No. 08-081120

IN THE

Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH, SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE AND GLAXOSMITHKLINE BIOLOGICALS, S.A.,

Petitioners,

v.

MARCELO A. FERRARI AND CAROLYN H. FERRARI, Individually and as Parents and Next Friend of STEFAN R. FERRARI,

Respondents.

On Petition for a Writ of Certiorari to the Supreme Court of Georgia

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?

LIST OF PARTIES AND RULE 29.6 STATEMENT

All parties to the proceedings in the Supreme Court of Georgia are listed in the caption.

Wyeth is a publicly traded corporation. No publicly held corporation owns 10% or more of its outstanding shares.

Through its wholly owned subsidiaries, GlaxoSmithKline plc owns 100% of both SmithKline Beecham Corporation and GlaxoSmithKline Biologicals, S.A. No publicly held corporations own 10% or more outstanding shares.

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The decision of the Supreme Court of Georgia is published at 668 S.E.2d 236, and is reproduced in the Appendix ("App.") at 1. The decision of the Georgia Court of Appeals, dated July 5, 2007, is published at 650 S.E.2d 585, and is reproduced at App. 19. The unpublished decision of the State Court of Fulton County, dated November 30, 2005, is reproduced at App. 33.

JURISDICTION

The Georgia trial court ruled that Section 22 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22, expressly preempted Respondents' design defect claims, and the court entered a partial summary judgment finally disposing of those claims. App. 42-49. The Georgia Court of Appeals reversed the trial court's order. App. 19. On October 6, 2008, the Georgia Supreme Court affirmed the Court of Appeals' order. App. 3-4. Upon Petitioners' application, on December 22, 2008, Justice Thomas extended the time to file a petition for a writ of certiorari in this case to and including March 5, 2009. This Court has jurisdiction under 28 U.S.C. § 1257(a).

The Georgia Supreme Court's decision is a final judgment for the purposes of 28 U.S.C. § 1257(a). *See Cox Broad. Corp. v. Cohn*, 420 U.S. 469, 482-83 (1975); *see also Belknap, Inc. v. Hale*, 463 U.S. 491,

497 n.5 (1983) (allowing review of a state court determination that state causes of action were not preempted by federal law). A decision not to review the Georgia Supreme Court's decision now will "seriously erode" the federal public health policies of the Vaccine Act. *Cox Broad. Corp.*, 420 U.S. at 483. The Vaccine Act's preemption of civil liability is integral to ensuring adequate supplies of vaccines necessary to protect the public from infectious disease. *See* H.R. Rep. No. 99-908, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348 [hereinafter "H.R. Rep. at __, 1986 U.S.C.C.A.N. at __"].

This case satisfies all three criteria necessary to justify immediate review of a state supreme court decision that threatens federal policy. *See Cox Broad. Corp.*, 420 U.S. at 482-83. First, the Georgia Supreme Court has finally determined that the Vaccine Act does not categorically preempt design defect claims. Second, the design defect claims could be resolved on other grounds on remand—such as the failure to prove, after trial, that the alleged injury was caused by the vaccines—depriving Petitioners of any opportunity to seek review of the preemption ruling. Third, if this Court reverses the Georgia Supreme Court's decision, the design defect claims will be conclusively resolved as preempted and will not be further litigated. The Court should not delay addressing this pressing preemption question, because the Georgia Supreme Court's decision invites litigation larger in scope than the onslaught two decades ago that impelled Congress to adopt the Vaccine Act.

CONSTITUTIONAL AND STATUTORY PROVISIONS

This case involves application of the Supremacy Clause of the United States Constitution, art. VI, § 1, cl. 2, which provides as follows:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The case revolves around the interpretation of 42 U.S.C. § 300aa-22, which provides, in relevant part, as follows:

> **§ 300aa-22. Standards of responsibility**
>
> (a) General Rule
>
> Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
>
> (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 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.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

> (A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or
>
> (B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

INTRODUCTION

Congress narrowly averted a public health crisis by enacting the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq.* (the "Vaccine Act" or "Act"). In a decision that avowedly rejects the position of every other jurisdiction to rule on the issue, the Georgia Supreme Court has invited that crisis back.

The crisis was an alarmingly unstable vaccine supply. As Congress declared, "[t]he availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities." H.R. Rep. at 5, 1986 U.S.C.C.A.N. at 6346. But vaccine manufacturers labored under the strain of crushing defense costs and potential liability from several hundred product liability cases pressing "design defect" claims—i.e., claims that the manufacturer should have adopted a vaccine design different from, and allegedly safer than, the Food and Drug Administration ("FDA") approved design. The litigation strain was driving vaccine manufacturers out of the market, causing vaccine shortages, and threatening a resurgence of infectious disease. Congress stabilized the vaccine market—and averted the public health crisis—by shielding vaccine manufacturers from tort liabilities (with specified exceptions), and creating a reliable and speedy no-fault remedy administered by a special federal court (colloquially known as "Vaccine Court").

The liability shield, which is at issue in this case, is in Section 22(b)(1) of the Vaccine Act. That

provision expressly preempts *all* civil liability "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).

