, although the EPA has 90 days to assure the information on the label is complete. According to EPA, "Occasionally, it is necessary [for EPA] to send the SLN for science review depending on the use pattern."[18]. With few exceptions, an EPA science review of a SLN label is triggered only in cases in which the use pattern authorized by the SLN label might increase exposures and/or risks sufficient to warrant EPA review.

A. State labeling is an integral part of EPA labeling

State-driven changes in EPA labels are routinely included in federal label amendment requests, and often on a near-annual basis. The important roles of state law and regulation in tort litigation is acknowledged in the *Bates* opinion:

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[17] EPA, Office of Pesticide Programs, *Label Review Manual* (Dec. 2024), at 3-3 (Supplemental Labeling), https://perma.cc/HLX8-GV7Q.

[18] *Id.* at 4-10 (Special Local Needs).

> "If Congress had intended [in crafting FIFRA] to deprive injured parties of a long available form of compensation [via state courts], it surely would have expressed that intent more clearly. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238,251 (1984)."

544 U.S. at 449; *see also id.* at n. 25 ("Given the inherently dangerous nature of pesticides, most safety gains are achieved not through modifying a pesticide's design, but by ***improving the warnings and instructions contained on its label***.") (emphasis added).

State pesticide regulatory officials are obligated to adhere to various procedures and requirements imposed upon them both via FIFRA and EPA regulations, and in state law and implementing regulations. Just as FIFRA imposes ongoing obligations on pesticide manufacturers to design safe products, label them accurately and fully, and conduct the testing needed to avoid hazardous exposures, state laws impose what are often referred to as "parallel requirements" on pesticide manufacturers.

For example, Chapter 206 (the "Pesticide Act of Iowa") of the Iowa Code addresses "PESTICIDES." It offers definitions that track those in FIFRA; Iowa's definition of "unreasonable adverse effects" is identical to FIFRA's. The "Pesticide Act of Iowa" states that:

> "3. It shall be unlawful...(b) For any person to use or cause to be used any pesticide contrary to its labeling or to rules of the state of Iowa ***if***

> ***those rules differ from or further restrict the usage***."

Iowa Code §206.11(3)(b) (emphasis added)

The bolded portion of the above statute means that under Iowa law it is unlawful to apply a pesticide in Iowa in a way allowed on its EPA-approved label, if the application is not allowed or consistent with "the rules of the state of Iowa."

This is a critical exception and fundamental principle in FIFRA. Petitioner is correct in stating that FIFRA unambiguously preempts a state's right to unilaterally authorize and/or change a pesticide label in a way that increases exposures and risk. But FIFRA does not preempt states from further *restricting* uses, exposures, and risks below those sanctioned on an EPA approved label. This is why it is often said FIFRA establishes the floor of regulation (i.e. mandatory restrictions on pesticide labels intended to avoid "unreasonable" adverse effects), but not the ceiling of such restrictions. Put simply, FIFRA prevents states from increasing risks, but allows states to act unilaterally to further reduce risks.

Much of the pesticide content in the Iowa Code specifies how and by whom Iowa government agencies and universities will carry out pesticide-related responsibilities vested in the state by FIFRA. Indeed, throughout FIFRA, Congress relies on states because of the existing capacity of state-based programs and universities to carry out research, training, and enforcement functions called for in FIFRA that are beyond what federal EPA could take on without creating a new, massive and costly federal bureaucracy.

B. Dealing with volatile herbicides since 2017 exemplifies the reliance of EPA on states in addressing new and emerging risks

The scope and diversity of pest control challenges across the country have risen steadily since the passage of the modern FIFRA in 1972. So too have the responsibilities borne by states. Consider, for example, an important, evolving example: the challenges imposed by EPA in 2026 on states by the agency's recent approvals of new registrations allowing over-the-top (OTT), post-emergence applications of dicamba herbicide on GMO soybeans and cotton.

A little background may be helpful. Labels were in place allowing OTT application of dicamba in 2017-2024. But the 2024 labels were vacated by the Ninth Circuit Court of Appeals, leading to an end of OTT applications in crop year 2025. The primary concerns with OTT dicamba applications are harm to non-target vegetation and human health during late spring and early summer months. This is because OTT dicamba formulations are prone to volatilization in hot weather, and movement off-target. Thousands of episodes of damage to non-GMO crops, vegetation, and trees from the movement of dicamba off fields treated OTT were reported to states, and had to be investigated,[19] and in some cases, adjudicated.

