No. 09-497

IN THE
Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD, AND IN THEIR OWN RIGHT,

Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES, AND LADERLE LABORATORIES,

Respondents.

On Writ Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE, PUBLIC JUSTICE, AND PUBLIC CITIZEN AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

The American Association for Justice ("AAJ"), formerly the Association of Trial Lawyers of America, Public Justice, and Public Citizen respectfully submit this brief as *amici curiae* in support of Petitioners. This brief is filed with consent of all parties.[1]

AAJ is a voluntary national bar association whose trial lawyer members primarily represent individual plaintiffs in civil suits and personal injury actions, including product liability cases and cases involving injuries caused by childhood vaccines. Throughout its history, AAJ has advocated in the courts, in Congress, and in state legislatures why it is essential to preserve the protections for ordinary citizens afforded by the common law and to ensure that state tort claims, such as product liability claims for defective design, provide injured persons with effective legal recourse and remedies for wrongful injuries. AAJ submits the lower court's decision in this case comprised an unwarranted expansion of the preemption doctrine that undermines those essential state law protections. By bringing such claims on behalf of people injured by vaccines, AAJ's members have helped to ensure that the nation's children and their families have access to safe and effective vaccines.

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[1] Letters of consent from the parties have been filed with the Clerk of Court. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored any part of this brief, nor did any person or entity other than *amici*, their members, or their counsel make a monetary contribution to its preparation or submission.

Public Justice is a national public interest law firm dedicated to pursuing justice for the victims of corporate and governmental abuses. Through involvement in precedent-setting and socially significant litigation, Public Justice seeks to ensure that tort law fully serves its dual purposes—compensating those injured by wrongful conduct and deterring similar conduct in the future. Public Justice is gravely concerned that, if the tort system is closed to innocent victims of defective childhood vaccines through application of the preemption doctrine in this case, neither of these purposes will be served.

Public Citizen, a national non-profit organization founded in 1971, works to advance consumers' interests on a broad range of issues. For example, through its Health Research Group, Public Citizen engages in research, education, and advocacy with respect to the safety of products regulated by the Food and Drug Administration (FDA). Where FDA regulation is insufficient to protect consumers against the consequences of unsafe medical products, Public Citizen supports injured patients' right to seek redress. In that regard, Public Citizen believes that, absent an express congressional determination to the contrary, states should remain free to compensate tort plaintiffs as they deem appropriate. With this principle in mind, Public Citizen, through its Litigation Group, has represented plaintiffs in several significant preemption cases involving FDA-regulated products. *See*, *e.g.*, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008)*; Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

SUMMARY OF ARGUMENT

This Court has long recognized the importance of providing a remedy to those injured by wrongful conduct. Access to common law tort remedies ensures confidence in our system of government. While recognizing Congress' authority to preempt state law, the Court sees Congressional abolition of state common law claims as rare, and requires that Congress be *clear* when it preempts state common law.

The court below erred in holding that the National Childhood Vaccine Injury Act ("NCVIA" or "Vaccine Act") expressly preempts *all* design defect claims against vaccine manufacturers under state product liability law. In so doing, the Third Circuit gave little weight to the presumption against preemption. Instead of identifying a "clear and manifest" purpose of Congress to preempt *all* design defect claims, the Third Circuit looked at the imagined consequences of *not* barring all such claims in order to piece together its determination that Congress could not have intended such consequences and so must have intended to preempt such claims. If the scope of the Vaccine Act's preemption provision cannot be resolved from the statutory text alone, as the Third Circuit itself said, the Third Circuit's reliance on policy arguments to infer Congressional intent effectively disregards the strong presumption against preemption and is unpersuasive even on its own terms.

The Third Circuit's interpretive choice turns the preemption provision of the Vaccine Act into an absolute immunity law and, for those injured by childhood vaccines, removes an important choice that

Congress intended to preserve—the choice to seek a common law remedy in court. Immunizing vaccine manufacturers from *all* state law claims for defective design would undermine one of the purposes of the federal regulation of vaccines and of tort liability—to make vaccines safer.

There was good reason for Congress to keep state tort law available to those injured by childhood vaccines. This country's civil justice system not only provides compensation to those injured by defective products, but also ensures that safer vaccines are made available by encouraging manufacturers to develop and seek licenses for better, safer vaccines. The state tort law system sheds light on previously unknown hazards, and allows discovery of information that is distinctly within the knowledge of vaccine manufacturers. Congress did not intend to dispose of the public health and safety benefits provided by the state tort law system.

ARGUMENT

I. RECOGNIZING THE IMPORTANCE OF REMEDYING INJURIES, THIS COURT HAS NOTED THAT CONGRESSIONAL ABOLITION OF STATE LAW CLAIMS IS RARE.

