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 STAND FOR HEALTH FREEDOM AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF AMICI CURIAE[1]

Stand for Health Freedom ("**SHF**") is a national nonprofit organization dedicated to protecting informed consent in health decision-making and the constitutional structure that safeguards those freedoms. Central to SHF's mission is the protection of the environmental foundations of human health, including the safety of the land, water, and ecosystems on which all Americans depend. Because chemical products designed to kill living organisms directly affect these foundational inputs to human health, transparency regarding their risks is essential to the informed decision-making that SHF exists to defend. SHF's interest extends not only to the disclosure of material risks, but also to the preservation of legal mechanisms, particularly state tort law, through which individuals can obtain that information and seek redress when it is withheld.

Through education, civic engagement, and public policy advocacy, SHF has mobilized more than one million Americans to participate in protecting informed consent, transparency, environmental stewardship, and governmental accountability. This includes efforts in ten states to preserve the right of individuals to seek legal redress when pesticide manufacturers fail to disclose known product risks. Those individuals rely on

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

accurate risk disclosures to make decisions about products used in their homes, communities, gardens, schools, and playgrounds.

The legal question presented in this case, whether states may allow courts and juries to review the adequacy of manufacturer warnings, directly affects SHF's mission and the interests of the Americans it represents. The elimination of those mechanisms would leave those individuals without any forum to test the adequacy of risk disclosures or obtain compensation for resulting injuries. SHF has no financial interest in the outcome of this case. It files this brief solely because of the implications the Court's decision will have for informed consent, the role of state courts in protecting public health, and the ability of individuals to obtain truthful information about risks posed by products in widespread use.

SUMMARY OF THE ARGUMENT

Monsanto asks this Court to hold that approval of a pesticide label by the United States Environmental Protection Agency ("**EPA**") eliminates all state tort accountability for injuries that label fails to prevent. That is not preemption. It is blanket immunity, and nothing in the Federal Insecticide, Fungicide, and Rodenticide Act ("**FIFRA**") authorizes it.

FIFRA's text forecloses that result. Congress provided that registration "shall not" be construed as a defense. 7 U.S.C. § 136a(f)(2). EPA approval creates only prima facie evidence of compliance, a rebuttable presumption, not a conclusive shield. *Carson v. Monsanto Co.*, 92 F.4th 980, 991 (11th Cir. 2024).

Federal law addresses risk through disclosure and informed choice, not immunity. Across regulatory regimes, agency approval reflects a procedural judgment and establishes a baseline, while manufacturers retain a continuing duty to disclose material risks. *See infra* Section I.

Monsanto's impossibility argument fares no better. A manufacturer must present "clear evidence" that the agency would have rejected a label change. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 313-14 (2019). Monsanto's own parent company unilaterally added a cancer warning to its LARVIN insecticide label through the same regulatory pathway available for Roundup, and EPA accepted the amendment. EPA data confirm that registrants obtained approval for thousands of post-registration label amendments in FY 2024 alone. The asserted inability is not legal; it is strategic.

Monsanto's rule would also displace state authority that States are actively exercising. Courts across multiple jurisdictions have rejected FIFRA preemption of failure-to-warn claims, and legislatures have considered and largely declined efforts to eliminate those claims. Nothing in FIFRA reflects the unmistakably clear congressional intent required to override that authority. *See infra* Section III.

The consequences are not merely statutory but constitutional. FIFRA provides no private right of action, and no federal forum exists to adjudicate pesticide injury claims. Eliminating state tort remedies would leave injured individuals with no forum, no jury, and no remedy, raising serious due process and

Seventh Amendment concerns. *See infra* Section IV.

ARGUMENT

I. Federal Law Protects Informed Consent Through Disclosure, Not Immunity.

A. The Law Protects the Right to Make Informed Decisions About Risk.

The right to determine what shall be done to one's own body is among the oldest and most deeply rooted principles in American law. More than a century ago, Justice Cardozo stated: "[E]very human being of adult years and sound mind has a right to determine what shall be done with his own body." *Schloendorff v. Soc'y of N.Y. Hosp.*, 211 N.Y. 125, 129 (1914). This Court has long recognized bodily integrity as a core component of personal liberty.