Outside of Georgia, every court to rule on the Vaccine Act's preemption provision has correctly interpreted it to categorically preempt all claims for vaccine-related injuries unless the vaccine at issue contained a manufacturing defect (i.e., was not "properly prepared") or was inadequately labeled (i.e., was not accompanied by "proper directions and warnings"). Thus, each one of these courts rejected attempts by plaintiffs to circumvent the Act through state law "design defect" claims.

In this case, however, the Georgia Supreme Court rejected the prevailing categorical rule. It held that Section 22(b)(1) 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. Under this rule, judges and juries in every case, in every state, would second-guess the balance that the FDA and several other federal agencies strike between vaccine safety and efficacy. To reach this conclusion, the Georgia Supreme Court improperly isolated Section 22(b)(1)'s language about "side effects that were unavoidable" from the rest of the sentence, disregarding Congress's intent to characterize a side effect from an FDA-approved vaccine as "unavoidable"—and therefore not subject to lawsuits—*as long as* "the vaccine was properly prepared and was accompanied by proper directions and warnings." The court also disregarded the legislative history confirming that

Section 22(b)(1) was intended to provide complete immunity from suit for claims based on design.

If the Georgia Supreme Court's interpretation of the preemption provision stands, tort litigation will once again swamp vaccine manufacturers in a way that could make the deluge of 1986 seem like a trickle. There are currently more than 4,900 claims pending in an "Omnibus Autism Proceeding" in Vaccine Court. Like the claim in this case, many of these thousands of claims are premised on the notion that a child's autism was caused by FDA-approved vaccines and could have been avoided by using a different, purportedly safer design.

Under the Georgia rule, every one of these claimants would have the option to reject the Vaccine Court's judgment and collaterally challenge the FDA's approval of a vaccine's design before a jury. The few remaining vaccine manufacturers will face the expense and uncertainty Congress averted 20 years ago—but this time, dialed up by an order of magnitude. The threat to the nation's vaccine supply and to the development of new vaccines is too grave to leave for another day. This Court should review the Georgia Supreme Court's decision now.

STATEMENT OF THE CASE

A Stable Vaccine Supply Is Critical To Public Health

As recently as the middle of the 20th century, infectious diseases crippled, or even killed, tens of thousands of children a year. Into the 1950s, polio killed nearly 1,900 Americans annually, and paralyzed over 16,000. CDC, *Ten Great Public*

Health Achievements—United States, 1900-1999, 48 *MMWR* 241, 246 (Apr. 2, 1999). Measles afflicted over half a million victims a year, killing more than 400. *Id.* The highly contagious pertussis disease (commonly known as whooping cough) infected over 140,000 victims. *See* Walter A. Orenstein et al., *Immunizations in the United States: Success, Structure, and Stress*, 24 Health Aff. 601, 602 (2005).

Over the decades, public health programs to vaccinate and immunize whole populations have virtually vanquished all these infectious diseases. Smallpox was literally eradicated worldwide by 1977. CDC, *Ten Great Public Health Achievements—United States, 1900-1999,* 48 *MMWR* 241, 246 (Apr. 2, 1999). Polio, diphtheria, and tetanus were effectively eliminated in the United States. H.R. Rep. at 5, 1986 U.S.C.C.A.N. at 6346. By the 1980s, whooping cough, measles, mumps, and rubella had been subdued by more than 98% of their peak levels. *National Childhood Vaccine Injury Compensation Act of 1985: Hearing on S. 827 Before the S. Comm. on Labor and Human Resources*, 99th Cong. 145 (July 18, 1985). Vaccines made these public health triumphs happen. It was no exaggeration when the congressional committee that reported on the Vaccine Act observed: "Vaccination 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. at 4, 1986 U.S.C.C.A.N. at 6345. But, as Congress also recognized, the program requires constant attention; the continued suppression of infectious disease depends upon ongoing universal vaccination, which

depends, in turn, on a stable supply of vaccines. *Id.* at 7, 1986 U.S.C.C.A.N. at 6348.

Vaccine Litigation Causes a Public Health Crisis

In the mid-1980s the requisite vaccine supply was teetering on the brink of disaster. The root cause was a proliferation of tort cases against vaccine manufacturers. The vast majority of the cases targeted the combined pediatric vaccine for diphtheria, tetanus, and pertussis ("DTP"). Plaintiffs brought design defect claims alleging that the only FDA-approved DTP vaccine design was unreasonably dangerous, and thus defective.

The litigation threat precipitated an exodus from the vaccine market. "The number of childhood vaccine manufacturers . . . declined significantly," *id.* at 4, 1986 U.S.C.C.A.N. at 6345, while the few that remained began "to question their continued participation in the vaccine market," *id.* at 7, 1986 U.S.C.C.A.N. at 6348. As of the end of 1984, two of the three domestic commercial manufacturers of the DTP vaccine had withdrawn from the market. *See Staff of Subcomm. on Health and the Environment, 99th Cong., Childhood Immunizations* 68 (Sept. 1986) [hereinafter "Subcomm. Rep."]. The fragility of supply was shown when the one remaining manufacturer experienced production problems. *Id.* at 69.

