No. 09-152

IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ, 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 LEDERLE LABORATORIES,

Respondents.

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

BRIEF IN RESPONSE TO PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In the 1980s, the costs and risks of product liability litigation drove several vaccine manufacturers out of the market, causing shortages of vaccines essential to public health programs. Congress averted a public health crisis by enacting the National Childhood Vaccine Injury Act of 1986. The Act shielded vaccine manufacturers from categories of tort litigation, directed federal agencies to develop safer childhood vaccines, and established a Vaccine Court to administer a no-fault remedy for vaccine-related injuries. The Act's express preemption provision states that "[n]o vaccine manufacturer shall be liable in a civil action" if the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

Does the Vaccine Act expressly preempt a state-law claim against a vaccine manufacturer based on an allegation that the vaccine-related injury could have been avoided by a vaccine design allegedly safer than the one approved by the U.S. Food and Drug Administration for use nationwide?

RULE 29.6 STATEMENT

Respondent Wyeth, Inc., improperly identified in the caption as Respondents "Wyeth, Inc. f/k/a Wyeth Laboratories, Wyeth-Ayerst Laboratories, Wyeth Lederle, Wyeth Lederle Vaccines and Lederle Laboratories," states that Wyeth is a publicly traded corporation. No publicly held corporation owns 10% or more of its outstanding shares.

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INTRODUCTION

Respondents ("Wyeth") agree with Petitioners ("plaintiffs") that the Court should grant certiorari in this case to resolve a crucial public health issue upon which the lower courts are split. Twenty-five years ago, a deluge of cases asserting claims just like this one drove vaccine manufacturers from the market and threatened the nation's supply of childhood vaccines. Congress stabilized the market by enacting the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq.* (the "Vaccine Act" or "Act"), which created a new, no-fault compensation program for vaccine-related injuries and included an express preemption provision (Section 22) that limits the scope of damage claims that can be advanced against vaccine manufacturers. The question presented by the petition is whether Section 22 categorically preempts all design defect claims, which were central to the 1980s litigation crisis.

In answering that question in the affirmative, the United States Court of Appeals for the Third Circuit expressly—and correctly—rejected the conclusion of the Georgia Supreme Court in *American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008).[1] The Georgia Supreme Court held that

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[1] The vaccine manufacturer defendants in *Ferrari* petitioned for a writ of certiorari, which petition is pending. No. 08-1120. This Court called for the views of the United States on the petition, *American Home Products Corp. v. Ferrari*, 129 S. Ct. 2786 (2009), but the Solicitor General has not yet filed her brief in response to the invitation.

Section 22 does not preclude design defect claims unless the manufacturer demonstrates, case by case, that there was no safer design that could have avoided the injury.

The Court should not wait for another case to take up the question of which interpretation of Section 22 is correct. The stability of the nation's childhood vaccine supply remains precarious. Determining which state law claims Section 22 allows against vaccine manufacturers will affect the development and supply of vaccines. If the conflicting interpretations of the Georgia Supreme Court and the Third Circuit are left unresolved, vaccine manufacturers will face the potentially devastating prospect of thousands of lawsuits challenging the design of their FDA-approved vaccines in courts across the country. Approximately 5,000 petitions—all premised on the claim that a child's autism was caused by vaccines—are pending in the federal no-fault vaccine compensation program ("Vaccine Court"). Regardless of how the Vaccine Court decides those petitions, every claimant has the potential to reject the judgment and elect to file a civil action for damages.

Apart from the need to review the question presented, however, Wyeth disagrees with almost everything else in plaintiffs' petition. Plaintiffs inject implied preemption issues into their petition; but those issues have no relevance to the question presented here of express preemption under the Vaccine Act. Wyeth also disagrees with plaintiffs that the Third Circuit erred in its ultimate result. The Third Circuit—joining every court to address

the issue outside Georgia—correctly decided that the Vaccine Act categorically preempts all design defect claims. The court properly rejected plaintiffs' construction of the statute—which would permit unfettered litigation against vaccine manufacturers—as antithetical to Congress's primary aim of ensuring a stable supply of childhood vaccines.

Because a litigation deluge would threaten the supply of childhood vaccines, the Court should grant certiorari in this case and verify which interpretation of the express preemption provision is correct, the Third Circuit's or the Georgia Supreme Court's.

STATEMENT OF THE CASE

In 1986, Congress Saw That Vaccine Litigation Threatened To Cause A Public Health Crisis

The petition's discussion of the Vaccine Act is incomplete. Plaintiffs write as if Congress intended for the Vaccine Act to compensate allegedly vaccine-injured individuals and nothing more. But the Vaccine Act's new approach to compensation for vaccine-related injuries is only one part of a multi-faceted public health program Congress created.

Congress recognized in 1986 that "[v]accination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. Rep. No. 99-908, at 4 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6345. For example, pertussis (or whooping cough) is a serious, highly communicable respiratory disease.

In 1934, there were 265,269 reported cases of pertussis and 7,518 deaths. *See* Staff of Subcomm. on Health and the Environment, 99th Cong., *Childhood Immunizations* 9-10 (Sept. 1986) ("Subcomm. Rep."). After 40 years of widespread use of the whole-cell pertussis vaccine, the incidence of pertussis dropped to 2,276 reported cases in 1984 and only 12 deaths. *Id.* Congress enacted the Vaccine Act when the burden of vaccine litigation costs threatened to undermine the spectacular public health gains brought about by nationwide vaccination.

In the 1980s, vaccine manufacturers faced a proliferation of product liability claims involving childhood vaccines. Most of these cases were like this one, involving claims that the diphtheria, tetanus, and pertussis ("DTP") vaccine was defectively designed because there was an unlicensed, allegedly safer, alternative vaccine in existence that would have prevented the same diseases. The result of that litigation explosion, according to Congress, was a vaccine market so "unstable and unpredictable" as to threaten the supply of vaccines necessary to carry out childhood immunization programs. *See* 1986 U.S.C.C.A.N. at 6346. Observing that litigation had already driven manufacturers from the market, Congress concluded that the "withdrawal of even a single [additional] manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." *Id.* at 6348. Congress addressed the public health crisis with the Vaccine Act.