In *Cruzan v. Dir., Mo. Dep't of Health*, this Court recognized a constitutionally protected interest in bodily integrity, including the right to refuse unwanted medical treatment. 497 U.S. 261, 278 (1990); *see also Washington v. Harper*, 494 U.S. 210, 221-22 (1990). In *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the Court reaffirmed that "[a]t the heart of liberty is the right to define one's own concept of existence." 505 U.S. 833, 851 (1992). These decisions establish that control over bodily risk is a constitutional commitment, not a policy choice. That commitment finds practical expression in the doctrine of informed consent.

In *Canterbury v. Spence*, the court held that a

physician's duty of disclosure is measured not by what the medical profession customarily reveals, but by what a reasonable patient would consider material to the decision at hand. 464 F.2d 772, 786-87 (D.C. Cir. 1972). A risk is "material" when "a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk." *Id.* at 787. The duty to disclose rests with the party possessing the information, while the right to decide rests with the individual who bears the risk.

These principles converge in a single rule: the right to make an informed decision about exposure to harm. Autonomy without information is illusory. Disclosure without choice is insufficient. Consent without information is not meaningful consent. The principle applies wherever an individual faces a risk that another party has both the power and the obligation to disclose.

B. The Law Requires Disclosure of Material Risk Before Exposure.

This principle is embedded in legal doctrine. The duty to disclose requires disclosure of material risks, not all information. *Canterbury* articulated this distinction: a risk is material when a reasonable person in the patient's position would likely attach significance to it in deciding whether to proceed. 464 F.2d at 786-87. The standard is objective, but it turns on what the individual bearing the risk needs to know, not what the information holder chooses to disclose.

Disclosure must precede exposure. A warning delivered too late, or withheld entirely, defeats consent. Withholding material risk information undermines the

validity of consent.

Products liability law reflects the same principle. The *Restatement (Third) of Torts: Products Liability* § 6(d) (1998) provides that a product is defective when it lacks adequate instructions or warnings about foreseeable risks of harm, imposing on manufacturers a duty to disclose known dangers before the product reaches the user. That duty exists independent of regulatory compliance.

The *Restatement (Third) of Torts: Products Liability* § 4 cmt. a (1998) makes the point directly: compliance with a governing safety statute or regulation is relevant evidence, but it is "not conclusive" on the question of liability. A manufacturer may satisfy every regulatory requirement and still face liability for failing to warn of a risk it knew or should have known. The duty to disclose material risk runs to the person exposed to harm, not to the agency overseeing the product. It is a duty owed to the individual whose consent the law protects.

C. Federal Law Consistently Requires Disclosure Before Exposure Across Regulatory Regimes.

Across federal regulatory regimes, the law adopts a consistent structure: disclosure before exposure and accountability when that duty is breached.

In pharmaceutical regulation, the manufacturer bears primary responsibility for the content of its label, and that responsibility continues after approval. In *Wyeth v. Levine*, this Court held that a manufacturer

may strengthen a drug's warning label through the Food and Drug Administration ("**FDA**") "changes being effected" process without prior agency approval, and that failure to do so may give rise to state tort liability. 555 U.S. 555, 570-71 (2009).

The duty is ongoing. When a manufacturer learns of a new risk, it must act, regardless of what the label said at the time of approval. In *Albrecht*, the Court reinforced this framework, holding that impossibility preemption requires "clear evidence" that the FDA would have rejected a proposed label change. 587 U.S. 299, 313-14 (2019). The burden rests on the manufacturer to show that it could not have warned, not on the injured party to prove that it should have. Federal law thus treats approval as the beginning of the duty to warn, not the end.

The regulation of medical devices follows the same logic. In *Medtronic, Inc. v. Lohr*, this Court emphasized that the FDA's § 510(k) clearance process is not a determination that a device is safe or effective, but a finding of substantial equivalence to a predicate device. 518 U.S. 470, 493-94 (1996). In *Sandoz Inc. v. Amgen Inc.*, the Court confirmed the broader point that an agency determination permitting a product to be marketed does not constitute an affirmative finding of safety. 582 U.S. 162, 167 (2017). Clearance permits marketing; it does not establish safety.

Even when risks are conveyed indirectly through a physician, the duty to disclose remains. In *Reyes v. Wyeth Laboratories*, the Fifth Circuit held that the learned-intermediary doctrine does not apply when vaccines are administered in mass immunization

programs without individualized medical judgment, because valid consent requires a physician capable of evaluating and communicating the risk. 498 F.2d 1264, 1276 (5th Cir. 1974). In *Centocor, Inc. v. Hamilton*, the Texas Supreme Court held that a manufacturer's duty to warn prescribing physicians includes disclosure of risks the manufacturer knew or should have known. 372 S.W.3d 140, 160-62 (Tex. 2012). In each instance, the validity of consent depends on the adequacy of the information that reaches the patient. Approval does not satisfy that requirement. Disclosure does.

