

No. 26–235

In the Supreme Court of the United States

PHILIP MORRIS USA INC.,

Petitioner,

v.

ARMAND FONTAINE, individually and as personal representative of the Estate of Barbara Ellen Fontaine,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO
THE MASSACHUSETTS SUPREME JUDICIAL
COURT

**BRIEF OF COALITION OF U.S. MANUFACTURING COMPANIES AS *AMICI CURIAE* IN
SUPPORT OF PETITIONER**

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INTERESTS OF THE *AMICI CURIAE*¹

Amici curiae are United States companies that, like Petitioner, manufacture and sell products throughout the country subject to comprehensive federal health and safety regulatory regimes.² The plain text, structure, purpose, and subject matter of the statutes that create these standards clearly evince Congress's intent to establish exclusive federal regulatory regimes. These federal standards are (i) adopted through rigorous, science-based deliberative processes that afford all constituents the opportunity to participate, (ii) revised on a prospective basis as new information or science comes to light, and (iii) enforced by federal agencies with the authority to impose civil or criminal penalties for non-compliance. The standards reflect Congress's considered judgment that compliance therewith is necessary *and* sufficient to protect the public welfare. And they provide the regulatory uniformity companies require to develop, market, and sell their products nationwide.

In recent years, *amici* have faced a deluge of litigation brought mainly by the mass tort plaintiffs' bar and some states, seeking to advance state law duties, claims, and remedies that unquestionably are

¹ Pursuant to Rule 37.2, ten days before this brief was due, counsel for *amici curiae* notified counsel of record for the parties of its intention to file this brief. Pursuant to Rule 37.6, counsel for *amici* certifies that this brief was not authored in whole or in part by counsel for any party, and that no person or entity, other than *amici* or their counsel, made a monetary contribution to the preparation or submission of the brief.

² This brief is submitted on behalf of the following coalition of *amici*: Johnson & Johnson, Exxon Mobil Corporation, Ford Motor Company, Kenvue Inc., Monsanto Company, and Textron Inc.

preempted by federal law. Certain lower courts permit these state law cases to proceed by endorsing the “artful” re-labeling of claims to circumvent the plain reading of the governing statute, or relying on a judicially created “presumption against preemption” to narrow its express terms.

In doing so, these courts abrogate the social bargain underpinning the regulatory regimes. In exchange for complying with federally mandated standards, U.S. companies were to receive the regulatory certainty they require to make the investments necessary to bring their products to market in the United States. Instead, the courts allow opportunistic plaintiffs’ lawyers to pursue contrived state law causes of action to recover extreme *retroactive* damages awards and penalties for federally compliant sales made in years and decades past.

Those claims are inequitable and contravene the intended supremacy and exclusivity of federal regulations. As this Court recently held, the law should not “retroactively penalize persons for doing what the Government had required them to do.” *Monsanto Co. v. Durnell*, 146 S. Ct. 2001, 2014 (2026). But that is exactly what *amici* (and similarly situated U.S. companies across myriad industries) experience every day.

Amici have added their names to the petition before this Court to underscore the importance of these issues to U.S. companies endeavoring to invest, manufacture, and sell in this country. The questions presented here are the same legal issues that *amici* repeatedly face and that must be dispositively decided to resolve the splits in the judiciary concerning the preemptive force of comprehensive federal health and safety regulatory regimes. Those legal issues are

well-framed by the record below, and can be readily resolved by: (1) a clear endorsement from this Court of a textual standard for interpreting the governing federal statutes, paired with (2) an absolute renunciation of the “presumption against preemption.”

SUMMARY OF ARGUMENT

Congress intentionally created comprehensive federal health and safety regulatory regimes to govern products across myriad industries that are sold into interstate commerce. These regimes—developed through science-based processes and maintained through federal oversight and enforcement—both protect the health and safety of the American people and provide the uniformity and predictability that companies need to operate. These dual goals can be accomplished only when the judiciary faithfully enforces Congress’s intent, as expressed through the plain text of Congress’s statutes: that federal health and safety standards should govern and state law may play a role only where the statutory text expressly permits it to do so.

The comprehensive federal health and safety regimes that govern *amici* and like companies must be given the supremacy and exclusivity that Congress intended by its plain text. That reading is required to (1) provide the regulatory uniformity that companies need to participate in interstate commerce, (2) afford U.S. companies the certainty they require to make long-term capital investments, (3) protect national interests by ensuring that U.S. companies are governed by U.S. standards, (4) ensure that health and safety standards are adopted through rigorous, scientifically grounded deliberative processes in which constituents may participate, (5) protect against inequitable retroactive penalties imposed on companies that have complied in good faith with federal requirements, and (6) reduce the appearance of political or parochial judicial activism in litigation.

