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

PETITION FOR A WRIT OF CERTIORARI

Collyn A. Peddie
Counsel of Record for Petitioners
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway, Suite 600
Houston, Texas
(713) 230-2200

LEGAL PRINTERS LLC, Washington DC • 202-747-2400 • legalprinters.com

Blank Page

QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 ["the Act"] expressly preempts certain design defect claims against vaccine manufacturers "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). A-104.

The Question Presented is

Whether the Third Circuit erred in holding that, contrary to its plain text and the decisions of this Court and others, Section 22(b)(1) preempts all vaccine design defect claims, whether the vaccine's side effects were unavoidable or not?[1]

---

[1] Whether Section 22(b)(1) of the Act encompasses both negligent and strict liability design defect claims is not at issue in this petition. Both the *Ferrari* court and the court below found that it encompasses both claims. *See* A-35; *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 242 (Ga. 2008).

RULE 14(b) STATEMENT

All parties to the proceedings in the United States Court of Appeals for the Third Circuit are listed in the caption.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases Page(s)

Constitution and Statutes

Rules and Regulations

Miscellaneous

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Third Circuit, March 27, 2009, is reported at 561 F.3d 233 (3d Cir. 2009). It is reproduced at A-1-52.

The opinion of the United States District Court for the Eastern District of Pennsylvania, August 24, 2007, is reported at 508 F. Supp. 2d 430 (E.D. Pa. 2007). It is reproduced at A-53-100.

JURISDICTION

This Court has jurisdiction to review the final judgment of the U.S. Court of Appeals for the Third Circuit, entered March 27, 2009, under 28 U.S.C. § 1254(1). A-1. A petition for panel rehearing and rehearing *en banc* was timely filed. The Third Circuit denied both motions on May 6, 2009. A-101. This petition is timely under 28 U.S.C. § 2101(c) and Supreme Court Rules 13.1 and 13.3 because it is being filed within 90 days of the date the Third Circuit denied rehearing.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the following constitutional and statutory provisions: The Supremacy Clause of the United States Constitution, art. VI, § 1, cl. 2; and 42 U.S.C. § 300aa-22, *et seq.* These provisions are reproduced at A-103-06.

INTRODUCTION

Responding to the pleas of parents of children catastrophically injured by vaccines, Congress passed the National Childhood Vaccine Injury Act which established a no-fault compensation program to streamline awards to vaccine-injured children. *See Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995). This administrative program does not and was never intended to provide an exclusive remedy for vaccine-related injuries. To the contrary, the Act expressly preserves state-law tort remedies 1) to insure parents' rights to seek compensation when it is not available under the program or is unsatisfactory; and 2) to retain vaccine manufacturers' incentives to improve the safety of their vaccines because the Act would otherwise shift all financial responsibility for vaccine-related injuries to parents and taxpayers.[2]

"The Act additionally helps manufacturers by providing certain federal modifications of state tort law. For example, it forbids the award of compensation for injuries that flow from 'unavoidable side effects.'" *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, C.J.). Thus, Section 22(b)(1) provides that "no manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable . . ." 42 U.S.C. § 300aa-22(b)(1). A-104.

---

[2]The Act's compensation program is funded through an excise tax on each dose of vaccine. *See* 26 U.S.C. § 4131.

The Third Circuit's interpretation of Section 22(b)(1) as preempting all vaccine design defect claims, whether side effects were unavoidable or not, renders its plain text a nullity. Worse, the Court's construction is grounded in three largely discredited notions: 1) that the Act provides an exclusive remedy, not an affirmative defense, for design defect claims; 2) that the alleged comprehensiveness of the U.S. Food and Drug Administration ["FDA"] approval process impliedly preempts vaccine design defect claims and renders the side effects of approved vaccines "unavoidable" as a matter of law; and 3) that Congress did not intend that there be any difference in the legal treatment of vaccines and other prescription drugs.

There are, therefore, three reasons why this Court should grant *certiorari*. First, there is a deep, direct, and mature conflict on the question presented between the unanimous Supreme Court of Georgia in *Am. Home Prods. Corp. v. Ferrari,* 668 S.E.2d 236 (2008) and the Third Circuit here. As a result of this split in authority, after exhausting administrative remedies in the vaccine program, children in Georgia who are injured by vaccines may bring design defect claims against vaccine manufacturers when the use of safer alternative vaccines could have avoided their injuries. By contrast, Hannah Bruesewitz and children like her in the Third Circuit and elsewhere may be precluded from pursuing identical design defect claims even when the same safer alternative vaccines could have avoided their suffering too. This intolerable disparity in treatment under the same federal statute is not only tragically unfair; it may have constitutional dimensions as well.

Second, the question presented is a critically important and recurring one requiring resolution by this Court. By holding all vaccine design defect claims preempted, the Third Circuit robs seriously-injured children and their parents of their right to seek compensation under state tort law when safer alternative vaccines would have prevented their injuries. Moreover, so long as the question presented remains unresolved, it will recur and courts will be forced to use scarce judicial resources to decide it. Most important, resolution now is essential because, by immunizing an entire industry from responsibility for the continuing safety of its products, the Third Circuit has disrupted a stable vaccine supply for all children, stifling innovation and removing incentives for manufacturers to develop and market safer vaccines.

Finally, *certiorari* is warranted because the Third Circuit grievously misinterprets Section 22 to preempt all vaccine design defect claims. Using questionable statutory construction principles, the Court improperly ignores Section 22(b)(1)'s conditional language, provisions expressly preserving tort claims, and Section 22(e), which expressly preempts state laws that would ***prevent*** the pursuit of state-law tort claims the Act itself does not preclude. The Court then expands improperly the scope of Section 22(b)(1)'s preemption clause to create an exclusive remedy in defiance of this Court's recent preemption decisions, those of courts around the country, the presumption against preemption, and the clearly expressed intent of Congress. And it does so even though the FDA itself, when specifically asked to opine on preemption in this case, neither considered such claims preempted nor asked that the trial court so hold. A-107-09; A-113.

