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 *AMICI CURIAE* AMERICAN TORT REFORM ASSOCIATION, TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT, CENTER FOR TRUTH IN SCIENCE, INTERNATIONAL SOCIETY FOR REGULATORY TOXICOLOGY AND PHARMACOLOGY, CIVIL JUSTICE ASSOCIATION OF CALIFORNIA, PENNSYLVANIA COALITION FOR CIVIL JUSTICE REFORM, NEW JERSEY CIVIL JUSTICE INSTITUTE, FLORIDA JUSTICE REFORM INSTITUTE, AND ILLINOIS COALITION FOR LEGAL REFORM IN SUPPORT OF MONSANTO COMPANY AND REVERSAL

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are organizations committed to ensuring that regulatory decision-making and civil liability are based on sound science rather than litigation-driven theories or hazard classifications divorced from real-world risk. Collectively, *amici* represent national and state civil justice groups, and scientific organizations. *Amici* have a substantial interest in this Court's resolution of the preemption question presented, as it will determine whether comprehensive federal risk assessments conducted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) will be displaced by state tort claims premised on faulty hazard classifications.

The American Tort Reform Association (ATRA) is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For more than three decades, ATRA has filed *amicus* briefs in cases involving important liability issues. ATRA has a longstanding interest in exposing questionable science that is manufactured or misused to support litigation.[2]

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[1] Pursuant to Rule 37.6, counsel for *amici curiae* authored this brief in whole. Counsel for *amici* discloses that other Shook, Hardy & Bacon LLP attorneys are among counsel to Monsanto Company in glyphosate litigation and appeared in the trial court below. No person or entity, other than *amici curiae*, their members, or their counsel made a monetary contribution to the preparation or submission of the brief.

[2] *See, e.g.,* American Tort Reform Ass'n, The Junk Science Playbook (2026).

Toxicology Excellence for Risk Assessment (TERA) is a 501(c)(3) nonprofit organization founded in 1995. TERA's mission is to assist governments, industries, and other nongovernmental organizations in evaluating the safety and risks associated with environmental chemical exposures; to develop toxicology and risk assessment values; and to educate both risk assessors and the public on environmental and public health issues.

Founded in 2020, the Center for Truth in Science ("the Center") is an independent, non-profit organization that focuses on issues at the intersection of science, justice, and the economy. The Center's objective is to contribute to a judicial system in which liability and damage awards are based on fact-based science. The Center has carefully examined whether conclusive, consistent scientific evidence demonstrates a link between exposure to glyphosate and the development of cancer or other chronic illnesses.

The International Society for Regulatory Toxicology and Pharmacology (ISRTP) is a 501(c)(3) scientific society formed in 1984. The purpose of ISRTP is to provide an open public forum for policy makers and scientists to promote sound toxicologic and pharmacologic science as a basis for regulation affecting human safety, health, and the environment. ISRTP is unique in its firm understanding of toxicology as it relates to regulatory policy.

The Civil Justice Association of California (CJAC) is a nonprofit organization whose members are businesses from a broad cross section of industries. CJAC's principal purpose is to educate the public and its governing bodies about how to make laws determining who gets paid, how much, and by whom

when the conduct of some causes harm to others – more fair, certain, and economical. Toward this end, CJAC regularly appears as amicus curiae in numerous cases of interest to its members, including those that raise issues of concern to the business community. CJAC and its members are particularly interested in making sure that the courts evaluate scientific evidence rigorously to prevent the use of junk science to expose businesses to unwarranted liability. Thousands of glyphosate cases are pending in coordinated litigation in California, and its courts have hosted a $2 billion Roundup verdict.

The Pennsylvania Coalition for Civil Justice Reform is a statewide, nonpartisan alliance of organizations and individuals representing health care providers, professional and trade associations, businesses, nonprofit entities, taxpayers, and other perspectives. The Coalition is dedicated to bringing fairness to litigants by elevating awareness of civil justice issues and advocating for reform. Pennsylvania has been the focus of numerous glyphosate lawsuits, with hundreds filed in the Philadelphia Court of Common Pleas, which have inconsistently resulted in massive plaintiffs' awards ($2.25 billion) and defense verdicts.

The New Jersey Civil Justice Institute (NJCJI) is a bipartisan, statewide group comprised of small businesses, individuals, not-for-profit groups, and many of the State's largest business associations and professional organizations. The NJCJI advocates for a civil justice system that treats all parties fairly, and it has a strong interest in the clear, predictable, and fair application of the law. The New Jersey judiciary established a multicounty litigation docket for Roundup product liability claims in 2025.

The Florida Justice Reform Institute ("Institute") is Florida's leading organization of concerned citizens, business owners, and business leaders who share the common goals of promoting predictability in Florida's civil justice system, protecting the rule of law, limiting excessive liability, and promoting fair and equitable legal practices. As a nonpartisan advocate for a stable and reliable legal framework, the Institute has a long history of participating as *amicus curiae* in significant appellate cases. The Institute has long supported efforts to ensure that liability is based on sound science.