As the decision below demonstrates, however, lower courts are not faithfully applying Congress’s and this Court’s directives. Respondent’s failure-to-warn theory of liability was expressly preempted by the plain terms of the Labeling Act, and yet the Massachusetts Supreme Judicial Court allowed liability to lie on evidence of conduct it recognized would be preempted if framed as a failure to warn. The court also applied a “presumption against preemption” to narrow the scope of the Labeling Act’s preemption clause, despite this Court’s admonition that the presumption has no place when an express preemption clause exists. *See Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 579 U.S. 115, 125 (2016) (“[B]ecause the statute contains an express pre-emption clause, we do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress’ pre-emptive intent.”) (internal quotation marks omitted). Across diverse and important industries, lower courts have repeated these errors, producing divergent rules, undermining Congress’s regulatory choices, and imposing mind-boggling litigation costs on U.S. companies (and, in turn, the American people).

This case presents an opportunity for this Court to adopt a clear textual standard to ensure that Congress’s carefully crafted regulatory framework is respected.

ARGUMENT

I. Congress Enacted Comprehensive Public Health and Safety Regulatory Regimes

Pursuant to its constitutional authority to regulate matters affecting national public health and safety in

interstate commerce, Congress has enacted comprehensive regulatory regimes specifying the standards that companies must meet to sell their products throughout the country. The plain text of these statutes reflects Congress’s intent that federal health and safety standards govern interstate commerce. Where Congress intends to allow incremental state law duties to be imposed, it does so explicitly through express language, through standalone “savings clauses,” *see, e.g.*, 42 U.S.C. § 7416 (standalone states’ rights savings clause in the Clean Air Act (“CAA”)); or “savings clauses” paired with “preemption clauses,” *see, e.g.*, 7 U.S.C. §§ 136v(a)–(b) (savings clause and preemption clause pairing in the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”)).

These comprehensive regimes span a range of industries, including tobacco, pesticides, medical devices, air transportation, automobiles, energy, and certain foods—embodying Congress’s reasoned judgment that uniform national standards, rather than a patchwork of conflicting state requirements, should govern products implicating public welfare that are sold nation- or worldwide. *See Durnell*, 146 S. Ct. at 2012. While these regulatory regimes are varied in subject matter, they share several structural features that evidence Congress’s intent to implement a comprehensive federal regulatory regime that (except where explicitly stated) is both exclusive and supreme.

Rigorous Deliberative Processes. Each regime requires a demanding, scientifically grounded deliberative process before standards are adopted. Federal agencies must conduct thorough reviews before establishing health and safety requirements. *See, e.g., Durnell*, 146 S. Ct. at 2006–07 (outlining EPA’s extensive

pesticide-registration and label-approval process under FIFRA); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18 (2008) (describing FDA’s “rigorous” premarket approval process for medical devices); *North Carolina, ex rel. Cooper v. Tennessee Valley Auth.*, 615 F.3d 291, 304 (4th Cir. 2010) (“The Clean Air Act’s extensive coverage allows regulators with expertise in the relevant scientific fields to . . . create empirically-based emissions standards.”). Interested parties have the opportunity to participate in these deliberative processes via mandated notice and comment periods. *See, e.g.*, 7 U.S.C. § 136c(4) (requiring notice and comment period for new pesticide registrations under FIFRA); *Tennessee Valley Auth.*, 615 F.3d at 299 (explaining that, before EPA adopts emissions standards, “interested persons [may] submit written comments”). Constituents may also challenge the regulatory process and agency determinations before implementation through administrative and judicial review. *See generally* 5 U.S.C. §§ 702, 704 (Administrative Procedure Act); *see also, e.g.*, 7 U.S.C. § 136n (providing for judicial review of EPA’s registration decisions).

Ongoing Regulatory Oversight. These regimes further require governing federal agencies to revise standards to account for new information, data, or science—whether discovered by the agency itself, disclosed by manufacturers pursuant to mandatory reporting obligations, or submitted by the public through mechanisms such as citizen petitions. *See, e.g.*, 7 U.S.C. § 136d(a)(2) (requiring pesticide manufacturers to report new information on adverse effects); 21 U.S.C. § 360i (requiring medical device manufacturers to report adverse events); *Durnell*, 146 S. Ct. at 2008 (explaining that “any person can petition

EPA to modify, suspend, or cancel a pesticide’s registration based on . . . new evidence”).