This Court has for more than two centuries held that "[o]ne of the first duties of government" is to safeguard "the right of every individual to claim the protection of the laws, whenever he receives an injury." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 163 (1803). Under the Due Process Clause of the Fourteenth Amendment, it is "the duty of every State to provide, in the administration of justice, for the

redress of private wrongs." *Missouri Pac. Ry. Co. v. Humes,* 115 U.S. 512, 521 (1885). Indeed, the right to recover damages for wrongful personal injury is among the "absolute rights of individuals" that the Founders intended to guarantee to all Americans. *See Ingraham v. Wright,* 430 U.S. 651, 661, 672-74 (1977).

Preservation of access to the courts for all is essential to promoting public confidence in and respect for our legal system, without which our courts cannot operate. The civil justice system provides the best opportunity for an average person to achieve redress of injuries against wrongdoers, regardless of wealth and rank. The political or economic advantages that unfairly favor powerful industries and the wealthy in the legislative arena do not matter in a courtroom. In American courtrooms, decisions are made according to the rule of law, not political or economic influence. *See Marbury v. Madison*, at 163 (this is a "government of law, and not of men."). *Cf. Chisholm v. Georgia*, 2 U.S. (2 Dall.) 419, 479 (1793) (The civil justice system "leaves not even the most obscure and friendless citizen without means of obtaining justice. . . . [I]t recognizes and strongly rests on this great moral truth, that justice is the same whether due from one man or a million, or from a million to one man; because it teaches and greatly appreciates the value of our free republican national Government, which places all our citizens on an equal footing, and enables each and every one of them to obtain justice without any danger of being overborne by the weight and number of their opponents."). The importance of the civil liability system weighs against federal preemption of state common law, except in rare circumstances.

While this Court has recognized Congress' authority to preempt state tort laws entirely, it has also recognized that Congress *rarely* expressly preempts state tort law. *See, e.g., Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 7 (2003); *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 69-70 (2002); *Bates v. Dow Agrosciences, LLC,* 544 U.S. 431, 449-50 (2005); *Geier v. Am. Honda Motor Co.,* 529 U.S. 861, 868 (2000). The court considers such sweeping preemption "unusually 'powerful,'" *Beneficial Nat'l Bank,* 539 U.S. at 7, and thus requires Congress to be very clear in expressly preempting state tort law. *See Medtronic, Inc., v. Lohr*, 518 U.S. 470, 487 (1996) (plurality opinion). For Congress to have eliminated that right for those injured by unreasonably dangerous vaccines, without specifically saying so, would have been "spectacularly odd." *Medtronic, Inc.,* 518 U.S. at 491 (1996).

II. THE THIRD CIRCUIT FAILED TO APPLY THE STRONG PRESUMPTION AGAINST PREEMPTION OF STATE LAW REMEDIES FOR PERSONAL INJURY.

One of two cornerstones of this Court's canons of construction regarding preemption provisions is the presumption against preemption. In *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), this Court reaffirmed that the presumption against preemption applies "in all pre-emption cases" and can be overcome only by a showing of "clear and manifest" purpose to preempt. *Id.* at 1194-95. The presumption applies "[w]hen addressing questions of express or implied pre-emption." *Altria Group, Inc. v. Good*, 129 S. Ct. 538,

543 (2008); *see also Medtronic, Inc.*, 518 U.S. at 485. Under this presumption, the Court assumes "'that the historic police powers of the State [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Altria Group, Inc.*, 129 S. Ct. at 543 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). *See also Bates,* 544 U.S. at 449 ("In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'"); *Cipollone,* 505 U.S. at 516.

The presumption against preemption is particularly strong where Congress preempts in a field of traditional state regulation. *Altria Group, Inc.*, 129 S. Ct. at 543; *Medtronic, Inc.*, 518 U.S. at 485. As this Court has acknowledged repeatedly, "regulation of health and safety matters is primarily, and historically, a matter of local concern," within the police powers of the States. *Hillsborough Cty. v. Automated Med. Labs., Inc.,* 471 U.S. 707, 719 (1985).

Issues of health and safety have traditionally fallen within the province of state regulation, *see, e.g.*, *Medtronic, Inc.*, 518 U.S. at 485. States have a powerful interest in regulating vaccination within their borders to protect the health of their citizens, and thus have an interest in providing a remedy when their citizens are injured by vaccines and do not receive adequate compensation from the National Vaccine Injury Compensation Program. When those injured by vaccines are not compensated or are inadequately compensated for their avoidable injuries, the States often bear the burden of providing financial and medical assistance to the

vaccine-injured and their families. Although the safety and availability of vaccines is also an area of federal interest, "'[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.'" *Levine*, 129 S. Ct. at 1200 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989)).