Federal law is most explicit about pre-exposure disclosure in human subjects research. The Common Rule, 45 C.F.R § 46.116, requires that a research subject receive a description of foreseeable risks before consenting to participate in a clinical trial. The regulation does not permit post hoc disclosure and does not treat institutional approval as a substitute for individual consent. In *Grimes v. Kennedy Krieger Institute, Inc.*, the Maryland Court of Appeals held that researchers owe a duty of informed consent to study participants and that institutional review board approval does not shield researchers from liability for nondisclosure. 366 Md. 29, 61-63 (2001).

Workplace safety law follows the same disclosure-based structure. The Occupational Safety and Health Administration ("**OSHA**") Hazard Communication Standard, 29 C.F.R. § 1910.1200, requires employers to inform workers of chemical hazards before exposure occurs. This Court recognized the federal interest in occupational safety disclosure in *Gade v. National Solid Wastes Management Ass'n*, while preserving complementary state authority. 505

U.S. 88, 98-99 (1992). And in *Pedraza v. Shell Oil Co.*, the First Circuit held that OSHA's disclosure requirements do not preempt state tort claims for failure to warn of chemical hazards, because the federal right-to-know regime establishes a floor for disclosure, not a ceiling on accountability. 942 F.2d 48, 53-54 (1st Cir. 1991).

A pattern emerges. In pharmaceuticals, manufacturers must update warnings when they learn of new risks, regardless of prior approval. In medical devices, agency clearance permits market entry but does not establish safety. In clinical research, institutional approval does not substitute for individual consent. In occupational safety, the right to know precedes and survives regulatory compliance. These are expressions of a single structural commitment: federal law manages risk through disclosure and informed choice, not through immunity from liability. Monsanto's theory is inconsistent with each of these frameworks.

Across these regimes, this Court has consistently refused to treat agency approval as displacing state-law remedies, recognizing that regulatory standards operate as minimum requirements rather than ceilings on liability. *Wyeth*, 555 U.S. at 568-69 (federal labeling requirements create a "floor, not a ceiling"); *Lohr*, 518 U.S. at 495 (state remedies preserved where they parallel federal requirements).

D. Tort Law Enforces Disclosure by Imposing Liability for Nondisclosure.

Disclosure obligations do not enforce themselves. They depend on consequences. A disclosure obligation without a consequence for breach is not a legal duty; it is an aspiration.

The common law reflects this principle. In *Canterbury*, the court held that failure to disclose material risks gives rise to liability, allowing a patient denied material information to recover for injuries that adequate disclosure would have prevented. 464 F.2d at 790. The same logic governs products liability. The *Restatement (Third) of Torts: Products Liability* § 4 cmt. a (1998) makes clear that regulatory compliance does not preclude tort liability, because a regulatory floor would lose its force if treated as a ceiling.

In *Lohr*, this Court cautioned against constructions that would grant "complete immunity" to an entire industry through a federal approval process lacking a private cause of action. 518 U.S. at 487. The point is structural. When the regulatory system provides no remedy for nondisclosure, eliminating the tort remedy leaves the duty unenforceable. Tort law ensures that disclosure obligations are real rather than aspirational.

Tort litigation does more than remedy past failures to disclose. It compels the production of information that the regulatory process alone may not uncover. In *Wyeth*, this Court observed that state tort suits serve an important information-forcing function, uncovering unknown hazards and creating incentives

for manufacturers to disclose safety risks promptly. 555 U.S. at 578-79. Federal agencies depend on manufacturer-submitted data. The adversarial process can produce evidence, including internal memoranda, suppressed studies, and undisclosed test results, that voluntary compliance and regulatory oversight do not.

Recent litigation illustrates this function. Through discovery, plaintiffs obtained internal documents showing that Monsanto ghostwrote scientific articles, suppressed adverse genotoxicity findings, and sought to influence the agency's review process. None of that evidence appeared in the regulatory record. Three juries considered it. The tort system did not duplicate the regulatory process; it supplemented it.

Regulation and tort liability are not competitors. They are complements, two parts of a single system designed to ensure that risk information reaches those who need it. Regulation sets the baseline: what must appear on the label, what data must be submitted, and what standards must be met. Tort liability provides the backstop: accountability when the baseline proves inadequate, when information is withheld, or when unanticipated risks emerge.

