No. 09-152

IN THE
Supreme Court of the United States

RUSSELL BRUESEWITZ, ET AL.,

Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, ET AL.,

Respondent.

On Writ of Certiorari
To the United States Court of Appeals
For the Third Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

Daniel J. Popeo
Cory L. Andrews
Counsel of Record
WASHINGTON LEGAL FOUNDATION
2009 Mass. Ave., NW
Washington, DC 20036
(202) 588-0302
candrews@wlf.org

Date: July 30, 2010

QUESTION PRESENTED

As part of a comprehensive scheme to shield vaccine manufacturers from the costs and risks of product liability litigation, the National Childhood Vaccine Injury Act of 1986 provides that "[n]o vaccine manufacturer shall be liable in a civil action" if the plaintiff's 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 Section 22(b)(1) expressly preempt all state-law claims against a vaccine manufacturer based on alleged defects in the design of a vaccine subject to the Act?

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iv

INTERESTS OF *AMICUS CURIAE* 1

STATEMENT OF THE CASE 2

SUMMARY OF THE ARGUMENT 5

ARGUMENT 9

I. PRIOR TO ENACTMENT OF THE VACCINE ACT, AN EXPLOSION IN LITIGATION AGAINST VACCINE MANUFACTURERS CAUSED A NATIONAL VACCINE CRISIS 9

II. IN DIRECT RESPONSE TO THE NATIONAL VACCINE CRISIS, CONGRESS PASSED THE VACCINE ACT TO HELP STABILIZE THE NATION'S VACCINE MARKET 14

CONCLUSION 19

TABLE OF AUTHORITIES

Page(s)

Cases:

Bates v. Dow Agrosciences LLC,
544 U.S. 431 (2005) 1

District of Columbia v. Heller,
128 S. Ct. 2783 (2008) 16

Geier v. Am. Honda Motor Co.,
529 U.S. 861 (2000) 1

Jacobson v. Massachusetts,
197 U.S. 11 (1905) 10

Reyes v. Wyeth Laboratories,
498 F.2d 1264 (5th Cir. 1974) 14

Riegel v. Medtronic, Inc.,
552 U.S. 312 (2008) 1, 18

Schafer v. Cyanamid Co.,
20 F.3d 1 (1st Cir. 1994) 16, 18

Sykes v. Glaxo-SmithKline,
484 F. Supp. 2d 289 (E.D. Pa. 2007) 17

Wyeth v. Levine,
129 S.Ct. 1187, 269 (2009) 1

Page(s)

Statutes:

26 U.S.C. § 4131 15

42 U.S.C. §§ 300aa-1, *et seq*. 2

42 U.S.C. § 300aa-10 15

42 U.S.C. § 300aa-11. . . . . 3, 15

42 U.S.C. § 300aa-15(a) 4, 15

42 U.S.C. § 300aa-15(e). 4, 15

42 U.S.C. § 300aa-19 15

42 U.S.C. § 300aa-22(b)(1). . . . . *passim*

Miscellaneous:

Breen, Elizabeth A., *A One Shot Deal: The National Childhood Vaccine Injury Act,* 41 Wm. & Mary L. Rev. 309 (1999) 9, 10, 12

Danzon, Patricia M., *et al.*, *Vaccine Supply: A Cross-National Perspective*, 24 Health Affairs 706 (May 27, 2005) 9

General Accountability Office, *Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily* (1999) 10

H.R. Rep. 99-908 (1986) . . . . . *passim*

Page(s)

Inglehart, John K., *Health Policy Report: Compensating Children with Vaccine-Related Injuries*, 316 New Eng. J. Med 1283 (1987) 13

Jacobi, Paula, *Pharmaceutical Tort Liability: A Justifiable Nemesis to Drug Innovation And Access?*, 38 J. Marshall L. Rev. 987 (2005) 13

Keiser, Randall B., *Deja Vu All Over Again? The National Childhood Vaccine Injury Compensation Act of 1986*, 47 Food & Drug L.J. 15 (1992) 11

Koch, Kathy, *Vaccine Controversies: Are Today's Vaccines Safe Enough?*, 10 Cong. Q. Researcher 641 (2000) 12

