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 Missouri Court of Appeals

BRIEF OF PHILIP LANDRIGAN, MD, MSC, LIANNE SHEPPARD, PHD, CHRISTOPHER PORTIER, PHD, DENNIS WEISENBURGER, MD, AND BRUCE P. LANPHEAR, MD, MPH AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

ALANI GOLANSKI
Counsel of Record
ROBIN L. GREENWALD
ALICIA BUTLER
ROBERT QUIGLEY
WEITZ & LUXENBERG P.C.
700 Broadway
New York, NY 10003
(212) 558-5500

DAVID WOOL
WOOL TRIAL LAW LLC
1001 Bannock Street
Suite 410
Denver, CO 80204
(720) 370-6576

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INTEREST OF *AMICI CURIAE*[1]

Amicus Philip Landrigan, MD, MSc, is a pediatrician and epidemiologist. He served as faculty of the Mount Sinai School of Medicine from 1985–2018, as Chair of the Department of Preventive Medicine from 1995–2015, and as Dean for Global Health beginning in 2010. Since July 2018, Dr. Landrigan has been the director of programs for Global Health and the Common Good at Boston College. His research in the 1970s is credited for making the association between childhood brain damage and lead exposure. That research, among other significant findings, was the first to show that lead can cause brain damage to children at levels too low to cause clinically evident signs and symptoms – a phenomenon now termed "subclinical toxicity." That research lent support to EPA's decision to remove lead from gasoline and paint, resulting in a 95% reduction of lead poisoning among US children. His research also includes a 1993 National Academy of Science report on Pesticides in the Diets of Infants and Children that provided the blueprint for the Food Quality Protection Act, the only federal environmental law that explicitly protects children's health. Dr. Landrigan was also involved in the medical and epidemiological studies following the World Trade Center attacks and resulting injuries from exposure to the destruction.

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[1] Pursuant to Rule 37.6, counsel for *amici curiae* are the sole authors of this brief. Counsel for *amici* disclose that they are counsel for Plaintiffs in other Roundup litigation. No person or entity, including *amici curiae*, made a monetary contribution to the preparation or submission of the brief.

Amicus Lianne Sheppard, PhD, is a biostatistician focused on environmental exposures and epidemiology. She has been a member of the University of Washington School of Public Health faculty since 1993, with appointments in two departments: Biostatistics, and Environmental and Occupational Health Sciences, where she served as Interim Chair from 2024–2025. Her research addresses the health effects of environmental and occupational exposures with particular attention to the impact of exposure assessment and modeling on understanding and making inference about health impacts. A Fellow of the American Statistical Association, Dr. Sheppard has served the U.S. Environmental Protection Agency (EPA) as a special government employee in multiple capacities, most recently as Chair of the Clean Air Scientific Advisory Committee from 2021–2014. In 2016–2017 she served as a member of the EPA Federal Insecticide, Rodenticide, and Fungicide Act Scientific Advisory Panel for Evaluation of the Carcinogenic Potential of Glyphosate. This led her to publish several follow-on glyphosate-related research papers. In 2020, Dr. Sheppard received the ISEE Research Integrity Award,[2] established to honor individuals working in the field of environmental epidemiology who have demonstrated exceptional integrity in the face of pressure from special interests. Dr. Sheppard has been the Rohm & Haas Endowed Professor in Public Health Sciences since 2021.

Amicus Christopher Portier, PhD, is a biostatistician. His PhD thesis addressed the optimal design for a two-year rodent carcinogenicity study.

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[2] *See* https://www.youtube.com/watch?v=8sPG8IsBv6Q.

Post-PhD, he had a joint appointment at the National Institute of Environmental Health Sciences and the National Toxicology Program (NIEHS/NTP) designing and analyzing toxicology experiments. Five years later, he developed his own research group that became the Laboratory of Computational Biology and Risk Assessment, focused on application of computational tools to identify chemicals toxic to humans. In 2006, Dr. Portier became the Associate Director of the NIEHS, and in 2010 the Director of the National Center for Environmental Health at the Centers for Disease Control and Prevention, while also serving as Director of the Agency for Toxic Substances and Disease Registry, where he was responsible for determining risks at toxic waste sites and EPA-designed clean-up. He also served from 2005–2010 as Chair of the Subcommittee on Toxics and Risk of the President's National Science and Technology Council, and from 1998–2003, Chair of EPA's Science Advisory Panel, focused on advising the pesticides program. He has also served as an expert witness for plaintiffs in Roundup litigation.

Amicus Dennis Weisenburger, MD, is a physician and pathologist specializing in the study of hematopoietic and immune systems diseases, with a specialty in non-Hodgkin lymphoma (NHL). From 1984–2012, he was a faculty member in the Department of Pathology and Microbiology at the University of Nebraska Medical Center, and was also the chief pathologist for the Nebraska Lymphoma Study Group. He collaborated with the National Cancer Institute (NCI) in a large epidemiologic study of NHL and related disorders in Eastern Nebraska. In 2012, Dr. Weisenburger became Chairman of the Department of Pathology at City of Hope National

Medical Center, an NCI-designated comprehensive cancer center. He has published over 300 peer-reviewed papers on NHL. He has also served as an expert witness for plaintiffs in Roundup litigation.

Amicus Bruce P. Lanphear, MD, MPH, is a physician specializing in preventive medicine and a professor in the Faculty of Health Sciences at Simon Fraser University in Vancouver, British Columbia. For over 30 years, he has conducted research on the health effects of environmental toxicants, with a focus on children's health and disease prevention. His work has informed federal standards for lead in air, water, and house dust and helped establish the now widely accepted conclusion that there is no safe level of lead exposure for children. Dr. Lanphear has served in key scientific advisory roles shaping environmental health policy in North America as a member of the Commission for Environmental Cooperation's Children's Health Expert Panel, on multiple EPA Science Advisory Boards, and as co-chair of Health Canada's Pest Management Regulatory Agency Science Advisory Committee on pest control products. He has also advised the Centers for Disease Control and Prevention, Health Canada, and other governmental bodies on environmental health standards and risk assessment.

INTRODUCTION AND SUMMARY OF ARGUMENT

Amici are among the many scientists, physicians, and public health professionals who have concluded that scientific evidence establishes that glyphosate and glyphosate-based herbicides (GBHs) cause cancer and other health effects in humans. This strong

scientific evidence matters deeply to the question now before this Court. Petitioner and its supporting *amici* inaccurately frame this as a case in which federal preemption is both legally required and prudentially necessary, because EPA made definitive scientific findings that glyphosate is not carcinogenic, and the jury that decided Mr. Durnell's case was misled by "junk science."[3]

Not so. EPA's review of glyphosate was narrow and incomplete, like all reviews that regulators perform at the pesticide registration stage. EPA's review was further hindered by Monsanto's decades-long suppression of adverse scientific evidence about Roundup's carcinogenicity. Meanwhile, epidemiological evidence, human studies, animal studies, and genetic testing have only strengthened the conclusion that glyphosate is linked to an increased risk of non-Hodgkin lymphoma (NHL) – the cancer of the lymphatic system that Mr. Durnell developed. Glyphosate is also linked to multiple additional adverse health effects, including kidney and liver diseases, and harms to the reproductive, endocrine, neurological, and other metabolic systems. Children, infants, and fetuses are the most susceptible.