Eliminating either component undermines the system.

A regulatory regime without tort enforcement invites the suppression of unfavorable data, because the only audience for disclosure is the agency the manufacturer is already attempting to persuade. This Court has preserved this dual structure in analogous contexts, including pharmaceuticals, medical devices,

motor vehicles, and consumer products. Monsanto asks the Court to depart from that approach for pesticides alone. Nothing in FIFRA supports that result.

E. Monsanto's Rule Would Eliminate Disclosure and Make Informed Consent Impossible.

Monsanto's rule would sever the connection between risk and accountability on which informed consent depends. If the EPA's approval of a pesticide label immunizes the manufacturer from failure-to-warn liability, the manufacturer has no legal incentive to disclose risks the label does not already reflect. The tort system's information-forcing function, which this Court recognized in Wyeth as essential to uncovering unknown hazards, would be eliminated for an entire category of products used in homes, schools, and communities.

No discovery would compel the production of suppressed studies. No jury would assess whether a manufacturer's warnings were adequate. No verdict would create a public record of concealed risk. Individuals exposed to these products would make decisions about their health, and their families' health, without access to information the manufacturer possesses and has chosen not to disclose. That result is incompatible with informed consent.

When Congress creates immunity, it does so expressly and provides a substitute remedy. The National Childhood Vaccine Injury Act ("**NVICA**") establishes a safe harbor for vaccine manufacturers, but only alongside a no-fault compensation program that preserves recovery for individuals who suffer

vaccine-related injuries. 42 U.S.C. §§ 300aa-10 to 300aa-22(b)(1); *see Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228-32 (2011).

The NVICA reflects a deliberate legislative judgment: immunity is permissible only when paired with a compensation mechanism that preserves access to remedies. Congress made that trade explicitly, with detailed limitations, mandatory reporting requirements, and a dedicated adjudicatory scheme. It did not delegate that decision to an agency, and it did not leave it to shifting litigation positions across administrations.

Congress enacted no comparable provision in FIFRA. There is no immunity clause. There is no substitute compensation scheme. There is no no-fault tribunal. There is no mandatory adverse-event reporting system equivalent to the Vaccine Adverse Event Reporting System. FIFRA instead establishes a regulatory process that depends on manufacturer-submitted data, has failed to complete numerous required safety reviews, and whose glyphosate determination has been judicially vacated.

Monsanto asks this Court to treat that process as the exclusive safeguard for public health while eliminating the only mechanism through which individuals can test the adequacy of a manufacturer's warnings and obtain a remedy when those warnings fail. A system that eliminates both liability and disclosure does not regulate risk; it obscures it.

Monsanto's proposed rule cannot be reconciled with this structure. The text and design of FIFRA confirm that Congress did not authorize the

elimination of state-law remedies that give effect to these principles.

II. FIFRA's Text Forecloses Monsanto's Claim That EPA Label Approval Creates Blanket Tort Immunity.

A. Registration Is Not a Defense and Label Approval Cannot Become One.

The analysis begins with the text. FIFRA provides that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this Act." 7 U.S.C. § 136a(f)(2). Monsanto's rule would do exactly what the statute forbids: treat EPA label approval, the product of registration, as a complete bar to liability.

That construction is foreclosed by the statute's plain terms. Registration may not be treated as a defense, and the text admits of no exception, express or implied. *See MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994). Other courts agree that EPA approval is at most "prima facie evidence" of compliance, not a conclusive determination. *Carson*, 92 F.4th at 991. Approval is therefore evidence, not a defense and not immunity.

Monsanto's theory would require more than statutory interpretation; it would require attributing to EPA the authority to extinguish state-law remedies. This Court has repeatedly declined to assign such sweeping consequences to agency action absent clear congressional authorization. Agency approval is therefore evidence of regulatory compliance, not a

delegation of authority to eliminate common-law liability.

Nor does EPA label approval constitute a safety determination. As explained supra Section I.C, agency approval reflects a procedural judgment rather than a conclusive finding of safety. EPA registration under FIFRA confirms the point: the statute requires only that a pesticide not cause "unreasonable adverse effects," a cost-benefit standard that weighs economic utility against risk rather than establishing that the product is safe. 7 U.S.C. § 136(bb). A pesticide may be misbranded under FIFRA even though its label was approved at the time of registration, because approval and violation coexist under the statute. *Hardeman v. Monsanto Co.*, 997 F.3d 941, 953-54 (9th Cir. 2021).

