No. 09-152

IN THE
Supreme Court of the United States

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

v.

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

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

BRIEF AMICI CURIAE OF THE AMERICAN ACADEMY OF PEDIATRICS AND 21 OTHER PHYSICIAN AND PUBLIC HEALTH ORGANIZATIONS IN SUPPORT OF RESPONDENT

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STATEMENT OF INTEREST OF AMICI CURIAE

Founded in 1930, amicus curiae the American Academy of Pediatrics ("AAP") is a national, not-for-profit organization dedicated to furthering the interests of children's health.[1] Since AAP's inception, its

[1] Pursuant to Sup. Ct. R. 37.6, amici note that no counsel or party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the

membership has grown from 60 pediatricians to over 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 80 years, AAP has become a powerful voice for children's health through education, research, advocacy, and the provision of expert advice. AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's children to ensure the availability of safe and effective childhood vaccines, the vast majority of which are administered in pediatricians' offices after careful consultation with parents. AAP was directly involved in the drafting of the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 *et seq*., and was a driving force behind the legislation.

Amicus curiae the AAP Section on Infectious Diseases was founded in 1990. It is comprised of AAP members who have a special interest in pediatric infectious diseases.

Amicus curiae the American Academy of Family Physicians ("AAFP"), founded in 1947 and headquartered in Leawood, Kansas, is the national association of family doctors. It is comprised of approximately 94,000 physician, resident, and student members in all 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, and the Uniformed Services of the United States. The overall mission of the AAFP is to improve the health of patients, families,

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preparation or submission of this brief. No person or entity other than amici or their members made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

and communities by serving the needs of members with professionalism and dignity.

Amicus curiae the American College of Osteopathic Pediatricians ("ACOP") is the official pediatric organization of the American Osteopathic Association. ACOP's advocacy efforts represent the interests of all U.S. osteopathic pediatricians before Congress and other governmental bodies as well as in coalition with other organizations that focus on children's welfare.

Amicus curiae the American College of Preventive Medicine ("ACPM") is the national medical society for nearly 2,500 preventive medicine physicians who are uniquely trained in both clinical and population-based medicine and who are committed to disease prevention and health promotion. Immunizations represent a major success in public health and their economic and health benefits have been well documented. ACPM believes adults and children should receive appropriately timed vaccinations that are safe and effective to protect individual and public health.

Amicus curiae the American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups, seated in the AMA's House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. Its members practice in every state

and in every field of medical specialization, including pediatrics. The AMA has long been a vocal advocate of the importance of vaccines in maintaining high standards of public health in the United States.

Founded in 1872, amicus curiae the American Public Health Association ("APHA"), is the oldest and most diverse organization of public health professionals in the world. The association aims to protect all Americans and their communities from preventable, serious health threats and strives to assure that population-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States. APHA represents a broad array of health providers, educators, environmentalists, policymakers, and health officers. APHA has a long-standing policy in support of safe and effective vaccines for children.

Amicus curiae the Association of State and Territorial Healthcare Officials ("ASTHO") is the national nonprofit organization representing the public health agencies of the United States, the U.S. Territories, and the District of Columbia, as well as the 120,000 public health professionals these agencies employ. ASTHO members, the chief health officials of these jurisdictions, are dedicated to formulating and influencing sound public health policy and to assuring excellence in state-based public health practice. ASTHO's vision is healthy people thriving in a nation free of preventable illness and injury.

Amicus curiae the Center for Vaccine Awareness and Research at Texas Children's Hospital in Houston was launched in 2008 to improve the health of mothers and children from infancy through adolescence by promoting and optimizing vaccine delivery

through research and through education of healthcare providers and families. The Center optimizes effective delivery of vaccinations through research, education, and advocacy, develops models to advance public health through maternal, infant, child, and adolescent immunization, and conducts vaccine research from initial feasibility studies through implementation.

Amicus curiae Every Child By Two, Carter/Bumpers Champions for Immunization ("ECBT") is a nonprofit health advocacy organization based in the United States and dedicated to protecting children from disease through promotion of vaccinations and raising parental awareness of potential vaccine benefits. ECBT was founded in 1991 by former First Lady of the United States Rosalynn Carter and former First Lady of Arkansas Betty Bumpers.

Amicus curiae the Immunization Action Coalition ("IAC") is a nonprofit organization that works to increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public that enhance the delivery of safe and effective immunization services. IAC also facilitates communication about the safety, efficacy, and use of vaccines within the broad immunization community of patients, parents, healthcare organizations, and government health agencies.

Amicus curiae the Infectious Diseases Society of America ("IDSA") represents more than 9,000 infectious disease physicians and scientists devoted to patient care, research, prevention, and public health. IDSA's purpose is to improve the health of individuals, communities, and society by promoting excel-

lence in patient care, education, research, public health, and prevention relating to infectious diseases. Its members care for patients of all ages with serious and life-threatening infections, including vaccine-preventable diseases.