This was the "unstable and unpredictable childhood vaccine market" Congress observed. H.R. Rep. at 5, 1986 U.S.C.C.A.N. at 6346. There was "a short term crisis of availability of DTP vaccine."

Subcomm. Rep. at 68. The shortage became so dire that the Centers for Disease Control and Prevention ("CDC") recommended stretching out the vaccination schedule—diluting children's protection. *Id.* at 69.

Congress sounded the alarm: 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 disease." H.R. Rep. at 7, 1986 U.S.C.C.A.N. at 6348.

Congress Averts the Crisis with the Vaccine Act

Congress responded to the public health crisis decisively—by passing the Vaccine Act. The Vaccine Act is an intricate and comprehensive federal scheme to insulate the remaining (and new) vaccine manufacturers from litigation, while both compensating the few individuals who suffer adverse side effects and fostering the development of safer and more effective vaccines.

Shielding vaccine manufacturers from tort litigation. The element of the statutory scheme that protects vaccine manufacturers from the potentially ruinous burden of litigation, which is at the heart of this petition, 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). This preemption clause preserves a limited tort remedy against a manufacturer for injuries caused by a vaccine not made according to its FDA-approved formula or that does not provide proper directions and warnings for use.[1] *See* H.R. Rep. at 26, 1986 U.S.C.C.A.N. at 6367 (claimants who "cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings should pursue recompense in the [administrative] compensation system, not the tort system."). Such claims, however, did not drive the litigation crisis. The question in this case is whether the reference to "unavoidable" injuries somehow leaves open the possibility of liability for design defect claims—the very sorts of claims that were central to the litigation in the 1980s.

Whatever the answer to this question, *any* claim for a vaccine-related injury must begin with 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). The Secretary of the United States Department of Health and Human Services ("HHS") appears as a respondent: vaccine manufacturers are not parties

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[1] The Vaccine Act allows a presumption that FDA-approved directions and warnings are adequate. 42 U.S.C. § 300aa-22(b)(2). That provision, and the scope of its effect upon failure-to-warn claims, is not at issue in this petition.

to Vaccine Court litigation. *See id.* § 300aa-12(b). Compensation, paid out of the proceeds from a vaccine tax, is awarded on a no-fault basis. *Id.* §§ 300aa-13, 14, 15(i). A Vaccine Court claimant need not prove that the vaccine was in any way defective or that the injury could have been avoided through a safer design or otherwise—as tort law would require—but only that there is a causal link between the injury and the vaccine. *See id.* § 300aa-13. Congress designed this mandatory federal remedy "to work faster and with greater ease than the civil tort system." *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995).

For vaccine-related injury claims preempted by Section 22(b), the Vaccine Court remedy (with its attendant appeals) is the only remedy available. For those vaccine-related injury claims that may be pursued in a civil action, the claimant who exhausts the Vaccine Court process has a choice to make: accept the Vaccine Court's judgment, or elect against it and litigate from square one in court, subject to several substantive and procedural constraints. *See* 42 U.S.C. § 300aa-21.

The National Vaccine Program. The Vaccine Act also established a National Vaccine Program to "promote the development of childhood vaccines that result in fewer and less serious adverse reactions," and to "assure improvements in . . . the licensing, manufacturing, processing, testing, labeling, warning, . . . and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." *Id.* § 300aa-27(a)(1)-(2). Through this program, lodged in HHS, nearly a dozen federal agencies ("NVP Agencies") collaborate "to achieve optimal

prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." *Id.* §§ 300aa-1, 2; HHS/Public Health Service/National Vaccine Program Office, *The U.S. National Vaccine Plan – 1994*, at 3 (1994) (listing responsibilities of various agencies).

One of the key agencies in the program is the FDA, which regulates the formulation, production, and labeling of childhood vaccines. *See* 21 U.S.C. § 301 *et seq.*; 42 U.S.C. § 262(c); 21 C.F.R. § 600 *et seq.* An FDA-licensed vaccine must be made according to its approved formula. *See* 21 C.F.R. §§ 601.2, 601.12. The FDA "makes approval decisions based not on abstract estimation of [a prescription product's] safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). The FDA strikes the delicate balance between safety and efficacy, ever aware that any vaccine inevitably causes some adverse reactions and that making a vaccine safer can sometimes compromise its efficacy. *Cf. Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) (describing FDA's balancing of medical device's costs and benefits). Even after approval, the FDA, the CDC, and the National Institutes of Health all monitor safety data from the vaccine manufacturers and several independent sources. *See* 42 U.S.C. § 300aa-2(a)(2)-(3).