The Illinois Coalition for Legal Reform (ICFLR) is a nonpartisan organization formed in 2023 to combat abusive litigation and excessive jury verdicts by creating a fair, efficient, and predictable legal system for all Illinois citizens. Active in the legislature and the courts, the ICFLR is dedicated to building a civil justice system that is fair to all litigants and conducive to job and economic growth.

SUMMARY OF ARGUMENT

The issue before this Court is whether the U.S. Environmental Protection Agency's (EPA) comprehensive review of the safety of glyphosate, and its approval of labeling for products that include glyphosate, under the Federal Insecticide, Fungicide, and Rodenticide Act's (FIFRA) regulatory framework, preempts state tort claims alleging that a manufacturer failed to warn of a risk of cancer that the EPA found unsubstantiated. When evaluating preemption, the Court should consider the alternative: substituting the EPA's analysis and conclusion with that of the International Agency for Research on Cancer

(IARC) and plaintiff-retained expert witnesses in numerous individual trials.

As this brief will show, mass tort litigation over glyphosate arose not from a scientific consensus that it presents a danger, but from IARC's classification of glyphosate as "probably carcinogenic," a designation that ignores exposure levels, dose-response relationships, and real-world risk. IARC's hazard-identification approach routinely labels everyday substances—from red meat to hot beverages—as carcinogenic with adjectives including "probably," "possibly," and "not classifiable" that are not scientific and confusing to both jurors and the public. Scientists have repeatedly criticized IARC for using an outdated, flawed method that leads to needless public concern. IARC's classification of glyphosate nevertheless sparked mass tort advertising campaigns and is the foundation for thousands of lawsuits targeting Roundup, illustrating how hazard-based determinations can be weaponized in litigation.

The EPA, by contrast, conducts full risk assessments of pesticides that incorporate hazard identification, dose-response analysis, exposure assessment, and risk characterization. After reviewing hundreds of studies under rigorous scientific protocols, EPA has repeatedly concluded that glyphosate does not pose a cancer risk and that cancer warnings are unwarranted.

Federal preemption ensures that warnings reflect comprehensive scientific evaluations by government agencies that have a statutory duty to protect the public rather than outlier views and litigation-driven narratives. Allowing juries to override EPA's scientific determinations would produce inconsistent la-

beling obligations and undermine federal regulatory judgments. Without preemption, litigation could result in the loss of products relied upon to produce food and raise costs for farmers and consumers.

ARGUMENT

I. REQUIREMENTS FOR HERBICIDE LABELING SHOULD NOT BE MADE CASE-BY-CASE IN LITIGATION SPARKED BY A FLAWED IARC CLASSIFICATION

IARC's designation of glyphosate as a probable carcinogen sparked and has fueled mass tort litigation despite the EPA and other health agencies' determination that glyphosate does not cause cancer. Absent preemption, this misleading classification will continue to be presented to juries, leading to inconsistent results. IARC's action, and the litigation it spurred, should be viewed in the context of what its designation actually means and the flaws in IARC's approach.

A. IARC's Propensity for Linking Substances to Cancer

IARC has a clear predisposition toward finding substances it studies can cause cancer, often with limited evidence in support and without considering the actual level of risk, based on the level of exposure, the substance presents.

Over five decades, IARC has classified chemical, physical, and biological substances, working conditions, and other exposures of everyday life and activities as carcinogenic (Group 1), probably carcinogenic (Group 2A), or possibly carcinogenic (Group 2B) to humans. *See* IARC, Preamble, IARC Monographs on the Identification of Carcinogenic Hazards to Hu-

mans, at 1 (amended Jan. 2019). Of 1,055 agents IARC has studied, it has placed more than half, 556, in one of these three cancer-causing categories.[3] As for the remainder, IARC places them in Group 3—"not classifiable." *See* IARC, *Preamble,* at 36 (cautioning that placement in Group 3 "is not a determination of non-carcinogenicity or overall safety," but that the agent is of "unknown carcinogenic potential" or indicates "significant gaps in research").

IARC has found that many products people use and ordinary activities possibly or probably cause cancer. For instance, IARC found, in 2011, that using a mobile phone is possibly carcinogenic, increasing the risk of a malignant type of brain cancer.[4] Individuals working as hairdressers or barbers, according to IARC, are subject to exposures that probably cause cancer.[5] Yet, there is no sign of an epidemic of brain cancer even as cell phone use has become ubiquitous or an outbreak of sick barbers.[6]

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[3] *See* IARC, Agents Classified by the IARC Monographs, Volumes 1–140, https://monographs.iarc.who.int/agents-classified-by-the-iarc/ (last visited Feb. 27, 2026).

[4] *See* IARC, Non-ionizing Radiation, Part 2: Radiofrequency Electromagnetic Fields, Vol. 102, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (2013).