STATEMENT OF THE CASE

Within hours after receiving the diphtheria, tetanus, and pertussis ["DTP"][3] vaccine manufactured by Respondents,[4] Hannah Bruesewitz, then a healthy six-month old, suffered catastrophic injuries and the first of a lifetime of agonizing seizures. A-6; 57. As a result of receiving Respondents' vaccine, Hannah, a teenager now, suffers from residual seizure disorder and remains profoundly developmentally impaired. A-6. She will need lifetime supervision and care. *Id.*

In 1995, Hannah and her parents began their long journey through the courts and administrative agencies, seeking "simple justice"[5] and compensation for her vaccine-related injuries. In 14 years, she has received neither. Whether her journey ends in the Third Circuit depends upon this Court's decision on her Petition for Writ of *Certiorari*.

---

[3]Although the references are interchangeable, the Department of Health and Human Services ["HHS"] and the Health Resources and Service Administration ["HRSA"] use the acronym "DTP" rather than the more commonly used "DPT." *See* http://www.hrsa.gov/vaccinecompensation/covered_vaccines.htm.

[4]Wyeth, Inc., f/k/a Wyeth Laboratories, Wyeth-Ayerst Laboratories, Wyeth-Lederle Vaccines, and Lederle Laboratories [hereafter "Wyeth" or "Respondents"].

[5]In describing the purposes of the Act at the time of its passage, Dr. Martin Smith, Chairman, American Association of Pediatrics, assured parents it would provide "simple justice to children." *See Compensating Vaccine Injuries: Are Reforms Needed?: Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Resources,* 106th Cong. (1999) (statement of Barbara Lou Fisher).

DTP Vaccines

Vaccines stimulate the production of antibodies that protect against disease. *Toner v. Lederle Labs., Div. of American Cyanamid Co.*, 779 F.2d 1429, 1430 (9th Cir. 1986). Some infectious organisms, including those causing diphtheria and tetanus, excrete insolable toxins. *Id.* When a toxin is inactivated, it is transformed into a toxoid. The toxoid is then used in a vaccine to immunize against disease by stimulating the production of antibodies in the recipient, even though it has lost its own poisonous qualities. *Id.*

This is not the case with Tri-Immunol, the vaccine manufactured by Respondents and administered to Hannah Bruesewitz. Tri-Immunol, which was licensed for production sixty years ago, A-58, is a "whole cell" vaccine because it contains whole killed pertussis organisms. *Toner,* 779 F2d at 1430. The whole organism was used because it contains many different antigens, and, initially, scientists had not isolated the one that stimulates protection against the disease. *Id.*

The whole cell pertussis vaccine, however, is neurotoxic and can cause both local and severe adverse reactions. *Id.* Severe reactions include encephalopathy, paralysis, and even death. *Id.* at 1430-31. The whole-cell vaccine, however, leaves no "footprint" evidencing that it was the catalyst for even the most severe injury.[6]

---

[6]*See Andreu v. Sec'y of HHS*, 569 F.3d 1367, 2009 U.S. App. LEXIS 13048 *36 (Fed. Cir. June 19, 2009); Division of Health Promotion and Disease Prevention, Institute of Medicine, *DPT Vaccine & Chronic Nervous System Dysfunction: A New Analysis* (Kathleen R. Stratton, Cynthia J. Howe, and Richard B.

Because of the well-known neurotoxicity of the whole-cell vaccine, during the 1950's, the Eli Lilly Company developed a fractionated or so-called "split" cell pertussis vaccine called Tri-Solgen that was prepared by treating whole killed pertussis cells with salt. *Toner,* 779 F.2d at 1431. Early studies indicated that this method of preparation resulted in a less toxic vaccine. *Id.* Following its approval by the FDA in 1967, Tri-Solgen occupied a substantial share of the DTP market. *Id.* Nevertheless, Lilly withdrew from the vaccine business in 1975 and voluntarily requested that its license to produce Tri-Solgen be withdrawn without prejudice. *See Foyle v. Lederle Labs.,* 674 F. Supp. 530, 534 (E.D.N.C. 1987). However, it sold its right to produce Tri-Solgen to Respondent Wyeth Laboratories. *Toner,* 779 F.2d at 1431.

Rather than seek FDA approval to market the safer, split-cell vaccine, however, Respondents asked the FDA only to allow them to market ***as*** Tri-Solgen a vaccine using their own more dangerous, but cheaper, whole-cell pertussis component. It is not surprising that the FDA refused to allow such bait and switch tactics. There is no indication that Respondents ever sought to market Tri-Solgen in its safer, original formulation during the 17 years before Hannah Bruesewitz received their more dangerous vaccine.

Hannah was injured when she received the third of five recommended doses in the DTP vaccination series. A-57. At the time of Hannah's vaccination, the FDA had already approved Respondents' application to market an alternative DTP vaccine, trade-named Acel-

---

Johnston, Jr., eds., 1994).

Imune, that contained an even safer, acellular pertussis component. A-58. The acellular vaccine is less reactive and causes fewer adverse events because it has been detoxified using chemical techniques. A-7. Thus, "the general consensus is that the older [whole-cell] vaccine is more dangerous than the newer [acellular] version." *Andreu,* 2009 U.S. App. LEXIS 13048 at *16.

Unfortunately, Respondents had only sought and obtained approval to market Acel-Imune for the fourth and fifth doses in Hannah's vaccination series. A-7. Respondents did not seek and obtain approval to use Acel-Imune for the first three doses until more than four years later. A-7-8. As a result, Hannah received the more dangerous whole-cell vaccine, which was not manufactured after 1998, even though safer alternatives had already been developed and marketed. A-8

The Vaccine Act

In the mid 1980's, thousands of American families faced a long, hard slog through the tort system or endless settlement negotiations with vaccine manufacturers to obtain compensation for vaccine-related injuries. Even then, "no recovery [might] be available. Yet futures have been destroyed and mounting expenses must be met." H.R. Rep. No. 99-908, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347. At the same time, some vaccine manufacturers threatened to abandon this field of therapy because of the threat of lawsuits over mounting vaccine-related injuries. *See Andreu*, 2009 U.S. App. LEXIS 13048 at *12; H.R. Rep. No. 99-908, at 6.

Responding to these concerns, Congress created a no-fault administrative program that "postpones actions in state court by requiring plaintiffs to pursue remedies under the NCVIA before attempting a tort claim in state court." Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L. J. 351, 355 (2001). Under this compensation scheme, awards were to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3. In this fashion, Congress sought to"[c]reate a compensation system that is speedy and generous enough to dissuade petitioners from going into court." H.R. Rep. 100-391(I), at 691 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365; H.R. Rep. No. 99-908, at 26 ("vaccine-injured persons will now have an appealing alternative to the tort system").