Here, Congress enacted the Vaccine Act to divert claims from the tort system for potential resolution in an administrative regime in order both to reduce the costs of litigation to those injured by vaccines and to provide injured victims compensation. However, because Congress understood that the traditional tort system "provide[s] important incentives for the safe manufacture and distribution of vaccines," *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, J.), it did not immunize manufacturers from suit. The Vaccine Act expressly permits tort suits if the injured party is unsatisfied with the award she receives, or if the administrative system fails to provide an award or judgment within a reasonable time. *See* 42 U.S.C. §§ 300aa-21, 300aa-11(a)(2)(A). Moreover, Congress expressly preempted state law that would prevent a vaccine-injured person from bringing suits not expressly barred by the Vaccine Act. In sum, Congress legislated against a backdrop where tort liability was available to those injured by vaccines, understood tort liability to be important for vaccine safety, and envisioned tort suits being available after the vaccine-injured exhaust their administrative remedies under the Vaccine Act.

Despite the presumption against preemption, the text of the Vaccine Act, and Congress' awareness of the operation of state law in this area, the Third Circuit found that Congress clearly and manifestly intended to bar all design defect claims against vaccine manufacturers. The Third Circuit paid lip service to the presumption against preemption, but failed to give it its proper weight. The Third Circuit defended its approach on the ground that interpreting the Vaccine Act to only preempt design defect cases in *some* cases—i.e., when an injury or death is "unavoidable"—would require case-by-case determinations by courts on whether the injury was avoidable or not. The lower court held that Congress *could not* have intended all design defect claims to be evaluated by the courts despite the absence of express language or evidence showing a *clear and manifest purpose* to preempt all design defect claims against vaccine manufacturers.

The Third Circuit also confused state law determinations that state substantive law of products liability bars certain design defect claims with Congressional intent to preempt. *Bruesewitz v. Wyeth*, 561 F.3d 233, 246 (3d Cir. 2009) (noting that in 1986, when Congress enacted the Vaccine Act, *some* courts had barred *some* design defect claims against *prescription drug manufacturers* under state law, and concluding that Congress "could not have intended" to allow even different design defect claims to go forward against vaccine manufacturers in those states). These state law determinations are particular to each state, and are not evidence of *Congress' purpose* in enacting the Vaccine Act.

The Third Circuit's attempt to cobble together some reason Congress would want to bar *all* design

defect claims against vaccine manufacturers flies in the face of this Court's repeated admonitions that only a "clear and manifest" Congressional purpose may overcome the presumption against preemption. The Third Circuit's approach effectively turns the presumption on its head to one that clearly *favors* preemption.

III. TRADITIONAL STATE TORT LAW COMPLEMENTS THE PURPOSES OF THE VACCINE ACT BY ENHANCING AND ENSURING THE SAFETY OF CHILDHOOD VACCINES.

The Third Circuit was incorrect when it held that allowing any design defect claims against vaccine manufacturers would undermine the objective of ensuring vaccine development and availability. *Bruesewitz*, 561 F.3d at 248-49. In so ruling, the lower court failed to recognize the value of the state tort law system, a recognition that Congress respected in designing the Vaccine Act, and failed to recognize that state tort law and federal regulation are complementary systems that can comfortably co-exist. The Third Circuit gave little heed to this Court's instruction to approach the question of federal preemption of state law with "the general understanding of common-law damages actions" and their role in product safety. *Cipollone,* 505 U.S. at 521.

The Vaccine Act created an administrative remedial system "that tries more quickly to deliver compensation to victims, while also reducing insurance and litigation costs to manufacturers." *Schafer*, 20 F.3d at 2. Indeed, it allows manufacturers to avoid or defer most litigation costs

because the manufacturers do not participate in the Vaccine Program proceedings at all. *See* 42 U.S.C. § 300aa-12(b) (the Secretary of Health and Human Services is the respondent in all proceedings); Vaccine R. of the U.S. Ct. of Fed. Claims 15 (no third parties may intervene, but "interested individuals" may "submit relevant written information"). The compensation and attorneys' fees provided by the Vaccine Act come from a fund created by Congress from appropriations in the first few years after enactment of the Vaccine Act, and afterward by an excise tax on each dose of vaccine. *See* 42 U.S.C. § 300aa-15(i); 26 U.S.C. §§ 4131, 9510.

While the Vaccine Act increased reporting requirements for vaccine manufacturers and health care providers, 42 U.S.C. § 300aa-25(b), and gave authority to the Secretary of Health and Human Services to promote the development and improvement of childhood vaccines, 42 U.S.C. § 300aa-27, the Vaccine Act does not contain any provisions that would directly encourage or require vaccine manufacturers, who generate profit from the distribution of childhood vaccines, to improve their own products. Thus, there is nothing in the Vaccine Act itself that requires a vaccine manufacturer with a license for a vaccine that was developed fifty years ago to research and develop a safer, cost-competitive alternate design.

The tort system, however, provides precisely this impetus to manufacturers. Congress recognized this fact, and accordingly rejected bills that would have immunized manufacturers from product liability claims. *See* H.R. 5184, 99th Cong. § 2122(c)(1) (1986); *National Childhood Vaccine Injury Compensation Act of 1985 (Part 2): Hearing on S.827*

Before the S. Comm. On Labor & Human Resources, 99th Cong. 16 (1985). It would be unwise for this Court now to deny this important tool to those who suffer avoidable injuries from childhood vaccines. Tort liability enhances the safety of products, particularly those that are as ubiquitous as childhood vaccines.