Trial Court Dismisses Plaintiffs' Design Defect Claims

Respondents (referred to here as "plaintiffs") are the parents of an autistic child. They claim that FDA-approved vaccines caused their child's autism—pinning the blame specifically on thimerosal, the preservative used in the FDA-approved formulations. While allegations of this sort have swept through the media and the internet, every reputable scientific body and governmental agency that has studied the question—including the FDA and CDC—has rejected any linkage between vaccines and autism. *See, e.g.*, FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/cber/vaccine/thimerosal.htm. (last modified Jan. 14, 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"); CDC, *Mercury and Vaccines (Thimerosal)*, http://www.cdc.gov/vaccinesafety/concerns/thimerosal.htm (last modified Feb. 8, 2008) ("There is no convincing scientific evidence of harm caused by the low doses of thimerosal in vaccines, except for minor effects like redness and swelling at the injection site.").

Most notable and comprehensive among 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).

Plaintiffs presented their claim to the Vaccine Court, which had already instituted an Omnibus Autism Proceeding. The omnibus proceeding will decide—for some 4,900 like claims—whether there is a causal link between childhood vaccines and autism. On February 12, 2009, 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. *See Cedillo v. Sec'y of HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009); *Hazlehurst v. Sec'y of HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009); *Snyder v. Sec'y of HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009). In nearly 700 pages of detailed analysis, the Vaccine Court rejected that theory. The Vaccine Court is expected to issue causation rulings later this year in test cases considering claimants' theory that thimerosal-containing vaccines *alone* could cause autism.

Rather than await a ruling on the merits in the omnibus proceeding, plaintiffs here invoked a provision of the Vaccine Act authorizing them to opt out of Vaccine Court and file a lawsuit in court if the Vaccine Court does not resolve the petition within 240 days. *See* 42 U.S.C. § 300aa-21(b)(1). Plaintiffs sued the vaccine manufacturers (Petitioners here) in state court in Georgia. They asserted claims for strict liability, negligence, fraud, negligent misrepresentation, and breach of warranty. App. 36.

As relevant here, their central theory of liability is design defect—that the FDA-approved designs for the vaccines administered are defective, and the manufacturers should not have used the thimerosal preservative as approved by the FDA.

The vaccine manufacturers moved for summary judgment on the basis that the Vaccine Act preempted plaintiffs' claims. App. 34-35. The trial court entered summary judgment, dismissing the design defect claims. The court reasoned that "Congress [did not] leave vaccine design standards open to reexamination under the laws of each state, with the potential for interstate conflict: the Vaccine Act sets one rule, applicable nationwide, that pre-empts design defect claims." App. 45. This ruling was consistent with the conclusions other courts had reached on the preemption of vaccine design defect claims. App. 43. The trial court denied summary judgment on the other claims. App. 55.

Georgia Appellate Courts Reverse

The Georgia Court of Appeals reversed. The court acknowledged that "when the contemporaneous legislative history of the Vaccine Act is examined, Congress's intent to preempt [design defect claims] becomes clear." App. 30. Nevertheless, the court felt compelled to disregard congressional intent because it found it could interpret the statutory language in two competing ways: (1) the statute preempts all design defect claims; or (2) design defect claims are preempted "only if the side effects are determined to be unavoidable on a case-by-case basis." App. 29-30. The Court of Appeals believed that this Court's

decision in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), obliged it "to accept the reading of an express preemption statute that disfavors preemption," and to focus on "the statutory language alone," without regard to structure, purpose, or legislative history. App. 28. The court observed that its denial of preemption "is anomalous given the clear legislative history to the contrary, but we are constrained to follow the Supreme Court's explicit guidance in *Bates*." App. 31.

The Georgia Supreme Court granted the vaccine manufacturers' petition to review the Court of Appeals' ruling that the Vaccine Act did not categorically preempt plaintiffs' design defect claims. App. 3. The Georgia Supreme Court rejected the Court of Appeals' logic—specifically, its peculiar reading of *Bates*—but upheld the result on different grounds. App. 3-4. It held that even in light of the Vaccine Act's structure and legislative history, there was no "clear and manifest congressional purpose" to preempt all design defect claims. App. 18.

The Georgia Supreme Court recognized that its ruling conflicted with all of the other courts to have decided the issue (except the Georgia Court of Appeals). App. 7. But it staked out that position for Georgia, "at least until the Supreme Court of the United States has spoken on the issue." App. 18.

REASONS FOR GRANTING THE PETITION

This case presents a stark choice between two rules. Outside of Georgia, courts have ruled that Congress categorically preempted all state-law claims asserting that the manufacturer should have

adopted a vaccine design that was safer than the one the FDA approved. Properly interpreting Section 22(b)(1), these courts have uniformly allowed only suits based on the theory that the vaccine was improperly prepared or labeled. The Georgia Supreme Court reached the opposite conclusion. It held that Congress preempted tort suits only if the manufacturer demonstrates factually, in the specific case presented, that there was *no safer design* that could have avoided the injuries at issue. According to the Georgia Supreme Court, the express preemption clause does not eliminate the need for discovery and trial because Congress intended to leave expert regulatory determinations about vaccine design open to jury re-examination.

In so holding, the court also did violence to the complex and interrelated purposes and structure of the Vaccine Act. It effectively eliminated one of the most important benefits of the Vaccine Act bargain to vaccine companies by subjecting them once again to costly litigation over matters of vaccine safety that Congress has entrusted to federal health agencies. There is no protection from litigation cost if preemption occurs only at the end of discovery and trial when a jury finds, in a specific case applying state law, that the vaccine had the safest possible design for the injury at issue.