Amicus curiae the March of Dimes Foundation is the leading U.S. nonprofit organization dedicated to pregnancy and the health of infants and children. Its mission is to improve the health of babies by preventing birth defects, premature birth, and infant mortality. The March of Dimes supports continuing efforts to increase immunization coverage so that children are protected from vaccine-preventable diseases to assure that diseases of the past do not return. The March of Dimes supports professional, general public, and parent education about the importance of immunizations, and also funds research into new vaccines with the potential for preventing birth defects.

Amicus curiae Meningitis Angels is a nonprofit, public advocacy organization founded in memory of Ryan Wayne Milley and dedicated to victims of bacterial meningitis and their families. Meningitis Angels educates the public, schools, daycares, colleges, the government, and the media on bacterial meningitis and its preventions, including immunizations, and promotes and sometimes conducts research on meningitis and its after-effects. Meningitis Angels works to ensure the continued availability and accessibility of immunizations to protect against vaccine-preventable diseases like bacterial meningitis.

Amicus curiae the National Association of Pediatric Nurse Practitioners ("NAPNAP") is an association of

nearly 7,500 health care providers who are committed to improving the health care of infants, children, adolescents, and young adults. NAPNAP publishes immunization materials regularly. Its Immunization Special Interest Group includes numerous experts who explore and discuss current issues of pediatric immunizations; participate at various national immunization meetings; and promote established immunization schedules and materials regarding vaccine preventable diseases and immunization practices.

Amicus curiae the National Foundation for Infectious Diseases is a nonprofit organization founded in 1973 and dedicated to providing professional and public education about the causes, prevention, and treatment of infectious diseases.

Amicus curiae the National Healthy Mothers, Healthy Babies Coalition promotes maternal and child health among a wide variety of audiences, including parents, health care professionals, and policymakers. Since its beginnings in 1981, the Coalition has promoted immunization across the lifespan as an essential strategy for optimal health. Education on this topic has been integral to the Coalition's work to ensure that every child has the best possible start and a safe and healthy environment in which to grow. The Coalition believes that it is particularly important that infants and children, those caring for them, and anyone they come in contact with be up-to-date on their immunizations so that they have full protection against vaccine-preventable diseases.

Amicus curiae the National Meningitis Association, Inc. ("NMA") is a nonprofit organization founded by

parents whose mission is to educate families, medical professionals, and others about meningococcal meningitis and prevention approaches to the disease. NMA is focused on raising awareness and protection among adolescents and young adults, many of whom can be protected through education and vaccination efforts.

Amicus curiae Parents of Kids with Infectious Diseases ("PKIDs"), a Washington nonprofit corporation, is a national association of individuals and families affected by infectious diseases, as well as healthcare professionals and others involved in disease prevention. PKIDs is the first parent nonprofit established in the United States to fight for the importance of vaccination. PKIDs was founded in 1997 to assist families affected by infectious diseases and to educate the public on various methods of disease prevention, and these remain its core purposes. PKIDs has long been a vocal advocate of the importance of vaccines in achieving high standards of public health in the United States.

Amicus curiae the Pediatric Infectious Diseases Society ("PIDS") is the world's largest organization of professionals dedicated to the treatment, control, and eradication of infectious diseases affecting children. PIDS's mission is to enhance the health of infants, children, and adolescents by promoting excellence in diagnosis, management, and understanding of infectious diseases through clinical care, education, research, and advocacy.

Founded in 1968, amicus curiae the Society for Adolescent Health and Medicine ("SAHM") is a multidisciplinary, international organization committed to improving the physical and psychosocial

health and well-being of all adolescents through advocacy, clinical care, health promotion, health service delivery, professional development, and research. The SAHM Vaccination Committee and SAHM members around the world actively work to ensure that all adolescents and young adults can access and afford recommended vaccines.

Amicus curiae the Vaccine Education Center at the Children's Hospital of Philadelphia was launched in 2000 to provide accurate, comprehensive, and up-to-date information about vaccines and the diseases they prevent to parents and healthcare professionals. The Center communicates facts about vaccines, including how vaccines are made, how and why vaccines work, who recommends them, whether they are safe, whether they are still necessary, and when they should be administered to patients.

Amici—all of whom support the routine vaccination of children against a host of vaccine-preventable infectious diseases—urge this Court to affirm the judgment of the Third Circuit below. As explained further below, Congress enacted the Vaccine Act to avert a public health crisis and thus safeguard the Nation's vaccine supply. As the Third Circuit correctly recognized, Congress achieved that objective in part by expressly preempting "*all* design defect claims, including those based in negligence." *Bruesewitz* v. *Wyeth Inc.*, 561 F.3d 233, 248 (3d Cir. 2009) (emphasis added).