This empirical evidence further confirms that the regulatory review scheme contemplated by FIFRA and conducted in practice is a narrow one. In *Bates*, the Court observed that "FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their

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[3] Brief of *Amici Curiae* Agricultural Retailers Association and National Agricultural Aviation Association at 2.

products' performance in diverse settings."[4] This evolution is a consequence of the toxic nature of pesticides and the limited review regulators perform at the time of registration. Pesticides are poisons designed to kill living things, and they lack any direct benefit to human health. Put another way, being exposed to pesticides never *improved* someone's health or cured their disease. Accordingly, and unlike pharmaceutical drugs which undergo multiple rounds of human clinical trials before they are brought to market and *are* designed to save lives and improve health, pesticides can never be ethically tested on human beings prior to sale. This means that functionally, direct evidence of a pesticide's adverse effects on human health will generally only surface *after* the pesticide is registered and brought to market.

Because of this, Congress imposed upon registrants "a continuing obligation to adhere to FIFRA's labeling requirements,"[5] as well as "a duty to report incidents involving a pesticide's toxic effects that may not be adequately reflected in its label's warnings."[6] And, as the Court recognized in *Bates*, "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA."[7] Moreover, "in all preemption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the

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[4] *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005).

[5] *Bates*, 544 U.S. at 438 (citing 7 U.S.C. § 136j(a)(1)(E)).

[6] *Id.* at 439 (citing 40 C.F.R. § 159.184(a), (b) (2004)).

[7] *Id.* at 451.

Federal Act unless that was the clear and manifest purpose of Congress."[8] Application of traditional state law to the tortious misconduct outlined below, traditionally policed by the State, does not conflict with and is not different from FIFRA's statutory goal of including "a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment."[9]

Roundup's history illustrates why a continuing duty to update the label exists under FIFRA, and why private tort suits like Mr. Durnell's are fully consistent with the limited preemptive scheme for pesticide regulation Congress enacted.

STATEMENT

A. Statutory and Regulatory Background

An estimated 325,000 synthetical chemicals and chemical mixtures exist in the world today. Most of these chemicals were invented post-1950.

The United States regulates these chemicals under three different legal regimes, depending on the type of chemical. First, ***pharmaceutical agents*** are regulated under the Federal Food, Drug, and Cosmetic Act.[10] The manufacturers of these agents must test them for safety and effectiveness before they are approved for sale, which includes clinical trials and post-marketing surveillance. The regulatory

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[8] *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

[9] 7 U.S.C. § 136(q)(1)(G).

[10] 21 U.S.C. § 301 *et seq*.

structure is designed to be strict and protective of public health. But it was not always that way. In the 1950s, a German manufacturer began selling the sedative drug thalidomide, which soon became a popular over-the-counter treatment for morning sickness in pregnant women in Europe. Based on animal testing, the drug was widely believed to be non-toxic in humans. After upwards of ten thousand babies were born with severe deformities to women who had taken thalidomide during pregnancy, the drug was banned. This tragedy forced regulators to address infants' unique vulnerability to manufactured chemicals and led to the strict testing requirements that exist today to ensure another thalidomide tragedy does not repeat itself.[11]

Second, ***industrial and consumer chemicals products*** are regulated under the Toxic Substances Control Act (TSCA).[12] TSCA is a weak law without mandatory pre-market screening and no

[11] Threats to fetal development such as thalidomide are not unique to pharmaceuticals, but can also result from pesticide exposure. *See* The Consortium for Children's Environmental Health, *Manufactured Chemicals and Children's Health – The Need for New Law.*, N ENGL J MED 392:3, (Jan. 16, 2025) https://www.nejm.org/doi/full/10.1056/NEJMms2409092. The pesticide chlorpyriphos causes long-term alterations in brain development and behavior of children and offers a prime example of the need to police pesticides. *See* https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health; Bradley S. Peterson et al., *Brain Abnormalities in Children Exposed Prenatally to the Pesticide Chlorpyrifos*, 82 JAMA NEURO. 1057–1068 (2025), http://doi.org/10.1001/jamaneurol.2025.2818.

[12] 15 U.S.C. § 2601 *et seq*.

postmarketing surveillance. Fewer than 20% of these chemicals have been tested for toxicity.

Third, ***pesticides,*** including herbicides such as Roundup, are regulated by the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) and the Food Quality Protection of Act of 1996 (FQPA),[13] which amended FIFRA. FIFRA requires EPA registration of all domestically sold pesticides. As part of the registration process, the registrant must perform long-term animal studies in two species on the active ingredient of the pesticide.[14] The registrant selects the laboratory to perform the tests (usually in rodents) and provides the results of the studies to EPA. These carcinogenicity studies are only performed on the active ingredient; EPA does not require a pesticide manufacturer to perform a carcinogenicity study on the formulated product. Because it would be unethical to test a pesticide – designed to kill weeds, insects, rodents, etc. – on a human subject, there are no human studies available when a product is first registered, and a pesticide's carcinogenicity is evaluated based on animal data alone. That makes the integrity of animal testing essential for protecting users of the product and the public at large. In the case of Roundup, the animal testing performed on glyphosate for initial registration in 1974 was fraudulent, leading EPA to invalidate those studies in 1978. *See* Argument II.B., *infra*.

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[13] Pub. L. No. 104-170, 110 Stat. 1489.

[14] 7 U.S.C. § 136(a)e(1).

The FQPA amended FIFRA in 1996 to, among other things, require registration review every 15 years.[15] That makes sense because, as people use or are otherwise exposed to the pesticide, human epidemiology and mechanistic data become increasingly available. It is critically important to evaluate the pesticides' potential dangers to human health as science develops. In addition, the FQPA employs a new standard for establishing pesticide tolerances, providing that EPA "may establish or leave in effect a tolerance for a pesticide . . . residue in or on a food only if the Administrator determines that the tolerance is safe."[16] "Safe" means "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide. . . ."[17] The statute omits a cost-benefit analysis for setting tolerances.

Finally, of utmost importance to the question presented, FIFRA also requires manufacturers to provide to EPA any adverse information about a pesticide's potential risks to human health.[18] The manufacturer cannot wait for registration review if it receives information that shows previously unknown dangers.