The Act was enacted in two phases and the House Energy and Commerce Committee had primary responsibility for both. In the first phase in 1986, Congress set up the structure of the vaccine compensation program; however, "the Act as passed did not include a source of payment for such compensation and made the compensation program and accompanying tort reforms contingent upon the enactment of a tax to provide funding for the compensation." H.R. Rep. No. 100-391(I), at 690; A-36. In 1987, Congress passed amendments to the Act that funded the program and rendered Section 22 effective in 1988. *Id.*

The Act provides two separate mechanisms to obtain benefits: table claims and causation in fact claims. In a table claim, a claimant who shows that he

or she received a vaccination listed in the Vaccine Injury Table within a prescribed period is afforded a presumption of causation. 42 U.S.C. §§ 300aa-11(c)(1)(C)(I), 300aa-14. "He need not prove fault. Nor, to prove causation, need he show more than that he received the vaccine and then suffered certain symptoms within a defined period of time." *Schafer*, 20 F.3d at 2 (citing §§ 300aa-13, 300aa-14).

Prior to March 10, 1995, "residual seizure disorder" following DTP vaccination was considered a table injury. *See Andreu,* 2009 U.S. App. LEXIS 13048 at *13. The disorder has accounted for approximately 40% of all claims filed in the vaccine program.[7] By the time Hannah's family filed her claim in April 1995, however, residual seizure disorder no longer qualified as a table injury. *See* 60 Fed. Reg. 7678 (Feb. 8, 1995). As a result, her family could not avail themselves of the table method of establishing causation and had to show that Hannah's seizure disorder was "caused in fact" by the DTP vaccine she received. *See Andreu,* 2009 U.S. App. LEXIS 13048 at *13.

To seek compensation for any vaccine-related injuries, victims and their families must first bring their claims in the Court of Federal Claims. *See* 42 U.S.C. § 300aa-12. If they are dissatisfied with the award obtained, receive no award, or the special master assigned to their case fails to rule within a

---

[7]*See* U.S. Gen'l Accounting Office, *Vaccine Injury Compensation; Program Challenged to Settle Claims Quickly and Easily*, 14, table 6 (Washington, D.C. Dec. 1999), *available at* http://www.gao.gov/new.items/he00008.pdf. In fact, more than 80% of all compensation awarded under the Act was for DTP cases. *See* Scott, *supra*, at 353, n.19.

specified time, they may decline any award and file a tort claim. 42 U.S.C. §§ 300aa-21(a), 21(b)(1), 21(c).

In passing the 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. As a result, it provided manufacturers with only limited immunity while expressly preserving state-law tort claims. *See* 42 U.S.C. §§ 300aa-22(a) (applying state law to civil action for damages for vaccine-related injuries). A-104.

To that end, Congress preempted certain design defect claims for damages only for "unavoidable" injuries. Section 22(b)(1) provides:

> (b) Unavoidable adverse side effects; warnings
>
> > (1) 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 the effective date of this subpart 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); A-104. To preserve incentives to innovate, Section 22(b)(1)'s conditional

phrase functions as a biologic "sunset" clause, ending the immunity from design defect claims it affords vaccine manufacturers who produce and market older, more dangerous vaccines when better alternatives become available.

For the purposes of Section 22(b)(1), the Act also defines "proper directions and warnings" and creates a rebuttable presumption addressing them in that context alone.[8] Finally, in Section 22(e), Congress sought to insure the right to file state-law claims by expressly preempting state law that would interfere with the pursuit of claims the Act itself does not prohibit.

Proceedings Below

On April 3, 1995, Hannah and her family filed a petition in the U.S. Court of Federal Claims. A-54; *Bruesewitz v. Sec'y of Dep't of HHS*, No. 95-0266V, 2002 WL 31965744, at *1 n.1 (Fed. Cl. Dec. 20, 2002). On February 14, 2003, they rejected the judgment of the Vaccine Court which had awarded them no compensation. *Id.*

Petitioners filed suit for damages in the Philadelphia County Court of Common Pleas in October, 2005. *Id.* Respondents removed the case based on diversity of citizenship, and filed their first Motion for Summary Judgment alleging that

---

[8] *Id.* at § 22(b)(2). The trial court and Third Circuit incorrectly found that Section 22(b)(2) provides a free-standing presumption of adequate warnings in all vaccine cases, not the support for Section 22(b)(1) the statute's plain text clearly provides.

Petitioners' claims were preempted. Since little, if any, discovery had taken place, the court denied the motion without prejudice by Order dated February 22, 2007. *Id.*

In the mean time, the court sought an amicus brief from the FDA on the question presented. A-113. On November 9, 2006, an HHS representative responded but asserted no preemption of all design defect claims. A-107-109.

After allowing Petitioners to amend and to conduct some discovery, the court granted summary judgment based upon the prior motion and subsequent briefing. It held Petitioners' design defect claims preempted by the Act and that Petitioners had failed to raise questions of material fact on their manufacturing defect and failure-to-warn claims. A-9; A-99.

Petitioners appealed to the Third Circuit which affirmed the summary judgment. A-1-52. Petitioners sought rehearing which was denied. A-101. From the Third Circuit's decision, Petitioners seek a writ of *certiorari*.

REASONS FOR GRANTING THE PETITION

This Court should grant *certiorari* for three reasons. First, there is a deep, direct, and mature conflict on the question presented between the unanimous Supreme Court of Georgia in *Ferrari* and the Third Circuit. Second, the question presented will increasingly recur if not resolved now and is of national importance. Finally, the Third Circuit grievously misinterprets Section 22(b)(1) to provide an exclusive remedy and to preempt claims it does not, in fact, preempt.

I. THERE IS A DEEP, DIRECT, AND MATURE CONFLICT OVER THE MEANING AND SCOPE OF SECTION 22(b)(1)'S EXPRESS PREEMPTION CLAUSE

A. The Conflict is Direct and Clean

The *Ferrari* and *Bruesewitz* courts reach opposite conclusions as to the "'domain expressly pre-empted by [the] language'" of the Act. A-13 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996)). While both courts agree that Section 22(b)(1)'s express preemption language applies to both negligent and strict liability design defect claims, *see supra* note 1, they disagree over the meaning of its conditional phrase: "if the injury or death resulted from side effects that were unavoidable. . . ." 42 U.S.C. § 300aa-22(b)(1). Thus, in *Ferrari*, the unanimous Georgia Supreme Court holds that

> [S]ubsection (b)(1) clearly does not preempt all design defect claims against vaccine manufacturers, but rather

> provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case by case basis, that the particular vaccine was unavoidably unsafe.