Federal Enforcement. Each regime provides the designated federal agency with the tools to enforce compliance with its health and safety requirements, including via civil and criminal penalties. *See, e.g.*, 7 U.S.C. §§ 136j(a)(1)(E) (unlawful acts under FIFRA), 136l (specifying civil and criminal penalties for non-compliance); 21 U.S.C. § 331 (prohibited acts under the Federal Food, Drug, and Cosmetic Act (“FDCA”)); 42 U.S.C. § 7413 (civil, criminal, and administrative penalties under the CAA).

Preemption of Incremental or Inconsistent State Requirements. The clear Congressional intent embodied in these statutes is that companies who comply with the applicable federal regulatory requirements shall not thereafter be subjected to inconsistent or additional obligations under state law. *See, e.g.*, 7 U.S.C. § 136v(b) (FIFRA preemption clause); 21 U.S.C. § 360k(a) (preemption clause in the Medical Device Amendments (“MDA”) to the FDCA). Where Congress intended to preserve state authority, it has said so explicitly through “savings clauses” in the governing statutes. *See City of New York v. Chevron Corp.*, 993 F.3d 81, 99 (2d Cir. 2021) (explaining that the CAA “plainly permit[s] states to create and enforce their own emissions standards applicable to in-state polluters”); *Durnell*, 146 S. Ct. at 2008 n.2 (explaining that, notwithstanding federal preemption of labeling or packaging requirements, states “remain free to ‘regulate the sale or use of any federally registered pesticide’”) (citing 7 U.S.C. § 136v(a)).

II. Lower Courts Disregard Congressional Intent and This Court’s Directives

Despite this Court’s guidance, lower courts routinely allow plaintiffs to circumvent the Congressional intent embodied in its federal legislative schemes through two related legal errors squarely implicated by the questions presented in this case.

a. Courts Permit State Law Claims that Statutory Text Proscribes

The plaintiffs’ bar has developed a playbook for circumventing preemption: re-label clearly preempted claims under other state law monikers and then insist that these restyled claims are outside the purview of the federal regulatory regime.

The decision below is a paradigmatic example. Respondent asserted the marquee theory of liability that Petitioner was liable under state law for failing to retain a warning in addition to those prescribed by federal law. Respondent conceded that any failure-to-warn claim was barred by the express preemption clause of the Labeling Act, which explicitly proscribed any state-law “requirement or prohibition based on smoking and health . . . with respect to the advertising or promotion of any cigarettes.” 15 U.S.C. § 1334(b). As this Court previously held, the Labeling Act preempts state law claims where the “predicate duty” or “gravamen” of the alleged claim was a “failure to warn” of health risks associated with smoking. *See Altria Grp., Inc. v. Good*, 555 U.S. 70, 81 (2008) (citing *Cipollone v. Liggett Grp.*, 505 U.S. 504, 548 (1992)).

To evade this holding, Respondent simply recast his challenge to Petitioner’s warnings as “fraud” and “conspiracy” claims rather than failure-to-warn—even though the gravamen of the restyled claims still

undisputedly arose from the removed warning. Relying on the purported “presumption against preemption,” the court below narrowly construed the preemption clause in the Labeling Act and affirmed \$64 million in compensatory liability and punitive damages, expressly condoning a theory of failure-to-warn liability so long as it is pursued under the caption of a different claim. As the petition rightfully recites, the court’s reasoning impermissibly elevates form over substance and transforms an express preemption provision into a mere pleading requirement. That approach disregards the Congressional intent evidenced by the clear text of the preemption clause and invites heavy penalties and punitive awards.