As is demonstrated more fully below, the differences between these two judicial interpretations could not be starker, and the conflict is entrenched and intractable—which is reason alone to grant certiorari. *See infra* Point II. But the main reason to grant certiorari is that the choice between the two approaches is a matter of profound national

importance. *See infra* Point I. The Georgia Supreme Court's approach is so demonstrably wrong, *see infra* Point III, and the threat to public health is so real and imminent, that the issue must be resolved now, without further percolation.

I. THIS CASE IS OF PROFOUND NATIONAL IMPORTANCE BECAUSE THE GEORGIA SUPREME COURT'S RULING UNDERCUTS CONGRESS'S LIMITS ON CIVIL LIABILITY AND THREATENS THE NATION'S VACCINE SUPPLY.

The Court should grant this petition because the Georgia Supreme Court's rule threatens public health by inviting a litigation deluge even bigger than the one that spurred Congress to urgent action in 1986. It does not take any imagination to foresee the consequences. First, as in 1986, the Georgia rule will de-stabilize the vaccine market, which could lead to potentially devastating vaccine shortages. Second, it could stall the development of new life-saving vaccines.

The threat to the vaccine supply. The litigation surge that Congress averted in 1986 was nothing compared to the tidal wave that the Georgia Supreme Court's ruling invites. The graph on page 21 shows how many cases it takes to make a crisis. In 1986, when vaccine litigation peaked, plaintiffs were filing hundreds of cases a year. Over 250 of the cases then pending related to the DTP vaccine. Geoffrey Evans, *Update on Vaccine Liability in the*

United States, 42 Clinical Infectious Diseases S130, S134 (2006). [2]

The costs of defending these hundreds of lawsuits were crushing, and increasing. *See* Subcomm. Rep. at 87; H.R. Rep. at 6, 1986 U.S.C.C.A.N. at 6347. Potential liability also loomed over the industry. In 1984, one major vaccine manufacturer (a corporate ancestor of Petitioner Wyeth) estimated that its potential liability from DTP vaccine lawsuits was 200 times its annual sales for the vaccine. Subcomm. Rep. at 69. The litigation costs and potential liability spawned real-world consequences: an unstable and constricted vaccine supply.

The Vaccine Act dramatically altered the litigation status quo through the preemption of certain tort claims and the no-fault compensation program. 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://newsroom.hrsa.gov/releases/2008/vaccinestudy.htm. As the graph on page 21 illustrates, litigation against DTP manufacturers slowed to a trickle after the law took effect. The same is true for cases involving other vaccines. *See id.* 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—much less to

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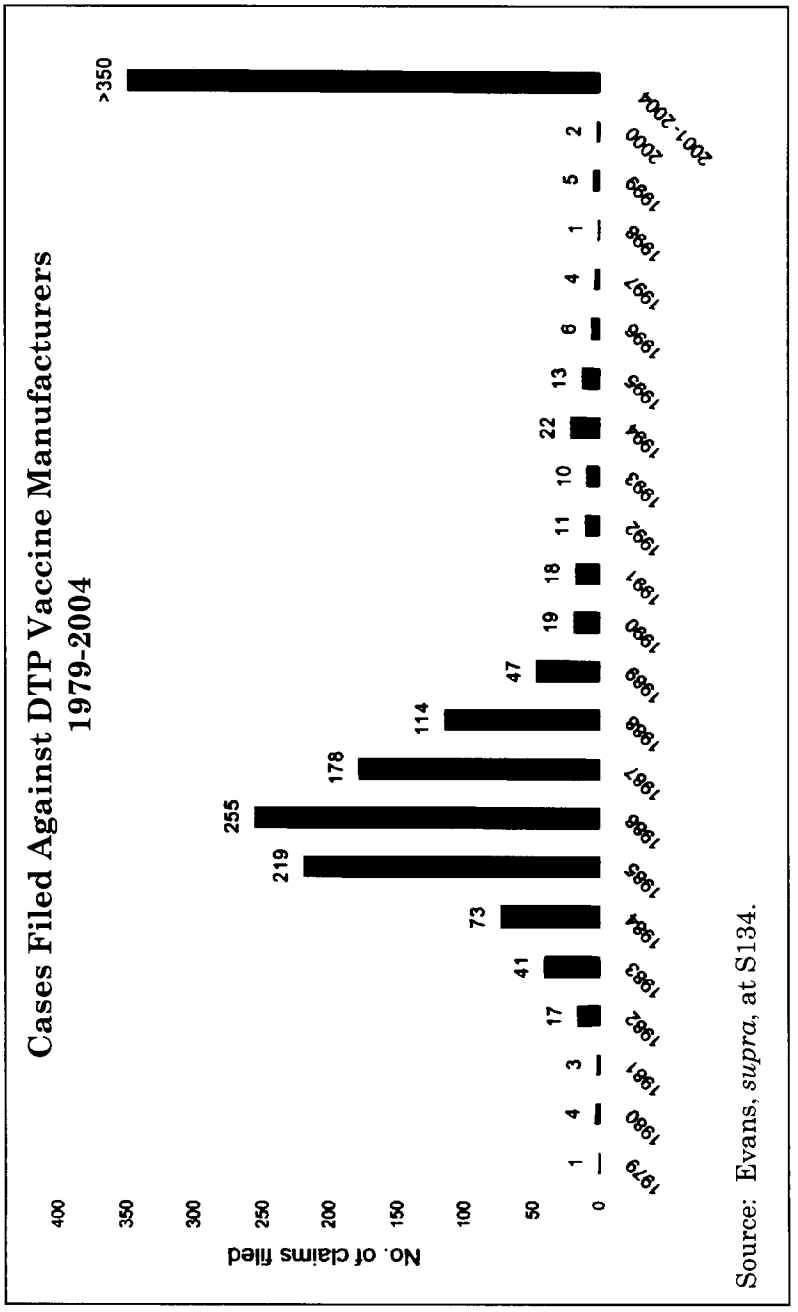
[2] For the most part, the DTP lawsuits alleged that the vaccine's design was defective because the pertussis component caused permanent neurological damage.



