**In the Supreme Court of the United States**

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Monsanto Company, Petitioner
v.
John L. Durnell, Respondent

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# Brief of the Heartland Health Research Alliance as *Amicus Curiae* in Support of Respondent

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Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973

## 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 results in approximately 75,000 maternal and 500,000 infant deaths annually; the rapid rise of metabolic syndrome among children, including evidence that glyphosate may be associated with the onset of liver disease in children as young as age four[3].

HHRA is committed to helping the nation achieve the regulatory goals set forth in the Federal Insecticide, Fungicide, and Rodenticide Act. Toward this 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, and will continue to grow in step with rising diversity in the ways pesticide are used across the country.

Scientists working with HHRA have been involved in pesticide rulemakings and litigation, including *Durnell v. Monsanto*, and cases involving the impacts of pesticides on cancer, Parkinson's disease, and a child's 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. In March, 2025 HHRA submitted comments on a petition submitted to EPA from 11 Attorneys General entitled **Petition Seeking Rulemaking to Modify Labeling Requirements for Pesticides and Devices, Docket ID# EPA-HQ-OPP-2024-0562**. These comments highlighted the ways that preemption[4] would impact the state-federal partnership created in FIFRA. The Attorneys General petition seeks an outcome via regulatory reform comparable to that sought here by petitioner Bayer/Monsanto, and by the pesticide industry via Congressional and/or state-level legislation.

[1] Petitioner's and Respondent's counsel were provided timely notice of this brief in accord with Supreme Court Rule 37.2. No party in this appeal, or counsel for a party, wrote or contributed to this brief. HHRA received no financial contribution in support of the preparation and submission of this brief.

[2] Freisthler et al., 2023. https://link.springer.com/article/10.1186/s12889-023-17171-9

[3] See the results of NIH-funded research at https://pubmed.ncbi.nlm.nih.gov/36856429/

[4] Throughout we use the terms "preempt" and "preemption". We refer to the petitioner as "Bayer/Monsanto" in the interest of clarity regarding the corporations advancing this petition, but refer to "Monsanto" when discussing issues and actions that occurred prior to Bayer's acquisition of Monsanto.

## SUMMARY OF ARGUMENT

The relief sought by Bayer/Monsanto would markedly curtail the role of states and state law in avoiding "unreasonable" adverse human, economic[5], and environmental effects stemming from legal and labeled pesticide use. In some venues (e.g., state legislatures), proponents of preemption have described the impact of the proposed changes as narrow, indeed little more than a technical correction. But the effectiveness of FIFRA rises and falls on the fluidity and coherence of state plus federal contributions to labeling. Petitioner claims EPA controls all aspects of labeling. This is not true. FIFRA provides states multiple mechanisms to alter existing label provisions, or add new ones via supplemental labeling, or 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 the EPA the "author" of such pesticide labeling, ***nor does it mean that the EPA has rendered judgement on the need for, or adequacy of such label changes***. EPA cannot render such judgements 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 prevent "unreasonable" adverse effects. Petitioner 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 judgement 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 in *Durnell* came to understand during trial.

[5] Economic losses like reduced crop yields as in *Bates*, income and health-care expenses as in *Durnell*, harm to companion animals, damage to bee hives.

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 tallowamine (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.[6] The EPA's analysis of glyphosate toxicology and dietary risks led to the agency's "not likely" to pose cancer risk judgement for the general population. Petitioner asks this Court to assume that the same judgement, 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 clearly are not, as became clear to the *Durnell* jury.

Since *Bates v. Dow Agrosciences*, 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, and sometimes for miles, as well as the proliferation of new pesticide uses that sometimes lead to high-risk exposure patterns.[7]

Without a full evaluation of the impacts of preemption on the roles of states and federal EPA in pesticide regulation, the law of unintended consequences will have a field day. When problems emerge with pesticide efficacy or human injury, Courts will be called upon to sort out who is liable, if anyone, and what constitutes fair compensation. The primary defense advanced by pesticide registrants will continue to be "we did what EPA required us to do", augmented by the assertion that EPA approval of a label means the label must be perfect and prescient, and must adequately address all potential high-risk scenarios. This assertion does not pass the laugh test and should no longer shield pesticide registrants from liability when they write and retain labels that fail to avoid unreasonable adverse effects, e.g., non-Hodgkin lymphoma.