But the case below is not an outlier, and the problem is not confined to tobacco. Take the Roundup litigation, for example. In 1974, EPA registered glyphosate-based pesticides and approved Roundup’s label without a cancer warning. Starting in 1991 and for the more than three decades since, “EPA has repeatedly re-evaluated glyphosate and has repeatedly concluded that glyphosate is not likely to cause cancer.” *Durnell*, 146 S. Ct. at 2008. Notwithstanding the governing federal agency’s repeated findings that glyphosate is safe, in 2017 the mass tort plaintiffs’ bar began filing large volumes of claims against Monsanto, claiming injuries based on its failure to warn of purported cancer risks associated with Roundup. The claims were mainly predicated on the classification of glyphosate as a “probable carcinogen” by a foreign organization—the International Agency for Research on Cancer (“IARC”), based in France. *Id.* at 2008–09. Yet, IARC simultaneously conceded that it had no

evidence of any causal relationship between Roundup’s use and cancer.³

After almost a decade of extraordinarily costly litigation, in June 2026, this Court held that state law failure-to-warn claims are preempted by FIFRA, which contains a preemption clause that “further underscores EPA’s comprehensive and exclusive authority in registering pesticides and approving labels.” *Durnell*, 146 S. Ct. at 2008. Yet within weeks of this Court’s decision, a Massachusetts court granted plaintiffs leave to recast their preempted failure-to-warn claims as other state-law causes of action, effectively inviting them to proceed with their claims against Monsanto on the same theory, facts, and harm. See *Rubin v. Monsanto Co.*, No. 4:26-CV-40079, D.E. 68 (D. Mass. 2026). Similarly, just this month, a Missouri state court flouted the *Durnell* decision and permitted claims resting on identical conduct to go to trial, styled as design-defect and negligence. See *Shull v. Monsanto*, No. 25BA-CV4355 (Mo. Cir. Ct. Boone Cnty. 2026). This is precisely the artful pleading dynamic that a decision for the Petitioner would foreclose.

The same issue has presented itself in the medical device context. Under the plain text of the MDA, there is no private right of action to enforce FDA regulations, and no state may establish any safety

³ See IARC Monographs, *Some Organophosphate Insecticides and Herbicides* (Vol. 112) at 398 (“There is *limited evidence* in humans for carcinogenicity of glyphosate.”); IARC Monographs on the Identification of Carcinogenic Hazards to Humans, *Questions and Answers* (Dec. 10, 2019) (“*Limited evidence of carcinogenicity* means that a positive association has been observed between exposure to the agent and cancer but that other explanations for the observations . . . could not be ruled out with reasonable confidence.”).

requirement “different from, or in addition to,” any federal requirement applicable to a medical device. 21 U.S.C. § 360k(a)(1). This Court has consistently held that claims asserting fraud on the FDA, or that seek to impose safety requirements additional or contrary to those required by the federal regime, are preempted. *See generally Riegel*, 552 U.S. 312; *Buckman Co v. Plaintiffs Legal Comm.*, 531 U.S. 341 (2001). Yet, thwarting this Court’s clear rulings, lower courts routinely permit artfully crafted claims asserting incremental or inconsistent state law duties to proceed anyway. *See, e.g., Hollenstein v. Bausch & Lomb Inc.*, No. 24 Civ. 03843, 2025 U.S. Dist. LEXIS 121547, *45–46 (S.D.N.Y. June 27, 2025) (allowing failure-to-warn claim to proceed under a new label, thereby sanctioning damages not called for or allowed by the statute); *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233–34 (9th Cir. 2013) (allowing plaintiffs to replead a preempted failure-to-warn claim premised on disclosure obligations incremental to those required by the FDA). And fraud-on-the-FDA claims continue to be advanced as well. *See, e.g., Gibson v. Advanced Bionics, LLC*, 2025 U.S. Dist. LEXIS 170605, *17 (C.D. Cal. Sep. 2, 2025).

Energy companies are seeing a similar pattern. In *International Paper Company v. Ouellette* and *American Electric Power v. Connecticut*, this Court explained that interstate air and water pollution are a “matter of federal, not state law.” 479 U.S. 481, 488 (1987); 564 U.S. 410, 422 (2011). The only permissible applications of state law, this Court further explained, are those “specifically preserved” by the savings clauses of the Clean Water Act and Clean Air Act. *Ouellette*, 479 U.S. at 492; *American Electric Power*, 564 U.S. at 429. Some lower courts have correctly

applied this Court’s precedent and dismissed opportunistic actions attempting to impose the costs of global climate change on U.S. energy companies under the CAA. *See generally Mayor & City Council of Baltimore v. B.P. P.L.C.*, 353 A.3d 1142 (2026); *City of New York v. Chevron Corp.*, 993 F.3d 81 (2d Cir. 2021). Other courts, however, have allowed these cases to proceed by endorsing plaintiffs’ artful framing of their claims, using labels such as nuisance, consumer deception, and civil conspiracy, to disguise their attempts to regulate interstate pollution in contravention of *Ouellette* and *American Electric Power*.⁴ In doing so, plaintiffs seek to use litigation to create (and enforce) policy that properly belongs with the federal government.