Policy Components Of The Vaccine Act

The objective of universal vaccination to combat infectious disease and promote the common public health requires a stable supply of safe and effective vaccines. Through the Vaccine Act, Congress sought: (1) to keep vaccine manufacturers in the market; (2) to provide fair compensation to the few who suffer adverse side effects from vaccination; and (3) to have improved vaccines developed. The key to achieving these goals was to create a comprehensive, national vaccine policy—from developing safer vaccines, to a new paradigm for providing compensation and litigating injury claims.

Keeping vaccine manufacturers in the market. The element of the statutory scheme that protects vaccine manufacturers from the sort of burdensome litigation that Congress found had driven manufacturers out of the market is Section 22(b)(1). It provides, in full:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1). Neither party interprets Section 22 to preclude any and all state tort claims. The parties agree that the Vaccine Act permits claims against a manufacturer for injuries caused by a vaccine not manufactured according to its FDA-

approved formula (i.e., not "properly prepared") or not accompanied by proper directions and warnings for use. The question presented by the petition is whether Section 22 leaves open the possibility of other claims for damages, specifically design defect claims, which were central to the litigation in the 1980s.

Before filing a civil action, a person seeking damages for a vaccine-related injury must file a petition for compensation in the Vaccine Court, which is an adjunct to the Court of Federal Claims. 42 U.S.C. §§ 300aa-11(a)(2), 12(c), 21(a). Compensation claims are decided on a no-fault basis. *Id.* §§ 300aa-13, 14, 15(i). A Vaccine Court claimant does not need to prove that the injury could have been avoided through a safer design or that the vaccine was otherwise defective—as tort law would require—but only that there is a causal link between the administered vaccine and the injury. *See id.* § 300aa-13. After receiving a judgment in Vaccine Court, the claimant can either accept the judgment or reject it and file a civil action, subject to several substantive and procedural constraints. *See* 42 U.S.C. § 300aa-21.

The National Vaccine Program. The Vaccine Act established a National Vaccine Program ("NVP") to promote the development of improved, safer vaccines for use in immunization programs nationwide. 42 U.S.C. § 300aa-27(a)(1). Through this program, nearly a dozen federal agencies, including the Food and Drug Administration ("FDA"), work together "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention

against adverse reactions to vaccines." 42 U.S.C. § 300aa-1. Congress established a "[m]andate for safer childhood vaccines" and assigned the Secretary of the Department of Health & Human Services ("HHS") with the responsibility to "assure improvements in ... licensing, manufacturing, processing, testing, labeling, warning, ... and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." 42 U.S.C. § 300aa-27(a)(1), (2).

The Vaccine Act left in place the laws and regulations that make the FDA responsible for regulating the formulation, production, and labeling of childhood vaccines, which are biological products subject to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Public Health Service Act, 42 U.S.C. § 262. Such oversight is done through the FDA's Center for Biologics Evaluation and Research ("CBER"), which was created in 1988, the same year the Vaccine Act became effective. CBER is entirely distinct from those aspects of the FDA that regulate drugs and devices. Following FDA licensure, a manufacturer cannot change the vaccine formula or the labeling without FDA approval. *See* 21 C.F.R. §§ 601.2, 601.12.

DTP Vaccine

Wyeth disputes almost all of the factual assertions in plaintiffs' Statement of the Case. Those assertions that purport to have citational support largely do not cite to the record below, but rather to statements made in decisions from completely unrelated cases. There is no need to

catalog all of those inaccuracies here because they are not relevant to the pure question of law presented by the petition. But Wyeth will address the most misleading of the statements about the regulatory history of the DTP vaccine at issue and purported safer alternative vaccines.[2]

The pertussis component in TRI-IMMUNOL®, the DTP vaccine at issue, consists of a suspension of whole, killed pertussis cells.[3] A. 1035a, ¶ 6; 866a, ¶ 6. Plaintiffs argue that Wyeth should have marketed a "safer alternative vaccine[ ]," i.e., an entirely different vaccine to prevent the same diseases that TRI-IMMUNOL® addresses. Pet. at 3. Plaintiffs contend that the "safer alternative vaccine[ ]" was either: (1) an acellular pertussis vaccine, which contained selected components of the

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[2] Wyeth denies that the DTP vaccine caused the minor plaintiff's injuries, a position which is consistent with the views of numerous medical organizations and agencies that have rejected plaintiffs' causation theory. *See, e.g.*, American Academy of Pediatrics, Committee on Infectious Diseases, *The Relationship Between Pertussis Vaccine and Central Nervous System Sequelae: Continuing Assessment*, 97 Pediatrics 279 (1996); Institute of Medicine, *DTP Vaccine and Chronic Nervous System Dysfunction: A New Analysis* (1994). Causation, however, was not at issue in plaintiffs' appeal to the Third Circuit and is not before this Court on the petition.

[3] Citations to A. __ are to the Appendix filed below. Plaintiffs admitted a number of facts in the district court summary judgment briefing. In this section, when two citations to the Appendix follow a sentence, they refer respectively to the relevant paragraph in Wyeth's statements of undisputed fact and plaintiffs' response admitting that the paragraph is not disputed.

pertussis cell; or (2) the Tri-Solgen vaccine, which was a "fractionated cell" vaccine that contained part of the pertussis bacterium, but unlike acellular vaccines, was neither characterized (identifying the parts of the cell) nor purified (utilizing only specific parts of the cell).