Source: Evans, *supra*, at S134.

verdict—in the two decades since the Vaccine Act became effective.

Since 2001, however, plaintiffs have increasingly tested what seemed to be settled limits on litigation. Civil suits against vaccine manufacturers are up again. The filings now number over 350. Evans, *supra*, at S134. Some of these suits involve multiple plaintiffs. Almost all of these suits include clones of this design defect claim. In Georgia alone, more than 20 cases like this one are pending, and Georgia's rule may attract even more suits against vaccine manufacturers.

Nationwide filings are also bound to spike, as plaintiffs, emboldened by the Georgia ruling, try to replicate the results in other states. The Vaccine Court's February 12 rulings rejecting claimants' general causation theory in MMR-thimerosal combined cases (*supra* p. 15) foreshadows a denial of Vaccine Act compensation to those claimants and also to those that cite only thimerosal-containing vaccines as the cause of their injuries. A civil action will be their next—and only remaining—avenue for relief. If any significant portion of the 4,900 vaccine-autism claimants in Vaccine Court exercise their statutory right to reject that court's judgment and file a civil action, hundreds or even thousands of new vaccine cases will flood the courts. The numbers could easily overtop the level of filings in 1986. Without the categorical preemption of vaccine design claims as intended by Congress, Vaccine Court could be reduced to a mere checkpoint plaintiffs pass through on their way to civil court.

As was true in 1986, the most immediate concern is not the potential liability, but the cost of defending hundreds or thousands of lawsuits. Even if judges and juries eventually accept the prevailing scientific view that vaccines do not cause autism (*see supra* pp. 14-15), the litigation expense will be even more crushing than it was back in 1986. To reach the stage in a litigation at which the discredited causation hypothesis could be challenged, a vaccine manufacturer would have to endure expensive discovery—thousands of times over if the deluge materializes.

This deluge could lead to the very same dangerous situation that existed in the mid-1980s—vaccine manufacturers abandoning the market, which in turn yields vaccine shortages and exposes the nation to the renewed threat of an epidemic. The number of vaccine manufacturers has not increased. 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* H.R. Rep. at 7, 1986 U.S.C.C.A.N. at 6348, *with* FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/CBER/vaccine/thimerosal.htm (last modified Jan. 14, 2009). The concerns that motivated Congress in 1986 would reappear: The loss of even one more vaccine manufacturer "could create a genuine public health hazard." H.R. Rep. at 7, 1986 U.S.C.C.A.N. at 6348. The same concerns that compelled Congress to intervene and pass the Vaccine Act in the first place, should compel the Court to intervene and verify which interpretation of the Act is correct—the one that has fulfilled Congress's goal in achieving vaccine stability or the

one that will revive the crisis Congress averted over two decades ago.

The threat to vaccine development. While the Congress that passed the Vaccine Act was most urgently concerned about the public health consequences of the litigation crisis, it recognized the need for vigilance in developing new vaccines and improving existing ones. Congress noticed that vaccine manufacturers were limiting their investment in research and development for two primary reasons. First, the cost of developing a new vaccine is prohibitive: The investment could be as much as 30% of the industry's total annual sales. Subcomm. Rep. at 72. Second, the staggering potential tort liability for vaccine-related injury claims, notwithstanding an FDA-approved vaccine design, could easily lead a drug manufacturer to conclude the investment is not worth the price. *Id.*

While Congress directed several federal agencies to supplement the vaccine research being conducted by the industry, Congress understood that efforts would fail unless the agencies collaborated closely with the industry. *See* H.R. Rep. at 11, 1986 U.S.C.C.A.N. at 6352. The public-private collaboration Congress envisioned has had astounding success. 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).