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[19] In Iowa for example, the number of agricultural drift and damage episodes reported increased from 91 in 2016 to 211 in 2017, with dicamba-drift episodes accounting for nearly all the increase, according to the Iowa Department of Agriculture and Land Stewardship.

University scientists have estimated that millions of acres each year have been adversely impacted by dicamba movement in 2017-2024. In the judgment of the Ninth Circuit, dicamba's proclivity to volatilize and move away from legally sprayed fields constituted an "unreasonable" environmental effect that the EPA and pesticide registrants had still not successfully quantified or mitigated, despite seven years of incrementally more restrictive label directions.

The headline accompanying the EPA's February 6, 2026, press release announcing re-approval of OTT dicamba uses asserts that "EPA Implements Strongest Protections in Agency History for Over-the-Top Dicamba Use on Cotton and Soybeans for Next Two Growing Seasons." The EPA determined that "strongest ever" restrictions were needed because the incrementally more restrictive provisions applicable in 2017-2024 had failed to sufficiently reduce the severity and frequency of dicamba damage to non-target vegetation.

There has been a six-fold increase in the use of dicamba nationwide since 2017, and OTT applications on GMO soybeans and cotton have accounted for essentially all the increase, as HHRA pointed out in 2022 comments to EPA.[20] This increase in reliance on dicamba was a key concern triggering the initiation of the Heartland Study (HS) and the formation of the Heartland Health Research Alliance (HHRA).

To track changes in dicamba exposures among pregnant women in the Midwest, HHRA invested over

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[20] Heartland Health Research Alliance, EPA Docket EPA-HQ-OPP-2016-0223-0026, *Heartland Health Research Alliance Comments* (Oct. 2022), https://perma.cc/3SVX-4WAW.

$65,000 in developing an improved, lower-cost method to quantify dicamba in urine.[21] The HS clinical team began collecting urine samples in 2019. The HS team has now compared the frequency and distribution of dicamba in the urine of pregnant women from samples collected during 2010-2012 as part of an NIH-funded birth cohort study, in comparison to dicamba in the urine of HS women who provided urine samples in 2020-2022, as the nearly six-fold increase in national dicamba use was occurring.

Key findings include that the percent of pregnant women with detectable levels of dicamba in their urine increased from 26% in 2010-2012 to 70% in 2020-2022, and the average measured level of dicamba in the urine samples rose from 0.066 ug/L to 0.271 ug/L, or 4-fold, over this period of time.[22]

In 2025 comments to EPA in the rulemaking focused on re-approval of the OTT dicamba labels vacated in 2024,[23] HHRA shared the above data

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[21] Jessica Larosse et al., Chemosphere, *New sensitive LC-MS/MS method for the simultaneous determination of 13 phenolic and carboxylic acid pesticide biomarkers in human urine, including dicamba* (Dec. 2023), https://www.sciencedirect.com/science/article/pii/S00456535230 2619X.

[22] Joanne K. Daggy et al., Agrochemicals, *Dicamba and 2,4-D in the Urine of Pregnant Women in the Midwest: Comparison of Two Cohorts* (Feb. 2024), https://www.mdpi.com/2813-3145/3/1/5.

[23] Heartland Health Research Alliance, EPA Docket EPA-HQ-OPP-2024-0154, *Heartland Health Research Alliance Comments* (Aug. 2025), https://perma.cc/X6X7-9B65.

showing markedly rising dicamba levels in the urine of pregnant women, and opined that the increase was almost certainly brought about by OTT dicamba applications. HHRA raised concerns over rising inhalation exposures and possible adverse reproductive and developmental outcomes. We questioned the reliability of EPA's conclusion in the dicamba human health risk assessment that inhalation exposures were "unlikely" beyond a few hundred feet from the edge of a treated field.