[5] *See* IARC, Occupational Exposures of Hairdressers and Barbers and Personal Use of Hair Colourants; Some Hair Dyes, Cosmetic Colourants, Industrial Dyestuffs and Aromatic Amines, Vol. 57, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 107 (1993).

[6] Over a decade later, after IARC suggested that five billion people were at risk for brain cancer from mobile phone use, IARC researchers reassessed the evidence and found that heavy mobile phone users do not have a greater risk than light users for brain cancer. *See* Maria Feychting et al., *Mobile Phone Use*

For decades, IARC classified coffee as "possibly carcinogenic," indicating it may cause bladder cancer. *See* IARC, Drinking Coffee, Mate, and Very Hot Beverages, Vol. 116, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, at 33 (2018). It took numerous studies finding otherwise, with some finding that coffee has health benefits, for IARC to reclassify drinking coffee as Class 3, indeterminate. *See id.* But while IARC exonerated coffee itself, it found that "drinking very hot beverages," including, but not limited to coffee, is "probably carcinogenic," potentially leading to cancer of the esophagus. *Id*. In addition, IARC noted that its carcinogenic classifications of several compounds present in coffee stemming from the roasting process remain. *See id.* at 65-68; *see also* Sharon Begley, *Coffee Doesn't Cause Cancer After All, May Be Protective, Says WHO*, Stat, June 15, 2016; Nick Triggle, *Cancer Risk from Coffee Downgraded*, BBC, June 15, 2016.

IARC has also declared that eating red meat, including steak and ground beef is probably carcinogenic (Group 2A), while classifying consumption of processed meats, such as bacon, at Group 1, the same level as plutonium and asbestos. *See* IARC, Red Meat and Processed Meat, Vol. 114, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (2018); *see also* Kate Kelland, *Who Says Bacon is Bad? How the World Health Organization's Cancer Agency Confuses Consumers*, Reuters, Apr. 18, 2016.

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and Brain Tumour Risk – COSMOS, A Prospective Cohort Study, Env. Int'l 185 (2024).

While, historically, IARC had a Group 4 for substances found to be "probably not" carcinogenic, IARC abandoned that classification in 2019, moving the one substance in it, a compound used to make nylon used in toothbrush bristles and surgical sutures, into Group 3.[7] In other words, IARC either finds that substances it reviews cause cancer or that there is not enough evidence yet to find that they cause cancer. IARC does not even provide itself with the option of finding that a substance is *not* or *not likely* carcinogenic.

B. Comparing Hazard Identification to a Risk-Based Approach

The reason IARC is prone to label substances, products, occupations, and activities as carcinogenic is that its classifications mean only that an agent is "capable" of causing cancer. *See* IARC Preamble, *supra*, at 2. As IARC itself explains, it engages in "hazard identification," which identifies agents as carcinogenic even when widespread exposure at low levels poses a low or unknown risk. *See id.* The organization does not attempt to assess exposure-response relationships, which is the purpose of epidemiological studies. *See id.*

Rather, the organization often bases its classifications on evidence that, when exposed to extreme amounts of a substance under what may be highly unlikely conditions, animals, often rodents, sometimes develop cancer. Of course, any substance, even water, can be toxic if too much is ingested or ab-

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[7] *See* IARC, List of Classifications, IARC Monographs, Volumes 1–140 (Caprolactam), https://monographs.iarc.who.int/list-of-classifications (last visited Feb. 27, 2026).

sorbed,[8] but that does not mean that water warrants a warning label.

In addition, IARC's classifications do not indicate the degree of that risk based on the potency of the substance. Obviously, eating bacon does not pose the same cancer threat as being exposed to plutonium, yet they share the same IARC classification level.

In other words, IARC's classification of a substance as carcinogenic does not consider a central tenet of toxicology: the dose makes the poison. As one toxicologist has observed, "There are a wide variety of substances that may be labeled as carcinogenic . . . but in real life we could never consume enough or be exposed to enough to suffer adverse consequences." In Defense of Scientific Integrity: Examining the IARC Monograph Programme and Glyphosate Review: Hearing Before the H. Comm. on Sci., Space & Tech., 115th Cong., 2d Sess., Serial No. 115-46, at 59 (Feb. 6, 2018) (testimony of Dr. Timothy Pastoor).

These nuances are often lost when IARC's classifications are communicated to the public or jurors. IARC's classification decisions are often accompanied by press releases that are picked up and amplified by the media, causing what is often unwarranted public concern.[9]

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[8] *See* Toxicology Educational Found., Toxicity Today – Botox®, https://www.youtube.com/watch?v=fFvYUdljVK0 (explaining how substances from Botox to water can be toxic depending on the exposure level).

[9] *See, e.g.*, IARC, Press Release, IARC Classifies Radiofrequency Electromagnetic Fields as Possibly Carcinogenic to Humans, May 31, 2011 (suggesting that an estimated five billion mobile phone users are at risk of brain cancer).