All three of the vaccines being challenged in this case were products of the National Vaccine Program. Among them is Wyeth's vaccine for *Haemophilus influenzae* type B ("Hib"), which is an especially good illustration of the Program's success. Hib—the leading cause of childhood bacterial meningitis and postnatal mental retardation—formerly afflicted some 20,000 children a year. *See* CDC, *Ten Great Public Health Achievements—United States, 1900-1999,* 48 MMWR 241, 246 (Apr. 2, 1999). In the decade after Wyeth introduced its vaccine for infants, the incidence of Hib invasive disease in children under five fell 99%. *See* Kashif Iqbal et al., *Haemophilus influenzae Type b Invasive Disease*, 2-1 (2008), http://www.cdc.gov/vaccines/pubs/surv-manual/chpt02-hib.pdf.

The work on vaccines is far from over. The need remains for improvement and invention. To take one example, current influenza and pneumococcal vaccines must be adapted to battle new strains of the disease. *See* Laura Beil, *Worrisome Infection Eludes a Leading Children's Vaccine*, N.Y. Times, Oct. 14, 2008. Beyond the diseases that currently afflict our population, public health authorities must guard against foreign invaders. A single peripatetic host carrying a foreign disease could spark an epidemic here, just as a Severe Acute Respiratory Syndrome ("SARS") epidemic spread from China to 37 countries in a matter of weeks. *See* Richard D. Smith, *Responding to Global Infectious Disease Outbreaks: Lessons from SARS on the Role of Risk Perception,*

Communication and Management, 63 Soc. Sci. & Med. 3113 (2006). A robust research program that explores new vaccines is our best protection from these intruders.

Congress worried that a wave of product liability litigation would deter investment in new or improved vaccines and undermine collaboration with federal agencies. That same concern is equally real now. Once again, the choice is as grave as it is clear: a legal rule that will extend the collaborative vaccine success over the past two decades versus the Georgia rule, which will encourage the pharmaceutical industry to withdraw from vaccine research.

II. THE SPLIT OVER WHETHER THE VACCINE ACT CATEGORICALLY PREEMPTS ALL DESIGN DEFECT CLAIMS IS ACKNOWLEDGED AND INTRACTABLE.

The conflict between the Georgia Supreme Court and the majority rule is stark, acknowledged, and intractable.

All courts outside of Georgia that have ruled on the issue have held that the Vaccine Act's preemption clause expressly preempts all design defect claims. *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); *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 444-46 (E.D. Pa. 2007), *appeal docketed*, No. 07-3794 (3d Cir. argued Sep. 11, 2008); *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), *appeal docketed*, No. 336 EDA 2008 (Pa. Super. Ct.). 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 or proper directions and warnings. "If the alleged defect that caused the claimant's injury does not fall into one of [those] two enumerated categories, the defect is considered 'unavoidable,' and the claimant's tort claim is barred." *Blackmon*, 328 F. Supp. 2d at 664.[3] These courts reach this conclusion as a matter of plain language, legislative history, and statutory structure.

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," App. 15, "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

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[3] This Court's recent decision in *Wyeth v. Levine,* No. 06-1249, 2009 WL 529172 (U.S. Mar. 4, 2009), is not relevant to the question presented by this petition. The Court held in *Levine* that the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, did not impliedly preempt plaintiff's failure-to-warn claim relating to the prescription drug Phenergan. *Id.* at *13. The question presented by this petition, however, is whether Congress intended for 42 U.S.C. § 300aa-22(b)(1) of the Vaccine Act to expressly preempt all design defect claims for childhood vaccines.

vaccine were unavoidable." App. 4. In so holding, the Georgia Supreme Court cited and analyzed the cases in the majority camp, but found them "erroneous[]" and "mistaken[]" on each point—statutory language, legislative history, and structure. App. 8-12, 16-18.

In short, courts presented with the same tort claims, the same statute, and the same legislative history have come to diametrically opposite conclusions. The conflict is entrenched and acknowledged, and the Georgia Supreme Court has declared that its decision would remain the law of Georgia "at least until the Supreme Court of the United States has spoken on the issue." App. 18. Until then, vaccine manufacturers sued in Georgia (or in other states that may follow Georgia's lead) will not have the benefit of the preemption defense—and the conflict among the lower courts will remain.

Admittedly, the conflict presented here has not ripened to the level this Court typically prefers—a conflict between a state's highest court and a federal court of appeals—at least not at this moment. The preferred sort of conflict may well materialize while this petition is pending. The Third Circuit is poised to issue an opinion on the issue presented here, as it is now reviewing a district court opinion holding that the Vaccine Act categorically preempts all design defect claims. *See Bruesewitz*, 508 F. Supp. 2d at 446, *appeal docketed*, No. 07-3794 (3d Cir.). The Third Circuit heard argument in mid-September, 2008, and its opinion is imminent.

In any event, for reasons already described, *see supra* Point I, the issue warrants this Court's

immediate attention. Neither Petitioners nor the public have the luxury to allow the issue to percolate further, because the Georgia Supreme Court's position will precipitate a litigation deluge that will threaten public health.