668 S.E.2d at 393. By contrast, the Third Circuit concludes that "a 'clear and manifest' expression of congressional intent supports" an interpretation of the Act that bars all design defect claims. Thus,"plaintiffs design defect claims are expressly preempted by the Vaccine Act" whether the vaccine's side effects were unavoidable or not. A-52.

In particular, the court rejects the *Ferrari* opinion, declaring that "we do not consider the *Ferrari* court's reading [of Section 22(b)(1)] to be compelling. . . More importantly, we think the *Ferrari* court's construction is contrary to the structure of the Act. . . " A-28-29.

The Third Circuit's analysis of the question presented could not be more simple, unambiguous, dispositive, or wrong. It first reviews Section 22's first three subsections and concludes that "by reading these three provisions together, it becomes clear that Congress intended that subsections (b) and(c) should be an outright bar to ***some*** claims." A-28 (emphasis supplied). Without reviewing any legislative history, the court rejects *Ferrari*'s construction of Section 22(b)(1) as "contrary to the structure of the Act because it does not bar ***any*** design defect claims." A-29 (emphasis supplied). It expresses no doubt in doing so. Instead, it explains: "if we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect

claim is subject to evaluation by a court." A-29. Summing up, it concludes that Congress could not have intended such a situation because, in some states, it "could create an awkward dichotomy in the case law of these states – their state would be required 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.

Although it reaches its decision on the question presented easily, the Third Circuit struggles to determine whether the preemption provisions apply to both negligent and strict liability claims. In answering ***that*** question, and ***not*** the question presented, the court wrestles with legislative history, some allegedly illustrating Congress' intention to shield DTP vaccine manufacturers. A-40-42.

It has been suggested by respondents in *Ferrari* that the court's reference to this background information constitutes some sort of fact-finding that the DTP vaccine's side effects were "unavoidable" for purposes of Section 22(b)(1). It does not. First, the quoted information does not so state. Second, the court makes clear that it does not answer the question presented using legislative history. A-28-30, 40-42. Third, even if it does, such an alleged statement of Congressional intent would merely "inform interpretive choice" regarding the Act's language, not act as a free-standing, dispositive fact. *See Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 261 (2004); *Richlin Sec. Serv. Co. v. Chertoff*, 128 S.Ct. 2007, 2016 (2008).

Finally, even if Congress had found that whole-cell DTP vaccines' side effects were unavoidable and subject to immunity ***in 1986***, there is nothing in the Act or its legislative history that evinces Congress' intention to protect such manufacturers forever, even when the development of an acellular vaccine renders the whole-cell vaccine's side effects "avoidable."

B. The Conflict is Deep and Mature Enough

Even before the Act's effective date in 1988, courts began wrestling with the scope of its preemption, if any, of state-law tort claims. At least thirteen courts have decided whether the Act provides an exclusive federal remedy and thus completely preempts state tort claims against vaccine manufacturers.[9] All held that, while it may provide a preemption defense subject to case-by-case evaluation by trial courts, the

---

[9] *Zatuchni v. Sec'y of HHS*, 516 F.3d 1312, 1321 n.10 (Fed. Cir. 2008); *Galindo v. Am. Home Prods.*, 2004 U.S. Dist. LEXIS 27752 *20 (S.D. Tex. Feb. 10, 2004); *Davila v. Am. Home Prods. Corp.*, 2004 U.S. Dist. LEXIS 4370 *17-18 (W.D. Tex. Feb. 3, 2004); *Shadie v. Aventis Pasteur, Inc.*, 254 F. Supp. 2d 509, 516-17 (M.D. Pa. 2003); *Bertrand v. Aventis Pasteur Labs., Inc.*, 226 F. Supp. 2d 1206, 1211 (D. Ariz. 2002); *Oxendine v. Merck & Co.*, 236 F. Supp. 2d 517, 523 n.3 (D. Md. 2002); *Mead v. Aventis Pasteur, Inc.*, 2002 U.S. Dist. LEXIS 25552 *13 (D. Or. June 7, 2002); *Doherty v. Pasteur*, 2002 U.S. Dist. LEXIS 9596 *10-12 (N.D. Cal. May 15, 2002); *Garcia v. Aventis Pasteur, Inc.*, 2002 U.S. Dist. LEXIS 15122 *11 (W.D. Wash. Apr. 22, 2002); *King v. Aventis Pasteur, Inc.*, 210 F. Supp. 2d 1201, 1207 (D. Or. 2002); *Haggerty v. Wyeth Ayerst Pharm.*, 79 F. Supp. 2d 182, 186, 189 (E.D.N.Y. 2000); *Jones v. Lederle Labs., Div. of Am. Cyanamid Co.*, 695 F. Supp. 700, 710 (E.D.N.Y. 1988); *Reilly v. Wyeth*, 876 N.E.2d 740, 752 (Ill. App. Ct. 2007).

Act does not preclude any state claim.[10] In rejecting Section 22(b)(1)'s case-by-case requirement because it concludes that the Act does ***not*** merely provide a preemption defense subject to evaluation by state courts but bars all design defect claims, the Third Circuit relied heavily upon the "complete" or field preemption principles these courts unanimously rejected.

At least fourteen other courts, including three circuits courts and two highest state courts,[11] have decided whether federal regulation of vaccines is so

---

[10] *See, e,g., Shadie,* 254 F. Supp. 2d at 516 (the court explained: "[e]ssentially, they are arguing that the Vaccine Act is not an affirmative defense to the plaintiffs' claims, but rather provides for an exclusive federal remedy that precludes separate state court causes of action. . . .").