A. Product Liability Law Plays a Distinct and Important Role in Protecting Public Safety.

Mass production and mass marketing of consumer products have brought great progress and prosperity to Americans over the past century. Indeed, mass vaccination programs have led to healthier children and communities, and long life-expectancy for all Americans. *See, e.g.*, H.R. Rep. No. 99-908, at 4 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6345. But unreasonably dangerous products also pose grave risks of personal injury and death. Thus, the United States has depended upon a two-pronged approach to ensuring product safety.

Governmental regulation assumes that the marketplace cannot achieve the desired level of safety and instead imposes safety by decree. Product liability, on the other hand, operates indirectly through the marketplace. By requiring the manufacturer to internalize the costs of injury as part of the price of the product, the market creates a financial incentive for manufacturers to make their products reasonably safe.

Product liability is an adaptation of the common-law fault principle to the modern

marketplace, beginning with Justice Cardozo's landmark decision in *MacPherson v. Buick Motor Co.,* 111 N.E. 1050 (N.Y. 1916), more fully developed in *Greenman v. Yuba Power Products,* 377 P.2d 897 (Cal. 1963), and reaching its most widely adopted formulation in Restatement (Second) of Torts § 402A (1965). *See generally*, Gary T. Schwartz, *The Vitality of Negligence and the Ethics of Strict Liability*, 15 Ga. L. Rev. 963 (1980). While tort law has been called "law with a human face," Peter H. Schuck, *Introduction: The Context of the Controversy* 17, 21, *Tort Law and the Public Interest* (Peter H. Schuck ed., 1991), with its primary purpose being compensation of those who have been wrongfully injured, tort law claims for product liability also play an indirect role providing market incentives for safety. *See* John W. Wade, *On the Nature of Strict Tort Liability for Products,* 44 Miss. L.J. 825, 826 (1973).

It is well-accepted that in a marketplace in which all actors have perfect knowledge of risks, the market itself would provide the most efficient allocation of resources to produce reasonably safe products. Ronald H. Coase, *The Problem of Social Cost*, 3 J.L. & Econ. 1 (1960); Jon D. Hanson & Kyle D. Logue, *The First-Party Insurance Externality: an Economic Justification for Enterprise Liability,* 76 Cornell L Rev. 129, 161 (1990) (noting that the Coase Theorem is "well accepted"). That is, the market would favor products with the lowest sum of the cost of injuries plus the cost of injury prevention.

Of course, real-world markets do not provide perfect consumer information. And manufacturers are able to "externalize" the injury costs of their products. Guido Calabresi, *The Costs of Accidents*

144-45 (1970). That is, the manufacturer can force consumers, taxpayers, and society generally to subsidize its products by bearing part of the cost of the injuries they cause. This places the manufacturer who invests in safety at a competitive disadvantage. Product liability rules, by assessing risk retrospectively, compensate for imperfect consumer information. Steven P. Croley & Jon D. Hanson, *Rescuing the Revolution: The Revived Case for Enterprise Liability*, 91 Mich. L. Rev. 683, 707-08 (1993). *See also* W. Kip Viscusi, *Reforming Products Liability* 66 (1991) ("The purpose of products liability is to fill the gaps left by market imperfections and to replicate the incentives that would have been generated had markets been functioning perfectly.").

In this way, product liability lawsuits "promot[e] optimal deterrence—the taking of precautions and selection of activities that minimize the sum of accident costs and accident avoidance costs." Kenneth S. Abraham, *The Insurance Effects of Regulation by Litigation*, *in Regulation Through Litigation*, 212, 232 (W. Kip Viscusi ed. 2002). It is for the manufacturer to decide rationally whether it is cheaper to prevent future injuries by investing in safety precautions or simply to compensate future victims. *Id*.

Product liability duties therefore reflect a policy of making dangerous products pay their own way, that is, internalizing costs to achieve an efficient level of manufacturing operations. William M. Landes & Richard A. Posner, *The Positive Economic Theory of Tort Law,* 15 Ga. L. Rev. 851, 871-77 (1980); Richard C. Ausness, *Compensation For Smoking-Related Injuries: An Alternative to Strict Liability in Tort*, 36 Wayne L. Rev. 1085, 1140

(1990) ("efficient allocation of resources is more likely if product prices reflect their actual social costs").

Viewed another way, the law requires the product's purchase price to reflect the costs of injuries so the "cheapest cost avoider" makes the most efficient allocation of resources. Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts,* 81 Yale L.J. 1055, 1060 (1972) ("The question for the court reduces to a search for the cheapest cost avoider," i.e., which of the parties to the accident is in the best position to make the cost-benefit analysis between accident costs and accident avoidance costs and to act on that decision once it is made.); *see also* Stephen G. Breyer, *Administration and Its Reform* 175 (1982) (favoring rule "likely to place costs on the party best able to avoid them").