Indisputably, at the time of the minor plaintiff's immunization in April 1992, the only DTP vaccines that were licensed for immunizing infants used a "whole cell" pertussis vaccine component. A. 1036a, ¶ 12; 867a, ¶ 12. The FDA did not license for infants a DTP vaccine containing an acellular pertussis component until mid-1996, more than four years after the immunization of the minor plaintiff. A. 1036a, ¶ 9; 867a, ¶ 9.

Nevertheless, plaintiffs argue that Wyeth should have marketed the Tri-Solgen vaccine (which was withdrawn in the 1970s by its manufacturer Eli Lilly) instead of the FDA-approved TRI-IMMUNOL® vaccine. The FDA, however, concluded that the Tri-Solgen design was inferior to that of TRI-IMMUNOL®. In 1982, Wyeth Laboratories sought approval to market a vaccine based on the Tri-Solgen design, but the FDA rejected the license application, expressing "the need for several design improvements." *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 753 (Ohio 1988).

Plaintiffs also argue that the FDA did not license an acellular vaccine for infants simply because Wyeth failed to seek FDA approval for such a vaccine. That is false. The delay in licensing the acellular vaccine for infants in the United States was the product of the FDA's appropriate insistence that

all such vaccines be proven through clinical trials to be as efficacious as the existing whole-cell vaccine. CDC, *Pertussis Vaccination: Acellular Pertussis Vaccine for Reinforcing and Booster Use*, 41 MMWR 1 (Feb. 7, 1992). That requirement took years to fulfill in the United States. A. 1036a, ¶ 9; 867a, ¶ 9. Japan did not have a similar requirement, and in the face of a pertussis epidemic in 1981, the Japanese government permitted acellular pertussis vaccines to go to market with no efficacy testing and only limited clinical studies of immunogenicity and safety. CDC, *Pertussis Vaccination: Acellular Pertussis Vaccine for Reinforcing and Booster Use*, 41(RR-1) MMWR 1 (Feb. 7, 1992). Indeed, having neither required nor received clinical trial data to show that acellular vaccines were efficacious, regulatory authorities in Japan limited administration of acellular pertussis vaccines to children with more developed immune systems, i.e., children two years of age and older. *Id.*

The Proceedings Below

On April 3, 1995, plaintiffs filed a Vaccine Court petition seeking compensation for injuries the minor plaintiff allegedly suffered as the result of a DTP vaccination administered in April 1992. After an evidentiary hearing, the Vaccine Court rendered a judgment dismissing plaintiffs' petition with prejudice for failing to establish that the DTP vaccine caused the minor plaintiff's injuries.[4]

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[4] Plaintiffs correctly assert that residual seizure disorder associated with DTP vaccine was removed from the Vaccine Injury Table in 1995, thus placing on plaintiffs the burden of

Bruesewitz v. Sec'y of HHS, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Dec. 20, 2002). Plaintiffs did not appeal that judgment to the Court of Federal Claims or the Federal Circuit; instead, they elected to reject the judgment of the Vaccine Court and to pursue civil litigation.

After Wyeth moved for summary judgment, the district court, *sua sponte*, invited the FDA and HHS to submit an amicus brief. A-112. Plaintiffs are simply wrong that HHS and FDA responded to the invitation by stating that in this case there was "no preemption of all design defect claims." Pet. at 13. Instead, the two agencies chose not to take a position on the preemptive scope of the Vaccine Act at that time. The FDA and HHS responded by letter to the district court that they did not then have an official view on the preemption issue because the agencies are not parties to civil actions commenced after a claimant has properly exhausted the administrative compensation process, and do not administer provisions that govern such civil actions. A-107-09.

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proof as to medical causation. What plaintiffs fail to mention, however, is that HHS removed residual seizure disorder from the Table because it determined there was no "*medical evidence* to support" the presumption. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7691 (Feb. 8, 1995) (emphasis added). Even with the condition removed from the Table, plaintiffs still were able to argue in Vaccine Court that the DTP vaccine in-fact caused the minor plaintiff's injuries. All of plaintiffs' causation theories were rejected by the special master. *Bruesewitz*, 2002 WL 31965744, at *12-*17.

After "extensive discovery," the district court granted summary judgment to Wyeth on plaintiffs' entire complaint. A-54-56. The district court held, *inter alia*, that Section 22(b)(1) of the Vaccine Act expressly preempted plaintiffs' design defect claims. A-87.

The Third Circuit affirmed the district court's judgment. The Third Circuit concluded that the statutory text, structure, and legislative history of Section 22 showed "a 'clear and manifest' expression of congressional intent" to preempt design defect claims. A-30. In so ruling, the Third Circuit considered and explicitly rejected the Georgia Supreme Court's analysis, stating that it did "not consider the *Ferrari* Court's reading [of Section 22] to be compelling." A-28. The court found that "[e]ach of the objectives [of the Vaccine Act] extolled by the Commerce Report would be undermined if design defect claims were permitted under the statute," leading to the "very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act." A-36.

ARGUMENT

I. ON THE QUESTION PRESENTED, THE THIRD CIRCUIT'S DECISION DIRECTLY CONFLICTS WITH THE GEORGIA SUPREME COURT'S DECISION.

Wyeth agrees with plaintiffs that there is a clear and irreconcilable conflict between a state's highest court (the Georgia Supreme Court) and a federal court of appeals (the Third Circuit) on whether the Vaccine Act expressly preempts all design defect

claims. The Third Circuit's holding that the Vaccine Act expressly preempts all design defect claims is consistent with all others on the issue outside of Georgia. *See Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 845-46 (Sup. Ct. 2003), *aff'd*, 810 N.Y.S.2d 506 (App. Div. 2006), *leave denied*, 857 N.E.2d 1137 (N.Y. 2006) (table); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 299-303 (E.D. Pa. 2007); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664-66 (S.D. Tex. 2004); *Wright v. Aventis Pasteur, Inc.*, No. 3861, 2008 WL 4144386 (Pa. Ct. Com. Pl. Aug. 27, 2008), No. 336 EDA 2008 (Pa. Super. Ct. *argued* June 9, 2009). These courts have concluded that the Vaccine Act expressly preempts all liability of vaccine manufacturers unless the claimed injury could have been avoided by proper preparation of the administered vaccine or by including proper directions and warnings with the administered vaccine.