B. Monsanto's Own Conduct Shows That Adding a Cancer Warning Was Not Impossible.

As discussed *supra* Section I.C, federal law permits manufacturers to strengthen warnings without prior approval in appropriate circumstances. Monsanto argues that compliance with both state tort law and federal registration requirements was "impossible." To prevail, a manufacturer must present "clear evidence" that the FDA would not have approved a change to the label. *Albrecht*, 587 U.S. at 313-14. This is a demanding defense. Monsanto does not meet that standard.

Bayer CropScience, Monsanto's parent company, unilaterally added a cancer warning to the label of its LARVIN Technical insecticide, notifying EPA of a "minor labeling amendment" under California

Proposition 65. EPA accepted the amendment. *See* EPA Pesticide Product Label, LARVIN Brand Technical, EPA Reg. No. 264-343. EPA's own Pesticide Registration Improvement Act ("**PRIA**") data document thousands of such registrant-initiated amendments annually, including streamlined notification procedures for added warnings. *See* EPA, FY 2024 PRIA Annual Report (June 2025).

Monsanto's conduct with respect to glyphosate reinforces the same point. EPA permitted the addition of a cancer warning for glyphosate products sold in California pursuant to Proposition 65. Rather than adopt that warning, Monsanto challenged the requirement on First Amendment grounds and obtained a permanent injunction barring its enforcement. *Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1275-78, 1283 (9th Cir. 2023); *see also* Letter from Michael Goodis, Dir., Registration Div., Office of Pesticide Programs, EPA, to Lauren Zeise, Cal. OEHHA (Apr. 8, 2022).

FIFRA's framework, including 40 C.F.R. § 152.44, does not prohibit manufacturers from adding safety warnings. It establishes a procedure for doing so. Bayer used that procedure for LARVIN. It chose not to do so for Roundup. The asserted impossibility is not legal; it is strategic, as Monsanto's own conduct confirms. That strategic choice defeats any claim of impossibility, which requires clear evidence that the agency would have rejected the warning. *Wyeth*, 555 U.S. at 568.

C. Preemption Would Reward the Concealment of Safety Data That FIFRA Prohibits.

FIFRA imposes on registrants an affirmative, ongoing obligation to disclose safety-relevant information. 7 U.S.C. § 136d(a)(2). Three separate juries have found that Monsanto possessed substantial evidence of glyphosate's carcinogenic potential and suppressed it. As discussed *supra* Section I.D, discovery in the Roundup litigation revealed internal evidence not before the agency, including suppression of safety data.

Monsanto's theory would convert that concealment into a litigation advantage. If EPA's label approval preempts state tort claims, a manufacturer that withholds adverse safety data is rewarded: the agency never learns of the risk, the label is never updated, and the manufacturer invokes the resulting silence as a preemptive shield. That result would transform § 136d(a)(2)'s disclosure mandate into a dead letter and deprive individuals of the truthful risk information on which informed decision-making depends.

D. The Government's Reversal Warrants Skepticism, Not Deference.

The current Solicitor General supports Monsanto's preemption theory. Three years earlier, the Solicitor General argued the opposite. No statute, regulation, or scientific finding changed in the interim. The sole explanation is a "change in Administration." Brief for the United States as *Amicus Curiae*

Supporting Petitioner at 2, *Monsanto Co. v. Durnell*, No. 24-1068 (U.S. Mar. 4, 2026). This Court has declined to credit such reversals. *Wyeth*, 555 U.S. at 577-78; *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41-42 (1983).

III. Monsanto's Rule Would Displace State Authority That States Are Actively Exercising and Defending.

A. This Case Concerns Active State Governance, Not Dormant Authority.

States are regulating, litigating, and legislating in the space Monsanto asks this Court to foreclose. The Congressional Research Service confirms a live and entrenched split, with multiple federal circuits and state appellate courts rejecting broad preemption. *See* U.S. Cong. Rsch. Serv., *Preemption in the FINRA*, LSB11304 (May 2, 2025). Industry-backed bills to eliminate these claims were introduced in more than twenty states; most were defeated. Monsanto asks this Court to displace systems that are currently operating, not hypothetical ones.

This Court has required that Congress speak "unmistakably clear[ly]" before displacing the States' traditional authority over health and safety. *Gregory v. Ashcroft*, 501 U.S. 452, 460-61 (1991); *Bond v. United States*, 572 U.S. 844, 858 (2014). Nothing in FIFRA meets that standard.