[11] *See Schafer,* 20 F.3d at 7 ("the Act's language suggests that pre-emption is not intended"); *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1988) & case cited therein; *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1113 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988); *Mazur v. Merck & Co.*, 742 F. Supp. 239, 246-47 (E.D. Pa. 1990), *aff'd on other grounds*, 964 F.2d 1348 (3d Cir. 1992); *Jones v. Lederle Labs.*, 695 F. Supp. at 712; *Foyle,* 674 F. Supp. at 534; *Martinkovic v. Wyeth Labs., Inc.*, 669 F. Supp. 212, 215 (N.D. Ill. 1987); *MacGillivray v. Lederle Labs.*, 667 F. Supp. 743, 746 n.1 (D.N.M. 1987); *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1340 (C.D. Cal. 1987) (discussing § 22(b)(1)); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1492 (D. Kan. 1987), *aff'd in part, rev'd on other grounds,* 906 F.2d 1399 (10th Cir. 1990); *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); *Koehler by Koehler v. Wyeth Lab. Div. of Am. Home Prods. Corp.*, 1987 U.S. Dist. LEXIS 16861 *6-8 (S.D. Ind. Sept. 8, 1987); *Shackil v. Lederle Labs., Div. of Am. Cyanamid, Co.*, 561 A.2d 511, 527 (N.J. 1989); *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 751 (Ohio 1988).

comprehensive as to preempt impliedly state tort claims like those asserted here. In answering "no," the vast majority of these courts relied on the Act itself as an expression of Congressional intent ***not*** to preempt broadly state tort law. In fact, many of these courts and numerous others held that the structure and purposes of the Act itself do not preempt and thus supplant civil tort remedies.[12] In fact, several courts specifically addressed the question of whether Section 22 expressly preempts state tort claims.

Before the Act became effective in 1988, the court, in *Reed v. Connaught Labs., Inc.*, 1987 Pa. Dist. & Cnty. Dec. LEXIS 79 *9 (Pa. C.P. 1987), relying Section 22 's language and legislative history, concluded "that there has been no express pre-emption of state tort remedies for vaccine-related injuries." In *Mazur v. Merck & Co.*, 742 F. Supp. 239, 246-47 (E.D. Pa. 1990), the court concurred and held that Subsections 22(a) and (e) "[c]ertainly manifest Congress's intent to preserve traditional state tort remedies for redress of injuries related to vaccine use." The Supreme Court of Nevada agreed in principle, holding that "certainly the Act contains no express language which would preempt the Allison's [strict liability] tort actions." *Allison v. Merck & Co.*, 878 P.2d 948, 961 (Nev. 1994). Thus, these decisions and those discussed above undercut the notion that the structure and purposes of Section 22 favor preempting all design defect claims. Equally important, all erode the Third Circuit's underlying assumption that the alleged comprehensiveness of the

---

[12]*See Hurley*, 851 F.2d at 1536, 1539-40; *Abbot*, 844 F.2d at 1112-13; *Foyle*, 674 F. Supp. at 533; *Martinkovic*, 669 F. Supp. at 212; *Graham*, 666 F. Supp. at 1491-92; *Patten*, 655 F. Supp. at 745.

FDA approval process for vaccines would impliedly preempt all design defect claims or somehow render the side effects of all approved vaccines "unavoidable" as a matter of law.[13]

Many of these decisions involve DTP vaccines. *See, e.g., Hurley*, 863 F.2d 1173; *Foyle*, 674 F. Supp. 530. In finding that claims involving such vaccines are not preempted, these opinions also address but run counter to the Third Circuit's alleged holding that Congress somehow singled out DTP claims for complete preemption. A-61-62.

In 2002, the FDA began to reverse its historic position that its regulations do not preempt state tort claims against manufacturers of prescription drugs.[14] For six years, it took a strong pro-preemption position with regard to prescription drugs generally.[15] Until late 2006, however, it did not specifically address the question of preemption of vaccine claims.

---

[13] *See* Nitin Shah, *When Injury is Unavoidable: The Vaccine Act's Limited Preemption of Design Defect Claims*, at 25 (May 19, 2009), *available at* http://ssrn.com/abstract=1407343 (to be published in the University of Virginia Law Review and concluding that Section 22(b)(1) preempts only those design defect claims where the side effects are first found unavoidable).

[14] The FDA had consistently recognized that state-law claims could coexist with federal prescription drug regulation. *See* 63 Fed. Reg. 66378, 66383-84 (Dec. 1, 1998), *quoted in In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 788 (E.D. La. 2007).

[15] These efforts culminated in the issuance of a "preamble to a 2006 FDA regulation" declaring that state-law failure-to-warn claims "threaten the FDA's statutorily prescribed role. . . ." *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009).

Within this larger discussion of the scope of preemption under the Act, a critical mass of trial and appellate courts have addressed the question presented directly and generated several lines of cases. In *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 665 (S.D. Tex. 2004), *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 308 (E.D. Pa. 2007), and *Wright v. Aventis Pasteur, Inc.*, 2008 Phila. Ct. Com. Pl. LEXIS 221 *29 (2008), the courts based their conclusion that Section 22(b)(1) bars all design defect claims on the conflict preemption principles many courts have rejected, holding that case-by-case determination "could interfere with the federal government's efforts to establish a uniform national standard for childhood vaccines" and thus "undermine the FDA's authority to set [such] standards. . . ." *Blackmon,* 328 F. Supp. 2d at 665. All also relied upon, at best, ambiguous legislative history and an unduly broad reading of Restatement comment k that the court in *Ferrari* recognized as fatally flawed.[16]

Despite its ultimate holding, the court in *Sykes* allowed that a "case-by-case" interpretation of Section 22(b)(1) was as plausible as the one it adopted. 484 F. Supp. 2d at 301. Similarly, both courts in *Militrano v. Lederle Labs.*,769 N.Y.S.2d 839, 844 (N.Y. Sup. Ct. 2003), *aff'd*, 810 N.Y.S.2d 506 (N.Y. App. Div., 2006), correctly recognized that the plain language of § 22(b) "could be read as barring defective design claims only where the injury was unavoidable, with a finding of unavoidability being determined on a case-by-case basis." Nevertheless, the trial court found preemption

---

[16] *See* A-82-85; *Ferrari,* 668 S.E.2d at 239-40; *Wright,* 2008 Phila. Ct. Com. Pl. LEXIS 221 at *29; RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

of all design defect claims because it concluded from selected legislative history that "Congress intended to view Comment k and the Act as immunizing vaccines from liability for design defects." 769 N.Y.S.2d at 845.