The Georgia Supreme Court reached the opposite conclusion when it held that the Vaccine Act's preemption clause "clearly does not preempt all design defect claims against vaccine manufacturers," "but instead provides that a vaccine manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the injurious side effects of the particular vaccine were unavoidable." *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 238, 242 (Ga. 2008).[5]

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[5] The uncertainty for vaccine manufacturers created by the split between the Georgia Supreme Court and the Third Circuit on the question presented is reason enough to grant review.

Wyeth also agrees with plaintiffs that the critical issue should not be left to percolate any further. Recent events in the *Ferrari* trial court only underscore the urgent need for this Court to review this question. The petition for a writ of certiorari in *Ferrari* (No. 08-1120) is still pending before this Court. On June 8, 2009, the Court called for the views of the United States on the petition. Before the Solicitor General filed her brief, the respondents (plaintiffs below) filed a voluntary notice of dismissal *without prejudice* in the trial court.

This nonprejudicial withdrawal (the *Ferrari* plaintiffs are free to refile their case at any time) does not eliminate the public health problem the *Ferrari* decision created. As the Georgia Supreme Court said: its decision is—and will remain—the law of Georgia "at least until the Supreme Court of the United States has spoken on the issue." *Ferrari*, 668 S.E.2d at 243. The vaccine manufacturer defendants petitioned this Court to review *Ferrari* because the Georgia Supreme Court's decision lays the foundation to renew the very litigation crisis and subsequent threat to the vaccine supply that

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The additional case law plaintiffs cite does nothing to illuminate the question. Not one of the more than 30 cases cited in pages 17-20 of the petition squarely addresses the question of whether Section 22 of the Vaccine Act expressly preempts all design defect claims. For example, many of those decisions address *implied* field and conflict preemption arguments arising *under the FDCA* concerning claims that arose *before* the effective date of the Vaccine Act, October 1, 1988. *See, e.g., Hurley v. Lederle Labs Div. Of Am. Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1989).

Congress sought to avert with the Vaccine Act. That threat is addressed in Point II, *infra*. It is also described in depth in the *Ferrari* petition, the reply brief, and in the amicus brief submitted in support of the *Ferrari* petitioners by the American Academy of Pediatrics and 10 other physician and public health organizations.

The *Ferrari* plaintiffs' strategic maneuvering does raise the issue as to whether *Ferrari*, although still a viable case for review, is now the best vehicle to address and resolve the question presented. Because the dismissal was without prejudice, the *Ferrari* plaintiffs can refile at any time, and a live controversy therefore remains. *See City of Erie v. Pap's A.M.*, 529 U.S. 277, 288 (2000). The *Ferrari* plaintiffs' nonprejudicial dismissal could be considered an attempt to "manipulate the Court's jurisdiction to insulate a favorable decision from review." *Id.* However, given the *Ferrari* plaintiffs' present intent not to litigate, Wyeth acknowledges that the Court may view this case as a more suitable vehicle to resolve the question identically presented here and in *Ferrari*. In that event, Wyeth requests that the Court hold the *Ferrari* petition pending the Court's granting of certiorari in, and the disposition of, this case.

II. WYETH AGREES THAT THE QUESTION PRESENTED IS ONE OF NATIONAL IMPORTANCE.

Wyeth agrees with plaintiffs that whether the Vaccine Act expressly preempts all design defect claims is a crucial question of national importance. The parties are in agreement that Congress enacted

the Vaccine Act to ensure that there would be a stable supply of safe and effective vaccines today and in the future. But the parties (or, looked at another way, the Third Circuit and the Georgia Supreme Court) are diametrically opposed as to what Section 22 means. Plaintiffs assert that litigation against vaccine manufacturers over design defect claims will lead to a stable vaccine supply and improved vaccines, and Congress wrote Section 22 to allow that. The Third Circuit rejected that argument. This sharp disagreement over how Congress intended to ensure the continued availability of essential childhood vaccines is precisely the type of issue that this Court should resolve now.

The threat to the vaccine supply. Plaintiffs' remarkable assertion that the Third Circuit's ruling precluding litigation over design defect claims somehow "disrupted a stable vaccine supply for all children" (Pet. at 4) defies common sense and is provided without any explanation or citation. To the contrary, the pre-Vaccine Act history of the childhood vaccine market demonstrates, and the relevant legislative history reflects, that Congress appreciated that litigation disrupts the vaccine market. That reality was a driving force for the passage of the Vaccine Act, the creation of a Vaccine Court, and the preemption of all but a narrow range of liability theories in post-Vaccine Court cases.

Between 1980 and 1985, 299 lawsuits were filed against vaccine manufacturers seeking damages for injuries alleged to be caused by vaccines. Subcomm. Rep. at 85; *see also* Geoffrey Evans, *Update on Vaccine Liability in the United States*, 42 Clinical Infectious Diseases S130, S134 (2006). Nearly two-

thirds of those lawsuits, like this case, claimed injury from an allegedly defective DTP vaccine. Subcomm. Rep. at 86. This onslaught of litigation led to a precarious vaccine supply and caused Congress to find that "the withdrawal of even a single manufacturer" could lead to vaccine shortages and the resurgence of preventable infectious diseases. 1986 U.S.C.C.A.N. at 6348.