Nonetheless, new OTT dicamba labels have been approved by the EPA. As part of the conditions for approval, state regulators are having to craft and approve supplemental labeling calling for, among other things, specific cut-off dates after which OTT dicamba applications cannot be made because of generally hot weather. For example, the first three state-specific supplemental labels, and state-centric versions of the federal EPA label for STRYAX[24] OTT dicamba, are in place and set forth these added restrictions:

- South Dakota, "**DO NOT** apply after June 30";
- Iowa, "**DO NOT** apply after June 12 or V4,[25] whichever comes first"; and

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[24] STRYAX brand dicamba is manufactured by Bayer/Monsanto. Similar state-specific labels and restrictions also have or will appear on Syngenta's and BASF's 2026 OTT dicamba labels.

[25] Soybean plant growth is tracked via stages; V4 is defined as the presence of four fully developed trifoliolate leaves on the main stem, beginning from the lowest node above the unifoliolate leaves.

- Minnesota, "**DO NOT** apply south of Interstate 94 after June 12. **DO NOT** apply north of Interstate 94 after June 30".

States will propose, and EPA will likely approve, 2026 OTT dicamba labels for three companies in some 34 states. Each state will issue supplemental labeling setting time restrictions on when the product can be applied, reductions in use rates, and sometimes different cut-off dates in different parts of a state. Accordingly, ***there will be as many as 102 versions of state-centric EPA-approved OTT dicamba labels on products sold this crop year*** (three companies with labels multiplied by 34 states).[26]

Bayer/Monsanto—and the government in its amicus brief—warn of a crazy-quilt of 50 state-driven labels for any given pesticide unless the Court preempts the role of states in pesticide labeling. They stress how confusing and costly such an outcome would be. Fortunately, this unwelcome outcome has not materialized in the 53 years since the modern FIFRA became law. But now, in an effort to keep another high-risk herbicide on the market, there is the likelihood of several hundred state-specific labels to allow OTT dicamba applications in 2026-2027.

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[26] Actually, it could be as much as 400 state-centric federal labels, since the three companies might market, on average, four OTT dicamba products in coming years.

III. The known and unknown consequences of preemption

Pesticide and herbicide preemption language and remedies advanced and supported by the pesticide industry have changed little in the last 45 years. Since 1980, efforts by pesticide registrants to preempt failure to warn claims, and curtail the role of states in pesticide regulation, have imposed costs on courts and regulatory agencies, and indirectly undermined the efficacy of FIFRA in avoiding "unreasonable" adverse effects.

The persistence of pesticide manufacturers in seeking preemption is clearly a reflection of the economic importance of the right of individuals who allege harm from a legal use of a pesticide to seek redress via the courts. Adoption of the preemption language currently promoted by the pesticide industry before state legislatures, the U.S. Congress, EPA, and this Court would help pesticide manufacturers avoid accountability for harm caused by their products, including harms arising from applications the registrants know can sometimes lead to high-risk exposure scenarios. It would also place added burden on EPA since federal regulators would have to wrestle with all the region-specific risk assessment and risk mitigation challenges that states are now addressing.

A. Pesticide industry efforts and arguments in support of preemption: 1981-2026

Petitioner argues that FIFRA's "uniformity" provision preempts the state-law based failure to warn claim. This argument would be more persuasive scientifically and legally had Mr. Durnell alleged that

his exposure to *pure glyphosate* through his diet had caused or contributed to his NHL. But like most plaintiffs in the Roundup litigation, it was Durnell's frequent and long-term handling and spraying of Roundup, and resulting dermal exposures, that contributed to his disease.

In *Bates*, this Court made a critical point that is relevant in weighing the arguments now advanced:

> "Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA. [] FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings. As one court explained, tort suits can serve as a catalyst in this process..."

544 U.S. at 451. *Bates* then quotes a passage from *Ferebee v. Chevron Chem. Co.,* 736 F.2d 1529 (D.C. Cir. 1984), pointing out that tort suits that allege new mechanisms and circumstances leading to allegedly "unreasonable" adverse health effects "may aid in the exposure of new dangers associated with pesticides" and "[s]uccessful actions of this sort may lead manufacturers to petition EPA to allow more detailed labeling of their products[.]" 544 U.S. at 451.