Across countless industries, the pattern is the same: plaintiffs re-label their claims to circumvent preemption, and lower courts endorse the evasion by embracing the pleading label rather than the substance of the duty the claim would impose. A clear-cut instruction from this Court that preemption turns on the substance of the state-law obligation—not its caption—would provide urgently needed clarity.

b. Courts Wrongly Apply a Presumption Against Preemption

Compounding the artful pleading problem, lower courts regularly invoke a “presumption against preemption” when purporting to interpret federal statutes, thereby narrowly (and incorrectly) interpreting the statutory text.

⁴ One example is *Suncor Energy (U.S.A.) Inc., et al. v. County Commissioners of Boulder County, et al.*, No. 25-170, now before this Court on writ of certiorari to the Supreme Court of Colorado.

At its core, this issue is one of statutory interpretation. This Court has repeatedly underscored the primacy of the text itself in that inquiry. *See, e.g., CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) (“[T]he task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress’s pre-emptive intent.”); *Oklahoma v. Castro-Huerta*, 597 U.S. 629, 642 (2022) (“As this Court has repeatedly stated, the text of a law controls over purported legislative intentions unmoored from any statutory text.”). Plain textual interpretation is the most faithful method of statutory interpretation, as Justice Scalia advocated for in his dissent in *Cipollone*. *See Cipollone*, 505 U.S. at 548.

A textualist approach begets simplicity and clarity. If a statute sets forth a comprehensive regulatory health and safety regime with no express authorization of state law claims, then federal preemption should apply. *See Buckman*, 531 U.S. at 348. If the statute contains a “savings clause,” then the plain reading of that clause dictates which state law claims are allowed. *Ouellette*, 479 U.S. at 497; *Mayor & City Council of Baltimore*, 353 A.3d at 1177–79. And if the statute contains a “preemption clause” and a “savings clause,” then both must be read together to discern Congressional intent. *See Durnell*, 146 S. Ct. at 2008 n.2.

“Federal statutes,” after all, “shall be the supreme Law of the Land.” U.S. Const. art. VI. Cl. 2. Neither blind deference to state law nor a “presumption against preemption” has any place in courts’ textual analysis of any federal statute. *See Franklin*, 579 U.S. at 125 (refusing to “invoke any presumption against preemption,” and instead “focus[ing] on the plain

wording”) (citation omitted); *Durnell*, 146 S. Ct. at 2009–10 (interpreting FIFRA’s express preemption clause based on the text itself without invoking any presumption); *Cal. Rest. Ass’n v. City of Berkeley*, 89 F.4th 1094, 1101 (9th Cir. 2024) (applying “textual analysis ‘without any presumptive thumb on the scale’ for or against preemption”) (citation omitted). The presumption certainly has no bearing on the interpretation of express preemption clauses.

Lower courts nonetheless continue to deploy the presumption to narrow the reach of express preemption provisions—including the Massachusetts Supreme Judicial Court in the decision below. There, the court invoked the *Cipollone* plurality’s reliance on the “presumption against pre-emption” as part of its analytical framework. *Fontaine v. Phillip Morris USA Inc.*, 277 N.E.3d 585, 608 (Mass. 2026) (quoting *Cipollone*, 505 U.S. at 523). The result: the largest punitive jury verdict in Massachusetts history.

Other lower courts have similarly shirked this Court’s guidance. *See, e.g., Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 (3d Cir. 2018) (reasoning that, despite the MDA’s express preemption provision, “the historic primacy of state regulation of matters of health and safety’ re-quire[d]” the court to “apply the presumption against pre-emption”) (citation omitted); *R.J. Reynolds Tobacco v. City of Edina*, 60 F.4th 1170, 1176, 1178 (8th Cir. 2023) (applying the presumption to narrowly construe the Tobacco Control Act’s express preemption provision).

The legal landscape resulting from lower courts’ diverging views on preemption is unworkable: it threatens to burden U.S. industry actors and interstate commerce with inconsistent legal precedent, forum-shopping plaintiffs, and judicial activism.