LaFetra, Deborah J., *Freedom, Responsibility, And Risk: Fundamental Principles Supporting Tort Reform*, 36 Ind. L. Rev. 645 (2003) 13

Levy, Elissa, *The Health Act's FDA Defense To Punitive Damages: A Gift to Drug Makers or to the Public?*, 74 Fordham L. Rev. 2425 (2006) 12

Neraas, Mary Beth, *Comment*, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 Wash. L. Rev. 149 (1988) 11, 12, 13

Page(s)

Offit, Paul A., *Lawsuits Won't Stop Pandemics*, Wall St. J., Dec. 1, 2005, at A16 . . . . . 9, 10

Ridgway, Derry, *No-Fault Vaccine Insurance: Lessons From the National Vaccine Injury Compensation Program*, 24 J. Health Pol. Pol'y & L. 59 (1999) 12

Schwartz, Victor E. & Goldberg, Phillip A., *Prescription for Drug Liability and Regulations*, 58 Okla. L. Rev. 135 (2005) 17

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit, public interest law and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. WLF regularly publishes monographs and other publications on these and related topics. In particular, WLF has regularly appeared as *amicus curiae* before this and numerous other federal courts in cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek to regulate the same activity. *See, e.g., Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000).

WLF is particularly concerned that individual freedom, the American economy, and the public health and welfare suffer whenever state law, especially state tort law, imposes on the vaccine industry additional costs and an unnecessary layer of regulation, both of which frustrate the objectives and operation of specific congressional schemes, such as (in this case) the National Childhood Vaccine Injury Act (the Vaccine Act).

---

[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief.

At issue here is whether Congress intended to preempt Petitioners' design defect claims. WLF agrees with Respondent and the U.S. Court of Appeals for the Third Circuit that Congress's preemptive intent under the facts of this case is expressly manifested by the Vaccine Act's preemption provision, 42 U.S.C. § 300aa-22(b)(1). WLF writes separately to emphasize that a contrary statutory interpretation undermines the important public policy undergirding the Vaccine Act's enactment–namely, the facilitation and stabilization of a robust childhood vaccine market.

WLF has no direct interest, financial or otherwise, in the outcome of this case. WLF submits this brief solely to further the public's interest in the important preemption issues raised by this case. All parties have consented to the filing of this brief by lodging their consents in the Court's docket.

STATEMENT OF THE CASE

This case raises important issues about the continued viability of a national childhood vaccine market, the preservation of which is a central aim of the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act), 42 U.S.C. §§ 300aa-1 *et seq*. In their efforts to expose the nation's vaccine manufacturers to state-court tort liability for alleged design defects, Petitioners ignore both the market realities and the important public policy considerations that initially prompted Congress to pass the Vaccine Act.

In response to an explosion in vaccine litigation costs that seriously threatened to destabilize the nation's vaccine market, Congress passed the Vaccine Act, which

established a national, comprehensive, no-fault compensation system for vaccine-related injuries. In order to protect vaccine manufacturers from the same kind of burdensome litigation that had already driven many manufacturers from the market, Congress included an express preemption provision in Section 22(b)(1) of the Vaccine Act to limit the scope of damage claims that can be brought against a vaccine manufacturer. Section 22(b)(1) 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 provision bars state-law tort liability against childhood vaccine manufacturers for all possible claims except those alleging a manufacturing defect or a failure to warn.

Although preempting all state-law tort claims (other than manufacturing defect and failure-to-warn claims), the Vaccine Act provides a generous administrative compensation scheme that is funded by Congressional appropriation and an excise tax on vaccines. Under this no-fault compensation scheme, claimants are relieved from the obligation to prove fault–they need establish only an injury that occurred within the time frame specified in the federal "vaccine table" or prove a vaccine-related injury. 42 U.S.C. §

300aa-11. A successful claimant may recover unlimited medical expenses, medical care, lost earnings, and up to $250,000 for pain and suffering. *Id.* at § 300aa-15(a). Regardless of whether they receive compensation, claimants may recover attorney's fees and costs. *Id.* at § 300aa-15(e).