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[15] 7 U.S.C. § 136a(g); 40 C.F.R. § 155.50(b).

[16] 21 U.S.C. 346a(b)(2)(B)(ii)–(iv); Thomas McGarity, *Politics by other means: law, science, and policy in EPA's implementation of the food quality protection act.,* ADMIN. LAW REV. 53: 1, 103–222 (2001), https://www.jstor.org/stable/40711949.

[17] *Id.*

[18] 7 U.S.C. § 136d(a)(2); 40 C.F.R. pt. 159.

B. Scientific and Factual Background

Glyphosate, a broad-spectrum herbicide (weed killer), was discovered by Monsanto in 1970 as having herbicidal qualities and patented in the United States by Monsanto as an herbicide from its registration in 1974 through 2000.[19] Glyphosate is the active ingredient in Monsanto's Roundup product lines. The diversity and magnitude of glyphosate/Roundup uses in agriculture, forestry, industrial and commercial settings, as well as residentially, have grown dramatically since first approval in 1974.

Humans are exposed to glyphosate by three pathways: dermal exposure, inhalation, and ingestion. Dermal and inhalation exposure occurs through direct spraying, occupational or residential proximity to sprayed areas, and dust. Oral exposure occurs through consumption of glyphosate residues in food and water. Food is the main route of exposure for most people in the United States. Recent nationwide biomonitoring surveys have detected glyphosate in samples collected from 70–80% of all people examined in the United States, including children.[20]

Once glyphosate enters the body, it is rapidly transported from the bloodstream to bone marrow, regardless of exposure route. At peak glyphosate

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[19] *See* U. S. Patent 3,799,758 (Mar. 26, 1974) https://patentimages.storage.googleapis.com/58/51/2c/48674f43baa042/US3799758.pdf.

[20] *See, e.g.*, Maria Ospina et al., *Temporal Trends of Exposure to the Herbicide Glyphosate in the United States (2013-2018): Data from the National Health and Nutrition Examination Survey*, 364 CHEMOSPHERE 142966 (2024), http://doi.org/10.1016/j.chemosphere.2024.142966.

levels in bone marrow – two to six hours after exposure – there are likely billions of glyphosate molecules for every hematopoietic (blood cell-generating) stem cell. There, glyphosate is known to trigger some of the precise mutations that initiate lymphocytes (a type of white blood cell) on the path to NHL and other blood cancers.

Monsanto has known these facts for most of the time it has sold Roundup to unsuspecting customers. The information is largely contained in its own metabolism studies conducted in the 1980s–1990s, but for years, rather than sharing the information with EPA as FIFRA requires (or with consumers to ensure they use Roundup safely), Monsanto either dismissed or downplayed these findings as irrelevant. The Roundup litigation unearthed these studies.

ARGUMENT

I. Overwhelming Evidence Establishes that Glyphosate and Glyphosate-Based Herbicides Cause Cancer.

Glyphosate-based herbicides (GBHs) have been strongly linked to cancer in humans, not only by the International Agency for Research on Cancer (IARC), but also by independent researchers across the globe. Following the 2015 IARC assessment, scientists, including *amicus* Dr. Landrigan, met to evaluate the existing scientific evidence of glyphosate's human health risks, including non-cancer outcomes. These researchers, in a peer-reviewed statement of concern about risks associated with GBH exposure, endorsed IARC's glyphosate carcinogenicity classification, concluding that substantial evidence existed at that time that GBHs could cause non-cancer diseases,

including "possible endocrine system-mediated and development impacts"; adverse effects on the liver and kidney; gastrointestinal microbiome alteration; oxidative stress in rat liver; and diseases that have devastating outcomes for human health.[21] In 2021, the French Institute of Health and Medical Research (Inserm) also found a link between glyphosate/GBH exposure and NHL risk in the epidemiologic studies.[22]

Just last week, a group of scientists held a symposium to discuss their views on health risks of GBH exposure. Following the symposium, they adopted and released a consensus Statement on Glyphosate, concluding that the evidence of cancer and non-cancer health effects has grown stronger over the last ten years:

> Glyphosate and glyphosate-based herbicides (GBHs) harm human health and can cause cancer. The comprehensive evidence supports this conclusion, with the strongest epidemiological evidence linking exposure to increased risk of non-Hodgkin lymphoma, a cancer of the lymphatic system.

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[21] *See* Myers, et al., *Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement.*, ENVIRON HEALTH 15:19 (2016). http://doi.org/10.1186/s12940-016-0117-0. (2016 Myers Statement of Concern), at 2–3, 5, 7.

[22] *See* INSERM Collective Expertise Centre, *Effects of pesticides on health: New data (EDP Sciences)* (2022), http://www.ncbi.nlm.nih.gov/books/NBK581472/.

There is additional evidence from human and/or animal studies that glyphosate and GBHs increase the risk of multiple adverse health effects in addition to cancer, including diseases of the kidney and liver, and impacts to the reproductive, endocrine, neurological, and other metabolic systems. Children, infants and fetuses are the most susceptible.

Further strong evidence finds that glyphosate and GBHs cause genetic damage, oxidative stress, and hormonal disruption — biological changes that can set disease in motion. Our understanding of glyphosate's ability to cause these changes has developed from multiple lines of evidence in animal, human and *in vitro* studies.

Additional research is needed to better understand the full extent of glyphosate's and GBH's effects on human health and the underlying mechanisms involved, such as epigenetic alterations, microbiome disruption and endocrine effects.

The evidence that glyphosate and GBHs harm human health at levels of current use is now so strong that no additional delays in regulation of glyphosate can be justified. Regulatory agencies in countries around the world should treat glyphosate and GBHs as hazardous, as some countries

> have started to do. Agencies should act without further delay to limit their use, or eliminate them if legally required, to protect public health. Preventive measures to reduce human exposures while handling and applying glyphosate are accessible, proven effective, and inexpensive. These actions should be implemented without delay while research continues.[23]

Since IARC's 2015 review, and the 2016 Myers Statement of Concern, additional peer-reviewed epidemiologic, animal, and mechanistic studies have continued to provide compelling evidence that glyphosate and GBHs are a cause of NHL, as the *Durnell* jury found.[24] Additional epidemiologic

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[23] Seattle Statement on Glyphosate and Public Health, available at https://deohs.washington.edu/sgs/statement (last visited Mar. 30, 2026) (emphasis added).