Petitioners contend that the Act preempts design defect claims "*only* upon a threshold showing that the vaccine's side effects could not have been prevented." Pet. Br. 25 (emphasis added). That approach—which would allow judges *and juries* to

decide on a case-by-case basis whether a particular vaccine can be made safer—threatens a resurgence of "the very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act" in the first place. *Bruesewitz,* 561 F.3d at 249. This Court should accordingly reject petitioners' attempt to render Congress's action an exercise in futility.

SUMMARY OF ARGUMENT

The public health benefits of childhood vaccines cannot be overstated. Because of vaccines, a number of debilitating and life-threatening infectious diseases have been eliminated or virtually eliminated in this country, thereby not only enhancing the length and quality of life of countless children, but also providing significant savings in direct and indirect costs. It is no wonder that Congress has declared that "[t]he availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities." H.R. Rep. No. 99-908, at 5 (1986).

In the mid-1980s, the number of vaccine-related lawsuits filed against vaccine manufacturers rose sharply. Although the tort system failed to provide adequate compensation for many children injured by vaccines, the flood of vaccine-related litigation overwhelmed vaccine manufacturers. A genuine threat to the public health emerged as manufacturers abandoned or considered abandoning the vaccine market. As the then-President of the AAP testified: "The threat to our vaccine supply in this country is a real one * * *. We could lose the remainder of our suppliers unless some positive legislative action is taken." *National Childhood Vaccine Injury Compensation Act of 1985: Hearing Before the S. Comm. on*

Labor and Human Resources, 99th Cong. 8 (Dec. 9, 1985) (hereinafter "*Dec. 9, 1985 Hearing*") (statement of Martin Smith, M.D., President of the AAP).

Congress responded by passing the Vaccine Act. The Act established a no-fault alternative compensation program intended to provide adequate compensation to children injured by vaccines and to ensure the stability of the vaccine market and thus safeguard the Nation's vaccine supply. As the Third Circuit below correctly recognized, the Act furthers that latter objective in part by expressly preempting "*all* design defect claims, including those based in negligence." *Bruesewitz*, 561 F.3d at 248 (emphasis added).

Petitioners contend that the Act preempts design defect claims "*only* upon a threshold showing that the vaccine's side effects could not have been prevented." Pet. Br. 25 (emphasis added). As the Third Circuit explained, however, if the Vaccine Act is interpreted "to allow case-by-case analysis of whether particular vaccine side effects are avoidable," then "*every* design defect claim is subject to evaluation by a court." *Bruesewitz*, 561 F.3d at 246 (emphasis added). Thus, adoption of petitioners' interpretation of the Act could precipitate the same crisis that Congress sought to avert in passing the Vaccine Act: "the very real possibility of vaccine shortages, and, in turn increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." H.R. Rep. No. 99-908, at 7.

ARGUMENT

I. VACCINE DEVELOPMENT IS ONE OF THE GREATEST PUBLIC HEALTH ACHIEVEMENTS OF THE TWENTIETH CENTURY.

The "[v]accination of children against deadly, disabling, but preventable infectious disease has been one of the most spectacularly effective public health initiatives this country has ever undertaken." *Id*. at 4. *See also* Centers for Disease Control and Prevention, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 MMWR 241 (Apr. 2, 1999) (listing vaccination as one of the ten greatest public health achievements of the twentieth century). Indeed, "the sharp and deep reduction in [infectious] diseases * * * is [largely] attributable to the development and employment of effective vaccines." *Immunization and Preventive Medicine, 1982: Hearing Before the Subcomm. on Investigations and General Oversight of the S. Comm. on Labor and Human Resources*, 97th Cong. 103 (May 7, 1982) (hereinafter "*1982 Hearing*") (statement of Vincent A. Fulginiti, MD, Chairman, Committee on Infectious Diseases, AAP).

Because of vaccines, smallpox has been eradicated worldwide, Sandra W. Roush, *et al*., *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 JAMA 2155, 2160 (2007), and polio, diphtheria, and tetanus have essentially been eliminated in the United States. H.R. Rep. No. 99-908, at 5. In 2007, cases of measles, mumps, rubella, and pertussis (whooping cough) were reduced by more than 90% of twentieth century baseline levels. American Academy of

Pediatrics, *Red Book: 2009 Report of the Comm. on Infectious Diseases* 2 (28th ed. 2009).

The significance of these developments is beyond dispute: "[C]hildren in the United States enjoy substantial freedom from the ravages of once common communicable infectious diseases and illnesses. These illnesses limited life expectancy and left tens of thousands disabled in their wake." *1982 Hearing*, *supra*, at 103 (statement of Vincent A. Fulginiti, MD, Chairman, Committee on Infectious Diseases, AAP). Indeed, it has been estimated that vaccination with just seven of the routinely recommended childhood vaccines "prevents an estimated 33,000 deaths and 14 million cases of disease in every birth cohort." Roush, *et al.*, *supra*, at 2160.