As discussed above, the Georgia Supreme Court and the court it affirmed in *Ferrari* reached the opposite conclusion. Unlike the previous courts to decide the question presented, the *Ferrari* courts discussed and properly applied the presumption against preemption which requires that the court "accept the reading that disfavors pre-emption . . ." *Ferrari,* 668 S.E.2d at 242. The court explained that "the long history of tort litigation against manufacturers of [prescription drugs and vaccines] adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Id.* (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

While the question presented has been percolating in the nation's courts for the last 20 years, Congress, the FDA and this Court have all weighed in. When specifically asked by the trial court ***in this case*** to express its opinion concerning the question presented in 2006, the FDA refused to assert that all design defect claims were expressly preempted, stating that it had no authority over such claims because "the Secretary is not a party to that civil action and does not administer the provisions, such as section 22(b), that govern such civil actions. A-107-08. Although this Court has made clear the FDA pronouncements are entitled to little or no weight, *see Levine*, 129 S. Ct. at 1204, in light of FDA's strong pro-preemption posture with regard to other prescription drugs in

2006, the FDA's refusal to assert that state tort claims interfere with its authority speaks volumes.[17]

Congress has also spoken to this issue, albeit indirectly. In 2004, it passed a law granting sole jurisdiction to federal courts over claims of injuries from any "covered countermeasure" against a pandemic or epidemics, which can include vaccines. Pub. L. No. 109-148 (2005); 42 U.S.C. §§ 247d-6d, 247d-6e. The law gives the Secretary of Health and Human Services broad authority to declare a drug or vaccine a "covered countermeasure" with attendant liability protection. *Id.* There 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.

Finally, in 2008, this Court addressed and narrowed the issues here when it reaffirmed that the presumption against preemption applies when addressing questions of express preemption, holding that "[w]hen the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors preemption.'" *Altria Group, Inc. v. Good*, 129 S.Ct. 538, 543 (2008) (quoting *Bates,* 544 U.S. at 449)). All of the appellate courts that have specifically addressed the question presented have held that a case-by-case

---

[17]Since that time, the Obama Administration has set new, strongly anti-preemption policy. *See* Memorandum to Heads of Executive Departments and Agencies from Barack Obama, President, May 20, 2009, *available at* http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/.

reading of Section 22(b)(1) is plausible. The court below should have followed *Altria* and adopted that reading.

C. The Conflict Creates Intolerable Unfairness to Litigants in Different Jurisdictions

Hannah Bruesewitz will turn 18 in October 2009. She suffered catastrophic injuries as a baby in 1992. Although her care will cost $9 million over her lifetime, to date, she has received no compensation whatsoever. Instead, she and her family have spent 14 years in courts and administrative proceedings. Because she lives in Pennsylvania, she can no longer seek recompense. If her family lived in Georgia, she could.

Unless this Court resolves the conflict between the *Bruesewitz* and *Ferrari* decisions, whether families have the right to sue for their children's vaccine-related injuries will remain largely a question of geography. Following *Bruesewitz, Sykes* and *Wright* [until the Superior Court rules], Pennsylvania courts will likely bar all design defect claims, whether safer alternatives exist or not. Following *Ferrari*, courts in Georgia will allow such claims to proceed if the manufacturer can show that no safer vaccine was available. Courts in Texas, following *Blackmon,* may bar claims just as courts in New York, following *Militrano*, will. Courts and litigants in other states will have to guess whether their design defect claims are preempted. "By itself, this confusion on an important and recurring question of federal law provides sufficient reason to grant *certiorari* in this case." *Swanner v. Anchorage Equal Rights Comm'n*, 513 U.S. 979, 982 (1994) (Thomas, J., dissenting).

Moreover, this dichotomy may have constitutional dimensions. Under the equal protection clause, similarly situated individuals may not be treated differently under a federal statute solely because of the state in which they reside. *See Village of Willowbrook v. Olech*, 528 U.S. 562, 564 (2000); *see also Golden State Transit Corp. v. Los Angeles*, 493 U.S. 103, 105 (1989) (deprivation of state right preempted by federal statute may be cognizable under 42 U.S.C. § 1983). Unless this Court resolves the question presented, this untenable geographic disparity will persist.

D. Further "Percolation" of the Question Presented Will Not Assist This Court

Because the decisions of this Court and of the other courts discussed above have narrowed and refined the issues here, there is little benefit in allowing the question presented to percolate further in the lower courts before this Court decides it. The compelling arguments raised by the court in *Ferrari* are unlikely to go away, especially since this Court has repeatedly reaffirmed the presumption against preemption on which that court relied. More than twenty courts, including four circuit courts and two highest state courts, have addressed and undercut the arguments the Third Circuit relied upon in finding all design defect claims preempted. In fact, it is unclear what further percolation would reveal, if anything. Because the marginal utility of waiting for additional courts to rule is thoroughly outweighed by the unfairness to litigants in failing to resolve the question presented, *certiorari* is warranted now.

II. THE MEANING AND SCOPE OF SECTION 22(B)(1)'S EXPRESS PREEMPTION CLAUSE IS A RECURRING QUESTION OF NATIONAL IMPORTANCE

A. The Question Presented Will Recur if Not Resolved by This Court Now

The failure of this Court to decide the question presented would waste judicial resources, those of litigants, and unduly delay the very compensation the Act was intended to speed. Defendants now file preemption motions as a matter of course in cases emerging from the vaccine program. Indeed, the question presented is pending before the Pennsylvania Superior Court in an appeal from a ruling in the thimerosal MDL. *Wright v. Aventis Pasteur, Inc.*, 2008 Phila. Ct. Com. Pl. LEXIS 221 (2008). Spurred by the opinion below, these motions will likely proliferate.

Moreover, the *Ferrari* petitioners allege that DTP filings outside the vaccine program are on the rise and that some 350 state-law DTP cases were filed in a 4-year period. *See* Geoffrey Evans, *Update on Vaccine Liability in the United States*, 42 CLINICAL INFECTIOUS DISEASES S130, S134 (2006). While these and other vaccine filings hardly illustrate the litigation crisis those petitioners claim warrants preempting all design defect claims,[18] they do suggest that the question presented will recur as these cases work their way through the courts.

---

[18]In fact, Dr. Evans, the Director of the Division of Vaccine Injury Compensation at HRSA, does not conclude that there is a current crisis in DTP litigation despite "uncertainty" over autism filings. *Id.* at S136.