[24] *See generally* Dennis Weisenburger, *An Update of Evidence that the Herbicide Glyphosate (Roundup) is a Cause of Non-Hodgkin Lymphoma,* CLINICAL LYMPHOMA MYELOMA & LEUKEMIA S2152265025042855 (2025), http://doi.org/10.1016/j.clml.2025.11.005 (reviewing relevant literature published between 2020 and 2025); Dennis Weisenburger, *A Review and Update with Perspective of Evidence that the Herbicide Glyphosate (Roundup) is a Cause of Non-Hodgkin Lymphoma*, 21 CLINICAL LYMPHOMA MYELOMA AND LEUKEMIA 621–630 (2021), http://doi.org/10.1016/j.clml.2021.04.009 (reviewing relevant literature published 2015–2020); Iemaan Rana, et al., *Mapping the key characteristics of carcinogens for glyphosate and its formulations: A systematic review*, 339 CHEMOSPHERE 139572 (2023), http://doi.org/10.1016/j.chemosphere.2023.139572 (presenting updated evaluation of mechanistic evidence,

evidence of statistically significant positive associations between exposure to GBHs and NHL and/or its various subtypes has emerged.[25] Notably, despite the insistence of Monsanto's in-house scientists and paid consultants that it would be impossible to perform an animal study on formulated Roundup, an independent Italian research institute completed and published such a study just last year, finding statistically-significant and dose-related increased trends or incidences of tumors at multiple anatomic sites in rats, at exposure levels even within permissible European dietary limits.[26] And a substantial body of additional literature provides

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including significant new studies published subsequent to the evidence assessed in 2015 by IARC Working Group).

[25] *See* Paolo Boffetta, et al., *Exposure to glyphosate and risk of non-Hodgkin lymphoma: an updated meta-analysis,* 112 LA MEDICINA DEL LAVORO 194–199 (2021), http://doi.org/10.23749/mdl.v112i3.11123 (presenting updated meta-analysis finding significantly increased risk for diffuse large B-cell NHL with higher exposure to glyphosate); Federico Meloni et al., *Occupational exposure to glyphosate and risk of lymphoma: results of an Italian multicenter case-control study*, 20 ENVT'L HEALTH 49 (2021), http://doi.org/10.1186/s12940-021-00729-8 (finding four-fold increase in risk of B-cell NHL among workers with medium to high intensity exposure); Lennart Hardell et al., *Exposure to phenoxyacetic acids and glyphosate as risk factors for non-Hodgkin lymphoma- pooled analysis of three Swedish case-control studies including the sub-type hairy cell leukemia*, 64 LEUKEMIA & LYMPHOMA 997–1004 (2023), http://doi.org/10.1080/10428194.2023.2190434 (finding statistically significant increased risk of NHL in pooled analysis of three case-control studies).

[26] Simona Panzacchi, et al., *Carcinogenic effects of long-term exposure from prenatal life to glyphosate and glyphosate-based herbicides in Sprague–Dawley rats*, 24 ENVIRON. HEALTH 36 (2025), http://doi.org/10.1186/s12940-025-01187-2 .

further evidence that glyphosate and GBHs are genotoxic to human lymphocytes and other cells, now including direct evidence of genetic damage in occupational glyphosate users.[27] Beyond NHL, emerging evidence of glyphosate's carcinogenicity also points to other cancer endpoints including acute myeloid leukemia,[28] multiple myeloma,[29] and breast cancer.[30]

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[27] Vicky Chang, et al., *The association between glyphosate use and mosaic loss of chromosome Y in buccal samples among male pesticide applicators in the Agricultural Health Study*, 203 ENVIRONMENT INTERNATIONAL 109755 (2025), http://doi.org/10.1016/j.envint.2025.109755 (reporting positive associations between exposure to GBHs and a chromosomal alteration indicative of genotoxicity, genomic instability, and immune dysregulation, based on buccal samples, supplementing similar findings by researchers in earlier study using blood samples).

[28] *See, e.g.,* Panzacchi (2025), *supra*.

[29] *See, e.g.,* Lei Wang, et al., *Glyphosate induces benign monoclonal gammopathy and promotes multiple myeloma progression in mice,* 12 J. HEMATOLOGY & ONCOLOGY 70 (2019), http://doi.org/10.1186/s13045-019-0767-9.

[30] *See, e.g.,* Hannah Schluter, et al., *Potential Role of Glyphosate, Glyphosate-Based Herbicides, and AMPA in Breast Cancer Development: A Review of Human and Human Cell-Based Studies*, 21 INT'L J. ENVIRON RESEARCH PUB. HEALTH 1087 (2024), http://doi.org/10.3390/ijerph21081087 (reviewing available literature on relationship between exposure to GBHs and breast cancer, including series of studies showing higher urinary levels of glyphosate and/or its metabolite AMPA were associated with breast cancer risk, higher levels of oxidative stress biomarkers, endocrine disruption, and DNA methylation differences); Lyvia Neves Rebello Alves et al., *Glyphosate-Based Herbicide as a Potential Risk Factor for Breast Cancer*, 200 FOOD CHEM. TOXICOL. 115404 (2025), http://doi.org/10.1016/j.fct.2025.115404 (reporting results of *in*

A growing body of research also links glyphosate and/or GBHs to other significant non-cancer health effects. For example, multiple studies employing different methodologies and examining distinct populations have shown an association, and a dose-response relationship, between glyphosate exposure and liver injury, fatty liver disease, metabolic syndrome, and glucose dysregulation including development of Type II diabetes.[31] Multiple studies have also found an association between glyphosate exposure and adverse neurodevelopmental outcomes, with similar findings arising whether exposure is assessed by proximity to the use of glyphosate-based herbicides or by direct measurement of glyphosate and its metabolite, AMPA, in urine.[32] Glyphosate – which Monsanto patented as an antibiotic – has also been shown to disrupt the human gut microbiome, with serious implications for human immune function, among other things.[33] And a growing body of

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vitro tests showing exposure to GBHs alters expression of key breast cancer-related genes).

[31] *See, e.g.,* Kexing Han, et al., *Analysis of the association between urinary glyphosate exposure and fatty liver index: a study for US adults*., BMC PUB. HEALTH 24:703 (2024) http://doi.org/10.1186/s12889-024-18189-3; Wenxiang Li, et al., *Association of glyphosate exposure with multiple adverse outcomes and potential mediators.,* CHEMOSPHERE 345:140477 (2023). http://doi.org/10.1016/j.chemosphere.2023.140477.

[32] *See, e.g.,* Ondine von Ehrenstein, et al., *Prenatal and infant exposure to ambient pesticides and autism spectrum disorder in children: population based case-control study,* 364 BMJ l962 (2019), http://doi.org/10.1136/bmj.l962.

[33] *See, e.g.,* Robin Mesnage et al., *Alterations in infant gut microbiome composition and metabolism after exposure to glyphosate and Roundup and/or a spore-based formulation using*

evidence points to GBHs as an endocrine disruptor[34] and potential reproductive toxicant,[35] at levels associated with dietary and bystander exposure.

II. Granting Immunity from Label-Based Tort Liability Would Incentivize the Type of Deceit Monsanto Exhibited in Relation to Roundup.