Notably, vaccines have achieved such success by protecting not only those who have been immunized, but others in the community who have not: "[F]or some diseases where there is person-to-person transmission, reducing the incidence by vaccination results in 'herd immunity,' with reduction of risk for all community members regardless of their individual immunization status." National Institute of Allergy and Infectious Diseases and National Institutes of Health, Task Force on Safer Childhood Vaccines, *Final Report and Recommendations* 12 (January 1998). *See also* Committee on Practice and Ambulatory Medicine and Council on Community Pediatrics, *Increasing Immunization Coverage*, 125 Pediatrics 1295, 1296 (2010) ("for most vaccine preventable diseases, achieving high levels of immunization in the community offers indirect protection to others").

Vaccines have also translated into direct savings in medical costs, as well as increased productivity from families that would otherwise be burdened by disease. Institute of Medicine, *Financing Vaccines in the 21st Century: Assuring Access and Availability* 27-29 (2004). It has been estimated that for every dollar invested in childhood vaccination against nine vaccine-preventable diseases, $5.80 is saved in direct medical costs; $17.70 is saved when indirect benefits, such as lost productivity, are taken into account. Walter A. Orenstein, *et al.*, *Immunizations in the United States: Success, Structure, and Stress*, 24 Health Affairs 599, 600 (2005). *See also* Fangjun Zhou, *et al.*, *Economic Evaluation of the 7-Vaccine Routine Childhood Immunization Schedule in the United States, 2001*, 159 Archives of Pediatrics & Adolescent Medicine 1136, 1141 (2005) (concluding that, for the 2001 U.S. birth cohort, every dollar spent on routine childhood immunization against seven vaccine-preventable diseases resulted in a savings of more than $5 in direct costs and approximately $11 in additional costs to society). Overall, "[b]illions of medical and health-related dollars have been saved by immunizations." H.R. Rep. No. 99-908, at 4.

Of course, "[n]o vaccine is completely safe or effective." Centers for Disease Control and Prevention, *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 55 MMWR 1 (Dec. 1, 2006). *See* H.R. Rep. No. 99-908, at 6 ("There is today no 'perfect' or reaction-free childhood vaccine on the market."). Even when vaccines are properly manufactured, distributed, and administered, a small number of children may suffer rare but serious

adverse reactions. *See* H.R. Rep. No. 99-908, at 4, 6. "Despite these possibilities, public health officials, private physician groups, and parent organizations have repeatedly stated that it is safer to take the required shots than to risk the health consequences of contracting the diseases immunizations are designed to prevent." *Id.* at 6. In other words, the enormous benefits of vaccination vastly outweigh the relatively small risk of injury. *See General Recommendations on Immunization*, *supra*, at 1 ("[R]ecommendations for vaccination practices balance scientific evidence of benefits for each person and to society against the potential costs and risks for vaccination for the individual and programs."); H.R. Rep. No. 99-908, at 6 ("in light of the overall success of immunization programs, the Federal government continues to support * * * immunizations to children").

II. CONGRESS ENACTED THE VACCINE ACT TO PROVIDE ADEQUATE COMPENSATION TO CHILDREN INJURED BY VACCINES AND TO SAFEGUARD THE NATION'S VACCINE SUPPLY.

In 1986, the Nation faced a public health crisis. Vaccine-related lawsuits against vaccine manufacturers had spiked, and rising litigation and insurance costs threatened to halt vaccine production in the United States. H.R. Rep. No. 99-908, at 4, 6-7. At the same time, however, the tort system had failed to provide adequate compensation for children injured by vaccines. *Id.* at 6. Congress responded by enacting the Vaccine Act, thereby ensuring adequate compensation for children injured by vaccines and safeguarding the Nation's vaccine supply.

A. The Costs Of Vaccine-Related Litigation Had Threatened To Halt Vaccine Production In The United States.

In the mid-1980s, the number of vaccine-related suits filed against vaccine manufacturers increased markedly. *Id*. at 4. According to a 1985 survey of the seven manufacturers producing childhood vaccines,[2] between January 1980 and March 1985, 299 lawsuits were filed against them seeking compensation for vaccine-related injuries; 84 percent of those suits were related to childhood vaccines. Staff of H. Subcomm. on Health and the Environment of the Comm. on Energy and Commerce, 99th Cong., *Childhood Immunizations* 85-86 (Comm. Print 1986) (hereinafter "*Childhood Immunizations*"). About 60 percent of all the suits filed sought damages in the aggregate of $3.5 billion. *Id*. Between 1983 and 1984 alone, litigation costs nearly doubled—climbing from $4.7 million to $9.8 million. *Id*. at 87.