B. State Courts and Local Governments Have Overwhelmingly Rejected Preemption.

The Missouri Court of Appeals held that FIFRA does not preempt Durnell's failure-to-warn claim. *Durnell v. Monsanto Co.*, No. ED112410, 2025 WL 1497539 (Mo. Ct. App. 2025). The Ninth Circuit reached the same conclusion in *Hardeman*, 997 F.3d 941, as did the Eleventh Circuit in *Carson*, 92 F.4th 980. State appellate courts in California and Oregon have likewise rejected preemption. Only the Third Circuit has held otherwise. *Schaffner v. Monsanto Corp.*, 113 F.4th 364 (3d Cir. 2024).

Even within the Third Circuit's jurisdiction, state courts have declined to follow *Schaffner*. In *Caranci v. Monsanto Co.,* the Pennsylvania Superior Court rejected Monsanto's preemption defense, emphasizing that it was "not bound by any decisions from a federal appeals court." No. 993 EDA 2024, 2025 WL 1340970 (Pa. Super. Ct. May 8, 2025). Local governments likewise rely on state tort causes of action as "essential complements to federal regulation for protecting public health." Brief for Nat'l Ass'n of Counties et al. as *Amici Curiae* Supporting Respondent, *Monsanto Co. v. Durnell*, No. 24-1068 (U.S. 2026).

C. Industry's Legislative Campaign Confirms That State Authority Is Real and Contested.

Even as Monsanto argues that FIFRA already preempts these claims, it has pursued a coordinated

legislative campaign to achieve the same result through statute. Bayer founded the Modern Ag Alliance, a coalition of over 110 agricultural organizations, to advocate for state bills shielding pesticide manufacturers from failure-to-warn liability. During the 2024-2026 legislative sessions, these bills were introduced in at least twenty-one states. *See* Nat'l Agric. L. Ctr., *States Introduce Pesticide Liability Limitation Bills in 2025 Legislative Session* (Jan. 2025). Only two states enacted such legislation. The bills were defeated or stalled everywhere else.

If FIFRA already preempted these claims, this campaign would be unnecessary. The industry's own conduct, deploying over 110 organizations across more than twenty states, is an implicit concession that state authority in this space is real and consequential. And the fact that most legislatures rejected these bills confirms that the authority is actively valued and defended.

D. The Scope of State Authority Cannot Depend on Changing Litigation Positions.

Monsanto does not rely on any statute, regulation, or formal agency action establishing preemption. It relies on the litigation position of the Solicitor General, a position that has reversed with changes in presidential administration and has not remained consistent over time. That inconsistency is not new. In prior litigation, the United States intervened to argue that courts had adopted a "widespread misunderstanding" of FIFRA and that federal law does not preempt state-law damages

actions, emphasizing that such remedies were intended to operate alongside the federal scheme. *See* Brief for the United States as Amicus Curiae in Support of Plaintiffs-Appellants at 5-8, *Etcheverry v. Tri-Ag Serv.*, Inc., 22 Cal. 4th 316, 993 P.2d 366 (2000) (No. S072524).

The federal government thus previously rejected FIFRA preemption and criticized contrary precedent as mistaken, confirming that executive-branch views on this question have shifted over time.

If the scope of state authority can expand and contract with changes in administration, federalism would cease to operate as a structural principle. But "[t]he Constitution divides authority between federal and state governments for the protection of individuals." *New York v. United States,* 505 U.S. 144, 181 (1992). The scope of that protection cannot depend on which party controls the White House or on shifting litigation positions of the Executive. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005); *Wyeth*, 555 U.S. at 565 n.3.

E. Monsanto's Rule Would Convert Regulatory Floors into Ceilings Across the Administrative State.

Monsanto's rule would extend beyond FIFRA, displacing state failure-to-warn claims across multiple regulatory regimes, including FDA-approved pharmaceutical labels, Consumer Product Safety Commission ("**CPSC**")-approved consumer product warnings, and National Highway Traffic Safety Administration ("**NHTSA**")-approved automotive safety disclosures. As explained *supra* Section I.C,

federal regulatory regimes establish minimum standards rather than ceilings on liability. This Court has repeatedly rejected efforts to convert federal regulatory standards into ceilings on state-law accountability. *See supra* Section I.C.

The consequences of departing from that principle here would not be confined to pesticides. Any agency approval of a product label across any sector could serve as the basis for extinguishing state tort claims. The spillover would reach every regulated industry in which federal approval coexists with state common-law remedies.