In 1995, Russell and Robalee Bruesewitz (the Bruesewitzes) petitioned the Vaccine Court to compensate their daughter's injuries, which they alleged were caused by a Diptheria, Tetanus, and Pertussis (DTP) vaccination administered in 1992. Pet. App. at A-8. After a full evidentiary hearing, the Vaccine Court dismissed with prejudice the Bruesewitzes' petition for failure to establish any causal link between the administered DTP vaccine and their daughter's injuries. *Id.* at A-9.

Rather than appeal their dismissal to the Court of Federal Claims, the Bruesewitzes rejected the judgment of the Vaccine Court and filed a products liability suit against Wyeth in the Philadelphia County Court of Common Pleas. *Id.* On the basis of diversity jurisdiction, Wyeth removed the suit to the United States District Court for the Eastern District of Pennsylvania. *Id.* The Bruesewitzes' complaint sought in part to recover damages in strict liability for an alleged design defect in the DTP vaccine. *Id.*

Following extensive discovery, Wyeth moved for summary judgment in part on the grounds that Section 22(b)(1) of the Vaccine Act preempts all design defect claims arising from a vaccine-related injury or death. The district court invited, *sua sponte*, the U.S. Food and Drug Administration (FDA) and the U.S. Department of

Health and Human Services (HHS) to submit an *amicus* brief on the preemption question. *Id.* at A-112. In a letter to the district court, both the FDA and HHS responded that they had no official view on preemption because neither is a party to a civil action commenced after a claimant exhausts the administrative compensation process, nor do they administer any of the statutory provisions that govern such actions. *Id.* at A-107-09.

Adopting the statutory interpretation urged by Wyeth, the district court held that Section 22(b)(1) expressly preempted the Bruesewitzes' design defect claim. *Id.* at A-87. On appeal, the U.S. Court of Appeals for the Third Circuit affirmed. Recognizing that the statutory text, structure, and legislative history of the Vaccine Act evidenced "a 'clear and manifest' expression of congressional intent" to preempt all design defect claims, the appeals court held that the Bruesewitzes' design defect claim was preempted by Section 22(b)(1). *Id.* at A-30. In doing so, the Third Circuit panel expressly rejected the construction of the Vaccine Act urged by the Bruesewitzes, concluding that allowing plaintiffs to bring design defect claims against vaccine manufacturers would yield the "very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act." *Id.* at A-36.

SUMMARY OF ARGUMENT

The Bruesewitzes urge this Court to construe the Vaccine Act in a way that ignores both the unique and vital role vaccines have historically played in safeguarding the public health, as well as the national

health emergency that arose in the 1980s due to the very patchwork of state tort liability that the Bruesewitzes now seek to revive. At issue is whether Congress intended to preempt the Bruesewitzes' design defect claims. As Respondent ably demonstrates, and the U.S. Court of Appeals for the Third Circuit correctly found, Congress's preemptive intent under the facts of this case is expressly manifested by the Vaccine Act's preemption provision, 42 U.S.C. § 300aa-22(b)(1). But a contrary statutory interpretation would also undermine the important public policy undergirding the Vaccine Act's enactment–namely, the facilitation and stabilization of a robust childhood vaccine market.

Since their widespread development and use over a century ago, childhood vaccines have enjoyed remarkable success. Vaccinations have saved countless lives and further prolonged the life expectancy of millions of people. Perhaps more than any other medical innovation, vaccines have played a decisive role in enhancing the quality of life of people in the United States**.** Likewise, childhood vaccines have enjoyed overwhelming success in reducing the incidence of communicable diseases. Physicians and other public health experts widely champion vaccines as the single most effective means of disease prevention. Yet, notwithstanding their immense benefit to the vast majority of recipients, vaccines are not immune from the law of unintended consequences. As is true for any prescription drug or pharmaceutical product on the market, childhood vaccines may pose adverse side effects to a small fraction of children who receive them.

Following an escalation in media coverage of vaccine-related injuries in the 1970s, more and more

allegedly injured individuals began bringing civil suits against vaccine manufacturers and administrators. In fact, between 1980 and 1986, plaintiffs sought claims against vaccine manufacturers in excess of $3.5 billion. During this time, juries issued increasingly extravagant punitive damages awards for plaintiffs, even in cases where no conclusive scientific evidence could causally link the administered vaccine to the plaintiff's injury.