With the deluge of lawsuits, vaccine manufacturers faced rising insurance premiums and a decreasing pool of insurers willing to cover them. H.R. Rep. No. 99-908, at 6-7; *Childhood Immunizations*, *supra*, at 73; *National Childhood Vaccine-Injury Compensation Act: Hearing Before the S. Committee on Labor and Human Resources*, 99th Cong. 288 (July 18, 1985) (hereinafter "*July 18, 1985 Hearing*") (statement of Stephen White, Vice President of Reed-Stenhouse, Ltd.) (explaining that insurance companies were struggling with losses from pharmaceutical, asbestos, and pollution claims). As litigation and

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[2] Two of the manufacturers were operated by State organizations in Michigan and Massachusetts. H.R. Rep. No. 99-908, at 7.

insurance costs soared, "the prices of vaccines * * * jumped enormously," H.R. Rep. No. 99-908, at 4—in some cases as much as 900 percent, *see Childhood Immunizations*, *supra*, at 90—and "[t]he number of childhood vaccine manufacturers * * * declined significantly." H. Rep. No. 99-908, at 4.

As it became increasingly clear that vaccine prices could not forever keep pace with escalating litigation and insurance costs, *see*, *e.g.*, *July 18, 1985 Hearing*, *supra*, at 240 (statement of Robert Johnson, President of Lederle Laboratories) (noting that "vaccine pricing" of the previous year would not "cover the projected costs of liability" for the following year), the few remaining vaccine manufacturers began "to question their continued participation in the vaccine market." H.R. Rep. No. 99-908, at 7. *See July 18, 1985 Hearing*, *supra*, at 256 (statement of Robert Johnson, President of Lederle Laboratories) ("If the current trend of spiraling litigation continues or worsens, there * * * is a very real possibility that we will be forced to abandon the vaccine business."); *id.* at 284 (statement of David J. Williams, Vice President and General Manager of Connaught Laboratories, Inc.) ("There is always a possibility that Connaught will be unable to remain in the vaccine business.").

As Congress recognized, "[t]he loss of any of the existing manufacturers of childhood vaccines * * * could create a genuine public health hazard in this country." H.R. Rep. No. 99-908, at 7. At that time, "there [was] only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the [diphtheria, pertussis, and tetanus] DPT vac-

cine." *Id.*[3] Thus, as the then-President of the AAP testified: "The threat to our vaccine supply in this country is a real one * * *. We could lose the remainder of our suppliers unless some positive legislative action is taken." *Dec. 9, 1985 Hearing*, *supra*, at 8 (statement of Martin Smith, M.D., President of the AAP).

B. The Tort System Had Failed To Provide Adequate Compensation For Children Injured By Vaccines.

Ironically, while lawsuits against vaccine manufacturers skyrocketed, some children injured by vaccines failed to receive any compensation. Despite their injuries, some children were simply not deemed good "candidates for litigation," *National Childhood Vaccine-Injury Compensation Act: Hearing Before the S. Committee on Labor and Human Resources*, 98th Cong. 171 (May 3, 1984) (hereinafter "*1984 Hearing*") (statement of Andrew Dodd, Attorney at Ward, Dodd & Grant, Torrance, California), because any prospective recovery was not "large enough" to make their cases attractive to an attorney. *Id.* at 146 (statement of Martin H. Smith, M.D., President-elect of the AAP).

Thus, while a few lawsuits reaped multi-million dollar awards, some injured children received no compensation at all. 132 Cong. Rec. H30751, H30760 (Oct. 14, 1986) (statement of Rep. Waxman); *id.* at H30762 (statement of Rep. Biaggi); *1984 Hearing*, *supra*, at 4 (statement of Senator Kennedy) (tort system "awards few handsomely and sends

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[3] Michigan and Massachusetts also produced their own DPT vaccine. H.R. Rep. No. 99-908, at 7.

others equally aggrieved away penniless"). The tort system was thus aptly described as a "lottery." *1984 Hearing*, *supra*, at 277 (statement of John E. Lyons, President of Merck Sharp & Dohme).

C. The Vaccine Act Provides Adequate Compensation To Children Injured By Vaccines And Ensures The Stability Of The Vaccine Market And The Nation's Vaccine Supply.

Congress responded to the looming crisis by enacting the Vaccine Act. The overriding goals of the Act were two-fold: (1) to ensure adequate compensation for children injured by vaccines, and (2) to stabilize the vaccine market and safeguard the Nation's vaccine supply. H.R. Rep. No. 99-908, at 7.