The Court should not solve Bayer/Monsanto's near-term, litigation-driven fiscal crisis via expanding the scope of preemption, thereby creating more consequential problems that will plague U.S. farmers and pest managers, the general public, and regulatory officials for many years, if not decades.

## ARGUMENT

## I. The Pesticide Industry's 2026 Quest for Preemption and Key Facts

[6] 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.

[7] 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.

Current Supreme Court precedence and guidance regarding preemption was established in the *Bates v. Dow Agrosciences* case brought to this Court in 2003 by Texas peanut farmers who had suffered economic losses in 2000 from lawful applications of Strongarm (diclosulam), a 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.[8] 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 such a warning was needed to avoid economic losses for farmers.

The Bayer/Monsanto argument advanced in support of preemption in *Durnell* 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. In its Amicus Brief, the government states that FIFRA "vests EPA with responsibility to determine" (p. 4) 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 lack thereof.

Regrettably, the EPA never has, and never will possess all the knowledge and scientific insights required to fully anticipate and mitigate all unreasonable adverse effects stemming from lawful pesticide use. The *Bates* Opinion includes a passage that quotes the opinion in *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991). This case involved the preemption of a town's ordinance requiring a special permit prior to a person making an aerial application of a pesticide. The Court's order acknowledges the limits of EPA's ability to address all local and regional risk scenarios given the tools and authorities provided in FIFRA:

> "Although the ordinance 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 %136v(a)."[9]

[8] 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'". (Emphasis added)

[9] It is worth noting that 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.

If the Court embraces Bayer/Monsanto's largely identical argument in this appeal of *Durnell*, the outcome would, in the words of the Court in *Bates*, "... give pesticide manufacturers virtual immunity from certain forms of tort liability." It is ironic that many farmers and most farm organizations are among the most ardent proponents of preemption since it would shift the burden of preventing herbicide crop damage from registrants to them. And when damage occurs, preemption will largely eliminate the only viable path to compensation opened up by the Texas peanut farmers in *Bates*.

In *Durnell*, the preemption dispute is over whether in the years Durnell purchased Roundup, Monsanto had an obligation embedded in FIFRA and state law to warn applicators that frequent and repeated use of formulated lawn and garden Roundup could lead to heightened risk of cancer.

### A. Distinctions Between Glyphosate and Formulated Roundup

To understand the legal issues in dispute in this case, 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, because of the presence of POEA surfactants.

Yet the toxicology studies Monsanto generated and supplied to EPA to gain Roundup registrations, and 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 bough 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, a handful has become hundreds of published studies supporting an association between repeated dermal exposures to formulated Roundup and cancer. In *Durnell*, 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.[10]

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.[11]

### B. The Illusory Distinction in FIFRA Between Pesticide Use and Labeling

In the government's Amicus Brief, the assertion is made that FIFRA draws "a bright line between pesticide use—where States have concurrent authority to regulate—and labeling—where EPA is in charge." (p.7)

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 can be treated, how a pesticide can be applied, 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.

[10] 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.

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

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, a point in time 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, and warnings and cautionary statements. That is the registrant's job, and ***responsibility*** under FIFRA.

Cut to its core, the question before the 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 offering use directions and warnings needed to reduce much higher risks via a different route of exposure (dermal) to a different chemical (formulated Roundup). HHRA believes it does not, and explains why in the balance of this brief.

### C. Pesticide Manufacturers Decide What to Place on Labels

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 sales and profits.

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

### D. Evidence Presented in Durnell Contradicts Bayer/Monsanto's Claim of "No Evidence" of Cancer Risk

Three causes of action are cited in most cases brought in the Roundup-NHL litigation: failure to warn, design defect,[12] and negligence. The Court is now asked to determine whether FIFRA preempts the *Durnell* failure to warn cause of action because Monsanto had chosen not to include a cancer warning, and EPA had not required 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 studies consistently confirmed Roundup posed no cancer risk. However, as the *Durnell* trial proceeded, juries 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, albeit disputed, epidemiology 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.