B. The Third Circuit's Ruling Robs Families of Important Statutory and Common Law Rights

This Court has repeatedly recognized the importance of resolving questions concerning the scope of express preemption by granting *certiorari* in a variety of such cases in the last two terms. *See, e.g.*, *Altria*, 129 S. Ct. at 543 (2008). Ascertaining the scope of Section 22(b)(1)'s preemption of vaccine design defect claims is no less important than was determining the reach of other express preemption provisions in *Altria* or *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), because it would define the rights the Act affords families to pursue state-law design defect claims against vaccine manufacturers.

As demonstrated, in the Act, Congress expressly preserved the right to pursue state tort claims and expressly preempted state laws that would prohibit individuals from bringing such actions if the claim is not prohibited by the Act itself. All parties here concede that Section 22(b)(1) preempts certain design defect claims if the side effects of the vaccine were unavoidable. The Third Circuit, however, also bars claims involving vaccines for which there were safer alternatives and prevents trial courts from making that determination. As a result, its ruling prevents the hundreds of families alleging injuries from DTP vaccine, and potentially thousands of others alleging injuries from other vaccines, from pursuing tort claims for vaccine-related injuries even though safer alternatives were available at the time.

C. The Third Circuit's Ruling Destroys Incentives for Manufacturers to Develop and Market Better Vaccines

In passing the Act, Congress understood that preserving a stable vaccine supply entails far more than completely immunizing the childhood vaccine industry from most lawsuits. Instead, the relevant committees took pains to strike a balance between providing limited immunity, caring for injured children, and maintaining incentives to make vaccines safer. To that end, "[t]he Act modifies, but does not eliminate, the traditional tort system, which . . . provide important incentives for the safe manufacture and distribution of vaccines." *Schafer*, 20 F.3d at 3. In fact, in its opinion, the Third Circuit admitted that Petitioners' interpretation of Section 22(b)(1) would impose just such an "affirmative obligation" on manufacturers to develop safer vaccines. A-36; *see also Levine*, 129 S. Ct. at 1203 ("state tort suits . . . provide incentives for drug manufacturers to disclose safety risks promptly").

By removing the influence of the tort system, the Third Circuit upsets the balance Congress carefully crafted and destroys incentives to make vaccines better. Worse, it rewards manufacturers who, like Respondents, buy rights to competitors' safer vaccines but put these drugs on the shelf while they market more dangerous ones. The House Energy and Commerce Committee, which had jurisdiction over both phases of the Act's enactment, had warned against just such tinkering.

> Taken together, such a system of Federal no-fault compensation and other rights of

> actions are intended to provide a stable vaccine market with care for the injured and incentives for safety. Weakening either safeguard might dislocate immunization programs by limiting the availability of vaccines or by failing to encourage research and development of better vaccines.

H.R. REP. 100-391(I), at 691. The Third Circuit should have heeded Congress' warning.

III. THE THIRD CIRCUIT'S INTERPRETATION OF SECTION 22(B)(1) IS FATALLY FLAWED

A. The Third Circuit Rewrites Section 22(b)(1)'s Plain Language and Ignores Important Rules of Statutory Construction

The Third Circuit interprets Section 22(b)(1) to omit its conditional phrase "if the injury or death resulted from side effects that were unavoidable . . ." All parties agree that the phrase is conditional and requires case-by-case determination of whether the conditions for preemption have been met. They differ only on the criteria to be used. In fact, even the Third Circuit agrees that the phrase is conditional. A-28. Nevertheless, it finds all design vaccine defect claims unconditionally preempted. In doing so, the Court ignores bedrock statutory construction principles and the statute's plain text.

Where, as here, a court concludes that a statute is susceptible of more than one plausible interpretation and the choice is between recognizing or ignoring its

plain language, that court should accept the statute as meaning what it says. *See, e.g.*, *United States v. John Doe, Inc. I*, 481 U.S. 102, 109 (1987). Moreover, this Court has long recognized the "canon of statutory construction that terms in a statute should not be construed so as to render any provision of that statute meaningless or superfluous." *Beck v. Prupis*, 529 U.S. 494, 506 (2000). In holding all design defect claims expressly preempted despite Section 22(b)(1)'s conditional phrase, the Third Circuit shredded that canon and rendered the phrase a nullity.

B. The Third Circuit Incorrectly Finds that Section 22(b)(1) Provides an Exclusive Remedy, Not a Preemption Defense

The Court justified its wholesale amendment of Section 22(b)(1) by holding that Section 22 as a whole essentially creates an exclusive remedy for vaccine-related injuries resulting from design defects. In so doing, the Court ignored considerable case law, cited above, that holds that the Act does not create exclusive remedies for vaccine-related injuries. *See supra* note 9.

The Court reached its conclusion first by postulating that "[i]f, as plaintiffs claim, Congress intended to carve out from subsection 22(b) a mechanism to enable states to determine what side effects could have been avoided through an alternate design, Congress could have done so in the manner used in subpart (b)(2) [which contains a rebuttable presumption]." A-29. Because Congress did not do so, the Court found that it intended to preempt all design defect claims.

In so holding, the Court effectively reverses the burden of proving "clear and manifest" intent to preempt and the presumption against preemption. *Levine*, 129 U.S. at 1195. Had Congress intended to preclude all design defect claims for vaccines in Section 22(b), it knew how to do so.[19] Yet it did not. Under *Levine*, such silence "is powerful evidence" that Congress did ***not*** intend to preempt all design defect claims. *Levine*, 129 U.S. at 1200.

Worse, the court misapprehends the nature of preemption. The court observes that, "[i]f we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court." A-29. Because case-by-case determination would thus "not bar any design defect claims," *id.*, the Court found all such vaccine claims expressly preempted.

This Court has long held that federal preemption is an affirmative defense on which a defendant has the burden of proof. *See, e.g., Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987). To say, as the court here does, that, because a defendant has the burden to prove that the conditions underlying its preemption defense are satisfied in each case, no claim is preempted, is legally incorrect.

---

[19] *See Bates*, 544 U.S. at 449; 42 U.S.C. § 300aa-22(c); 42 U.S.C. § 300aa-11(a)(2)(B); *see also Hasler v. United States*, 718 F.2d 202, 204 (6th Cir. 1983) (discussing an old federal statute expressly creating an exclusive federal remedy for injuries resulting from administration of the swine flu vaccine).