Vaccine manufacturers responded to the increased threat of exorbitant litigation costs by exiting the marketplace, which threatened to leave children vulnerable to many preventable diseases. In four short years, the cost for a dose of the DTP vaccine increased from only $0.11 in 1982 to $11.40 in 1986, with approximately $8.00 of that price strictly allocated to liability insurance. By 1985, only four manufacturers still produced the childhood vaccines that states required for public school immunizations. By the end of the 1980s, ten of the thirteen companies manufacturing crucial childhood vaccines had exited the marketplace. Crippled by the explosive costs of surging vaccine-related litigation, vaccine manufacturers became both unable and unwilling to meet the nation's childhood vaccine needs.

In direct response to the nation's emerging vaccine crisis, a national consensus quickly developed in favor of creating a no-fault reimbursement regime to shield manufacturers from liability, which in turn would help to promote the continued, long-term viability of a national vaccine market. At the same time, even victims of vaccine-related injuries criticized the high cost of litigation necessary to obtain an adequate recovery, which could remain uncertain and elusive under a

traditional tort-law civil justice system. It was against this backdrop of vaccine shortages and out-of-control costs that Congress passed the National Childhood Vaccine Injury Act of 1986, which established a national, comprehensive, no-fault compensation system for vaccine-related injuries.

In considering the Vaccine Act, Congress found that "[t]he number of childhood vaccine manufacturers [had] declined significantly," while the remaining few were forced "to question their continued participation in the vaccine market." H.R. Rep. No 908, 99th Cong., 2d Sess. 7 (1986). Congress specifically recognized that the "withdrawal of even a[nother] single manufacturer would present a very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." *Id*. In order to protect vaccine manufacturers from the same kind of burdensome litigation that had already driven many manufacturers from the market, Congress included an express preemption provision in Section 22(b)(1) to limit the scope of damage claims that can be brought against a vaccine manufacturer. This preemption provision, by shielding vaccine manufacturers from design defect liability, is the linchpin of the Vaccine Act.

The contrary interpretation of the Vaccine Act urged by the Bruesewitzes would completely undermine one of the principal policy considerations that influenced Congress's decision to pass the Vaccine Act. Allowing a disappointed vaccine claimant who lost in the Vaccine Court to then seek compensation for design defects via civil tort litigation would exacerbate, not remedy, the burden of litigation and the threat of large and

unpredictable jury awards against vaccine manufacturers. Nor would it do anything to help to control the skyrocketing costs that would result from extravagant civil jury awards. In weighing the costs and benefits of a robust vaccine market, Congress elected for uniform administrative regulation over a patchwork of state tort law.

ARGUMENT

I. PRIOR TO ENACTMENT OF THE VACCINE ACT, AN EXPLOSION IN LITIGATION AGAINST VACCINE MANUFACTURERS CAUSED A NATIONAL VACCINE CRISIS

Since their widespread development and use over a century ago, childhood vaccines have enjoyed remarkable success. Vaccinations have saved countless lives and further prolonged the life expectancy of millions of people. Perhaps more than any other medical innovation, vaccines have played a decisive role in enhancing the quality of life of people in the United States, where vaccines provide "an extremely cost-effective technology for dealing with killer diseases, saving lives, and averting millions of dollars of potential health spending." Patricia M. Danzon, *et al.*, *Vaccine Supply: A Cross-National Persepctive*, 24 Health Affairs 706 (May 27, 2005). During the 20th century, for example, "the lifespan of Americans increased by 30 years–mostly because of vaccines." Paul A. Offit, *Lawsuits Won't Stop Pandemics*, Wall St. J., Dec. 1, 2005, at A16.