Congress addressed both of those goals in part by establishing the National Vaccine Injury Compensation Program ("VICP"), a no-fault alternative compensation system under which children injured by certain vaccines would receive "expeditious and fair" compensation for their injuries. *Id.* at 12. *See* 42 U.S.C. § 300aa-10 *et seq*. Under the VICP, a person seeking compensation for an injury caused by a vaccine covered by the Act must file a petition with the United States Court of Federal Claims, which refers the petition to a "Vaccine Court"—an office within the court of special masters appointed to four-year terms by the court to hear VICP claims. 42 U.S.C. §§ 300aa-11(a)(1)-(2), 300aa-12(c), 300aa-21(a). The Secretary of Health and Human Services is named as a respondent; vaccine manufacturers are not parties to VICP proceedings. *Id.* § 300aa-12(b)(1).

A petitioner is entitled to compensation if he or she has suffered an injury set forth in the "Vaccine Injury Table"—a table of vaccines and the injuries presumed to be caused by those vaccines—unless it can be shown by a preponderance of the evidence that the petitioner's injury was not caused by the vaccine. *Id.* §§ 300aa-11(b), (c), 300aa-13(a)(1), 300aa-14. A petitioner who has not suffered a "Table Injury" may still obtain compensation by proving that his or her injury was in fact caused by a vaccine covered by the Act. *Id.* § 300aa-11(c)(1)(C)(ii). *See Grant* v. *Secretary of HHS*, 956 F.2d 1144, 1147-48 (Fed. Cir. 1992).[4] Payment of compensation is made

[4] The special masters of the Vaccine Court have developed a proficiency in the complex medical and scientific issues involved in causation claims. Indeed, the Court of Federal Claims has observed that, "instead of being passive recipients of information, such as jurors, special masters are given an active role in determining the facts relevant to Vaccine Act petitions," and that "special masters have the expertise and experience to know the type of information that is most probative of a claim." *Doe* v. *Secretary, HHS,* 76 Fed. Cl. 328, 338-339 (Fed. Cl. 2007).

The expertise of the special masters in evaluating causation claims has been amply demonstrated in a multi-phase Omnibus Autism Proceeding ("OAP") established under the VICP to determine whether there is a causal link between childhood vaccines and autism. Approximately 5,000 cases alleging an association between autism and either vaccines containing the preservative thimerosal, the MMR vaccine (which does not contain thimerosal), or a combination thereof, have been filed with the Vaccine Court. *See* http://www.hrsa.gov/vaccinecompensation. In 2009, special masters in three "test" cases issued voluminous opinions evaluating evidence based on the theory that the MMR vaccine, in combination with vaccines containing thimerosal, causes autism. *See Cedillo* v. *Secretary of HHS*, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *appeal pending*, No. 2010-5004 (Fed. Cir.); *Hazlehurst* v. *Secretary of HHS,* 2009 WL 332306 (Fed. Cl. Feb. 12, 2009),

from a "Vaccine Injury Compensation Trust Fund"—funded by a manufacturers excise tax on those vaccines covered by the Act, *see* 26 U.S.C. §§ 4131, 9510—on a no-fault basis. 42 U.S.C. §§ 300aa-13, 300aa-14, 300aa-15(i). Since 1989, the Vaccine Court has issued more than 2,400 awards totaling over $1.8 billion. *See* National Vaccine Injury Compensation Program, *Statistics Report* (June 7, 2010), *available*

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aff'd, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder* v. *Secretary of HHS*, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009). All three special masters rejected the proposition that the vaccines in question caused autism. *See id*.

In reaching their decisions, the special masters in each case considered a wealth of scientific evidence. As the special master in *Snyder* observed: "The evidentiary record in this case * * * encompasses, *inter alia*, nearly four weeks of testimony, including that offered in the *Cedillo* and *Hazlehurst* cases; over 900 medical and scientific journal articles; 50 expert reports (including several reports of witnesses who did not testify); supplemental expert reports filed by both parties post-hearing, [and] the testimony of fact witnesses on behalf of [the injured child and his] medical records." *Snyder*, 2009 WL 332044, at *8. Each of the special master's decisions have been affirmed by the Court of Federal Claims; of the two cases that have been further appealed, one has been affirmed by the Federal Circuit and the other is still pending before that court. *See supra*.