To the extent that preventing injury is cheaper than compensating the injured, tort liability provides manufacturers with an economic incentive to make their products safer. *Id.* In this way, tort liability "is broadly consistent with an optimum investment in accident prevention by the enterprises subject to the standard." Richard A. Posner, *A Theory of Negligence*, 1 J. Legal Stud. 29, 30 (1972).

Simply the *prospect* of product liability claims, without any actual liability, can deter negligent behavior and can drive product manufacturers to make safety improvements long before regulation or the market alone could force such developments. *See* John D. Graham, *Product Liability and Motor Vehicle Safety*, *in The Liability Maze: The Impact of Liability Law on Safety and Innovation* 120, 180-81 (Peter W. Huber & Robert E. Litan eds., 1991). The

fear of unwanted publicity of product liability suits, too, regardless of any actual liability, can be a catalyst for safety improvements. *Id.* at 181-82. *See* Gary T. Schwartz, *Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?*, 42 U.C.L.A. L. Rev. 377, 409, 415-16 (1994) (discussing risk managers' assessments of the impact of tort liability on their own safety efforts).

Safety by government regulation is a much different regime. It is premised on the belief that the marketplace cannot achieve the level of safety society demands. Croley & Hansen, *supra* at 736. In many ways, regulation and tort liability are polar opposites. Administrative regulations are prospective; tort liability assesses past conduct. Regulations may mandate specific design or performance standards; a jury verdict assesses whether a manufacturer met a duty of care. Regulatory penalties can be imposed to enforce compliance; a liability verdict is measured to compensate for wrongful death and injury. *See generally*, Steven Shavell, *Liability for Harm Versus Regulation of Safety,* 13 J. Legal Stud. 357 (1984).

In his classic exposition, Judge Calabresi contrasts the indirect influence exerted on the market by tort law ("general deterrence") with governmental regulatory mandates ("specific deterrence"). Calabresi, *The Costs of Accidents*, *supra*, at 68-129. As one scholar summarized: "[U]nder a *general deterrence* regime, manufacturers, not government officials, make decisions about product safety." Richard C. Ausness, *Cigarette Company Liability: Preemption, Public Policy, and Alternative Compensation Systems*, 39 Syracuse L. Rev. 897, 927 (1988) (emphasis added).

For this reason, this Court has consistently held that even where a federal agency has authority to oversee regulation of a particular national concern, state tort liability is not inconsistent with federal authority. *See, e.g.*, *Wyeth v. Levine*, 129 S. Ct. at 1200-04; *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988). *See also English v. General Elec. Co.,* 496 U.S. 72, 85 (1990) (the effect of tort awards "is neither direct nor substantial enough to place petitioner's claim in the pre-empted field" with administrative regulations); *Silkwood v. Kerr-McGee Corp*., 464 U.S. 238, 258 (1984) (vesting federal agency "with exclusive regulatory authority over the safety aspects of nuclear development" was not inconsistent with allowing plaintiffs to recover for injuries caused by nuclear hazards).

In addition, "tort law often informs regulatory decisions, and the FDA has often acted in response to information that has come to light in state damages litigation." David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warm Claims*, 96 Geo. L.J. 461, 477 (2007-2008) (citing *Bates*, 544 U.S. at 451); *see also* Karen E. Lasser, *et al.*, *Timing of New Black Box Warnings & Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (2002). The "legal system [has] played an important role in spurring change in regulatory or corporate procedures, as well as extending knowledge about drug risks by adding to the evidence available for evaluation by physicians, patients, and regulators." Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 310 (2007).

In all of these ways state product liability law plays an important role in ensuring the safety of consumer products.

B. The Third Circuit's Holding That the Vaccine Act Bars *all* Design Defect Claims Undermines the Goal of Vaccine Safety.

It is well understood that imposing liability on manufacturers for their defective products will encourage the development of safer products because it

> discourages others from similar tortious behavior, fosters safer products . . . , vindicates reasonable conduct that has regard for the safety of others, and, ultimately, shifts the risk of loss and associated costs of dangerous activities to those who should be and are best able to bear them.

Shackil v. Lederle Labs., 561 A.2d 511, 537 (N.J. 1989) (O'Hern, J., dissenting). The Third Circuit's holding fails to explain how the Vaccine Act promotes the discovery and development of safer vaccines if manufacturers are given a "blanket tort immunity for design defects." *Am. Home Prods. v. Ferrari*, 668 S.E. 2d 236, 242-43 (Ga. 2008).

Within the Vaccine Program, vaccine manufacturers are not held directly liable for anything. Even if the Special Master determines that a child was injured by a vaccine that could have been safer, i.e., a vaccine suffering from a design defect, the manufacturer of that vaccine never has to internalize the cost of its defective design. The Fund

pays compensation to the injured parties, and deterrence is lost. The Vaccine Program itself provides no incentive to vaccine manufacturers to make their vaccines safer.