Based on Monsanto's 50-year history of hiding important adverse health information from the public and denigrating scientists who dare to publish adverse information about Roundup's safety,[36] *amici* are concerned that a decision that Mr. Durnell's claims are preempted would incentivize future pesticide registrants to deceive EPA in the registration process. As to existing registrants, a finding of preemption would incentivize them to hide

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the SHIME technology, 3 GUT MICROBIOME (Cambridge, England) e6 (2022), http://doi.org/ 10.1017/gmb.2022.5.

[34] *See, e.g.,* Siriporn Thongprakaisang et al., *Glyphosate induces human breast cancer cells growth via estrogen receptors*, 59 FOOD & CHEM. TOX. 129–136 (2013), http://doi.org/10.1016/j.fct.2013.05.057.

[35] *See, e.g.,* David Haas et al., *First trimester urine glyphosate concentrations and gestational diabetes in nulliparas: a nested case-control study*, 24 ENVT'L HEALTH 71 (2025), http://doi.org/10.1186/s12940-025-01183-6.

[36] *See, e.g.*, Gilles-Eric Séralini et al., *Conflicts of interests, confidentiality and censorship in health risk assessment: the example of an herbicide and a GMO*, 26 ENVT'L SCI. EUROPE 13 (2014), http://doi.org/10.1186/s12302-014-0013-6; Int'l Agency for Research on Cancer, *IARC Response to criticisms of the Monographs and the glyphosate evaluation* (Jan. 2018), https://www.iarc.who.int/wp-content/uploads/2018/07/IARC_response_to_criticisms_of_the_Monographs_and_the_glyphosate_evaluation.pdf.

adverse public health information they receive after registration. These perverse outcomes are inimical to Congress' intent when it established our pesticide regulation scheme. The Roundup litigation confirms that EPA's registration review is incomplete, non-definitive, and not an appropriate basis for preemption given its factual and scientific deficiencies. But for the Roundup litigation and the information plaintiffs uncovered about Monsanto's decades-long suppression of adverse scientific evidence about Roundup's carcinogenicity (and other negative health outcomes) from EPA and the public, the important health-based evidence Monsanto possessed but "archived" before it had to produce it in discovery would never have seen the light of day.

Monsanto's manipulation of the science – illustrated by key events in the history of Roundup regulation – cannot be overstated.

A. The IBT Scandal

In 1971, Monsanto contracted with a commercial laboratory, Industrial Bio-Test (IBT), to perform most of the testing necessary to support EPA's Roundup registration, including two long-term cancer tests in rodents (rats and mice). At the time, no other manufacturers had reason to test glyphosate, which Monsanto patented, and human studies would have been impossible and unethical. IBT's rodent studies would remain the ***only*** available carcinogenicity studies on glyphosate for the first nine years of Roundup's registration for sale in the United States.

But those tests were fraudulent.[37] At IBT, a former Monsanto toxicologist named Paul Wright – whom IBT hired at the request of a Monsanto executive – planned and oversaw the rodent and dog studies on glyphosate. According to a lab technician who worked in the rat study room, IBT had so many ongoing studies that technicians could not keep up with the necessary tasks – weighing the animals, measuring and logging their feed, and removing dead animals for pathologic examination. To cure the gaps this left in their lab notebooks, Wright and another IBT toxicologist, James Plank, falsified the missing data.[38] Meanwhile, when test animals died, some were replaced with healthy substitutes, while others were not discovered until they were too decomposed for the necessary pathology examinations.[39] Wright saw these conditions daily. Fourteen months after IBT undertook the glyphosate studies, Wright returned to work at Monsanto, where he supervised the completion of IBT's glyphosate studies and approved the final study reports submitted to EPA.[40]

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[37] *See, e.g.,* Tr. 1020–1023; David Rosner & Gerald Markowitz, *"Ashamed to Put My Name to It": Monsanto, Industrial Bio-Test Laboratories, and the Use of Fraudulent Science, 1969-1985,* 113 AM. J. PUB. HEALTH 661–666 (2023) https://pmc.ncbi.nlm.nih.gov/articles/PMC10186829/; Keith Schneider, et al., *Faking It: The Case Against Industrial Bio-Test Laboratories*, Amicus Journal (Spring 1983) https://www.centerforfoodsafety.org/files/schneider-1983_42309.pdf.

[38] *See United States v. Keplinger*, 776 F.2d 678, 685 (1985), *cert. denied.*, 476 U.S. 1183 (1986); *Pilliod v. Monsanto Co.*, 282 Cal.Rptr.3d 679, 710 (Cal. App. 1 Dist., 2021).

[39] *See, e.g., Keplinger,* 776 F.2d at 697.

[40] *Pilliod,* 282 Cal.Rptr.3d at 710.

IBT issued its final report on the 18-month mouse study in September 1973, and its report on the 2-year rat study followed a few months later, both written by Manuel S. Reyna and approved by Moreno Keplinger, IBT's Manager of Toxicology. Neither study reported any indication of cancer risk, though EPA found treatment-related liver changes in the rat study forecasting what researchers have found in more recent human studies.[41] EPA granted the registration of glyphosate within a few months of receiving the IBT reports.

In 1976, the Food and Drug Administration (FDA) conducted a routine inspection of IBT's laboratories, revealing gross deficiencies that cast doubt on the integrity of *all* IBT's rodent studies. Because IBT's safety tests had supported the regulatory approvals for hundreds of products sold in the United States, EPA and FDA announced plans to audit *all* IBT toxicity tests supporting pesticide registrations.[42] To say that this provoked a regulatory crisis would be an understatement – the IBT scandal triggered a Congressional investigation and ultimately a wholesale revision of regulatory requirements,

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[41] *See, e.g.,* Luana Riechelmann-Casarin et al., *Are Glyphosate or Glyphosate-Based Herbicides Linked to Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)? The Weight of Current Evidence*, 116 ENVIRON. TOXICOL. PHARMACOL. 104705 (2025), http://doi.org/10.1016/j.etap.2025.104705.

[42] *See generally* Office of Pesticide Programs, *Summary of the IBT Review Program* (July 1983). https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=91014ULV.txt. (EPA Summary).

including the implementation of the Good Laboratory Practice standards still used today.[43]

News of the federal government's investigation naturally alarmed IBT and one of its biggest customers, Monsanto. In July 1977, IBT's president and legal counsel met with Monsanto executives, telling them point blank that IBT's animal studies – specifically the glyphosate mouse and rat carcinogenicity studies – contained "extrapolation" and "faulty interpretations" that likely constituted "fraud."[44] Though Wright had directly overseen those likely fraudulent studies from start to finish, Monsanto promptly put him in charge of its newly established in-house animal testing lab. Monsanto also hired two other scientists who had worked on studies of various Monsanto products at IBT: Reyna (co-author of the IBT glyphosate rodent studies) and a veterinary pathologist, William Ribelin, whom it put to work re-examining the tissue samples from the IBT rat study. Meanwhile, Monsanto continued selling Roundup products without warning farmers or residential users that the product's safety was in question (as it had no valid carcinogenicity studies) and without telling the EPA (before EPA found out on its own the following year) about the fraud in the IBT studies that supported EPA's registration of Roundup.