III. U.S. Companies Require a Textual Standard that Enforces Congress’s Intent to Preempt

Congress intended to achieve and maintain national uniformity of regulation for industries that implicate public health and safety. Although the scope of preemption may differ by statute, companies’ reliance on the certainty afforded by those statutes remains the same. This reliance is possible only if courts enforce the statutes as written by Congress.

a. Uniformity Is Necessary for Interstate Commerce

The foundational principle of the Supremacy Clause is uniformity. Two centuries ago, this Court recognized that the federal government “had its immediate origin in the necessities of commerce” and was designed to provide “the relief of those necessities . . . by establishing a *uniform* and steady system.” *Gibbons v. Ogden*, 22 U.S. 1, 13 (1824) (emphasis in original). Accordingly, state law incompatible with the “uniform whole” must yield. *Id.* at 209–10; *see also Cooley v. Bd. of Wardens of Port of Phila.*, 53 U.S. 299, 319 (1851) (recognizing that Congress’s Article I commerce power “embraces a vast field” covering subjects “imperatively demanding a single uniform rule”); *Mayo v. U.S.*, 319 U.S. 441, 445 (1943) (emphasizing the “essential principle” of the Supremacy Clause that “it is necessary for uniformity that the laws of the United States be dominant over those of any state”).

Nowhere is this principle more critical than in setting the standards governing the nationwide sale of products that impact the health and safety of the general public. *See, e.g., Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 871 (2000) (recognizing Congress’s

“desire to subject the [automotive] industry to a single, uniform set of federal safety standards” to “avoid the conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety-standard cooks might otherwise create”) (citation omitted). Uniformity in these markets is more important than ever, because technological advances of staggering scale and scope have unmoored the distribution, marketing, and sale of goods from geographic boundaries.⁵

As this Court explained when evaluating the preemptive force of disclosure requirements for interstate commerce, federal preemption embodies “Congress’ judgment that the ability to sell a product throughout the country with a single label can be important to maintaining an efficient nationwide market.” *Durnell*, 146 S. Ct. at 2012. The converse is equally true: Subjecting companies to a 50-state patchwork of compliance obligations would significantly impair *amici*’s and other U.S. companies’ ability to participate in interstate commerce. See *Buckman*, 531 U.S. at 350 (“As a practical matter, complying with the FDA’s detailed regulatory regime in the shadow of 50 States’ tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA.”); *Bates v. Dow Agrosciences*, 544 U.S. 431, 452 (2005) (noting that permitting “50 different labeling regimes prescribing the color, font size, and wording of warnings” would “create significant inefficiencies for manufacturers”). Any additional or inconsistent requirements imposed by individual states

⁵ See, e.g., Ash Johnson, *How Congress Can Foster a Digital Single Market in America*, Info. Tech. & Innovation Found. (Feb. 20, 2024).

“would lead to chaotic confrontation,” making compliance all but impossible. *Ouellette*, 479 U.S. at 496.

b. U.S. Companies Require Certainty to Invest

Businesses, like markets, thrive with certainty, and suffer without.⁶ Like Petitioner, *amici* operate in highly regulated industries. These industries require significant capital investment—to finance innovation, supply chains, manufacturing, distribution, marketing, and sales—in order to bring products to market.

The regulatory regime governing the sale of these products is a factor in any decision to invest capital in the United States.⁷ A uniform federal regulatory regime provides certainty by setting defined standards that companies must satisfy, which in turn allows for quantification of the associated costs before investment decisions are made.

By the same reasoning, subjecting companies to regulation through litigation, based on nebulous state-law theories crafted by the plaintiffs’ bar after products are already on the market, is untenable. As the Fourth Circuit aptly put it, replacing uniform

⁶ Glenn Lammi, *Keep Federal Preemption of Railroad Regulation on Track*, WLF Legal Pulse (Apr. 23, 2025), available at: <https://www.wlf.org/2025/04/23/wlf-legal-pulse/keep-federal-preemption-of-railroad-regulation-on-track-2/> (“Businesses crave certainty more than anything else and navigating disparate state regulatory regimes is not only inefficient but costly.”).

⁷ Am. Chemistry Council, *New Survey Finds Dramatic Rise in Regulations Undercuts American Manufacturing and National Priorities* (Jan. 17, 2024) (79% of companies “would increase investment in R&D, new technologies, and new products” if compliance costs were reduced); Am. Chemistry Council, *Regulation* (2026) (cumulative compliance costs on businesses “are estimated to be in the hundreds of billions of dollars annually[.]”).