"Rather than working at odds with each other, federal regulation and state common law acting in concert can improve vaccine safety of existing vaccines and spur the development of improved vaccines." *Mazur v. Merck & Co.*, 742 F. Supp. 239, 248 (E.D. Pa. 1990), *aff'd on other grounds*, 964 F.2d 1348 (3d Cir. 1992). *See also MacGillivray v. Lederle Labs. Div. of Am. Cyanamid Co.*, 667 F. Supp. 743, 745 (D.N.M. 1987) ("[F]ederal regulations are designed to assure the manufacture and distribution of effective, safe pharmaceutical products for the consumer. A tort judgment against a drug manufacturer may in fact accelerate the development of better, safer products."). Tort actions may lead manufacturers to seek approval of safer alternatives to the vaccines for which they already have licenses, or lead the National Vaccine Advisory Committee to call for the development of new vaccines or the refinement of current vaccines. Discovery may bring new information to light that spurs agency action to ensure the safety of vaccines, or leads regulators to reassess their prior safety determinations. As the former FDA Chief Counsel has written, "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." Margaret J. Porter, *The Lohr Decision: FDA Perspective and Position,* 52 Food & Drug L.J. 7, 11 (1997). *See also* 1 American Law Institute, *Reporters' Study: Enterprise Responsibility For Personal Injury* 50 (1991); Steven Shavell, *Liability for Harm Versus Regulation of Safety,* 13 J.

Legal Stud. 357 (1984); Susan Rose-Ackerman, *Tort Law in the Regulatory State*, *in Tort Law and the Public Interest* 80, 82-83 (Peter H. Schuck ed., 1991).

The specter of damage actions may provide the manufacturers themselves with added dynamic incentives to improve their products and develop new ones. The goal of vaccine safety "is more enhanced than frustrated by state law." *Abbot by Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1113 (4th Cir. 1988).

> [B]y allowing a tort action . . . to proceed the national goal of optimum vaccine safety is actually enhanced. While Congress intends vaccines to be at least as uniformly safe as the FDA regulations require, there has never been a congressional intent that innocent victims of adverse reactions should be precluded from being compensated or from demonstrating that the vaccines could be even safer thereby encouraging additional efforts on the part of the vaccine manufacturers.

Graham v. Wyeth Labs., 666 F. Supp. 1483, 1493 (D. Kan. 1987), *aff'd in part, rev'd on other grounds*, 906 F.2d 1399 (10th Cir. 1990). In passing the Vaccine Act, Congress recognized that immunizing an entire industry from tort claims and thus shifting financial responsibility for the injuries caused by its products to others could destroy incentives to make vaccines safer. *Schafer*, 20 F.3d at 3. By barring *all* design defect claims, the Third Circuit crippled the efforts of *everyone* concerned with vaccine safety, not just those who were injured by avoidably unsafe vaccines.

C. The Availability of State Tort Law Claims for Design Defects Against Vaccine Manufacturers Will Not Harm the Safety or Availability of Vaccines.

This is not the first time that a vaccine manufacturer has sought immunity from design defect claims. Prior to the enactment of the Vaccine Act, vaccine manufacturers sought refuge under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Public Health Service Act ("PHSA"), 42 U.S.C. §§ 247b and 262. *See, e.g.*, *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1988); *Abbot* 844 F.2d at 1112 n.1; *Mazur*, 742 F. Supp. at 239; *Foyle v. Lederle Labs.*, 674 F. Supp. 530, 534 (E.D.N.C. 1987); *Martinkovic v. Wyeth Labs., Inc.*, 669 F. Supp. 212, 215 (N.D. Ill. 1987); *MacGillivray*, 667 F. Supp. at 746 n.1; *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1340 (C.D. Cal. 1987); *Graham*, 666 F. Supp. at 1492; *Patten v. Lederle Labs.*, 655 F. Supp. 745, 749 (D. Utah 1987); *Wack v. Lederle Labs.*, 666 F. Supp. 123, 127-28 (N.D. Ohio 1987).

Vaccine manufacturers have consistently argued that common law tort actions interfere with federal determinations regarding the safety of vaccines, impose a heavy cost on manufacturers resulting in price increases for vaccines, and have the potential to lead to withdrawal of manufacturers from the vaccine market. *See, e.g.*, *Hurley*, 863 F.2d at 1177; *Abbot*, 844 F.2d at 1113. Yet faced with these claims from the manufacturers, the courts that have addressed the purported conflict between federal regulation of vaccines and state common law liability for unsafe products consistently refused to

give vaccine manufacturers the immunity from suit that they sought. *Hurley*, 863 F.2d at 1177, 1178 ("Moreover, it is not clear that the cost of compensating children injured by the vaccine would drive manufacturers from the business; the manufacturers may be able to raise prices and preserve their profit margins. Because the vaccine price is paid by the federal government, this would make the vaccination program a greater burden on the public fisc, but it would not discourage parents from having their children vaccinated."); *Abbot*, 844 F.2d at 1113; *Mazur*, 742 F. Supp. at 246-47; *Foyle*, 674 F. Supp. at 534; *Martinkovic*, 669 F. Supp. at 215; *MacGillivray*, 667 F. Supp. at 746 n.1; *Morris*, 667 F. Supp. at 1340; *Graham*, 666 F. Supp. at 1492; *Patten*, 655 F. Supp. at 749; *Wack*, 666 F. Supp. at 127-28.