Monsanto could have, and should have added a cancer warning on its Roundup labels in the early 2000s in response to multiple published studies reporting the capacity of glyphosate to damage DNA, thereby increasing the risk of cancer. It did not do so.

Instead, among other things, Monsanto hired Dr. James Parry, a world-renowned expert in

genotoxicology, and asked him to review published studies reporting that glyphosate can damage DNA. In his reports to Monsanto delivered in 2000-2001, Dr. Parry mostly agreed with the published findings of damage to DNA. He also became convinced by published studies that the genotoxicity of formulated Roundup was greater than pure glyphosate, and informed Monsanto of this insight.[27]

Monsanto disagreed with Dr. Parry's conclusions and stopped further work with him. They decided to not provide the EPA with Parry's reports as required by FIFRA's Section 6(a)2 "adverse health effects" reporting requirement. Not only did Monsanto fail to warn Roundup users like Durnell of the risks associated with heavy and repeated dermal exposures, the company took steps to lock away Dr. Parry's reports.[28]

Preemption is of growing importance to the pesticide industry because new scientific tools are making it possible to identify how and why exposure to certain pesticides is sometimes harming people. As a result, the pesticide industry is facing unwelcome consequences from successful efforts to get or keep risky pesticide uses onto EPA approved labels, and without adding label provisions and warnings to mitigate newly recognized risks.

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[27] In other words, a given dose of glyphosate delivered as part of formulated Roundup triggered more damage to DNA than the same amount of pure glyphosate.

[28] Once the existence of the three Parry reports was disclosed in the early stages of the Roundup-NHL litigation, Monsanto provided copies of Dr. Parry's reports to the EPA, albeit ~20-years after it was obligated to do so under FIFRA.

Bayer, as a result of its misguided 2018 acquisition of Monsanto, is leading the charge. The solution Bayer/Monsanto hopes to bring about is turning all EPA-approved labels into something they never have been, and never can be, namely: a universal guarantee that any and all labeled uses of pesticides cannot cause unreasonable adverse effects on human health or the environment because, at some prior point in time, the EPA approved a label allowing such uses.

In the case of lawn and garden Roundup brands, and as the litigation progressed, Bayer/Monsanto chose to replace glyphosate in most of its lawn and garden formulations with more toxic active ingredients.[29] Alternatively, Bayer/Monsanto could have chosen to:

- Replace the high-risk POEA surfactants with the safer surfactant the company has used in the Roundup sold in Europe over the last ~ five years,
- Require that applicators wear long sleeve shirts, long pants, shoes, and gloves when applying the product, thereby lowering dermal exposures by 20-fold or more compared to how many plaintiffs in the litigation sprayed the product, and
- Add necessary warnings such as "Frequent and long-term users of this product should exercise caution and take extra steps to minimize exposures," and "Avoid any contact

[29] For details, see https://foe.org/resources/new-roundup-new-risks/.

> with this product if you have cancer or are in remission, if you are immuno-compromised, or are pregnant or hoping to soon become pregnant."

But Bayer/Monsanto did not do those things.

B. Preemption would reward registrants for resisting warning statements and ignoring new science

Most pesticide manufacturers are concerned that if they place a health warning on a pesticide label, the warning may reduce the demand for the product. Plus, avoiding the presence of any health-related warnings or cautionary statements on a product's label provides the registrant the opportunity to challenge failure to warn claims in state courts on the grounds of preemption (i.e. the scenario in this case).

In the 1980s there were no studies published reporting that glyphosate could damage DNA and thereby increase the risk of cancer. But in the 1990s such studies began to appear in peer-reviewed journals. Had Monsanto alerted EPA to such new scientific insights, and shared Dr. Parry's reports, the EPA might have re-evaluated glyphosate and Roundup's genotoxicity, and determined that glyphosate does have the ability to damage DNA. If this scenario had played out in the 2000s, it is unlikely that glyphosate would be classified today as "not likely" to pose cancer risk, nor would almost all Roundup labels fail to require applicators to wear gloves.