In March 2010, special masters in three additional "test" cases issued voluminous opinions evaluating evidence based on the theory that thimerosal-containing vaccines alone can cause autism. *See Dwyer v. Secretary of HHS*, 2010 WL 892250 (Fed. Cl. March 12, 2010); *King v. Secretary of HHS*, 2010 WL 892296 (Fed. Cl. March 12, 2010); *Mead v. Secretary of HHS*, 2010 WL 892248 (Fed. Cl. March 12, 2010). Once again—upon consideration of a "massive" record—each of the special masters concluded that the vaccines in question did not cause autism. *King*, 2010 WL 892296, at *12. *See Dwyer*, 2010 WL 892250, at *7; *Mead*, 2010 WL 892248, at *5.

at http://www.hrsa.gov/vaccinecompensation/statistics_report.htm.[5]

After the Vaccine Court has issued a final judgment, a petitioner may accept or reject it. 42 U.S.C. § 300aa-21(a).[6] Although a party who rejects the Vaccine Court's judgment may pursue certain *limited* claims in state or federal court, design defect

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[5] Certain of petitioners' amici make much of the fact that the majority of claims filed today involve so-called "off-Table" injuries which require proof of causation. *See* Br. Marguerite Willner 22; Br. National Vaccine Information Center, *et al.* 14. Yet it would not appear that claimants have been unduly hampered by the burden of proof on causation, as amici suggest. In 2009—and to date, in 2010—compensation has been paid in over 70% of adjudicated non-autism cases. *See* National Vaccine Injury Compensation Program, *Statistics Report* (June 7, 2010). And while amici bemoan the Secretary's removal of certain injuries from the Vaccine Injury Table, *see* Br. Marguerite Willner 21-22; Br. National Vaccine Information Center, *et al.* 15-16, Congress "anticipate[d] that the research on vaccine injury and vaccine safety [then] ongoing * * * [would] soon provide more definitive information about the incidence of vaccine injury and that, when such information [were] available, the Secretary * * * [might] propose to revise the Table." H.R. Rep. No. 99-908, at 18. Thus, the Act specifically provides for the removal of injuries through notice-and-comment rulemaking. *See* 42 U.S.C. § 300aa-14(c). As contemplated by Congress, the original table was modified "to make it consistent with current medical and scientific knowledge regarding adverse events associated with certain vaccines." HHS, *National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table*, 60 Fed. Reg. 7678, 7678 (Feb. 8, 1995).

[6] The Vaccine Act also authorizes petitioners to "opt out" of a VICP proceeding if a special master has not resolved his or her petition within 240 days or if the Court of Federal Claims has not completed its review of a special master's decision within 420 days of the date on which the petition was filed. *See* 42 U.S.C. § 300aa-21(b).

claims are not among them. *Id.* § 300aa-21(a), (b). As the Third Circuit correctly held, Congress expressly preempted "*all* design defect claims, including those based in negligence." *Bruesewitz*, 561 F.3d at 248 (emphasis added). *See* 42 U.S.C. § 300aa-22(b)(1). If an injured person has such a claim, he or she "should pursue recompense in the compensation system, not the tort system." H.R. Rep. No. 99-908, at 26. The preemption of all design defect claims is critical to Congress's objective of stabilizing the vaccine market and safeguarding the Nation's vaccine supply. As the Third Circuit explained: "Congress[] belie[ved] that an alternate compensation system would reduce awards and create a stable, predictable basis for estimating liability." *Bruesewitz*, 561 F.3d at 247. Indeed, as the legislative history makes clear, Congress "believe[d] that once this system [was] in place and manufacturers ha[d] a better sense of their potential litigation obligations, a more stable childhood vaccine market [would] evolve." H.R. Rep. No. 99-908, at 7.

III. PETITIONERS' INTERPRETATION OF THE VACCINE ACT POSES A THREAT TO THE FUTURE PRODUCTION AND DEVELOPMENT OF VACCINES.

Contrary to all clear indications of congressional intent, petitioners maintain that the Vaccine Act preempts design defect claims "*only* upon a threshold showing that the vaccine's side effects could not have been prevented." Pet. Br. 25 (emphasis added). As the Third Circuit below concluded, that interpretation of the Act is simply wrong. *See Bruesewitz*, 561 F.3d at 246. As the Third Circuit explained, if the Act is interpreted "to allow case-by-case analysis of

whether particular vaccine side effects are avoidable," then "*every* design defect claim is subject to evaluation by a court." *Id.* (emphasis added).

If that were the case, "[e]ach of the objectives extolled [in the Vaccine Act's legislative history] would be undermined." *Id.* at 249. Thus, petitioners' interpretation of the statute—which allows judges *and juries* to decide whether a particular vaccine can be made safer[7]—threatens a resurgence of "the very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act" in the first place. *Id.* That threat is extremely palpable, as the recent decisions issued by the Vaccine Court in the OAP promise to unleash a barrage of claims in the courts. *See supra* at 20-21 n.4. Thus, adoption of petitioners' interpretation could drive vaccine manufacturers from the market and halt the future production and development of childhood vaccines in this country.

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[7] As this Court noted in *Riegal* v. *Medtronic, Inc.*, 552 U.S. 312, 325 (2008), with respect to medical devices, juries cannot be expected to conduct the cost-benefit analysis performed by expert regulators in balancing a device's safety and efficacy. "A jury * * * sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped the benefits are not represented in court." *Id.* That concern applies with even greater force with respect to vaccines, which benefit not only those who have been immunized but those who have not, and which thus directly benefit society at large. *See supra* at 13. In making recommendations for childhood vaccines, public officials and others have carefully "balance[d] scientific evidence of benefits for each person and to society against the potential costs and risks for vaccination for the individual and programs." *General Recommendations on Immunization*, *supra*, at 1.