The Vaccine Act—through the no-fault compensation program and the preemption of certain tort claims—fundamentally changed the litigation status quo. In just two decades, the compensation fund has awarded more than $1.8 billion to over 2,200 families and individuals. HHS, *HRSA Awards Contract to Study Adverse Events in Childhood Vaccines* (Oct. 23, 2008), http://archive.hrsa.gov/newsroom/releases/2008/vaccinestudy.htm. Additionally, litigation against manufacturers of DTP and other vaccines slowed dramatically after the law took effect in 1988. *See id.*; Evans, *supra*, at S134. The post-Vaccine Act litigation that has been filed to date has been less costly. No case governed by the Vaccine Act against a vaccine manufacturer has proceeded to trial in the two decades since the Vaccine Act became effective.

Today, a new litigation threat to the nation's vaccine supply exists. Approximately 5,000 petitions are currently pending in the "Omnibus Autism Proceeding" in Vaccine Court. HRSA, *National Vaccine Injury Compensation Program Statistics Report* (Sep. 14, 2009, http://www.hrsa.gov/vaccinecompensation/statistics_report.htm. While the omnibus proceeding will decide for all of the pending cases whether there is a causal link between

childhood vaccines and autism, that ruling will have no preclusive effect outside of Vaccine Court. 42 U.S.C. § 300aa-23(e). Each claimant may elect to file a civil action after proceeding through Vaccine Court. Over 350 civil actions have been filed against vaccine manufacturers in various courts with allegations that childhood vaccines caused the recipient to develop autism.

The potential deluge of post-Vaccine Court litigation could lead to the same dangerous situation that existed in the mid-1980s. The number of childhood vaccine manufacturers has not increased since the enactment of the Vaccine Act. In the United States market today, as in 1986, there is still just one manufacturer for the polio vaccine, one for MMR, and two for the DTP vaccine. *Compare* 1986 U.S.C.C.A.N. at 6348, *with* FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/CBER/vaccine/thimerosal.htm (last updated Aug. 31, 2009). Thus, what Congress said in 1986 is true today: "The loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard." 1986 U.S.C.C.A.N. at 6348.

Plaintiffs and their amici argue that the Vaccine Act permits individuals who have exhausted the Vaccine Court remedy to elect to file civil actions asserting all the same sorts of claims that could have been asserted before the Act changed national policy. Indeed, plaintiffs argue that the Vaccine Act made it *easier* to sue vaccine manufacturers by *requiring* all states to allow design defect claims against manufacturers even if the state's common law does not recognize the theory. *See* Pet. at 36-37. Plaintiffs' amici postulate that the finished Vaccine

Act was a "compromise" (Amicus Br. at 4), but under their and plaintiffs' interpretation of the Act, this "compromise" resulted in a new no-fault compensation scheme, but no change at all to the rules governing civil actions or lessening of litigation risks that vaccine manufacturers faced.

Plaintiffs' view of the Vaccine Act flies in the face of Congress's clearly expressed intent. Congress erected two barriers to reduce lawsuits and thus keep manufacturers in the market: (1) it created a no-fault compensation system; and (2) it preempted all tort claims except manufacturing defect claims and certain failure-to-warn claims. Plaintiffs' interpretation of Section 22 renders both barriers essentially meaningless. Without the categorical preemption of vaccine design claims as intended by Congress, Vaccine Court could be reduced to just a checkpoint plaintiffs pass through on their way to civil court. Making it easier for plaintiffs to sue vaccine manufacturers would do nothing to ensure a stable vaccine supply because it would not lessen the litigation burden on vaccine manufacturers. That is not what Congress intended.

Regardless of Congress's intent with the Vaccine Act, amici argue that a civil remedy for design defect claims should be available because the "vaccine court has failed." Amicus Br. at 15. The premise of amici's argument is erroneous; Vaccine Court has not failed. The entire amicus brief, and much of plaintiffs', rests on the assumption that most, if not all, vaccine-related injury claims are valid. In fact, many of the claims asserted by claimants lack any

scientific basis whatsoever and thus denial of recovery in those actions is not a sign of failure.[6]

The vaccine/autism allegations at issue in the Omnibus Autism Proceeding are a case in point. Every government public health agency and reputable scientific body to address the question—including the FDA—has rejected allegations that childhood vaccines cause autism. *See, e.g.*, FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/cber/vaccine/thimerosal.htm. (last updated Aug. 31, 2009) (stating that FDA "conducted a comprehensive review of the use of thimerosal in childhood vaccines," and concluding that there was "no evidence of harm from the use of thimerosal as a vaccine preservative, other than local hypersensitivity reactions").

The most notable of the scientific reviews was the report of a panel of world-renowned experts appointed by the National Academy of Science's Institute of Medicine, which decisively declared that "**the evidence favors rejection of a causal relationship between thimerosal containing vaccines and autism.**" Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* 7 (2004) (emphasis in original).

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[6] Even if one assumed that amici's criticisms of the Vaccine Act are valid (which they are not), that the no-fault compensation program has failed in the eyes of certain parents is not a reason to ignore the language of the statute or the intent of the Congress that passed it.

In February, the Vaccine Court issued opinions in three test cases considering claimants' theory that the Measles-Mump-Rubella ("MMR") vaccine, in combination with thimerosal-containing vaccines, could cause autism. In each case, the Special Master found that the claimant had utterly failed to prove causation. All three of those decisions by the Special Masters were recently affirmed by the Court of Federal Claims.[7] Decisions by the Special Masters are soon expected on the three test cases considering claimants' theory that thimerosal-containing vaccines *alone* cause autism.