Likewise, childhood vaccines have enjoyed overwhelming success in reducing the incidence of

communicable diseases. Physicians and other public health experts widely champion vaccines as the "single most effective [means of] health prevention." Elizabeth A. Breen, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 Wm. & Mary L. Rev. 309, 311-12 (1999) (citation omitted). Indeed, "[v]accination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. Rep. No 908, 99th Cong., 2d Sess. 4 (1986). According to the U. S. General Accountability Office (GAO), vaccination in the United States has resulted in a ninety-five percent reduction in the total number of people who contract "vaccine-preventable diseases." GAO, *Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily*, at 1 (1999). The introduction of widespread vaccinations saw the number of children afflicted by polio decrease from over 15,000 each year to zero. *See* Offit, *supra* at A16.

As early as 1905, this Court acknowledged the vital role vaccines play in safeguarding America's public health. In *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), the Court upheld a local ordinance requiring mandatory smallpox vaccinations for all residents. Writing for the Court, Justice Harlan emphasized that because "vaccination, as a means of protecting a community against smallpox, finds strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that particular method was–perhaps or possibly–not the best for either children or adults." *Jacobson*, 197 U.S. at 35. Following the Court's ruling in *Jacobson*, other states

quickly followed suit, and widespread mandatory vaccine use was implemented across the country. In fact, "[a]ll fifty states and the District of Columbia have immunization requirements for children that must be met before they may attend public school." Breen, *supra* at 311.

Notwithstanding their immense benefit to the vast majority of recipients, vaccines are not immune from the law of unintended consequences. As is true for any prescription drug or pharmaceutical product on the market, childhood vaccines may give rise to adverse side effects among a small fraction of children who receive them. As the number of doses of vaccines administered has risen dramatically, so too has the number of reported but unintentional side effects. *See, e.g.,* Randall B. Keiser, *Deja Vu All Over Again? The National Childhood Vaccine Injury Compensation Act of 1986*, 47 Food & Drug L.J. 15, 15 (1992). Adverse reactions can vary from "local reactions at the injection sight [sic], such as redness or swelling, to more systemic reactions such as convulsions or very high fevers." *Id.* at 16.

Of course, it is virtually impossible to predict precisely what reaction, if any, a child will have to a given vaccine. *See* H.R. Rep. No. 99-908, at 6 (1986) (confirming that there is no "reaction-free" vaccine available, and that it is "not always possible to predict" which children will react adversely or how severe those reactions will be). Ultimately, only a small percentage of children who are vaccinated will ever suffer a serious injury. *See, e.g.,* Mary Beth Neraas, *Comment*, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 Wash. L. Rev. 149, 150 (1988) (explaining that only a "tiny fraction" of

children will suffer from a significant adverse reaction to a vaccination). And the overwhelming majority of adverse reactions to vaccines are found to result from the "unavoidable cost of mass inoculation" and are not the fault of the vaccine manufacturer. *Id.* at 150-51.

With millions of vaccinations administered in the United States each and every year, the number of reported cases of adverse reactions resulting in vaccine-related injuries grew. By 1976, highly publicized reports in the media only further sensationalized the issue of vaccination, at a time when "many people reportedly contracted Gullain-Barré Syndrome after being vaccinated against the swine flu, an epidemic that never materialized." Kathy Koch, *Vaccine Controversies: Are Today's Vaccines Safe Enough?*, 10 Cong. Q. Researcher 641, 645 (2000). A 1982 television documentary entitled "DPT Vaccine Roulette" further stoked fears about the dangers of the DTP vaccine by highlighting the stories of children who suffered neurological disabilities after receiving their DTP vaccinations. *Id.*; *see also* Breen, *supra* at 315.

In the wake of escalating media coverage, more and more allegedly injured individuals began bringing civil suits against vaccine manufacturers and administrators. By the 1980s, the prospect of obtaining a lucrative jury verdict led a growing number of civil plaintiffs to file "ever larger claims against [vaccine] manufacturers." Derry Ridgway, *No-Fault Vaccine Insurance: Lessons From the National Vaccine Injury Compensation Program*, 24 J. Health Pol. Pol'y & L. 59, 60 (1999). In fact, between 1980 and 1986, plaintiffs sought claims in excess of $3.5 billion, and many observers predicted potentially unlimited liability for

vaccine manufacturers in the future. *Id.* at 60-61. During this time, juries issued increasingly extravagant punitive damages awards even in cases where no conclusive scientific evidence could causally link the administered vaccine to the plaintiff's injury. Elissa Levy, *The Health Act's FDA Defense to Punitive Damages: A Gift to Drug Makers or to the Public?*, 74 Fordham L. Rev. 2425, 2431 (1006).