C. The Third Circuit Dismisses *Levine*, *Altria*, *Bates*, and *Cipollone* to Marginalize the Presumption Against Preemption

In *Levine*, this Court reaffirmed that a presumption against preemption applies "in all preemption cases" and can be overcome only by a showing of "clear and manifest" purpose to preempt. 129 S. Ct. at 1194-95. The presumption applies to express preemption clauses, *see, e.g.*, *Lohr*, 518 U.S. at 485, and requires that they be read "fairly but narrowly." *Altria*, 129 S. Ct. at 549; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523 (1992). Thus, when a preemption clause is open to two plausible readings, courts have a "[d]uty to accept the reading that disfavors pre-emption." *Bates*, 544 U.S. at 449.

The presumption is particularly strong here because Congress preempted in a field of traditional state regulation: health and safety. *Altria*, 129 S. Ct. at 543; *Lohr*, 518 U.S. at 485. In addition, because Section 22(e) expressly preempts state law that bars claims the Act does not, "'[t]he case for federal pre-emption is particularly weak [because] 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)).

A fair but narrow reading of Section 22(b)(1) mandates case-by-case determination of whether a vaccine is unavoidably unsafe. Because the Third

Circuit found that there were at least two plausible readings of § 22(b)(1), it had a duty to apply the presumption and accept the reading of Section 22(b)(1) that avoids preemption. It failed to do so.

The Court ostensibly used "obstacle" preemption to overcome the presumption against preemption here. A-13-14 (using dicta from *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 374, n.8 (2000)). Yet the Court placed no apparent floor on how low an obstacle to the achievement of Congressional purpose case-by-case determination could be before the presumption could be overcome. Thus unfettered, the Court was free to engage in the "freewheeling, extratextual, and broad evaluations of Congressional purpose" Justice Thomas has condemned. *Levine,* 129 S. Ct. at 1217 (Thomas, J., concurring). As a result, the Third Circuit reached a legally unsustainable conclusion about the Act's purpose and text.

D. The Third Circuit Fails to Utilize Crystalline Legislative History Supporting Petitioners' Construction of Section 22(b)(1)

Although the Third Circuit did not consider any legislative history in deciding that Section 22(b)(1) does not permit inquiry into unavoidability, it should have done so because the legislative history supporting such an inquiry is clear and would have assisted the Court in interpreting Section 22(b)(1).

When it amended the Act to fund its compensation program, the House Energy and Commerce Committee made clear that Section 22(b)(1) did not preempt all design defect claims, irrespective of safer alternatives.

It stated:

> With these amendments in place, the Committee believes that a complete system of vaccine compensation can take effect which will provide compensation to those persons who are inadvertently injured by routine immunizations while allowing those persons who believe that they have a claim for remedies in court to pursue it. It is the Committee's intention to create a compensation system that is speedy and generous enough to dissuade petitioners from going on to court. . . [B]oth at the time of the original enactment and in passing this legislation, the Committee acted with the understanding that tort remedies were and are available. . .
>
> * * * *
>
> [T]he codification of Comment (k) of the Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.

H.R. REP. 100-391(I), at 691. The Court rejects this legislative history, although in another context, because it contends that it was improper subsequent legislative history and from the wrong committee. A quick review of the relevant committee report reveals its proper pedigree. *Id.* at 690-700. Thus, the only question is whether this crystalline expression of Congressional intent may be discarded as "subsequent" legislative history.

The Third Circuit concedes that "[t]he Vaccine Act . . . made the compensation program and accompanying tort reforms contingent upon the enactment of a tax to provide funding for the compensation." A-36. In fact, in recognition of the fact that the Act was not effective until both parts had been enacted and, at the time, the vaccine tax had not passed, the court, in *Wack,* 666 F. Supp. at 127 n.1, refused to consider the Act as evidence of Congress' intent not to preempt state claims.

In *District of Columbia v. Heller*, 128 S. Ct. 2783, 2805 (2008), this Court distinguished pre-enactment from subsequent legislative history in terms of its effect on a congressional vote. To the extent Congress' vote to fund the vaccine compensation program and make effective its limited liability limits was "contingent" upon assurances that unavoidability would be determined on a case-by-case basis, legislative history from the 1987 amendments cannot be considered "subsequent" and rejected as such.

E. Congress Created and This Court Has Ratified the Dichotomies the Third Circuit Claims Congress Could Never Have Intended

The Third Circuit also rejects the *Ferrari* court's reading of Section 22(b)(1) because it

> [c]ould create an awkward dichotomy in the case law of these states – their courts would be required to engage in case-by-case analysis of all strict liability and negligent design defect claim brought under the Vaccine Act, while barring strict liability design defect claims against prescription drug manufacturers.

A-30. In passing the Act, however, Congress expressly created the very dichotomy the Third Circuit claims it could not have intended when, in Section 22(e), it expressly preempted state law that would prevent the pursuit of state claims not barred by the Act. State litigants are, therefore, expressly authorized to pursue claims against vaccine defendants they might not be able to pursue against other drug manufacturers.

The Third Circuit also ignores the dichotomies this Court ratified in *Riegel, Lohr*, and *Levine*. In *Riegel* and *Lohr*, the Court found state failure-to-warn claims against medical device manufacturers preempted if their devices went through the pre-market approval process, *Riegel*, 128 U.S. at 1006-07, but not if the same manufacturers' products went through the lesser "510(k)" approval process. *Lohr*, 518 U.S. at 513. By contrast, in *Levine*, it found no intent to preempt all

failure-to-warn claims in the alleged comprehensiveness of the New Drug Application process. 129 S. Ct. at 1196. Against this backdrop, it is not surprising – or dispositive – that Congress would have chosen to impose a slightly different burden of *proof on vaccine manufacturers who had already been* given the considerable advantage of forcing potential litigants to exhaust administrative remedies before they could pursue state-law tort claims.

CONCLUSION

For the reasons stated, this Court should grant the petition for writ of *certiorari*.

Respectfully submitted,

Collyn A. Peddie
Counsel of Record
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway, Suite 600
Houston, Texas 77017
Telephone: (713) 230-2200
Facsimile: (713) 643-6226

Attorneys for Petitioners, Russell, Robalee, and Hannah Bruesewitz

Blank Page