While IARC's approach might have been reasonable a half century ago when the organization established its monograph program, the wealth of knowledge and understanding on how chemicals cause cancer since then has fueled the development of risk-based approaches. *See* Richard A. Becker, et al., *Beyond Key Characteristics of Carcinogens: An Archetypal MOA-based Evidence System for Hypothesis Testing to Advance Carcinogen Risk Assessment*, J. of Toxicology & Reg. Pol'y 1, 5 (2025). In a seminal report, the National Research Council explained the risk-based approach. *See* National Research Council, Committee on the Institutional Means for Assessment of Risks to Public Health, Risk Assessment in the Federal Government: Managing the Process (Nat'l Academies Press 1983). As that report recognizes, hazard identification is just the first step in assessing the health effects of exposure to a substance. *See id*. at 3. If a substance is identified as capable of causing cancer during that first step, a risk-based approach also includes:

- Dose-response assessment: The determination of the relation between the magnitude of exposure and the probability of occurrence of the health effects in question.
- Exposure assessment: The determination of the extent of human exposure before or after application of regulatory controls.
- Risk characterization: The description of the nature and often the magnitude of human risk, including attendant uncertainty.

Id. At any of these steps, the evaluation might indicate that a substance poses little or no risk and

therefore can be removed from regulatory consideration until new data indicate a need for reevaluation." *Id*. at 39. Today, health organizations worldwide, including the EPA, use this risk-based approach. In the absence of preemption, juries will be pushed to determine the adequacy of labeling based on IARC's hazard identification rather than the EPA's more robust risk-based analysis.

C. IARC's Process is Contrary to Sound Science and Criticized as Fearmongering

IARC's findings are often directly contradicted by health experts and government agencies that carefully study the health and safety impacts of products and activities.

"[E]xperts from academia, industry and public health say IARC confuses the public and policymakers" and criticize its approach as "flawed." Kelland, *Who Says Bacon is Bad?, supra.* For instance, Geoffrey Kabat, a cancer epidemiologist at the Albert Einstein College of Medicine, has expressed concern that IARC's classifications do the public a "disservice" by focusing on "theoretical exposures which might, under some far-fetched conditions, possibly have an effect." *Id*.

For example, in 2023, IARC announced that it had classified the sweetener aspartame as "possibly carcinogenic." *See* IARC, Aspartame, Methyleugenol, and Isoeugenol, Vol. 134, IARC Monographs on the Identification of Carcinogenic Hazards to Humans 488 (2024). As a result, consumers were alerted that products from diet soda to chewing gum, according to IARC, cause cancer. *See* Richa Naidu & Savyata Mishra, *Consumers, Food-makers Face Choice as*

WHO Cancer Agency Set to Warn on Aspartame Sweeteners, Reuters, June 30, 2023. The U.S. Food and Drug Administration promptly rejected IARC's conclusion, noting that "[a]spartame is one of the most studied food additives in the human food supply," reassuring consumers that "FDA scientists do not have safety concerns when aspartame is used under the approved conditions." U.S. Food & Drug Admin., Press Release, *Aspartame and Other Sweeteners in Food*, July 14, 2023. The FDA noted "significant shortcomings in the studies on which IARC relied" and emphasized that "being labeled by IARC as 'possibly carcinogenic to humans' does not mean that aspartame is actually linked to cancer." *Id*. IARC's determination is reminiscent of the late 1970s, when saccharin (e.g., Sweet 'N Low) was nearly banned and, instead, a cancer warning was mandated on the product, based on studies in which generations of rats were fed the equivalent of 800 cans of soda or 10,000 packets per day.[10]

Another example of IARC's flawed methodology at work is implicated in the litigation before this Court: IARC's classification of glyphosate. Glyphosate is a widely used herbicide that is critical to agriculture, land management, and food production worldwide because it can kill weeds and grasses without causing material risks to human health. In 2015, IARC classified glyphosate as "probably car-

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[10] *See* Rich Cohen, Sweet and Low 134-37 (Farrar, Straus and Giroux 2006). IARC reclassified saccharin from possibly carcinogenic to not classifiable in 1999. IARC, Some Chemicals that Cause Tumours of the Kidney or Urinary Bladder in Rodents and Some Other Substances: Saccharin and its Salts, Vol. 73, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, at 517-607 (1999).

cinogenic" and noted a "positive association" with non-Hodgkin lymphoma. IARC, Some Organophosphate Insecticides and Herbicides, Vol. 112, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 398 (2017). IARC acknowledged that this finding was primarily based on evidence from high-dose animal studies of pure glyphosate.[11] It reached this outcome even as global health and environmental regulators, including the EPA, deemed it safe for use. *See National Ass'n of Wheat Growers v. Bonta,* 85 F.4th 1263, 1270 (9th Cir. 2023) ("[W]hile IARC deems glyphosate 'probably carcinogenic to humans,' as the district court observed, 'apparently all other regulatory and governmental bodies have found the opposite.'").