While the allegations in the Omnibus Autism Proceeding represent the current litigation threat to vaccine manufacturers, there is little reason to doubt that vaccines will continue to be blamed for a host of unrelated conditions. As the FDA has stated, vaccines are commonly accused of causing a wide variety of illnesses that happen to manifest themselves in early childhood at the time when children are also receiving vaccines. FDA, *VAERS Overview*, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/Overview/default.htm (last updated July 10, 2009). For example, one of plaintiffs' amici,

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[7] *See Cedillo v. Sec'y of HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *sustained,* No. 98-916V, 2009 WL 2998429 (Fed. Cl. Aug. 6, 2009); *Hazlehurst v. Sec'y of HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), *sustained*, No. 03-654V, 2009 WL 2371336 (Fed. Cl. July 24, 2009); *Snyder v. Sec'y of HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), *sustained,* No. 01-162V, 2009 WL 2517755 (Fed. Cl. Aug. 11, 2009).

SafeMinds, has blamed essentially every major component of vaccines for causing autism, including "aluminum adjuvant, mercury preservative, endotoxins, and viral or bacterial antigens." SafeMinds, *Vaccines and Autism*, http://www.safeminds.org/mercury/vaccines-and-autism.html (last visited Oct. 7, 2009). It is a short step from such allegations to design defect litigation claims.

As long as vaccines are on the market, they will be blamed for one disease or another, regardless of whether those claims have any scientific merit. By preempting design claims, Congress intended to prevent meritless claims from ever being filed against manufacturers. But plaintiffs' Section 22 interpretation provides no such disincentive. It leaves the courthouse door wide open for approximately 5,000 claimants who—if plaintiffs' amici is to be believed—think they have a better chance for recovery before a jury than the Vaccine Court special masters. Amicus Br. at 13. The stakes for public health are high, and the Court should not leave the Vaccine Act preemption question for another day.

The threat to vaccine development. Plaintiffs also contend that the Third Circuit's interpretation of Section 22 destroys the manufacturers' incentive to create new and improved vaccines. Pet. at 28. This too is incorrect and was not the determination made by Congress in 1986.

In passing the Act, Congress recognized the need to spur the development of new vaccines and the improvement of existing ones. Congress determined that the development and evaluation of new and

improved vaccines to protect the population as a whole required a comprehensive and collaborative program among scientists in public health agencies, industry, and academic institutions. *See* 1986 U.S.C.C.A.N. at 6352. But Congress recognized that the high costs of, and potential liability from, product liability litigation involving existing vaccines threatened the development of new vaccines. 1986 U.S.C.C.A.N. at 6345; Subcomm. Rep. at 72. Thus, Congress limited the tort claims that could be brought against manufacturers by enacting Section 22.

The scope of the protection afforded to vaccine manufacturers by Section 22 relates directly to the policy decisions Congress made in creating the National Vaccine Program. To the extent that state tort law traditionally provides an incentive for manufacturers to develop safer products, Congress addressed that policy goal by establishing a National Vaccine Program to research and develop improved, safer vaccines. For example, Section 27 of the Act mandates that HHS "promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines." 42 U.S.C. § 300aa-27(a)(1). There is no comparable program for prescription drugs or medical devices. For vaccines, product improvement and reevaluation to reduce risk and improve safety is not left solely to the marketplace and the self-interest of the private sector; nor is it to be indirectly prompted by the threat of jury verdicts over allegedly "unsafe" vaccine designs. Under the National Vaccine

Program, safer vaccines are to be actively pursued in the public interest, and the limited exceptions to Section 22(b)'s preemptive scope do not provide any "after-the-fact" evaluation role to juries.

Freed from the crush of product liability litigation, vaccine manufacturers, in conjunction with the various expert federal agencies, have had great success in developing new and improved vaccines. Since 1986, the collaboration has yielded seven new vaccines now on the routine childhood immunization schedule: hepatitis B; varicella; pneumococcal disease; influenza; hepatitis A; meningococcal disease; and rotavirus. *Compare* CDC, *Recommendation of the Immunization Practices Advisory Committee New Recommended Schedule for Active Immunization of Normal Infants and Children*, 35 MMWR 577 (Sep. 19, 1986), *with* CDC, *Recommended Immunization Schedules for Persons Aged 0-18 Years—United States, 2008*, 57 MMWR Q1 (Jan. 11, 2008).

For vaccine manufacturers, the combination of substantial protection from tort liability and government collaboration has led to recent successes outside of the Vaccine Act context. The H1N1 vaccine is a prime example. Multiple public health agencies, working with the manufacturers, have collaborated to design a new vaccine in record time to protect the population against the novel influenza A (H1N1) (commonly referred to as "swine flu") pandemic. *CDC, Questions & Answers—2009 H1N1 Influenza Vaccine*, http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm (last updated Oct. 5, 2009).

Pursuant to the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148 (2006), Kathleen Sebelius, Secretary of HHS, granted nearly complete legal immunity to the manufacturers of the H1N1 vaccines. Pandemic Influenza Vaccines—Amendment, 74 Fed. Reg. 30294-01 (June 25, 2009); 42 U.S.C. § 247d-6d. The PREP Act does provide one very limited exception to immunity if the "death or serious physical injury [was] proximately caused by willful misconduct" by a company or person covered by the Act. 42 U.S.C. § 247d-6d(d). Contrary to plaintiffs' argument that immunity from design defect claims would "destroy incentives" to make new and improved vaccines, the H1N1 vaccine experience demonstrates that limiting tort liability can result in unprecedented vaccine development.

Plaintiffs also argue that the PREP Act supports their interpretation of Section 22 because "[t]here would have been no need to make vaccines already covered by the Act subject to such legislation if Congress had already created an exclusive remedy for vaccine-related injuries." Pet. at 23. This argument fails for at least two reasons.

First, there is no overlap between the vaccines subject to the PREP Act and those covered by the Vaccine Act. Section 22 applies only to vaccines covered by the Act, which are those vaccines recommended for routine administration to children. *See* 42 U.S.C. §§ 300aa-14(e), 22(b), 33(5). The H1N1 vaccine and the other vaccines covered by the

PREP Act[8] are those that the Secretary of HHS has deemed necessary to respond to public health emergencies; these vaccines are not for routine administration to children.