Resisting the addition of cautionary statements or warnings on Roundup labels has been one of the two central goals in what is referred to inside Monsanto as Roundup's "Freedom to Operate" (FTO).[30] For example, the EPA released a Glyphosate Registration Standard document in 1986 that spelled out what Monsanto needed to do to retain its current Roundup labels. This EPA document required Monsanto to add several new provisions on Roundup labels to reduce dermal exposures (e.g., wear gloves and chemical-resistant footwear when applying the product). Monsanto refused to make such additions. This course of action also preserved the opportunity for Monsanto to invoke preemption as a defense in the event of future civil litigation asserting a failure to warn, or the lack of proven PPE requirements like "wear gloves."

In response to Monsanto's refusal in 1987 to add the exposure reduction provisions called for by EPA in the 1986 Glyphosate Registration Standard,[31] the agency's only recourse would have been initiating steps that could lead to cancellation of existing Roundup registrations, a course of action the agency did not pursue. Had EPA moved to cancel Roundup labels, it would have been challenged on the grounds that the agency had not found that Roundup risks exceed its benefits.

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[30] The other core FTO goal is gaining approval of as many new Roundup uses as possible, including non-agricultural applications.

[31] Most of the 1986 exposure-reduction requirements are still not incorporated in Roundup labels.

CONCLUSION

The diversity and frequency of Roundup uses have risen sharply since the early 1980s, as have routes of exposure and levels of exposure. Monsanto was aware that some Roundup users were applying the herbicide more often, and more intensively, than analyzed by EPA. Hence, the company knew some users were likely to experience higher levels of exposure than anticipated by the EPA. Well before Mr. Durnell bought his first Roundup, Monsanto could have augmented lawn and garden Roundup labels to provide frequent users with guidance on how to reduce exposures and risk levels.

If the Petitioner prevails, one consequence will be vesting in the EPA's initial approval of a label an unwarranted degree of scientific certainty across all possible ways and intensities of pesticide use. EPA approval does not mean the agency has assessed all possible exposure and risk scenarios.

Every decade, new mechanisms are identified through which exposure to pesticides can harm people. How the EPA keeps up with evolving science, and who bears the burden of proof of safety, or lack thereof, has been a recurrent focus of debate when Congress has considered amendments to FIFRA. Currently, pesticide registrants bear the burden of generating data in response to EPA data requirements. Such testing requirements cover some common mechanisms through which pesticides can harm people, but clearly not all.

Congress added Section 6(a)2 to FIFRA, the so-called adverse effects reporting requirement, to require pesticide registrants to provide EPA any new information that becomes available to the registrant.

The purpose is to keep the EPA abreast of new science and insights. This would then presumably allow such new information to be drawn upon in fine-tuning pesticide risk assessments, and when justified, *adding new risk-mitigation measures onto labels*.

But as a matter of corporate policy, some registrants are hesitant to add new warnings onto labels even when evolving science points to the need for such measures and warnings. Preemption would markedly enhance the long-term benefits of such reticence. It would constitute a gift to the pesticide industry that would emasculate FIFRA and reward the sorts of corporate behavior that brought the *Bates* case and this case before the Court.

FIFRA provides many mechanisms through which state-specific control needs and risk mitigation goals can be accomplished. Preempting the role of states in pesticide regulation will make such cooperative state-federal efforts more difficult. It could also render them more vulnerable to future legal challenges on the basis of deviation from the provisions on EPA-approved labels.

The Court's task is to determine if glyphosate exposure through the diet is equivalent under the law to dermal exposures to Roundup. The convoluted and strained pro-preemption arguments advanced by Bayer/Monsanto and its supporters in this case are the same as those advanced periodically since the 1980s. They have not improved with age.

By affirming the judgment of the Missouri Court of Appeals, this Court can encourage Congress to revisit and reform the provisions in FIFRA that have allowed mismanagement and ineffectual regulation of pesticides to persist, and indeed worsen in the case of

Roundup over four decades. Recent regulatory developments and litigation illustrate the degree to which pesticide regulatory science and decision-making in the U.S. is strained, if not broken. The underlying tensions that have again brought this preemption case before the Court surely belong among the issues Congress should now address.

For the foregoing reasons, the Court should affirm the judgment of the Missouri Court of Appeals.

Respectfully submitted,

Jesse A. Buss
WILLAMETTE LAW GROUP, PC
411 Fifth Street
Oregon City, OR 97045

Counsel of Record for Heartland Health Research Alliance

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