The EPA considered and disagreed with IARC's classification of glyphosate, noting that the agency "considered a significantly more extensive and relevant dataset" than IARC, including both studies submitted to support registration of glyphosate and studies EPA identified in the open literature. *See* EPA, Glyphosate, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate (last updated May 9, 2025). The EPA has also rejected IARC's classification of atrazine, the second most widely used herbicide in the United States, as "probably carcinogenic to humans,"[12] finding the classification based on a "deeply flawed approach" that would "unnecessarily stir up fear." Sophia Samantaroy, *US EPA Dismisses WHO Cancer Agency Determination that*

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[11] *See* IARC, Q&A on Glyphosate, Mar. 1, 2016.

[12] Russell C. Cattley et al., *Carcinogenicity of Atrazine, Alachlor, and Vinclozolin,* 27 The Lancet 11 (Nov. 2025) (to be published as an IARC monograph).

Widely Used Herbicide is 'Probably Carcinogenic', Health Policy Watch, Jan. 5, 2026 (quoting EPA press office).

Recently, the Alliance for Risk Assessment (ARA), a collaboration of organizations that foster the development of technical chemical risk assessment products and services, conducted a workshop that included a debate on the carcinogenicity of glyphosate.[13] The primary point of contention during this debate was IARC's focus on hazard identification versus all other organizations' reliance on risk-based approaches, as discussed earlier.[14] This distinction, participants observed, led to IARC's determination that glyphosate causes cancer, while government agencies find that it does not.

Accordingly, IARC's hazard-only approach should be considered outdated and its erroneous judgment that glyphosate causes cancer should not be substituted for that of the EPA, particularly when the EPA has done an extensive risk assessment, as opposed to IARC's reliance on identification of a hazard, not a risk.

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[13] The ARA is affiliated with *amicus curiae* TERA. Since 2010, ARA has sponsored a workshop series titled Beyond Science & Decisions: From Problem Formulation to Comprehensive Risk Assessment. This was the fifteenth such workshop. IARC was invited but declined to participate in the workshop. *See* Alliance for Risk Assessment, Beyond Science and Decisions: From Problem Formulation to Dose-Response Assessment, Workshop XV, Nov. 19-20, 2025, https://www.tera.org/Alliance%20for%20Risk/ARA_Dose-Response.htm.

[14] *See* Alliance for Risk Assessment, Case Study #1 Summary, Does Glyphosate Cause Cancer?, https://www.tera.org/Alliance%20for%20Risk/Workshop%20XV/CaseStudy1/CaseStudy1Summary.pdf.

D. Potential Conflicts of Interest

IARC has been criticized for failing to address potential conflicts of interests. Members of its working groups "generally have published research related to the exposure or carcinogenicity of the agents being reviewed." *See* IARC, Preamble, *supra*, at 4. Given this background, members of IARC working groups may have pre-determined viewpoints, and a vested interest, in finding that certain products should be classified as a carcinogen. *See* Kelland, *Who Says Bacon is Bad?*, *supra*. Of 18 monographs published by IARC between 2012 and 2015, 61 of the 314 scientists who served on these working groups relied on "their own scientific research" as the bases for IARC conclusions. *Id.* A longtime former IARC staff member, who continues to support the agency, has acknowledged that "IARC's approach sometimes lacks 'scientific rigour' because its judgments can involve experts reviewing their own research or that of colleagues." *See* Kelland, *Who Says Bacon is Bad?*, *supra* (quoting Paolo Boffetta, who worked at IARC for 19 years, rising to become head of the genetics and epidemiology team).

Some individuals involved in the development of IARC monographs have direct ties to the plaintiffs' bar or advocacy groups, receiving compensation as consultants or expert witnesses. For example, Dr. Christopher Portier contributed to IARC's assessment of glyphosate—as an "invited specialist" to its working group. Simon Marks, *The Man Who Haunts Europe's Food Safety Watchdog*, Politico, July 9, 2018. Before the monograph's release, Dr. Portier reportedly received at least $160,000 from lawyers who claim glyphosate exposure causes cancer. *See id.*

Dr. Portier also reportedly received consulting fees from the Environmental Defense Fund, an organization opposed to glyphosate. *See* Hank Campbell, *California Pulls the Plug on Trial Lawyers Hoping to Get Rich Off Glyphosate Lawsuits*, Am. Council on Science & Health, Feb. 27, 2018.

Following Dr. Portier's arrival at IARC, the organization's glyphosate study was altered in at least ten significant ways to remove or reverse conclusions finding no evidence of carcinogenicity, a *Reuters* investigation found. *See* Kate Kelland, *In Glyphosate Review, WHO Cancer Agency Edited Out 'Non-carcinogenic' Findings*, Reuters, Oct. 19, 2017. After IARC released the monograph, Dr. Portier went on a self-described "counteroffensive policy" to undermine scientists who did not agree with IARC's classification of glyphosate as a "probable" carcinogen. Marks, *supra*.