Second, the PREP Act grants nearly complete legal immunity to manufacturers of the H1N1 vaccine. By contrast, the Vaccine Act strikes a careful balance between the compensation of vaccine-injured persons and the limitation of claims that can be brought against vaccine manufacturers in a civil action. Individuals alleging injury from a vaccine covered by the Vaccine Act could seek compensation if the injury was caused by a manufacturing defect or inadequate warnings, but as to vaccines covered by the PREP Act, no such claims may be asserted. The PREP Act therefore demonstrates that Congress felt it necessary to provide vaccine manufacturers with even greater protections from tort liability than is provided in the Vaccine Act.[9]

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[8] The countermeasures currently covered by declarations issued by the Secretary of HHS are: H1N1, H5N1, H2, H6, H7, and H9 pandemic influenza vaccines; anthrax; botulism; smallpox, and acute radiation syndrome. *See* HRSA, *Countermeasures Injury Compensation Program—Covered Countermeasures*, http://www.hrsa.gov/countermeasurescomp/countermeasures.htm. (last visited Oct. 7, 2009).

[9] Subsection (h) of section 247d-6d states that nothing in the section "shall be construed to affect the National Vaccine Injury Compensation Program under title XIX of this chapter." 42 U.S.C. § 247d-6d(h). This rule of construction demonstrates that Congress was aware of the Vaccine Act when it enacted PREP and that it intended for the different programs to occupy two distinct regimes.

III. THE THIRD CIRCUIT CORRECTLY FOUND THAT THE VACCINE ACT EXPRESSLY PREEMPTS ALL DESIGN DEFECT CLAIMS.

The Third Circuit correctly held that Section 22(b) of the Vaccine Act categorically preempts all design defect claims. While plaintiffs agree that this was the Third Circuit's holding (Pet. at 15-16), they contend that the court "relied heavily upon the 'complete' or field preemption principles." Pet. at 18. The Third Circuit did no such thing. The court relied on the text of Section 22, the legislative history of the Act, and the structure of the Vaccine Act to reach its decision that the statute expressly preempts design defect claims. A-42. What plaintiffs actually are criticizing is the court's use of the Vaccine Act's structure to support its interpretation of Section 22's text. That use is a common and accepted statutory interpretation technique when construing an express preemption provision. *See Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71 (2006) (relying on the structure, the purpose, and the legislative history of the federal statute to support the conclusion that the statute expressly preempts state law).

The Third Circuit, consistent with this Court's precedent, properly began its analysis with the presumption against preemption.[10] A-15-16. The

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[10] The petition's description of the presumption against preemption—an incomplete quotation from *Bates v. Dow Agrosciences LLC*—is inaccurate. Pet. at 32. This Court has

court found that the presumption was overcome because Congress clearly intended to preempt all design defect claims. A-42.

Citing to *Wyeth v. Levine*, plaintiffs contend that the case for preemption here is "'particularly weak [because] Congress had 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.'" Pet. at 32 (quoting *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009)). Plaintiffs' attempt to analogize this case to *Levine* is unavailing; the two cases present starkly different situations. The quoted excerpt from *Levine* was preceded by the statement that "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." *Id.* While Congress did not enact an express preemption provision for prescription drugs, it did, of course, enact one specifically for vaccines precisely because of the threat that state-law tort suits posed to the vaccine supply and, consequently, to public health.

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stated that it has a duty to accept a reading of a statute that disfavors preemption if that reading is equally or more plausible than the reading that favors preemption. *Bates*, 544 U.S. 431, 449 (2005). The Court has never ruled, however, that a merely plausible reading that results in no preemption must be followed over a more plausible reading that preempts state law.

The Language Of Section 22(b) Preempts Design Defect Claims. After addressing the presumption against preemption, the Third Circuit turned to the text of Section 22. Plaintiffs argue that the Third Circuit's interpretation omits the conditional phrase "'if the injury or death resulted from side effects that were unavoidable.'" Pet. at 29. This is incorrect. Reading the provision as a whole, the word "unavoidable" is modified by the 15 words that follow, so that vaccine manufacturers are immune from all civil liability except where the injury could have been avoided in either of two ways that Congress specified: (1) by proper preparation; or (2) by providing proper directions and warnings. There are no other exceptions to the broad scope of preemption in Section 22(b). Plaintiffs misread Section 22(b) as preemptive only where the alleged injury or death resulted from side effects that are proved to have been unavoidable *under any circumstances*. That construction simply reads out of the statute the words that follow "unavoidable."

Plaintiffs' reading also ignores how the phrase "the vaccine" is used after "unavoidable." The provision states that a manufacturer is not liable if the injury "resulted from side effects that were unavoidable even though *the vaccine* was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1) (emphasis added). Here, plaintiffs are alleging that the side effects could have been avoided if Wyeth marketed a "safer alternative vaccine[ ]" (Pet. at 3) that would have been designed to protect against the same diseases. However, allegations that a differently designed (purportedly safer) vaccine

would have avoided the plaintiff's injury are the type of claims that Congress intended to preempt. "[T]he vaccine" in Section 22 refers to the vaccine administered to the child, not a different vaccine that theoretically *could have been* designed, manufactured, tested, licensed, approved, and then given to the child.

In criticizing the Third Circuit's ruling, plaintiffs also assert that the absence of language in Section 22(b) explicitly identifying "design defect" claims supports their interpretation of the statute because Congress could have included such unequivocal language. Pet. at 31. Plaintiffs' criticism of statutory drafting misses the mark. Congress chose language to bar all claims—not just those explicitly labeled "design defect"—except for manufacturing defect and failure-to-warn claims.