III. THE GEORGIA SUPREME COURT ERRED IN HOLDING THAT THE VACCINE ACT DOES NOT PREEMPT ALL DESIGN DEFECT CLAIMS.

Review is also warranted because the Georgia Supreme Court erred at every step of its analysis—on its construction of the language of the preemption provision, the legislative history, and the structure of the Vaccine Act. The Court read the statute in a truncated fashion, improperly fixating upon Section 22(b)(1)'s language about "side effects that were unavoidable" and disregarding the remainder of the sentence. By ignoring those words, it arrived at a construction that betrayed Congress's intent that a side effect from an FDA-approved vaccine be considered "unavoidable" *as long as* "the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1). In other words, the provision immunizes vaccine manufacturers from *all* liability in any civil action for vaccine-related injury regardless of legal theory, unless the injury at issue could have been avoided by proper preparation or "proper directions and warnings"—with the proviso that directions and warnings are ordinarily presumed to be "proper" if they were FDA approved. 42 U.S.C. § 300aa-22(b)(2).

Like the other courts to address the issue, the Georgia Supreme Court recognized that Section 22(b)(1)'s language derives from the well-known Comment k to Section 402(A) of the Restatement (Second) of Torts. App. 7. Comment k protects a certain class of products from strict liability: products deemed to be "unavoidably unsafe" because they carry an inherent risk of injury. Restatement (Second) of Torts § 402A cmt. k. While various states have taken different paths to determining whether products are entitled to the protection of Comment k, the Georgia Supreme Court erred in failing to recognize that Congress made the blanket determination that childhood vaccines are "unavoidably unsafe" and should be categorically exempt from liability for injuries resulting from inherent risks. *See* H.R. Rep. at 26, 1986 U.S.C.C.A.N. at 6367 (stating that the principle of Comment k "appl[ies] to the vaccines covered in the [Act] and that such products not be the subject of liability in the tort system").

As to legislative history, the courts adhering to the majority view—and even the Georgia Court of Appeals, App. 30—have correctly pointed out that congressional intent could not be clearer. The legislative history "indicates rather clearly the Committee's intent to relegate design defect claims to the [Vaccine Court] compensation system." *Blackmon*, 328 F. Supp. 2d at 665; *see also Militrano*, 810 N.Y.S.2d at 508 (holding that the "Committee's discussion of the issue clearly establishes Congress' determination that the Comment k defense bars all [vaccine design defect] claims"). The key 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.*

H.R. Rep. at 26, 1986 U.S.C.C.A.N. at 6367 (emphasis added).

The Georgia Supreme Court erred in relying instead on a post-enactment legislative statement that other courts correctly ignored. *See* App. 13-14. Such subsequent legislative history is "a 'hazardous basis for inferring the intent of an earlier' Congress." *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)). That cautionary note is especially apt here. The 1987 committee report on which the court relied to discern Congress's intent a year earlier related to the funding of the Act. The funding amendments had nothing to do with the preemption clause's limitations on liability that govern post-Vaccine Court civil actions.

Perhaps the Georgia Supreme Court's most fundamental error, however, was to ignore the statutory structure and context for Section 22. The

Georgia Supreme Court declared, without any elaboration, that its analysis was "consistent with the structure and purpose of the Vaccine Act." App. 15 (citation omitted). In fact, the decision is at war with the Act's structure and purpose. While the Georgia Supreme Court's ruling assumes that permitting litigation over vaccine designs would lead to safer vaccines, *see* App. 17, Congress chose a very different policy. Congress saw the consequences of leaving vaccine injury litigation to a tort regime like the one the Georgia Supreme Court adopted here: a dangerously unstable vaccine market and the constant threat of a public health crisis.

The Georgia Supreme Court overlooked the perfect symmetry between a single federal standard for vaccine design and the Vaccine Act's complementary components. Congress commits the controlling evaluation of vaccine design to the FDA, with the input, monitoring, and enhancement of other NVP Agencies. This decision to empower a network of federal agencies to strike the optimum balance between safety and efficacy complements the decision to allow any person injured by a vaccine approved for nationwide use to seek no-fault compensation in the Vaccine Court, without having to prove (as state tort-law would require) that the safety-efficacy trade-off was unreasonable. With that uncommonly generous compensation program in place, Congress preempted tort litigation premised on the view that the vaccine that the FDA approved, and the other NVP Agencies vetted and monitored, should have been safer.

When Congress created this comprehensive scheme, it left no role for juries in 50 disparate state

tort regimes to second-guess the safety of a vaccine's approved design. Inconsistent determinations of the "safest" vaccine design by courts in different states would undermine the NVP Agencies' central role in combating the spread of infectious diseases. As this Court recognized just last Term, "[s]tate tort law that requires a manufacturer's [medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Riegel*, 128 S. Ct. at 1008. For reasons discussed above, this admonition is even truer for vaccines.

With the comprehensive and integrated program created by the Vaccine Act, Congress averted the public health crisis in 1986. This Court should grant this petition to review an opinion that invites the public health crisis back.

CONCLUSION

For the foregoing reasons, this Court should grant a writ of certiorari to review the judgment of the Supreme Court of Georgia.

Respectfully submitted,

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