A. Unpredictable Litigation Costs Could Once Again Force Vaccine Manufacturers To Abandon Or Consider Abandoning The Vaccine Market.

By eliminating the threat of most lawsuits, the Vaccine Act has prevented manufacturers from abandoning the vaccine market, thus ensuring a stable supply of vaccines. *See* Louis Z. Cooper, *et al.*, *Protecting Public Trust in Immunization*, 122 Pediatrics 149, 150 (2008). Case-by-case consideration of whether vaccines are unavoidably unsafe, on the other hand, would "undoubtedly increase the costs and risks associated with litigation and would undermine a manufacturer's efforts to estimate and control costs." *Bruesewitz*, 561 F.3d at 249. Thus, adoption of petitioners' interpretation would create the "very real possibility" that vaccine manufacturers will once again abandon or be forced to consider abandoning the vaccine market. H.R. Rep. No. 99-908, at 7.

That is particularly so given the precarious state of the vaccine industry. Today, as in 1986, there continues to be only *one* manufacturer of a measles-mumps-rubella vaccine, and only *two* manufacturers of a diptheria-tetanus-pertussis vaccine. *See* American Academy of Pediatrics, *Status of Recently Submitted, Licensed, and Recommended Vaccines*, *Red Book Online: Vaccine Status Table* (2010), *available at* http://aapredbook.aappublications.org/news/vaccstatus.dtl; *Childhood Immunizations*, *supra*, at 67; H.R. Rep. No. 99-908, at 7. And while the Vaccine Act has been instrumental in preventing manufacturers from fleeing the vaccine market, the number of vaccine manufacturers has not greatly increased

since the Act's passage. *See Status of Recently Submitted, Licensed, and Recommended Vaccines*, *supra*. The costs of developing and producing vaccines have also increased over the years. Between 1991 and 2003, for instance, costs for research and development, postlicensure clinical studies, and production process improvements grew from $231 million to $802 million. Stanley A. Plotkin, *et al.*, *Vaccines* 38 (5th ed. 2008).

Thus, vaccine manufacturers today are no better—and, indeed, are perhaps even more poorly—situated to handle the unpredictability and expense of litigation. Yet, as was true in 1986, "the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." H.R. Rep. No. 99-908, at 7.

B. The Progress That Has Been Made In Vaccine Development Since The Passage Of The Vaccine Act Could Come To A Halt.

In addition to ensuring the stability of the existing childhood vaccine market, one of Congress's objectives in passing the Vaccine Act was to ensure "that a greater number of vaccine products will become available to prevent disease." H.R. Rep. No. 99-908, at 4. In that regard, the Act has been unquestionably successful. Vaccine development has flourished since 1986 with the number of vaccine-preventable diseases having more than doubled. *See Childhood Immunizations*, *supra*, at 1; Centers for Disease Control and Prevention, *Recommended Immuniza-*

tion Schedules for Persons Aged 0 Through 18 Years–United States, 58 MMWR Q1-Q4 (Jan. 8, 2010).

In 1986, children were routinely vaccinated against seven diseases (diphtheria, measles, mumps, pertussis, poliomyelitis, rubella, and tetanus). *Childhood Immunizations*, *supra*, at 1. Today, children are also routinely immunized against an additional eight diseases: *Haemophilus influenzae* type b (Hib), hepatitis A, hepatitis B, influenza, meningococcal disease, pneumococcal disease, rotavirus, and varicella (chicken pox). *Recommended Immunization Schedules for Persons Aged 0 Through 18 Years–United States*, *supra*, at Q1-Q4. Research and development of new vaccines is always ongoing. *See* Immunization Action Coalition, *Vaccine-Related Journal Articles*, *available at* http://www.immunize.org/journalarticles/ (listing, by year, published articles regarding vaccine development).

Vaccine manufacturers face many challenges in bringing new vaccines to market. *See* Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24 Health Affairs 622, 623-629 (2005). In addition to research and development, vaccine manufacturers are also "almost exclusively" responsible for the production and distribution of such vaccines. *See* Orenstein, *et al.*, *supra*, at 601-603. As noted, by eliminating the threat of most lawsuits, the Vaccine Act has kept manufacturers from abandoning vaccine production. *See* Cooper, *et al.*, *supra*, at 150. If the decision below is reversed, the prognosis for future vaccine development will be extremely poor.

CONCLUSION

For the foregoing reasons, and those stated in respondent's brief, the judgment below should be affirmed.

Respectfully submitted,

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