federal standards with those “whose content must await the uncertain twists and turns of litigation will leave whole . . . industries at sea and potentially expose them to a welter of conflicting court orders across the country.” *Tennessee Valley Auth.*, 615 F.3d at 301; *see also Geier*, 529 U.S. at 871 (noting that state tort suits engender “uncertainty and even conflict” especially where “different juries in different States reach different decisions on similar facts”). There is no way to prepare for such exposure in advance, as companies are afforded no notice of the duties that will be contrived or the remedies that will be sought. That is the current state of play for *amici* and U.S. companies across many industries. It is extraordinarily costly and unsustainable.

c. Preemption Furthers National Interests in the Global Market

Congress has determined that the standards for the manufacture and nationwide sale of products that impact the health and safety of U.S. citizens should be set by the U.S. government. But too often, the standards are now set through state court litigation that is often financed by foreign entities, resulting in the adoption of standards developed by foreign bodies. The expertise of federal agencies should not be superseded by foreign governments and international agencies with no accountability to the American people. Nor should private litigants invoking the findings of foreign organizations be permitted to hold American companies liable for selling products which the federal government approved.

Yet that is precisely what has occurred. As discussed, plaintiffs in the Roundup litigation relied heavily on a classification by IARC to support state-

law claims that Monsanto should have added cancer warnings to its EPA-approved label. This Court’s decision in *Durnell* rejected the premise that a state tort verdict could override EPA’s considered scientific judgment. 146 S. Ct. at 2008–09 (noting that EPA repeatedly concluded that glyphosate is not likely to cause cancer, a conclusion shared by numerous international regulators). That decision aligns with the recent joint statement regarding IARC issued by the Department of State and Department of Health, which concluded that “American regulatory decisions should be made by American institutions accountable to the American people.”⁸

Likewise, growing foreign financing of U.S. litigation also allows for increasing foreign intrusion into public health and safety determinations. As Senator Kennedy stated in introducing bipartisan legislation to “[m]andate disclosure of third-party litigation funding in mass tort or class action lawsuits,” “[t]he American people deserve to know when . . . foreign states pour money into . . . lawsuits to influence outcomes.”⁹ But as long as the *Altria* framework permits artful re-characterization of warning-based claims, the threat of foreign-driven regulation remains.

Similarly, in the climate change litigation context, state and municipal plaintiffs have sought to hold

⁸ U.S. Dep’t of State & U.S. Dep’t of Health & Hum. Servs., *Joint Statement on the Preeminence of the U.S. Government Regulating Health Risks for Americans* (June 8, 2026) (“IARC’s research provides diminishing returns on scientific enterprise, while advancing politicized narratives that are often cited for U.S. domestic legal contexts.”).

⁹ John Kennedy, Chuck Grassley, et al., *Kennedy, Grassley, Colleagues Introduce Bill to Expose Third-Party Funding Behind Lawsuits*, Press Release (Feb. 11, 2026).

American energy companies liable under state common law for *worldwide* greenhouse gas emissions—effectively seeking to rewrite through tort litigation the policy choices made by Congress and the executive branch. These suits not only implicate preemption principles, they threaten to subject vital national defense, energy, and infrastructure assets to foreign regulatory standards or decisions by individual state court juries. *See Chevron*, 993 F.3d at 86, 93–94 (state tort suits “risk upsetting the careful balance that has been struck between the prevention of global warming, a project that necessarily requires national standards and global participation, on the one hand, and energy production, economic growth, foreign policy, and national security, on the other”). The sums sought are staggering: one Oregon county seeks nearly \$52 billion for a single 2021 heat wave; and New York’s Climate “Superfund” statute sought to impose a \$75 billion retroactive payment—all while sixteen of the twenty largest emitters globally are beyond the reach of American courts.¹⁰

d. Science-Based Safety Standards Must Govern

U.S. expert agencies set health and safety standards through rigorous, scientifically grounded, and deliberative processes. The EPA, for example, evaluates toxicological and epidemiological evidence before registering a pesticide and approving its label. *See Durnell*, 146 S. Ct. at 2006–07. The FDA conducts a “rigorous” premarket approval process for medical devices—which takes “an average of 1,200 hours” per

¹⁰ *See* Heather Mac Donald, *The Climate Litigation Swindle*, City J. (Spring 2026).

application—reviewing clinical and laboratory data before clearing a device and its labeling. *Riegel*, 552 U.S. at 317–18. It is crucial “that courts in th[ese] highly technical arena[s] respect the strengths of the agency processes on which Congress has placed its imprimatur.” *Tennessee Valley Auth.*, 615 F.3d at 305–06.