Vaccine manufacturers' doomsday claims are not new. Respondents and their *amici* raise the same policy arguments that were made more than 20 years ago, prior to the Vaccine Act's enactment—i.e., that safety is ensured by FDA approval of vaccines and that civil juries are poorly equipped to judge the safety of vaccines. *See* Brief of United States as Amicus Curiae at 14-15 *Am. Home Prods. Corp. v. Ferrari*, 129 S. Ct. 2786 (Mem.) (2009) (No. 08-1120), 2010 WL 342143. These arguments were rejected under the FDCA and PHSA, and the Vaccine Act does not change the analysis.

While the intervention of the Vaccine Act added a new remedial scheme and modified some tort law, the Vaccine Act did not change the way vaccine safety is regulated by the FDA. The FDA still only considers the safety and effectiveness of the vaccines submitted to it by the manufacturers, and

cannot force manufacturers to seek approval for safer, alternative designs. *See* 21 U.S.C. §§ 301-393. While the Vaccine Act added reporting requirements and gave the Secretary of Health and Human Services authority to promote research and development of safer vaccines, it did not change the passive nature of FDA regulation of vaccines. *See* 42 U.S.C. §§ 300aa-25-28. Thus, under the Vaccine Act, state tort claims for design defect *still* complement the federal regulation of vaccines and do not frustrate federal law objectives in the regulation of vaccines.

The arguments favoring preemption of all state law design defect claims fail to recognize that state tort law enhances the safety of vaccines by giving manufacturers incentive to make safer vaccines. Those arguments also fail to recognize that even without complete immunity from design defect claims, the Vaccine Act significantly reduces insurance and litigation costs to vaccine manufacturers through other means, and that abolishing tort law claims for defective design would threaten the public health.

1. The Vaccine Act provides adequate protection to the stability of the vaccine market even without providing absolute immunity from suit for design defects.

Under the Vaccine Act, a person injured by a vaccine administered after October 1, 1988, is effectively prohibited from filing a civil action until *after* his or her claim under the Act has been adjudicated in the Vaccine Program. 42 U.S.C. §

300aa-11(a). The party can file suit at that time only if it waives any compensation awarded under the Act. 42 U.S.C. § 300aa-21. Within the Program, vaccine manufacturers are not party to the proceedings, and thus bear no litigation costs unless and until the injured person exhausts her administrative remedy. 42 U.S.C. § 300aa-12(b). Even if an injured person proves that the vaccine that caused her injury was defectively designed, and is awarded compensation, the vaccine manufacturer is not directly liable for the award.

By requiring claimants to exhaust their administrative remedies in the Program prior to filing a court action, Congress hoped to divert a significant number of litigants, and thus save manufacturers a great sum in litigation costs. It is only after this administrative remedy proves unfruitful or unsatisfactory that the manufacturers ever are called to account for their defective products in a court of law. The purpose of the system is to *reduce* litigation, but not entirely preempt state laws. *See Abbot*, 844 F.2d at 1117 (Wilkins, J., concurring).

Given the differences in state products liability law, many common law actions are difficult to win. This makes it unlikely that many vaccine-injured claimants will risk an award of compensation from the Vaccine Program to pursue a tort action, and makes it even less likely that claimants who are unsuccessful under the Vaccine Program will be successful under state common law. *See, e.g. Schafer*, 20 F.3d at 6.

Even if a vaccine-injured person pursues a tort action alleging design defect, manufacturers have additional protections built into the Vaccine Act:

Congress prohibited tort awards for "unavoidable" injuries from vaccines, 42 U.S.C. § 300aa-22(b), abolished any obligation of manufacturers to provide direct warnings to those injured by vaccines or their legal representatives, 42 U.S.C. § 300aa-22(c), imposed a presumption that vaccines contained adequate warnings if the manufacturer complied with federal regulations, 42 U.S.C. § 300aa-22(b)(2) and eliminated punitive damages in most cases, 42 U.S.C. § 300aa-23. *See Schafer*, 20 F.3d at 3. All of these measures aim to reduce the burden of tort litigation on vaccine manufacturers. But the manufacturers and their *amici* now claim that these protections are not enough, and seek from this Court what they were unable to gain from Congress in the Vaccine Act: complete immunity from *all* design defect claims.

The manufacturers' assertions that allowing claims like the Petitioners' to go forward will result in catastrophic results is hyperbole, at best. Just as the courts that addressed similar claims by vaccine manufacturers recognized in the 1980s, the state tort law system is complementary to the purposes of federal law, and there is good reason to allow such claims to be evaluated by the courts.