IV. Monsanto's Rule Would Eliminate All Forums for Adjudicating Pesticide Injury Claims, a Result the Constitution Does Not Permit.

A. Monsanto's Rule Would Produce Complete Remedial Foreclosure.

"The fundamental requisite of due process of law is the opportunity to be heard." *Mullane v. Cent. Hanover Bank & Tr. Co.*, 339 U.S. 306, 314 (1950). Monsanto's rule would extinguish every state tort claim for pesticide injury without providing any forum, federal or state, in which the injured individual may be heard. That feature distinguishes this case from the rare instances in which Congress has displaced state tort remedies. When Congress has elected to limit tort liability, it has done so expressly and paired that limitation with a substitute compensation scheme and adjudicatory forum. The NVICA provides a no-fault compensation program and specialized tribunal as a substitute for certain tort claims. 42 U.S.C. §§

300aa-10 to 300aa-34; *Bruesewitz*, 562 U.S. at 228-32. Here, by contrast, Monsanto asks the Court to infer complete immunity from an agency approval process that provides no private right of action, no compensation scheme, and no forum at all. This Court has been reluctant to adopt interpretations that would "remove all means of judicial recourse" for injured individuals absent clear congressional direction. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *English v. Gen. Elec. Co.*, 496 U.S. 72, 87-90 (1990). Monsanto's rule is therefore not ordinary preemption; it is complete remedial foreclosure. *Wyeth*, 555 U.S. at 574-75; *Uzuegbunam v. Preczewski*, 592 U.S. 279, 289 (2021).

FIFRA provides no private right of action. *Bates*, 544 U.S. at 448. No federal damages remedy exists. No federal forum adjudicates individual pesticide injury claims. State tort law is the only remaining mechanism through which such claims may be adjudicated. If the Court agrees with Monsanto, the result is not ordinary preemption; it is complete remedial foreclosure.

This Court has consistently resisted interpretations that produce such an outcome. *See Uzuegbunam*, 592 U.S. at 289; *Wyeth*, 555 U.S. at 574-75.

B. The Seventh Amendment Protects the Claims at Issue.

Failure-to-warn claims against manufacturers of dangerous products are among the oldest tort actions recognized at common law. The Seventh Amendment preserves the right to jury trial in such suits. *See Curtis v. Loether*, 415 U.S. 189, 194 (1974).

The Founders regarded the civil jury as what Hamilton called "the very palladium of free government." The Federalist No. 83.

The constitutional concern here is not the loss of a procedural right. It is the elimination of a structural safeguard. "The right of access to the courts is" itself "one of the fundamental rights" protected by the Constitution. *Tennessee v. Lane*, 541 U.S. 509, 523 (2004). The jury's role is especially critical where individuals must rely on manufacturers to disclose complex health risks. Monsanto's rule would foreclose that submission entirely, not by replacing it with an alternative forum, but by eliminating all forums.

C. The Regulatory Process Cannot Substitute for Adjudication of Individual Claims.

Monsanto's theory rests on the implicit premise that EPA's label-approval process adequately protects public health, making tort remedies unnecessary. As explained *supra* Section I.D, and as the regulatory record here confirms, the regulatory process does not provide a substitute for adjudication of individual claims.

EPA's Office of Pesticide Programs is responsible for thousands of active pesticide ingredients. FIFRA requires EPA to complete a registration review for each pesticide every fifteen years. 7 U.S.C. § 136a(g). As of 2022, approximately 799 such decisions were overdue. *See* Government Accountability Office ("**GAO**"), Pesticide Registration Review (2022). The office operates with fewer than 500 staff evaluating safety data for a market encompassing approximately 17,000

pesticide formulations. This is not an agency positioned to serve as the exclusive safeguard for public health.