IARC's process and the EPA's assessment are very different in these respects. For example, the Federal Advisory Committee Act requires that the FIFRA Scientific Advisory Panel be "fairly balanced in terms of the points of view represented and the functions to be performed." 5 U.S.C. 1004(b)(2); *see also* EPA, FIFRA Scientific Advisory Panel, https://www.epa.gov/sap (last updated Jan. 6, 2026). And where EPA publishes its findings and requests public comment, under the IARC monograph process, "only a select few observers are permitted to attend working group meetings, and no draft documents are ever released for public scrutiny and input." David B. Fischer, *The IARC Monographs Program – Sowing Public Confusion, Controversy, and Criticism: A Commentary*, 1 J. Toxicology & Reg. Pol'y 1, 4 (2025).

The Court should not overlook that IARC has significant potential conflicts of interest that make it prone to finding that an ever-growing number of substances "cause" cancer.

E. IARC Classifications Fuel Litigation

Despite these scientific and ethical shortcomings, IARC's classifications have served as the foundation for mass tort and other litigation. As the *National Law Review* reported, "IARC's findings with respect to carcinogenicity are oftentimes very influential on the course of litigation in the United States." John Gardella, *IARC PFAS Findings Will Influence Litigation and EPA Challenges*, Nat'l L. Rev., Dec. 4, 2023.

IARC's classifications have been used in advertisements to spur or build mass tort litigations, including lawsuits targeting the heartburn drug Zantac,[15] PFAS chemicals,[16] and the artificial sweetener aspartame.[17] In addition, IARC's designation of acrylamide, a compound naturally formed during cooking or food processing at high temperatures, as "probably carcinogenic" contributed to years of litigation in California over whether businesses that roast coffee beans or make French fries should be liable for

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[15] Malman Law, *Zantac Victims Filing Mass Tort Claims*, Mar. 18, 2021 (legal advertisement indicating that IARC has labeled NDMA a likely carcinogen).

[16] Miller & Zois, *Water Contamination Cancer Lawsuits*, (last visited Feb. 27, 2026) (highlighting IARC's determination of a positive association between exposure to PFOA and certain cancers).

[17] TorHoerman Law, *Aspartame Cancer Lawsuit*, July 9, 2024 (inviting the public to contact the law firm as it investigates potential litigation over the cancer effects of aspartame consumption spurred by IARC's classification).

not warning consumers that these foods posed cancer risks.[18]

IARC's classification of glyphosate as probably carcinogenic is another case study. Within months of IARC's issuance of the glyphosate monograph, "personal injury law firms around the United States [were] lining up plaintiffs" to bring mass tort litigation against Monsanto. Carey Gillam, *U.S. Lawsuits Build Against Monsanto Over Alleged Roundup Cancer Link*, Reuters, Oct. 15, 2015. By early 2020, law firms and lead generating companies had spent over $100 million on advertisements to recruit plaintiffs for the litigation. *See* Cary Silverman, Gaming the System: How Lawsuit Advertising Drives the Litigation Lifecycle 44 (U.S. Chamber Inst. for Legal Reform, Apr. 2020). IARC's findings and the World Health Organization logo featured prominently in some of these advertisements.[19] More than 100,000 plaintiffs have sued Monsanto as a result. *See* Pet. Br. at 18-19.

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[18] *See California Chamber of Commerce v. Bonta*, 781 F. Supp. 3d 1071, 1074, 1077 (E.D. Cal. May 2, 2025) (ruling that a California's agency's requirement that foods containing acrylamide include cancer warnings violates the First Amendment because "they convey the message that those foods will cause cancer in humans despite a lack of scientific consensus supporting that conclusion" and distinguishing "hazard assessments" from "risk determinations").

[19] *See, e.g.*, Roundup Legal Helpline TV Spot, 'Roundup Exposure', iSpot.tv, Mar. 29, 2019; Fears Nachawati TV Spot, 'Roundup Lawsuit', iSpot.tv, Mar. 27, 2019; Roundup Advocates TV Spot, 'Alert', iSpot.tv, Dec. 18, 2018; Weitz and Luxenberg TV Spot, 'Monsanto Roundup Legal Helpline', iSpot.tv, June 14, 2017.

In this case, as in other Roundup litigation, IARC's classification was central to the plaintiff's advocacy. The complaint invoked IARC's classification of glyphosate within Group 2A as probably carcinogenic and relied on IARC's conclusion that non-Hodgkin lymphoma is associated with glyphosate exposure. *See* JA 42. The complaint characterized IARC's conclusion as "significant," confirming that "glyphosate is toxic to humans." *Id*. Several pages of the complaint focused on IARC's monograph. *See* JA 57-60. In fact, IARC is referenced 29 times in the complaint. *See* JA 15-87. At trial, jurors were told by the plaintiff's expert witnesses and in the plaintiff's closing argument that IARC was "the gold standard," funded by the World Health Organization and the United State Government. *See Durnell v. Monsanto Co*., No. 1922-CC00221, Tr. Trans., Vol. 12A, at 2968 (Oct. 19, 2023).

II. WHO DECIDES WARNINGS: AGENCIES BASED ON A COMPREHENSIVE EVALUATION OF THE SCIENCE OR INCONSISTENT VERDICTS INFLUENCED BY OUTLIER VIEWS?