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[43] *See generally* Anne Baldeshwiler, *History of FDA good laboratory practices*, 7 QUALITY ASSURANCE J. 157–161 (2003), http://doi.org/10.1002/qaj.228.

[44] *See* Mem. re: IBT Audit and Revalidation of Toxicology Studies Letter (July 13, 1977), PCB-ARCH0705738–41, https://www.toxicdocs.org/d/r3EnYLgeRGvQVrRwOQN7ev2q?lightbox=1.

By August 1978, the federal government had audited most of IBT's glyphosate studies. EPA declared IBT's 18-month glyphosate mouse study invalid after finding too many test animals missing.[45] In the 2-year rat study, EPA found insufficient reporting on the histopathology findings in the control and treatment groups and approximately 70 animals unaccounted for across the study.[46] EPA further invalidated three of IBT's four glyphosate genotoxicity (mutagenicity) studies because of missing vital validation data.[47] EPA concluded that "adequate oncologic studies should be initiated as soon as possible."[48] In response, ***five years later***, Monsanto submitted a mouse carcinogenicity study that, to Monsanto's surprise, led EPA to initially categorize glyphosate as "Category C oncogen," *i.e.*, a possible human carcinogen. Meanwhile, Monsanto publicly maintained that based on these long-term animal studies, glyphosate had been shown not to cause cancer.[49]

By 1983, the government's investigation found that nearly three-quarters of the 801 IBT health effects studies submitted for regulatory approvals were

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[45] *See* EPA Summary at 37.

[46] P-0309-128 (citations in this format refer to exhibits admitted in the trial below and included in the appellate record).

[47] *See* Revised Glyphosate Issue Paper at 70.

[48] EPA Mem. re: Glyphosate tolerances (Aug. 22, 1978), https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-065.pdf.

[49] Monsanto, *Roundup® Herbicide Bulletin No. 1* (Dec. 1980), MONGLY04267426.

invalid.[50] A grand jury indicted Wright, Keplinger, and Plank for fraud in connection with four different IBT studies, including a study on Monsanto's product TCC.[51] In the six-month criminal trial that followed, Monsanto's employees featured prominently: Wright, as a defendant, and Reyna and Ribelin as scientists who had worked on the TCC studies. In October 1983, the jury convicted all three defendants of various federal crimes. The Seventh Circuit Court of Appeals affirmed their convictions, and this Court denied a writ of *certiorari*.

Rather than firing Wright and distancing itself from his fraud, Monsanto employed him for months after his criminal conviction and paid over a million dollars for his legal defense. Monsanto also continued to employ Reyna, who, in 1990, authored a rodent study that Monsanto used to persuade EPA to dramatically increase the permissible level of glyphosate consumed by Americans – despite an earlier study by an outside laboratory showing kidney lesions at those dose levels.[52]

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[50] EPA Summary at 3.

[51] *Keplinger*, 776 F.2d at 684.

[52] *See, e.g.,* EPA, *Drinking Water Criteria Document for Glyphosate Final* (Jan. 1992), at 40. https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=901H0700.txt (citing M.S. Reyna, Final Report, *Two Generation Reproduction Feeding Study with Glyphosate in Sprague-Dawley Rats*, Project No. ML-88-106/EHL 88038 (Aug. 27, 1990)).

B. Continued Manipulation of Carcinogenicity Data: The Magic Tumor

Based on the study data from the repeat mouse study, which showed a statistically significant, dose-related tumor increase, EPA determined in March 1985 that glyphosate should be classified as a possible human carcinogen.[53] Monsanto met with EPA, hoping to prevent EPA's proposed classification from becoming official.[54] Monsanto understood there was only one way to avoid an oncogen classification: to convince EPA to allow it to re-review the slides and to "find" a tumor in the control group.[55] And that is what occurred: EPA allowed Monsanto to re-review the slides, and Monsanto hired a friendly animal pathologist named Dr. Kuschner to do so. Another internal Monsanto memorandum shows Kuschner and Monsanto decided, before Kuschner even received the slides, that Kuschner would find a kidney tumor in the control group.[56] And lo and behold, Monsanto sent Kuschner's report to the EPA, reporting that Kuschner "discovered a tumor in a control mouse" but otherwise confirmed the original study findings.[57] EPA scientists disputed Kuschner's finding, but nevertheless informed Monsanto that "the Agency is requiring that this study be repeated with a larger number of animals in each test group, so that the

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[53] EPA, *Glyphosate; Pesticide Tolerances*, 62 Fed. Reg. 17723, 17724 (April 11, 1987).

[54] P-0316-001.

[55] P-0316-003.

[56] P-0318-001.

[57] P-1655-001.

statistical power of the study is increased."[58] To this day – 40 years and billions of dollars in sales later – Monsanto has not conducted the repeat mouse study.

C. Suppression of Expert Information Relating to Roundup's Genotoxicity

In the mid-1990s, Monsanto learned about recently published, peer reviewed articles that showed Roundup to be genotoxic. These studies coincided with Monsanto's upcoming re-registration of glyphosate in Europe. Monsanto hired a world-renowned toxicologist, Dr. James Parry, to assess the published genotoxicity studies and make recommendations for countering their conclusions. Monsanto's chief toxicologist, Williams Heydens, proposed that Parry should only review four of the studies and, depending on his viewpoint, the company would decide whether to expand his work or terminate him.[59] In an initial report dated February 11, 1999, Parry wrote that based on his review of the first four papers, "[t]he overall data . . . provide evidence to support a model that Glyphosate is capable of producing genotoxicity both *in vivo* and *in vitro* by a mechanism based upon the production of oxidative damage."[60] Monsanto executives privately debated whether it was possible to "turn his opinion around."[61] They decided to let

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[58] P-1532-018.

[59] *See* Memo and Emails re: DRAFT of Minutes (Jan. 28, 1999), https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/01/Monsanto-1999-email-thread-re-Parry-and-testing.pdf.

[60] P-0758-011.