The glyphosate review illustrates the problem. Glyphosate was registered in 1974. EPA initiated its registration review in 2009, thirty-five years later. In 2020, EPA concluded glyphosate is "not likely to be carcinogenic," but that followed decades of evolving agency assessments and disagreement regarding glyphosate's carcinogenic potential. *See* U.S. Env't Prot. Agency, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* § 1.2, at 12–13 (Sept. 12, 2016) (draft) (describing EPA classifications shifting from "possible human carcinogen" (1985) to "evidence of non-carcinogenicity" (1991) to "not likely" (2015)); *Natural Res. Def. Council v. EPA*, 38 F.4th 34, 45-52 (9th Cir. 2022) (noting internal disagreement and Scientific Advisory Panel division regarding carcinogenicity). The agency's determination was itself contested, with internal EPA scientists and an independent Scientific Advisory Panel expressing disagreement with the "not likely" classification. In 2022, the Ninth Circuit vacated that conclusion, finding that EPA had failed to support it with substantial evidence. *Nat. Res. Def. Council*, 38 F.4th at 45-52. EPA then withdrew all remaining portions of its Interim Decision. As of this filing, no valid registration review decision for glyphosate exists. Discovery in the Roundup litigation further revealed internal evidence not before the agency, including evidence that Monsanto influenced scientific publications and sought to shape the evidentiary record considered in regulatory review. *In re Roundup Prods. Liab. Litig.*, Multidistrict Litigation ("**MDL**")

No. 2741, Pretrial Order No. 45, at 4-6, 33-35 (N.D. Cal. July 10, 2018); *Hardeman v. Monsanto Co.*, No. 16-cv-00525-VC (N.D. Cal. Jan. 3, 2019) (permitting evidence that Monsanto "manipulated the outcome of scientific studies"). That divergence reflects a limitation of the regulatory process, which relies on manufacturer-submitted data and does not capture the full evidentiary record that emerges through adversarial litigation. *Wyeth*, 555 U.S. at 569, 575 n.10.

The pattern extends beyond glyphosate. Chlorpyrifos, linked to neurodevelopmental harm in children, was introduced in 1965. A petition to ban it was filed in 2007. After fourteen years of proceedings, EPA revoked tolerances in 2021, a ban subsequently vacated by the Eighth Circuit. The Ninth Circuit observed that "EPA's egregious delay exposed a generation of American children to unsafe levels of chlorpyrifos." *League of United Latin Am. Citizens v. Ruckelshaus*, 996 F.3d 673, 702 (9th Cir. 2021). Paraquat, linked to Parkinson's disease in epidemiological studies, has been banned in over sixty countries, yet EPA continues to permit its sale in the United States without a Parkinson's disease warning. For the individuals harmed, the tort system is the only accountability mechanism that exists.

D. Adjudication Uncovers What Regulation Misses.

As discussed *supra* Section I.D, state tort litigation can uncover evidence not reflected in the regulatory record. Discovery in the Roundup litigation revealed internal evidence not before the agency, confirming the limits of regulatory review. Bayer has

paid approximately $11 billion in settlements arising from over 100,000 claims.

Three juries have found Monsanto liable, including awards of punitive damages reflecting findings that the company acted with knowledge of the risk. These verdicts are the product of the adversarial process, the mechanism our legal system provides for testing claims the regulatory system has not addressed. To nullify those verdicts through preemption would be to hold that regulatory approval, even when judicially invalidated, is more reliable than the constitutional adjudicatory process.

E. The Court Should Not Infer Total Remedial Elimination Absent Clear Congressional Command.

Monsanto's rule would produce a regime in which FIFRA provides no private right of action, EPA's own glyphosate review has been judicially vacated, the manufacturer possessed and concealed evidence of carcinogenic risk, and no forum, federal or state, remains to adjudicate the injured plaintiff's claim. That result is not preemption; it is immunity.

John Durnell testified that he did not see any cancer warning on the Roundup label but would have heeded such a warning had one been provided. A Missouri jury heard that testimony, weighed the evidence, and awarded $1.25 million. That verdict is the only accountability mechanism the law provides. Monsanto's rule would eliminate it and leave Durnell and every similarly situated American with no remedy at all.

The Constitution disfavors that result. The structural design of the federal system presumes that state tort remedies remain available absent unmistakably clear congressional intent to displace them. *See Lohr*, 518 U.S. at 487. Congress expressed no such intent in FIFRA. It provided no substitute remedy. This Court should not infer an immunity that Congress did not enact.

CONCLUSION

Monsanto asks this Court to convert EPA's approval of a pesticide label into blanket tort immunity. FIFRA's text forbids that result. The statute provides that registration "shall not" be construed as a defense. 7 U.S.C. § 136a(f)(2).

Adopting Monsanto's rule would eliminate the only forum in which injured individuals can test the adequacy of risk disclosures, displace state authority that States are actively exercising, and create a regime of immunity that Congress did not enact. Because FIFRA provides no substitute remedy and no federal forum, the result would be complete remedial foreclosure. This Court should decline to infer such a result absent unmistakably clear congressional command.

The judgment of the Missouri Court of Appeals should be affirmed.

Respectfully submitted,

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