The preemption issue before this Court presents two paths for determining the labeling of herbicide products and, potentially, whether those products (and others subject to similar federal regulatory approval) remain available in the United States. The first option is for the Court to find that the product registration process under FIFRA establishes the requirements for product labeling based on the agency's comprehensive, periodic review of all available science. The alternative is to rule that, regardless of the EPA's determinations, whether the products ad-

equately warn of a risk of cancer can be determined, without consistency, in thousands of trials, spurred and supported by the flawed IARC classification.

A. The EPA's Thorough, Risk-Based Evaluation of Pesticides

The briefs of the parties and other *amici* will, no doubt, closely examine the federal statutory and regulatory systems governing pesticide registration and labeling,[20] and EPA's actions related to glyphosate, which are central to determining preemption.[21] This brief contributes to this discussion based on *amici's* experience with this process.

Under FIFRA, EPA must determine that the pesticide does not pose any "unreasonable risk to man or the environment." 7 U.S.C. § 136(bb). To fulfill this statutory responsibility, the EPA's Office of Pesticide Programs (OPP) conducts a risk assessment of each pesticide as part of its registration review. That risk assessment includes the National Research Council's four steps discussed earlier in this brief: hazard identification, dose-response assessment, exposure assessment, and risk characterization.[22] The EPA de-

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[20] *See generally* 7 U.S.C. § 136j(a)(1)(A) (requiring registration of pesticides before it can be sold); 7 U.S.C. §§ 136, 136a (prohibiting misbranded pesticides, including those that the EPA finds lack a warning or cautionary statement that is necessary to protect health or the environment or that is false or misleading).

[21] 7 U.S.C. § 136v(b) (preempting any state "requirements for labeling or packaging in addition to or different from those required under" FIFRA).

[22] *See* EPA, Overview of Risk Assessment in the Pesticide Program, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program (last updated Jan. 23, 2026).

scribes this risk assessment process as "crucial to the process of making decisions about pesticides, both new and existing." *Id*.

OPP is divided into several divisions, each of which analyzes an important part of the risk assessment paradigm.[23] For example, the Health Effects Division reviews experimental animal and human data to determine what level of chemical exposure is safe and what kinds of effects occur when the safe dose is exceeded. That division performs an independent review of studies to evaluate the carcinogenic potential of pesticides, the outcome of which is peer reviewed by a Cancer Assessment Review Committee.[24] Other OPP divisions tackle additional important aspects of a complete risk assessment. In some instances, the EPA requests that a Scientific Advisory Panel evaluate the completeness of the EPA's review, make recommendations for improving the process, and consider whether the scientific literature supports a determination that a pesticide is or is not carcinogenic.[25]

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[23] *See* EPA, Organization Chart for the Office of Chemical Safety and Pollution Prevention (OCSPP), https://www.epa.gov/aboutepa/organization-chart-office-chemical-safety-and-pollution-prevention-ocspp (last updated Feb. 23, 2026).

[24] *See* EPA, Evaluating Pesticides for Carcinogenic Potential, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluating-pesticides-carcinogenic-potential (last updated Oct. 16, 2025).

[25] *See, e.g.*, FIFRA Scientific Advisory Panel Meeting Minutes and Final Report, No. 2017-01, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: EPA's Evaluation of the Carcinogenic Potential of Glyphosate, Dec. 13-16, 2016 (agreeing, based on evidence presented, that "there is no reliable evidence of an association between glypho-

As Monsanto's brief details, the EPA has repeatedly reviewed glyphosate and consistently concluded that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans. The OPP's evaluations of glyphosate have followed its typical procedure in the review of hundreds of studies in experimental animals or exposure studies in humans. Many of these studies were developed under good laboratory practice (GLP) procedures, which give assurance to reviewers and the public that the study was conducted according to risk assessment guidelines and proper quality control.[26]

Certain studies are voluminous including as many as 2,000 pages. Based on the experience of *amici*, it often takes an individual scientist from the OPP up to two weeks to review just one study. OPP reviews all aspects of a study including animal husbandry, dosing formulations and regimes, changes in laboratory conditions, and any other factor that may affect its outcome. If a pesticide scientist at the EPA is not satisfied, he or she can ask the sponsor of the study for additional material, which is not uncommon. Of course, new studies should always be considered, and EPA has done this routinely. It is unsurprising that government agencies throughout the

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sate exposure and any solid tumor, or between glyphosate exposure and leukemia or Hodgkin's lymphoma").

[26] *See* 40 C.F.R. part 160 (prescribing good laboratory practices for conducting studies that support applications for research or marketing permits for pesticide products regulated by the EPA); *see also* EPA, Pesticide Registration Manual, Chapter 15 – Submitting Data and Confidential Business Information (2021) (requiring statement of compliance or noncompliance with GLP standards).

world have reached similar conclusions to EPA. *See, e.g.*, European Food Safety Auth., Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate (2015).