As a consequence of the unpredictable nature of tort liability, which typically varied widely from state to state, many pharmaceutical companies simply stopped manufacturing and distributing vaccines. *See* Neraas, *supra* at 152. Indeed, "exposure to large damage awards provided the economic justification for companies to stop research and production." Paula Jacobi, *Pharmaceutical Tort Liability: A Justifiable Nemesis to Drug Innovation and Access?*, 38 J. Marshall L. Rev. 987, 989 (2005). As a result, vaccine prices skyrocketed. For example, in four short years, the cost for a dose of the DTP vaccine increased from only $0.11 in 1982 to $11.40 in 1986, with approximately $8.00 of that price explicitly allocated to liability insurance. John K. Inglehart, *Health Policy Report: Compensating Children with Vaccine-Related Injuries*, 316 New Eng. J. Med. 1283, 1286 (1987).

Such increased exposure to tort liability quickly forced the few remaining vaccine manufacturers to dedicate "an ever larger percentage of revenues from vaccine sales to the costs of insurance and of defending against potential liability." Deborah J. LaFetra, *Freedom, Responsibility, and Risk: Fundamental Principles Supporting Tort Reform*, 36 Ind. L. Rev. 645, 650 (2003). By 1985, only four manufacturers still produced the childhood vaccines that states required for

public school immunizations. *See* Neraas, *supra* at 152. By the end of the 1980s, ten of the thirteen companies manufacturing crucial childhood vaccines had exited the marketplace. *See* Lafetra, *supra* at 650. Crippled by the explosive costs of surging vaccine-related litigation, vaccine manufacturers became both unable and unwilling to meet the nation's childhood vaccine needs. It was against this backdrop of vaccine shortages and out-of-control costs that Congress passed the Vaccine Act.

II. IN DIRECT RESPONSE TO THE NATIONAL VACCINE CRISIS, CONGRESS PASSED THE VACCINE ACT TO HELP STABILIZE THE NATION'S VACCINE MARKET

As early as 1974, in the case of *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974), Judge John Minor Wisdom suggested (in dicta) that compensation for unavoidable vaccine-related injuries should be borne primarily by price increases passed on to the public, without a finding of negligence on the part of manufacturers. This proposal was later reinforced in influential peer-reviewed pediatric journals, which helped to rally policy makers behind a no-fault liability scheme for vaccine-related injuries. Ridgway, *supra* at 41.

In direct response to the nation's emerging vaccine crisis, a national consensus quickly developed in favor of creating a no-fault reimbursement regime to shield manufacturers from liability, which in turn would help to promote the continued, long-term viability of a national vaccine market. At the same time, even victims of vaccine-related injuries criticized the high cost of

litigation necessary to obtain an adequate recovery, which could remain uncertain and elusive under a traditional tort-law civil justice system. Most experts agreed that any viable no-fault compensation scheme would need to remedy each of these concerns.

In 1986, Congress enacted the Vaccine Act, which established a national, comprehensive, no-fault compensation system for vaccine-related injuries. Designed to encourage "development and distribution of vaccines that will further enhance the public health," the Vaccine Act establishes the National Vaccine Injury Compensation Program, which offers monetary awards to those who suffer injuries causally linked to specific childhood vaccines. H.R. Rep. No. 99-908, at 7 (1986). In order to protect vaccine manufacturers from the same kind of burdensome litigation that had already driven many manufacturers from the market, Congress included an express preemption provision in Section 22(b)(1) to limit the scope of damage claims that can be brought against a vaccine manufacturer. This provision bars state-law tort liability against vaccine manufacturers for all claims except those alleging manufacturing defect and failure to warn. *See* 42 U.S.C. § 300aa-22(b)(1).