Juries 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 *Durnell* jury also heard extensive testimony, and viewed multiple Monsanto documents, describing efforts by Monsanto 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 hid relevant data from EPA, or obscured the results of some of its own studies that reinforced an association between Roundup and cancer.[13]

## II. State Roles in Pesticide Regulation and the Mitigation of Risks

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

[13] 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).

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

> "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 %136v."

Congress authorized states to propose and gain EPA approval of supplemental labels.[14] According to EPA, "Compliance with both the product label and supplemental labeling is required to safely and effectively use the product" (Label Review Manual, p. 3.3). 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" (Label Review Manual p. 4-10). 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 Federal 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:

> "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).**[25]**"

Footnote **25** in the above quoted passage encapsulates several contested issues in *Durnell*:

> "Given the inherently dangerous nature of pesticides, most safety gains are achieved not through modifying a pesticide's design, but by ***improving warnings and instructions contained on the label***." (Emphasized 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

[14] 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

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 in 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 Chapter 206 Section 206.11) (Emphasis added)

The highlighted portion of the above quote codifies the fact that under Iowa law, it can be 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,*** and is highly relevant in this case. 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 sates 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 on 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 9$^{th}$ Circuit, 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,[15] and in some cases, adjudicated.

University scientists have estimated that millions of acres each year have been adversely impacted by dicamba movement in 2017-2024. In the judgement of the 9th 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 was 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.[16] 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 tract changes in dicamba exposures among pregnant women in the Midwest, HHRA invested over $65,000 in developing an improved, lower-cost method to quantify dicamba in urine.[17] 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.[18]

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[15] 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.

[16] https://hh-ra.org/wp-content/uploads/2023/01/HHRA_Dicamba_Comments_10-17-22.pdf

[17] The published methods paper is Larosse et al., 2023.
https://www.sciencedirect.com/science/article/pii/S004565352302619X

[18] Daggy et al., 2024. https://www.mdpi.com/2813-3145/3/1/5

In 2024 comments to EPA in the rulemaking focused on re-approval of the OTT dicamba labels vacated in 2024,[19] HHRA shared the above data showing markedly rising dicamba levels in the urine of pregnant women, and opining that the increase was almost certainly brought about by OTT dicamba applications. We raised concern 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[20] 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,[21] whichever comes first"; and
- 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*** (3 companies with labels multiplied by 34 states).[22]

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 unwelcomed 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.

## III. The Known and Unknown Consequences of Preemption

[19] https://hh-ra.org/wp-content/uploads/2023/01/HHRA_Dicamba_Comments_10-17-22.pdf

[20] 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.

[21] 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.

[22] Actually, it will likely be over 400 state-centric federal labels, since the three companies are expected to market, on average, at least four OTT dicamba products to market in 2026.

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 application 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 in *Durnell*. This argument would be more persuasive 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 its *Bates* opinion, the Court makes 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..."

The Opinion then quotes a passage from *Ferebee*, 736 F. 2d, at 1541-1542. 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. Successful actions of this sort may lead manufacturers to petition EPA to allow more detailed labeling of their products..."

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.[23]

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 arguably unlawful steps to lock away Dr. Parry's reports.[24]

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 unwelcomed consequences from successful efforts to get or keep risky pesticide uses onto EPA approved labels, and without adding label provisions to mitigate newly recognized risks.

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 -- 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.[25] 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,
- Required 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 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".

[23] 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.

[24] Once the existence of the three Parry reports was disclosed as part of the early trials in 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.

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

### B. Preemption Will Award 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 *Durnell* scenario).

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).[26] 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,[27] 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.

## IV. Conclusions

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

[26] The other core FTO goal is gaining approval of as many new Roundup uses as possible, including non-agricultural applications.
[27] Most of the 1986 exposure-reduction requirements are still not incorporated in Roundup labels.

by the EPA. Well before 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 a 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* and *Durnell* cases 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 the government via its Amicus Brief, are the same as those advanced periodically since the 1980s. They have not improved with age.

The Court should affirm, and encourage the 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 court cases drive home 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 a preemption case before the Court surely belong among the issues Congress should now address.