In this respect, the Vaccine Act's preemption clause is unique among the express preemption provisions that this Court has examined in the past two decades in the context of common law tort claims. Unlike the provisions at issue in *Cipollone/Altria*, *Lohr/Riegel*, and *Bates*, which precluded general state law "requirements or prohibitions," the Vaccine Act's express preemption provision is aimed at tort claims. The sweeping terms of the provision—"no vaccine manufacturer shall be liable in a civil action for damages"—avoids the type of claim-by-claim preemption inquiry that was necessary in interpreting the preemption provisions in *Cipollone* or *Bates*. *See Bates*, 544 U.S. at 443-54; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 524-530 (1992). The language preempts *all*

claims, however pleaded, *except* for the two Congress specified. *See* 42 U.S.C. § 300aa-22(b).

The Authoritative Legislative History Reflects Congress's Intention To Bar Design Defect Claims. The Third Circuit also correctly found that the Committee Report on the bill supports the interpretation that the Vaccine Act preempts all design defect claims. The court found that the Committee Report "explicitly stated that injured individuals could only seek redress in the state tort system for certain manufacturing defect and warning claims." A-35-36. Specifically, the Committee Report explains:

> Given the existence of the compensation system in [the Vaccine Act], the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was *improperly prepared* or that it was *accompanied by improper directions or inadequate warnings* [they] *should pursue recompense in the compensation system, not the tort system.*

1986 U.S.C.C.A.N. at 6367 (emphasis added).

The Third Circuit properly rejected plaintiffs' reliance on "legislative history" from a subsequent Congress. Plaintiffs argue that a Committee Report that accompanied certain amendments made to the Vaccine Act in *1987* (relating to the funding of the

Act) constitutes evidence of Congress's intent in *1986*, when it adopted Section 22. That material is not entitled to consideration, much less reliance: it is not competent legislative history of the provision at issue in this case. *See Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)) ("subsequent legislative history is a 'hazardous basis for inferring the intent of an earlier' Congress"). The funding of the Act via the 1987 amendments did not concern in any way the Section 22 limitations on liability of vaccine manufacturers in civil actions and so do not provide any guidance on the intent behind the enacted law. The only modification the 1987 amendments made to Section 22 was to replace the words "effective date of this subpart" with "effective date of this part." Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330-221.

Plaintiffs contend that this Court's decision in *District of Columbia v. Heller*, 128 S. Ct. 2783, 2805 (2008), supports their argument that the post-enactment legislative statements should have been given weight by the Third Circuit. Pet. at 35. In fact, the decision demonstrates that the Third Circuit correctly rejected the post-enactment statements. In *Heller*, the Court distinguished between two types of statements. The Court found that "the examination of . . . sources to determine *the public understanding* of a legal text in the period after its enactment . . . is a critical tool of constitutional interpretation." *Id.* (emphasis in original). But the Court rejected precisely the type of post-enactment *legislative* statements plaintiffs rely on here. "'Postenactment legislative history,' a deprecatory contradiction in

terms, refers to statements of those who drafted or voted for the law that are made after its enactment and hence could have had no effect on the congressional vote." *Id.* That is exactly the case here. The statements made in 1987 could have had no effect on the Congress that enacted the language of Section 22 in 1986.

Plaintiffs' Construction Of Section 22 Is Contrary To The Structure Of The Vaccine Act. The Third Circuit was also correct in finding that the construction of Section 22 adopted by the Georgia Supreme Court was contrary to the structure of the Vaccine Act. As stated by the Third Circuit, the Georgia Supreme Court's construction "does not bar any design defect claims," but rather subjects all such claims to the evaluation of the court. A-29. In other words, plaintiffs' reading of Section 22(b) would not provide protection to a vaccine manufacturer unless and until the manufacturer made a showing at trial that no safer vaccine design was feasible. That would make Section 22(b) pointless. If read as plaintiffs propose, Section 22 would protect vaccine manufacturers only from a non-existent risk, because no state in 1986 imposed (or today imposes) design defect liability on vaccine manufacturers for injuries that could not have been avoided under any circumstances. Furthermore, vaccine manufacturers would only gain this "protection" in each case after incurring the substantial cost of litigating design defect claims to a jury verdict, which would be inconsistent with Congress's goal of reducing manufacturers' litigation costs.

Finally, the petition contends that Congress intended to create the "'awkward dichotomy'" that

plaintiffs' construction of Section 22 would entail. Pet. at 36 (quoting A-30). Some states, such as Pennsylvania and California, have concluded that strict liability is inapplicable to design defect claims involving prescription drugs. *See Hahn v. Richter*, 673 A.2d 888, 889-90 (Pa. 1996); *Brown v. Superior Ct.*, 751 P.2d 470 (Ca. 1988). The Third Circuit found that plaintiffs' construction would "create an awkward dichotomy" in such states by requiring courts to "engage in case-by-case analysis of all strict liability and negligent design defect claims brought under the Vaccine Act, while barring strict liability design defect claims against prescription drug manufacturers." A-30. There is certainly no evidence that Congress intended vaccine manufacturers to be subjected to *greater* litigation risk than drug manufacturers.

Plaintiffs attempt to counter this point by arguing that Congress has treated prescription drugs and medical devices differently by including an express preemption provision for medical devices, but not for prescription drugs. Pet. at 36. Plaintiffs' argument misses the Third Circuit's point. Congress wrote the Vaccine Act in response to a litigation crisis that threatened the supply of vaccines necessary to promote public health. The Vaccine Act overhauled the legal system and rules for compensating vaccine-related injuries with the intent, among others, to protect manufacturers from the type of litigation that had put them under such pressure in the 1980s. There was absolutely *no* intent on the part of Congress to open additional pathways for civil suits against vaccine

manufacturers, or to make such suits easier for plaintiffs to pursue.

CONCLUSION

The Court should grant the petition for a writ of certiorari in this case on the question as presented by Respondents and affirm the judgment of the United States Court of Appeals for the Third Circuit.

Respectfully submitted,

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