It is disingenuous for scientists unfamiliar with the OPP process or for those who do not have the requisite expertise to contend that the EPA-OPP process and judgment of glyphosate's safety is erroneous. Quite the opposite is true. EPA's judgment that glyphosate does not cause cancer is well established and highly valued by other governments and independent scientists worldwide.

B. Preemption Provides Consistency and Clarity in Product Safety

While this case specifically involves FIFRA's preemption of state tort claims challenging the adequacy of herbicide labeling, the underlying public policy supporting preemption here is applicable to other closely regulated products.

Congress has charged federal regulators with protecting the public interest by approving practices, setting standards, and requiring labeling for a variety of products such as prescription drugs, medical devices, and workplace safety equipment. *See generally* Victor E. Schwartz & Cary Silverman, *Preemption of State Common Law by Federal Agency Action: Striking the Appropriate Balance that Protects Public Safety*, 84 Tulane L. Rev. 1204 (2010). Federal agencies, like the EPA here, can comprehensively evaluate the universe of scientific information available. *See id.* at 1208. Agencies can consider the expertise of advisory committees and public comment. They can carefully evaluate the wider impact of their deci-

sions, such as risk-benefit and risk-risk tradeoffs. *See id.* at 1208-09. In addition, when federal agencies set labeling or other requirements for products, they provide clear guidance to manufacturers and other employers. *See id.* Federal preemption advances these public policy goals.

On the other hand, courts and lay juries do not have these tools available to them. They are confined to evaluating the safety of a product and adequacy of its labeling as argued by counsel for the parties in the context of a single case through presentations by retained expert witnesses. *See id.* This case often will involve a highly sympathetic plaintiff who has suffered a tragic injury, even if not caused by the product at issue. The case may be an aberration, rather than a widespread problem. While judges have an obligation to serve as gatekeepers over the reliability of proposed expert testimony, in cases involving closely regulated products, Congress has placed authority to make certain decisions with federal agencies.

The registration and labeling of herbicides is one such area. Here, support for preemption is particularly strong, as FIFRA includes express language precluding state labeling requirements that are in addition to or different from those required by the EPA. *See* 7 U.S.C. § 136v(b). And the EPA has specifically instructed manufacturers of products that contain glyphosate that adding a warning statement regarding glyphosate's carcinogenicity, based on an IARC assessment that the EPA has rejected, would render the product "misbranded." *See* Dear Registrant Letter from Michael L. Goodis, P.E., Director,

Registration Division, Office of Pesticide Programs, EPA, Aug. 7, 2019.

Allowing cases to go to trial will result in unpredictable and inconsistent rulings, and wildly varying verdicts. *See* Diana Novak Jones, *Missouri Supreme Court Won't Take Up Bayer Appeal of $611M Roundup Verdict*, Reuters, Oct. 2, 2025 ("While Bayer has prevailed in many of the Roundup trials, plaintiffs have won more than $4 billion of verdicts."). In fact, here, the plaintiff's $1.25 million verdict in a St. Louis courthouse came after nine consecutive defense verdicts in similar cases around the country. *See* David Siegel, *$1.25M Verdict in Zero-Offer Cases Breaks Monsanto's Roundup Trial Winning Streak*, Courtroom View Network, Oct. 24, 2023.

Absent preemption, the litigation will create confusion for manufacturers as to their labeling obligations and lead them to question whether they can continue to make and sell EPA-approved products. *See* Patricia Weiss & Ludwig Burger, *Bayer Tells US It Could Halt Roundup Weedkiller Sales Over Legal Risks*, Reuters, Mar. 7, 2025. The litigation has already forced Monsanto to remove glyphosate-based consumer products from the market and could jeopardize its availability to farmers, leading them to use harsher, more toxic, or foreign alternatives. *See id.*

This litigation, particularly if influenced by IARC's outlier classification of glyphosate as a probable cause of cancer, can itself cause harm. IARC's determination, through a hazard identification approach that has labeled hundreds of substances as carcinogenic, many without adequate scientific support, may lead to a few plaintiffs receiving multimil-

lion or billion-dollar awards. But these outcomes will adversely affect farmers, raise food prices for consumers, lead to use of riskier or less effective substitutes, and jeopardize the food supply worldwide.[27]

CONCLUSION

For these reasons, *amici curiae* respectfully request that this Court reverse the Missouri Court of Appeals and find FIFRA preempts state tort claims that would require warnings on pesticide labels that deviate from those mandated by the EPA.

Respectfully submitted,

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[27] *See* Graham Brookes, et al., *The Contribution of Glyphosate to Agriculture and Potential Impact of Restrictions on Use at the Global Level*, 8 GM Crops Food 216-28 (2017).

International Society for Regulatory Toxicology and Pharmacology, Civil Justice Association of California, Pennsylvania Coalition for Civil Justice Reform, New Jersey Civil Justice Institute, Florida Justice Reform Institute, and Illinois Coalition for Legal Reform

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