But courts are not doing that. Instead, state tort suits, advancing theories at odds with regulations established through the sanctioned deliberative process, task lay juries with resolving scientific disputes armed only with junk science advanced by partisan “expert” witnesses or outside organizations that do not apply the same exacting methodologies as federal agencies.¹¹ For example, IARC’s hazard-based classifications ignore dose, duration, and route of exposure—the real-world factors that determine whether a substance actually poses a cancer risk. The plaintiffs’ bar has exploited the resulting fear and confusion to fuel mass-tort litigation.¹²

In the comprehensive health and safety regulatory regimes to which *amici* are subject, federal agency determinations should not be replaced by the flawed and misleading conclusions of IARC and similar organizations. State-law claims premised on those conclusions undermine the very regulatory framework that

¹¹ See, e.g., Am. Tort Reform Ass’n, *The Junk Science Playbook* (Jan. 2026) (“Health Canada, an outlier among regulatory bodies and public health agencies in finding talc is a possible cause of ovarian cancer, relied on paid plaintiffs’ expert reports in U.S. litigation in deriving its talc Screening Assessment.”).

¹² See, e.g., John Gardella, *IARC PFAS Findings Will Influence Litigation and EPA Challenges*, Nat’l L. Rev. (Dec. 4, 2023) (“IARC’s findings with respect to carcinogenicity are oftentimes very influential on the course of litigation in the United States.”).

Congress established. *See Lead Indus. Ass’n, Inc. v. EPA*, 647 F.2d 1130, 1146 (D.C. Cir. 1980) (“Congress has entrusted the Agency with the responsibility for making these scientific and other judgments, and we must respect both Congress’ decision and the Agency’s ability to rely on the expertise that it develops.”).

e. Preemption Minimizes Abusive Claims and Inequitable Retrospective Penalties

“The law is not ordinarily read to retroactively penalize persons for doing what the Government had required them to do.” *Durnell*, 146 S. Ct. at 2014 (citing *Landgraf v. USI Film Prods.*, 511 U.S. 244 (1994)). That principle is especially important where, as in the case at hand, the challenged label was fully compliant with federal labeling requirements. A citizen who learns of new safety concerns “is free to bring the information to [the agency’s] attention,” but that “is quite different from seeking to *retroactively* penalize a manufacturer for doing what it was legally required to do at the time.” *Durnell*, 146 S. Ct. at 2016 n.10 (emphasis in original). A clear, text-based preemption standard prevents state common-law claims from upsetting “reliance interests and expectations on the part of those . . . enterprises that have complied with [the federal government’s] requirements.” *Tennessee Valley Auth.*, 615 F.3d at 301.

Absent such a rule, harsh retrospective penalties have two consequences. First, they expose companies like *amici* to astronomical damages awards that can threaten their survival. In 2025, for example, corporate defendants faced nearly 200 jury awards of \$10 million or more, with more than 40 exceeding \$100 million; one Roundup verdict reached \$2.1 billion,

with compensatory damages roughly 145 times the plaintiff's stipulated \$450,000 in medical bills and punitive damages more than thirty times the compensatory award.¹³ Second, these penalties impose substantial costs on the U.S. economy and the U.S. taxpayer: excessive litigation is estimated to cost \$367.8 billion each year, eliminate 4.8 million jobs, and cost the average American approximately \$1,666 annually.¹⁴

f. Preemption Mitigates the Appearance of Judicial Activism

The role of the judiciary is to enforce the law, not rewrite it. The most faithful way to do so is through a plain, textualist reading of the words chosen by the legislature. A textual analysis of preemption provisions is agnostic with respect to product, industry, or asserted claim. Any other approach risks enlisting the judiciary to take sides in difficult policy debates that are best left to the political branches. Textualism asks only what the statute says, and by avoiding subjective speculation as to what it should say, removes the appearance of judicial activism or impression that parochial, political, or social perspectives influence the outcome of a particular case.

The Court should grant certiorari in this case and reaffirm the principle that, where Congress has expressed its intent to commit an area of law to comprehensive federal regulation, it is that judgment—and not a “presumption against preemption” or any

¹³ See Marathon Strategies, *Corporate Verdicts Go Thermonuclear: 2026 Edition* (Aug. 18, 2026); Am. Tort Reform Found., *Judicial Hellholes 2025/2026* (2025) at 61.

¹⁴ See Am. Tort Reform Ass'n, *America's \$367 Billion Lawsuit Epidemic* (Apr. 7, 2025).

other conflicting principle not found in the statute's text—that must prevail.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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