[61] Email from Martens (Apr. 19, 1999), MONGLY06486905. https://usrtk.org/wp-content/uploads/bsk-pdf-

Parry review all the mechanistic data and report his findings, hoping that the larger body of literature would change his mind. But they first required Parry to sign a "secrecy agreement."[62] He did so, and continued his review, suggesting additional research and concluding that:

> If the genotoxic activity of glyphosate and its formulations is confirmed it would be advisable to determine whether there are exposed individuals and groups within the human population. If such individuals can be identified, then the extent of exposure should be determined and their lymphocytes analyzed for the presence of chromosome aberrations.[63]

In response, Monsanto executives privately complained they had fallen into a "genotox hole" and wondered whether they could find an "independent" scientist to dig them out.[64] Monsanto's chief toxicologist Heydens, acknowledged that the company "was vulnerable in [the] area" of genotoxicity, but determined that Monsanto would not conduct any of the follow-up studies Parry recommended.[65]

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manager/2019/01/Exhibit-1999-meeting-minutes-re-Parry-and-genotox-issues.pdf.

[62] *Id.*

[63] P-0153-035.

[64] P-0154-001.

[65] P-0156-001.

The Parry reports are the type of information that FIFRA section 6(a)(2) required Monsanto to provide to EPA: "new **adverse data on a pesticide** in the possession of registrants must be **reported to the EPA within 90 days**, including data in preliminary reports." But Monsanto never provided Parry's report to the EPA. It was only revealed to the public eighteen years later, through the Roundup litigation.

With Parry fired and no cover for the genotoxicity threat, Monsanto decided to ghostwrite an article and pay Dr. Gary Williams, "recognized internationally as a genotox expert," to "author" the paper.[66] Williams published the paper, entitled "Safety Evaluation and Risk Assessment of the Herbicide Roundup and its Active Ingredient, Glyphosate, for Humans" in the journal *Regulatory Toxicology and Pharmacology* in 2000, without crediting the Monsanto scientists who had actually written it.[67] A post-publication internal memorandum touts the work of Monsanto's in-house scientists in publishing the article, bragging that it would be used "in both the defense of Roundup and Roundup Ready crops worldwide."[68] EPA and many other regulatory agencies around the world, as well as academics and other researchers, relied on the Williams paper, not knowing it was written by

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[66] P-0757-002.

[67] Gary Williams et al., *Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans*, 31 REG. TOX. & PHARM. 117–165 (2000), http://doi.org/10.1006/rtph.1999.1371.

[68] Email from Grant (May 12, 2000), MONGLY02624347–49. https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/04/Ghostwriting-Monsantos-CEO-praises-employees-for-publication-of-Williams-Kroes-Munro-Study.pdf.

Monsanto.[69] Twenty-five years later, in October 2025, the journal retracted the paper, in response to information about Monsanto's ghostwriting practices that only became public through the Roundup litigation.[70]

D. The Dermal Penetration Study Coverup

In the early 2000s, Monsanto hired the laboratory TNO to conduct rat and human dermal penetration tests for Roundup. Initial results showed dermal absorption of glyphosate at rates more than three times what had previously been assumed. When Monsanto's chief toxicologist Heydens learned about the high penetration results, his primary concern was "the potential for this work to blow Roundup risk evaluations.[71] Monsanto halted the study.[72]

Monsanto did not share these adverse findings with EPA, in violation of FIFRA. Studies that a registrant

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[69] Alexander Kaurov et al., *The afterlife of a ghost-written paper: How corporate authorship shaped two decades of glyphosate safety discourse*, 171 ENVIRONMENTAL SCIENCE & POLICY 104160 (Sept. 2025). http://doi.org/10.1016/j.envsci.2025.104160.

[70] Martin van den Berg, *Retraction Notice for "Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans,"* REG. TOX & PHARM. (2025), http://doi.org/10.1016/j.yrtph.2025.106006.

[71] Email from Heydens (Apr. 2, 2002), MONGLY03738295–6, https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/01/Monsanto-discussion-of-dermal-absorption-issues.pdf.

[72] Email from Garnett (Apr. 5, 2002), MONGLY03737015, https://corporateeurope.org/sites/default/files/attachments/47-monsanto-personnel-further-study-on-glyphosate-absorption.pdf.

terminates before completion must be reported to EPA, with the reasons for termination.[73]

III. IARC's 2015 Findings Linking Glyphosate with Cancer Have Ample Scientific Support, Notwithstanding Petitioner and Its *Amici's* Criticisms.

Rather than address the strong scientific evidence linking glyphosate with cancer, Petitioner and its supporting *amici* characterize this as an invention of IARC, which they wrongly caricature as a flawed and conflicted body biased towards finding hazards where none exist.[74] This mockery of IARC has no legs. IARC's detailed and well-supported finding that glyphosate is carcinogenic disclosed to the public critically important health information, despite Petitioner's and its industry trade groups' successful suppression of science for decades.

IARC's scientific cancer reviews and monographs are well known and highly respected in the scientific community and routinely relied upon by courts.[75] It is exactly that prestige that caused Monsanto (for years) to dread IARC's review of glyphosate. To neutralize IARC's glyphosate assessment, Monsanto planned an "orchestrated outcry" in advance, and convened a panel of paid-for "independent experts" to discredit IARC's assessment before it was even completed or

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[73] 40 C.F.R. § 159.167.

[74] *E.g.*, Brief of *Amici Curiae* Americal Tort Reform Association, at 6–18.

[75] "[W]hen IARC monographs are available, courts generally recognize them as authoritative." Fed. Judicial Ctr., REF. MAN. ON SCIENTIFIC EVID. (4th ed. 2025) at 920.

published.[76]

In March 2015, an IARC working group of 17 independent experts from 11 countries, having spent months reviewing the published scientific evidence, met to evaluate the carcinogenicity of five organophosphate insecticides and herbicides including glyphosate.[77] Based on the Working Group's analysis of animal data, mechanistic data, and epidemiology, IARC classified glyphosate as "probably carcinogenic to humans" (Group 2A). The pesticide Monograph, like other IARC monographs, was "based on the systematic assembly and review of all publicly available and pertinent [peer-reviewed] studies, by independent experts, free from vested interests."[78]

Petitioner and *amici* mischaracterize the significance of hazard assessments like those performed by IARC. IARC's hazard assessments address an agent's carcinogenic potential to cause cancer (and as to Roundup, whether Roundup exposure can cause NHL). Regulatory bodies like EPA undertake the same hazard analysis but never reach the next regulatory step of performing a "risk assessment" unless they first determine that a substance is a "hazard." Contrary to *amici* Americal Tort Reform Association, the EPA did not conduct a

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[76] *See, e.g.,* P-0746-007, P-0393-003; Email from Link (Feb. 12, 2015), MONGLY01021708–711, http://www.wisnerbaum.com/wp-content/uploads/ptx-0379-mon-email-revised-iarc-reactive-meeting.pdf.

[77] *IARC Monograph on Glyphosate*, IARC: WHO (July 19, 2018), https://www.iarc.who.int/featured-news/media-centre-iarc-news-glyphosate/.