While preempting all state-law tort claims (other than manufacturing defect and failure-to-warn claims), the Vaccine Act also provides a generous administrative compensation scheme that is funded by Congressional appropriations and an excise tax on vaccines. *Id.* at § 300aa-10 to 300aa-19; 26 U.S.C. § 4131. Under this no-fault compensation scheme, claimants are relieved from the obligation to prove fault–they only need establish an injury that occurred within the time frame specified in

the federal "vaccine table" or else prove a vaccine-related injury. 42 U.S.C. § 300aa-11. A successful claimant may recover unlimited medical expenses, medical care, lost earnings, and up to $250,000 for pain and suffering. *Id.* at § 300aa-15(a). And, regardless of whether they receive compensation, claimants may recover attorney's fees and costs. *Id.* at § 300aa-15(e).

Although not dispositive, it is often useful to consult a statute's legislative history to determine the goals articulated by members of Congress while debating the proposed statute. As this Court has recently recognized, historical statements by those who drafted or voted for a law are relevant "not because they reflect the general understanding of the disputed terms, but because the legislators who heard or read those statements presumably voted with that understanding." *District of Columbia v. Heller*, 128 S. Ct. 2783, 2805 (2008). Examination of the Congressional Record makes clear that those members of Congress who debated the Vaccine Act legislation in 1986 believed they were enacting a law aimed at addressing "two overriding concerns": (1) "the inadequacy–from both the perspective of vaccine-injured persons as well as vaccine manufacturers–of [a tort-based] approach to compensating those who have been damaged by a vaccine," and (2) "the instability and unpredictability of the childhood vaccine market" arising from the manufacturers' increased exposure to tort liability. H.R. Rep. No. 99-908, at 7 (1986).

In considering the Vaccine Act, Congress found that "[t]he number of childhood vaccine manufacturers [had] declined significantly, while the remaining few were forced "to question their continued participation in

the vaccine market." *Id.* at 4, 7. Congress specifically recognized that the "withdrawal of even a[nother] single manufacturer would present a very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." *Id*

Most relevant here, the Vaccine Act's preemption of state tort law under Section 22(b)(1) is the linchpin by which Congress sought to allay the vaccine industry's fears of "instability and unpredictability of the childhood vaccine market" due to abusive tort liability. *See, e.g., Schafer v. Am. Cyanamid Co.,* 20 F.3d 1, 4 (1st Cir. 1994) ("[A]n important federal purpose of the Act is to free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufacturers in the market."); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007) (confirming that the Vaccine Act was enacted "to prevent manufacturers from leaving vaccine production or significantly increasing prices, while at the same time compensat[ing] victims of vaccine related injuries quickly").

In weighing the costs and benefits of a robust vaccine market, Congress elected for uniform administrative regulation over a patchwork of state tort law. In the context of childhood vaccines, a national preemption scheme is absolutely crucial because the risk analysis for vaccines involves a "forward-looking" assessment of future liability for future conduct before any injury occurs. Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 Okla. L. Rev. 135, 135-136 (2005). And by preempting tort law claims, the Vaccine Act has succeeded in

promoting a robust national vaccine market. Indeed, since the Vaccine Act took effect over 20 years ago, more than 20 new childhood vaccines have obtained FDA approval and been introduced to the market. *See* Resp. Br. at 15-16.

In sum, the interpretation of the Vaccine Act urged by the Bruesewitzes would completely undermine one of the principal policy considerations that influenced Congress's decision to pass the Act. Allowing a disappointed vaccine claimant who lost in the Vaccine Court to then seek full compensation via civil tort litigation would exacerbate, not remedy, the burden of litigation and the threat of large and unpredictable jury awards against vaccine manufacturers. Nor would it do anything to help to control the skyrocketing costs that would result from extravagant civil jury awards. As this Court has previously acknowledged in the related area of medical devices, "[a] jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008). Nowhere is this truer than in the context of childhood vaccines, where, "even though vaccines themselves cause a small number of serious injuries or deaths, their widespread use dramatically reduces fatalities." *Schafer,* 20 F.3d at 4.

CONCLUSION

Amicus curiae WLF requests that the Court affirm the judgment below.

Respectfully submitted,

Daniel J. Popeo
Cory L. Andrews
Counsel of Record
WASHINGTON LEGAL FOUNDATION
2009 Mass. Ave., NW
Washington, DC 20036
(202) 588-0302
candrews@wlf.org

Date: July 30, 2010