2. The absence of State tort liability for defective vaccines would lead to more severe consequences than those the vaccine manufacturers predict would result from the availability of such claims.

Contrary to Respondents' claims, it is the *absence* of state tort liability for design defects that

would harm public safety by both reducing incentives for vaccine manufacturers to make safer vaccines and by discouraging vaccine use by increasing fears about vaccine safety. Extinguishing tort liability for defective design would also force consumers and the States to bear the cost of any avoidable injury caused by vaccination that is not compensated (or is inadequately compensated) by the Vaccine Program.

Most states require children to be vaccinated in order to attend public school, and most children must be vaccinated in order to attend private school or participate in most of the recreational sports and activities that many children enjoy. While the States have a strong interest in having children vaccinated, they also have a strong interest in providing a remedy for children who are injured by vaccines and who elect a state tort law remedy rather than an award by the Vaccine Program. Furthermore, the States have an interest in "encouraging drug manufacturers to provide the safest possible vaccines," *see Graham*, 666 F. Supp. at 1493 n.5, otherwise the States themselves may have to bear the costs of those who suffer avoidable injures from vaccines. If a vaccine-injured individual and her family do not have the resources to cover the costs of her avoidable injury, state public assistance programs, hospitals and other state resources may be forced to pay for these costs.

With regard to mandatory vaccination, parents do not have any *real* choice as to whether their children receive the vaccines that they do. Even if parents are properly warned of the actual risks of a particular vaccine, they can hardly be said to freely accept the risk of horrible injuries that result in rare cases. It is one thing to proffer a

medicine to a prospective user and tell them that the drug that can save them from a debilitating disease has serious side effects, and then allow the consumer to choose. It is something else to require parents to vaccinate their children and also require them to carry the entire burden when their children suffer a serious side effect caused by the vaccine and when the Vaccine Program fails to provide them adequate compensation.

In these circumstances, the marketplace and federal regulation are inadequate to protect individuals *or* the States. If there is only one vaccine available on the market because the manufacturer only sought approval for that vaccine, market forces and federal regulation cannot make that vaccine safer. Consumers do not have a choice of a safer vaccine, and they *must* inoculate in order to participate in other areas of daily life. The federal regulators cannot force the manufacturer to apply for a license for a different, safer vaccine. And if a person injured by that vaccine is uncompensated or unsatisfied with the compensation provided by the Vaccine Program, the Third Circuit's interpretation of the Vaccine Act leaves the States and the individuals themselves to bear the costs of those avoidable injuries.

"A state may decide that while it must abide by the FDA's determination that a drug is marketable, the manufacturer must nonetheless bear the expense of the risk of injuries, particularly where there is evidence that suggests that the product may be subject to improvement." *MacGillivray*, 667 F. Supp. at 745-46. Abolishing state tort law claims for design defects might lead the States to reassess and change their vaccination

requirements. Parents might lobby for such a change or simply refuse to vaccinate their children, choosing to bear the cost of a potential illness rather than a debilitating life-long condition. Either of these outcomes would degrade the public health.

CONCLUSION

For the foregoing reasons, *amici curiae* the American Association for Justice, Public Justice, and Public Citizen urge this Court to reverse the judgment of the United States Court of Appeals for the Third Circuit.

Respectfully Submitted,

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June 1, 2010

No. 09-152

IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ,
PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ,
A MINOR CHILD, AND IN THEIR OWN RIGHT,

Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES,
WYETH-AYERST LABORATORIES, WYETH LEDERLE,
WYETH LEDERLE VACCINES, AND LADERLE LABORATORIES,

Respondents.

On Writ Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE, PUBLIC JUSTICE, AND PUBLIC CITIZEN AS AMICI CURIAE IN SUPPORT OF PETITIONERS

CERTIFICATE OF COMPLIANCE

As required by Supreme Court Rule 33.1(h), I certify that the Brief of the American Association of Justice, Public Justice, and Public Citizen as *Amici Curiae* in Support of Petitioners contains 6,921 words, excluding the parts of the document that are exempted by Supreme Court Rule 33.1(d).

I declare under penalty of perjury that the foregoing is true and correct.

June 1, 2010.

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CERTIFICATE OF SERVICE

I, Valerie Nannery, a member of the Bar of this Court, hereby certify that on this 1st day of June, 2010, three copies of the Brief of the American Association of Justice, Public Justice, and Public Citizen as *Amici Curiae* in Support of Petitioners in the above-entitled case were served via Federal Express for overnight delivery, to each counsel listed below. I further certify that all parties required to be served have been served.

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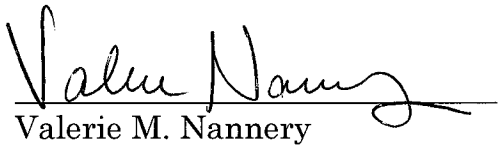

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