[78] *Id.*

risk assessment for glyphosate "that incorporate[s] hazard identification, dose-response analysis, exposure assessment, and risk characterization."[79] EPA, like IARC, performed a glyphosate hazard assessment; but in the course of doing so, violated its own carcinogenicity guidelines.[80]

Petitioner and *amici's* criticism that IARC considers only published papers similarly lacks merit. IARC's practice avoids to the extent possible unpublished, unreviewed, and possibly biased findings pushed by registrants seeking regulatory approval. This ensures that IARC's assessment rests on transparent and reproducible findings that have withstood the scrutiny of peer review.[81]

Last, *amici* criticize IARC for changing its classification system to remove Group 4 ("probably not carcinogenic"), leaving Group 3 ("not classifiable as to

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[79] Brief of *Amici Curiae* Americal Tort Reform Association at 5.

[80] *Nat. Res. Def. Council v. EPA*, 38 F. 4th 34, 47, 49 (9th Cir. 2022) (vacating EPA analysis in part because "EPA's Cancer Paper uses historical-control data selectively and in a manner that is inconsistent with the Cancer Guidelines," and "EPA's disregard of tumor results occurring at high dosages conflicts with the guidelines EPA purports to follow").

[81] Petitioner and its *amici* spuriously suggest IARC is a fringe organization by referring to other assessments, such as those for red meat and processed meats, and very hot beverages. *See, e.g.,* Brief of *Amicus Curiae* Americal Tort Reform Ass'n at 8. While *amici* mock these as far-fetched, they rest in scientific evidence and reflect well-known associations accepted by groups such as the American Cancer Society (which warns of the risk associated with red and processed meat consumption) and the American Institute for Cancer Research (which also acknowledges these links).

its carcinogenicity") as the category reflecting the lowest level of evidence. *Amici* brief at 9. That change simply reflects IARC's role in reviewing agents for which some data already indicates a potential carcinogenic hazard.[82] It has no bearing on whether IARC validly assesses some agents as probable or known carcinogens.

IV. The Scientific Evidence Linking Glyphosate with Cancer Goes Far Beyond IARC's Analysis and Has Only Become Stronger Over Time.

Mr. Durnell's trial evidence that Roundup causes cancer was not limited to IARC's analysis, nor are successful Roundup plaintiffs meeting their demanding scientific evidentiary burdens by relying on IARC alone. Before any Roundup trials ever took place, the Judge overseeing the federal multi-district litigation found that plaintiffs' experts' opinions were admissible *only* where they "went beyond the inquiry conducted by IARC."[83] Accordingly, experts at Roundup trials have been allowed to testify that Roundup causes cancer *only* where they have "offer[ed] independent and relatively comprehensive opinions that the epidemiological and other evidence demonstrates glyphosate causes NHL in some people who are exposed to it."[84] So where "expert opinions [] simply parrot[ed] IARC's analysis" they were

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[82] *See* IARC Monographs Preamble (2019). https://monographs.iarc.who.int/wp-content/uploads/2019/07/Preamble-2019.pdf.

[83] *In re Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102, 1109 (N.D. Cal. 2018).

[84] *Id.*

excluded as "insufficient to satisfy the plaintiffs' burden."[85]

Indeed, since the 2015 IARC-issued glyphosate monograph, the body of evidence supporting Roundup's link to cancer has exploded. And importantly this explosion of science includes direct human evidence. As one scientific publication noted: "The number of journal articles published yearly on glyphosate and GBHs has increased steadily since the commercialization of glyphosate in 1974, with nearly a 4-fold increase in the last 10 years alone" as illustrated by the following chart:[86]

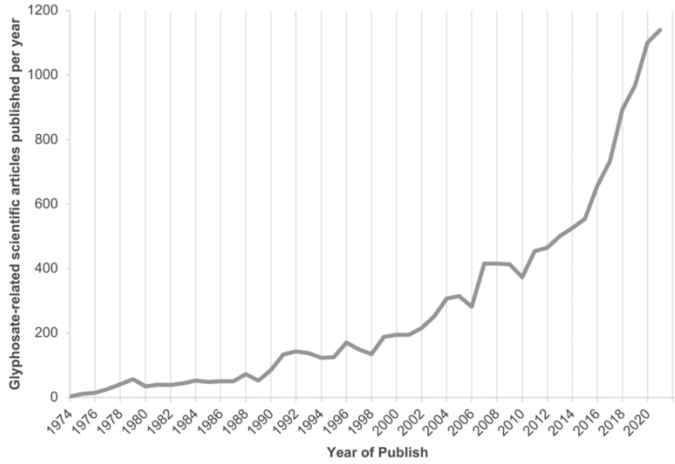

Figure 3. Increasing trend of scientific papers published on glyphosate or GBHs from 1974 to 2021. Chart depicting the increase year-over-year in scientific interest in glyphosate and GBHs. Data collected from Web of Science database. "glyphosate" and "glyphosate-based herbicides" were used as topic keywords.

[85] *Id.* at 1115.

[86] Rachel Lacroix & Deborah Kurrasch, *Glyphosate Toxicity: In Vivo, In Vitro, and Epidemiological Evidence*, 192 TOX. SCIS. 131 (2023), http://doi.org/10.1093/toxsci/kfad018.

Thus, most of the science that the parties rely on at Roundup trials postdates IARC, as well as the EPA assessments that were unanimously vacated by a Ninth Circuit panel consisting of Judge Wallace, Judge Boggs (sitting by designation), and Judge Friedland.[87] Not only is Monsanto's depiction of Durnell's scientific case objectively wrong in light of this record, the rule Monsanto asks for would be antithetical to the functioning of FIFRA, which "contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings,"[88] Congress understood this evolution was necessary, because direct human health studies can only occur *after* pesticides are brought to market and their labels approved by EPA. And where the endpoint being studied is one involving a long latency period like cancer, knowledge can take decades to develop.

Affirming the Missouri Court of Appeals' decision would therefore be fully consistent with the pesticide regulatory scheme set forth by Congress. EPA's upfront review of all pesticide registrations is limited; its review of Roundup in particular was marred by fraudulent misconduct, and further hobbled by Monsanto's deceptive conduct; and years of subsequent research have confirmed the strong association between glyphosate and cancer in humans.

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[87] *See Nat. Res. Def. Council*, 38 F. 4th at 34.

[88] *Bates*, 544 U.S. at 451.

CONCLUSION

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

Respectfully submitted,

ALANI GOLANSKI
Counsel of Record
ROBIN L. GREENWALD
ALICIA BUTLER
ROBERT QUIGLEY
WEITZ & LUXENBERG P.C.
700 Broadway
New York, NY 10003
(212) 558-5500

DAVID WOOL
WOOL TRIAL LAW LLC
1001 Bannock Street
Suite 410
Denver, CO 80204
(720) 370-6576

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